

Public Law 102-410
102d Congress

An Act

Oct. 13, 1992
[H.R. 5673]

To amend the Public Health Service Act to revise and extend the programs of the Agency for Health Care Policy and Research.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Agency for
Health Care
Policy and
Research
Reauthorization
Act of 1992.
42 USC 201 note.

SECTION 1. SHORT TITLE; AMENDATORY REFERENCES.

(a) **SHORT TITLE.**—This Act may be cited as the “Agency for Health Care Policy and Research Reauthorization Act of 1992”.

(b) **AMENDATORY REFERENCES.**—Except as otherwise specifically provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or a repeal of, a section or other provision, the reference shall be considered to be made to that section or other provision of the Public Health Service Act (42 U.S.C. 201 et seq.).

SEC. 2. ESTABLISHMENT AND GENERAL AUTHORITIES.

(a) **ESTABLISHMENT.**—Section 901(b) (42 U.S.C. 299(b)) is amended by inserting after “improvements in clinical practice” the following: “(including the prevention of diseases and other health conditions)”.

(b) **GENERAL AUTHORITIES.**—Section 902 (42 U.S.C. 299a) is amended—

(1) by redesignating subsections (c) and (d) as subsections (d) and (e), respectively; and

(2) by inserting after subsection (b), the following subsection:

“(c) **HEALTH SERVICES TRAINING GRANTS.**—The Administrator may provide training grants in the field of health services research related to activities authorized under subsection (a), to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate.”.

SEC. 3. DISSEMINATION.

Section 903 (42 U.S.C. 299a-1) is amended by adding at the end the following subsection:

“(e) **INFORMATION CENTER.**—

“(1) **IN GENERAL.**—There shall be established at the National Library of Medicine an information center on health services research, and on selected technology assessments and clinical practice guidelines produced by the Agency and other public and private sources.

“(2) **IDENTIFICATION SYSTEM.**—The Administrator shall ensure that information under paragraph (1) concerning clinical practice guidelines is collected and maintained electronically and in a convenient format. The Administrator, in consultation with the Director of the National Library of Medicine, shall develop and publish criteria for the inclusion of practice guide-

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lines and technology assessments in the information center database.

“(3) INTERAGENCY AGREEMENT.—The Administrator shall enter into an agreement providing for the implementation of paragraph (1) with the Director of the National Library of Medicine.”.

SEC. 4. HEALTH CARE TECHNOLOGY ASSESSMENT.

(a) IN GENERAL.—Section 904 (42 U.S.C. 299a-2) is amended—

(1) in subsection (a)—

(A) by striking “and” at the end of paragraph (4);

(B) by striking the period at the end of paragraph

(5) and inserting “; and”; and

(C) by adding at the end the following paragraph:

“(6) by conducting assessments and reassessments of existing and new health care technologies.”;

(2) in subsection (b)(2)—

(A) by striking “cost-effectiveness.”; and

(B) by adding at the end the following sentence: “In carrying out such paragraph, the Administrator shall also consider the cost effectiveness of such technologies where cost information is available and reliable.”; and

(3) in subsection (c) to read as follows:

“(c) AGENDA AND PRIORITIES.—

“(1) ESTABLISHMENT OF PRIORITIES.—In accordance with paragraph (2), the Administrator, in consultation with the Advisory Council established under section 921, shall establish an annual list of technology assessments under consideration by the Agency, including those assessments performed at the request of the Health Care Financing Administration and the Department of Defense and those assessments performed under subsections (d) and (f).

“(2) PUBLIC NOTICE.—The Administrator, in consultation with the Advisory Council, shall publish the list established in paragraph (1) annually in the Federal Register.”;

(4) in subsection (d), to read as follows:

“(d) CONDUCT OF ASSESSMENTS.—

“(1) IN GENERAL.—The Administrator may conduct technology assessments in addition to those assessments performed at the request of the Administrator of the Health Care Financing Administration or of the Secretary of Defense.

“(2) CRITERIA.—The Administrator shall develop criteria for determining the priority of assessments performed under this subsection. Such criteria shall include—

“(A) the prevalence of the health condition for which the technology aims to prevent, diagnose, treat and clinically manage;

“(B) variations in current practice;

“(C) the economic burden posed by the prevention, diagnosis, treatment, and clinical management of the health condition, including the impact on publicly-funded programs;

“(D) aggregate cost of the use of technology;

“(E) the morbidity and mortality associated with the health condition; and

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“(F) the potential of an assessment to improve health outcomes or affect costs associated with the prevention, diagnosis, or treatment of the condition.”; and

(5) by adding at the end the following subsections:

“(e) **DESCRIPTION OF PROCESS.**—Not later than January 1, 1994, the Administrator shall develop and publish a description of the methodology used to establish priorities for technology assessment and the process used to conduct its technology assessments under this section.

“(f) **PROGRAM OF INNOVATIVE ASSESSMENTS.**—

“(1) **IN GENERAL.**—The Administrator may make grants to, or enter cooperative agreements or contracts with, entities described in paragraph (2) for the establishment of collaborative arrangements for the purpose of conducting assessments of experimental, emerging, existing, or potentially outmoded health care technologies, and for related activities. Such assessments may include controlled clinical trials, large simple trials, and other methodologies that can be conducted in partnership between the public and private sectors or among multiple government agencies.

“(2) **ELIGIBLE ENTITIES.**—The entities referred to in paragraph (1) are entities determined to be appropriate by the Administrator, which entities may include academic medical centers, research institutions, nonprofit professional organizations, public or private third party payers, other governmental agencies, and consortia of appropriate research entities established for the purpose of conducting technology assessments.

“(3) **USE OF AWARD.**—A grant, cooperative agreement, or contract under paragraph (1) may be expended for data collection, data analysis, protocol development, report development, dissemination and evaluation, and other activities determined to be appropriate by the Administrator. Such funds shall not be used for direct services.

“(4) **APPLICATION FOR AWARD.**—To be eligible to receive a grant, cooperative agreement, or contract under paragraph (1), an entity shall prepare and submit to the Administrator an application, at such time, in such form, and containing such information as the Administrator may require.

“(5) **INTERAGENCY MEMORANDA OF UNDERSTANDING.**—In carrying out paragraph (1), the Administrator may enter into memoranda of understanding with the heads of other Federal agencies.”.

(b) **REPORT REGARDING INNOVATIVE ASSESSMENTS.**—Not later than January 1, 1994, the Administrator for Health Care Policy and Research shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report concerning the program established in section 904(f) of the Public Health Service Act (as added by subsection (a) of this section), including the plan of such Administrator for implementing the program.

SEC. 5. FORUM FOR QUALITY AND EFFECTIVENESS IN HEALTH CARE.

(a) **REQUIREMENTS FOR GUIDELINES, STANDARDS, PERFORMANCE MEASURES, AND REVIEW CRITERIA.**—

(1) **ADDITIONAL REQUIREMENTS.**—Section 912(b) (42 U.S.C. 299b-1) is amended—

(A) in paragraph (2), by striking “and” after the semicolon at the end;

(B) in paragraph (3), by striking the period at the end and inserting “; and”; and

(C) by adding at the end the following paragraphs:

“(4) include information on risks and benefits of alternative strategies for prevention, diagnosis, treatment, and management of a given disease, disorder, or other health condition; and

“(5) include information on the costs of alternative strategies for the prevention, diagnosis, treatment, and management of a given disease, disorder, or other health condition, where cost information is available and reliable.”

(2) STUDY.—

(A) To assist in carrying out the requirements of section 912(b)(4) of the Public Health Service Act, as added by paragraph (1) of this subsection, the Administrator for Health Care Policy and Research shall conduct or support a study to develop methods for collecting and analyzing primary and secondary data to be used in generating cost estimates of alternative strategies for the prevention, diagnosis, treatment, and management of a given disease, disorder, or the health condition to be included in guideline documents.

(B) Not later than June 1, 1994, the Administrator for Health Care Policy and Research shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report concerning the study conducted under subparagraph (A).

(b) ADMINISTRATION OF OFFICE.—Section 911 (42 U.S.C. 299b) is amended by adding at the end the following sentence: “The Administrator shall carry out this part acting through the Director.”

(c) CONFORMING AMENDMENTS.—Part B of title IX (42 U.S.C. 299b et seq.) is amended—

(1) in section 912—

(A) in subsection (a)—

(i) in the first sentence, by striking “The” and all that follows through “shall” and inserting “The Administrator shall”; and

(ii) in the second sentence, by striking “Director” and inserting “Administrator”; and

(B) in subsection (c), by striking “Director” and inserting “Administrator”;

(2) in section 913—

(A) in subsection (a), in the matter preceding paragraph (1), by striking “Director” and inserting “Administrator”;

(B) in subsection (b), in the matter preceding paragraph (1), by striking “Director” and inserting “Administrator”; and

(C) in subsection (c), by striking “Director” each place such term appears and inserting “Administrator”; and

(3) in section 914—

(A) in subsection (b)—

(i) in paragraph (1), by striking “Director” and inserting “Administrator”;

42 USC 299b-1
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42 USC 299b-1.

42 USC 299b-2.

42 USC 299b-3.

(ii) in paragraph (2), by striking "Director" and inserting "Administrator";

(iii) in paragraph (3), in the matter preceding subparagraph (A), by striking "Director" and inserting "Administrator"; and

(iv) in paragraph (4), by striking "Director" and inserting "Administrator";

(B) in subsection (c), in the first sentence, by striking "Director" and inserting "Administrator";

(C) in subsection (d), in the first sentence, by striking "Director" and inserting "Administrator"; and

(D) in subsection (e), by striking "Director" and inserting "Administrator".

(d) PEER REVIEW WITH RESPECT TO GRANTS AND CONTRACTS.—

(1) ESTABLISHMENT OF PEER REVIEW GROUPS.—Section 922(c)(2) (42 U.S.C. 299c-1(c)(2)) is amended—

(A) by striking "from among individuals" and all that follows through "virtue" and inserting "from among individuals who by virtue"; and

(B) by adding at the end the following sentences: "Officers and employees of the United States may not constitute more than 25 percent of the membership of any such group. Such officers and employees may not receive compensation for service on such groups in addition to the compensation otherwise received for duties carried out as such officers and employees."

(2) CATEGORIES OF REVIEW.—Section 922(d)(1) (42 U.S.C. 299c-1(d)(1)) is amended to read as follows:

"(1) IN GENERAL.—With respect to technical and scientific peer review under this section, there shall be two categories of peer review groups as follows:

"(A) One category of such groups shall, subject to subparagraph (B), review applications with respect to research, demonstration projects, or evaluations.

"(B) The other category of such groups shall review applications with respect to dissemination activities or the development of research agendas (including conferences, workshops, and meetings). If the purpose of a proposal presented in an application is a matter described in the preceding sentence, the application shall be reviewed by the groups referred to in such sentence, notwithstanding that the proposal involves research, demonstration projects, or evaluations."

(e) CERTAIN PROVISIONS WITH RESPECT TO DEVELOPMENT, COLLECTION, AND DISSEMINATION OF DATA.—Section 923 (42 U.S.C. 299c-2) is amended by adding at the end the following subsection:

"(c) AUTHORITY REGARDING CERTAIN REQUESTS.—Upon the request of a public or nonprofit private entity, the Administrator may tabulate and analyze statistics under arrangements under which such entity will pay the cost of the service provided. Amounts appropriated to the Administrator from payments made under such arrangements shall be available to the Administrator for obligation until expended."

(f) PROCESS FOR DEVELOPMENT OF GUIDELINES AND STANDARDS.—

(1) MEMBERSHIP OF PANELS.—

(A) Section 913(c) (42 U.S.C. 299b-2(c)) is amended—

(i) by inserting after the subsection designation the following sentence: "The Administrator shall select the chairpersons and the members of the panels convened as well as other participants in the guideline process under this section."; and

(ii) by adding at the end the following sentences: "In making such selections, the Administrator shall ensure that a balance is maintained between individuals selected from academic settings and individuals selected without full-time academic appointments. At least two other members of such panels shall be individuals who do not derive their primary source of revenue directly from the performance of procedures discussed in the guideline. The Administrator shall ensure that at least one participant in the guideline process shall have expertise in epidemiology as well as familiarity with the clinical condition or treatment in question. The Administrator shall also ensure that at least one participant in the guideline process shall have expertise in health services research or health economics as well as familiarity with the clinical condition or treatment in question."

(B) The amendments made by subparagraph (A) shall apply only with respect to panels convened under section 913 of the Public Health Service Act on or after the date of enactment of this Act.

42 USC 299b-2
note.

(2) STUDY OF PROCESS.—

42 USC 299b-2
note.

(A) The Administrator for Health Care Policy and Research shall conduct or support a study to evaluate the process described in section 913 of the Public Health Service Act for the development of guidelines, standards, and review criteria. The evaluation shall address—

(i) the optimal methods for setting priorities for guideline topics;

(ii) the different methods for generating guidelines, comparing the cost of producing the guidelines and the validity and utility of the guidelines produced; and

(iii) the methods for assessing the quality of practice guidelines, including an evaluation of the validity, reliability, and impact of the guidelines.

(B) Not later than June 1, 1995, the Administrator for Health Care Policy and Research shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report concerning the study conducted under subparagraph (A).

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SEC. 6. PREVENTION.

(a) PROGRAM AGENDA.—Section 914(a)(2)(A) (42 U.S.C. 299b-3(a)(2)(A)) is amended—

(1) by striking clause (i);

(2) by redesignating clauses (ii) and (iii) as clauses (iii) and (iv), respectively; and

(3) by inserting before clause (iii) (as so redesignated) the following clauses:

"(i) to improve methods for disease prevention;

“(ii) to improve methods of diagnosis, treatment, and clinical management for the benefit of a significant number of individuals;” and

(b) DUTIES.—Section 912 (42 U.S.C. 299b-1) is amended by adding at the end the following subsection:

“(f) DEVELOPMENT OF CERTAIN GUIDELINES AND STANDARDS.—Not later than January 1, 1996, the Administrator shall ensure that a set of guidelines, standards, performance measures, and review criteria, are developed under subsection (a)(1) that address the prevention of not fewer than three conditions that account for significant national health expenditures. In carrying out this subsection the Administrator shall consult with the United States Preventive Services Task Force and other recognized experts in the field of disease prevention.”.

SEC. 7. ADDITIONAL REQUIREMENTS.

Section 914 (42 U.S.C. 299b-3) is amended—

(1) in subsection (a)(2), by adding at the end the following subparagraph:

“(C) The Administrator shall develop and publish a methodology for establishing priorities for guideline topics. Such methodology may include the considerations described in section 904(c)(2) or 914(a)(2), and other considerations determined by the Administrator to be appropriate. Using such methodology, the Administrator shall establish and publish annually in the Federal Register a list of guideline topics under consideration.”; and

(2) in subsection (e), by adding at the end the following sentence: “Evaluations shall be developed prior to the completion and release of the guideline, so that baseline data concerning practice patterns and health care costs may be obtained as part of the evaluation.”.

SEC. 8. ADVISORY COUNCIL.

Section 921 (42 U.S.C. 299c) is amended—

(1) by striking subsection (d);

(2) by redesignating subsections (e) through (k) as subsections (d) through (j), respectively; and

(3) in subsection (e) (as so redesignated), by striking “subsection (e)” and inserting “subsection (d)”.

SEC. 9. FINANCIAL CONFLICTS OF INTEREST.

Section 924 (42 U.S.C. 299c-3) is amended—

(1) by redesignating subsections (a) through (c) as subsections (b) through (d), respectively; and

(2) by inserting before subsection (b) (as so redesignated) the following subsection:

“(a) FINANCIAL CONFLICTS OF INTEREST.—With respect to projects for which awards of grants, cooperative agreements, or contracts are authorized to be made under this title, the Administrator shall by regulation define—

“(1) the specific circumstances that constitute financial interests in such projects that will, or may be reasonably expected to, create a bias in favor of obtaining results in the projects that are consistent with such interests; and

“(2) the actions that will be taken by the Administrator in response to any such interests identified by the Administrator.”.

SEC. 10. AUTHORIZATION OF APPROPRIATIONS.

Section 926 (42 U.S.C. 299c-5) is amended—

(1) in subsection (a), to read as follows:

“(a) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this title, there are authorized to be appropriated \$115,000,000 for fiscal year 1993, \$145,000,000 for fiscal year 1994, and \$175,000,000 for fiscal year 1995.”; and

(2) by adding at the end the following subsections:

“(c) **INFORMATION CENTER.**—For purposes of carrying out the activities under section 903(e), there are authorized to be appropriated \$3,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 and 1995.

“(d) **HEALTH CARE TECHNOLOGY ASSESSMENT.**—For the purpose of carrying out technology assessment activities under section 904(d), there are authorized to be appropriated \$2,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 and 1995.

“(e) **PROGRAM OF INNOVATIVE ASSESSMENTS.**—For purposes of establishing the program of innovative assessments under section 904(f), there are authorized to be appropriated \$2,000,000 for fiscal year 1993, and such sums as may be necessary in each of the fiscal years 1994 and 1995.”.

SEC. 11. EMERGENCY MEDICAL SERVICE FOR CHILDREN.

Section 1910 (42 U.S.C. 300w-9) is amended—

(1) in subsection (a), by striking “not more than four grants in any fiscal year” and inserting “grants”; and

(2) in subsection (d)—

(A) by striking “and \$5,000,000” and inserting “\$5,000,000”; and

(B) by inserting before the period the following: “, and such sums as may be necessary for each of the fiscal years 1993 through 1997”.

Approved October 13, 1992.

LEGISLATIVE HISTORY—H.R. 5673:

HOUSE REPORTS: No. 102-892 (Comm. on Energy and Commerce).

CONGRESSIONAL RECORD, Vol. 138 (1992):

Sept. 22, 24, considered and passed House.

Sept. 30, considered and passed Senate.