

Public Law 95-622
95th Congress

An Act

Nov. 9, 1978

[S. 2450]

To amend the Community Mental Health Centers Act to revise and extend the programs under that Act, to amend the Public Health Service Act to revise and extend the programs of assistance for libraries of medicine, the programs of the National Heart, Lung, and Blood Institute, and of the National Cancer Institute, and the program for National Research Service Awards, to establish the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, and for other purposes.

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

TITLE I—COMMUNITY MENTAL HEALTH CENTERS
EXTENSION

SHORT TITLE; REFERENCE TO ACT

SEC. 101. (a) This title may be cited as the "Community Mental Health Centers Extension Act of 1978".

(b) Whenever in this title (other than in sections 109 and 110(d)) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Community Mental Health Centers Act.

EXTENSIONS OF AUTHORIZATIONS

SEC. 102. (a) Section 202(d) is amended by striking out "and" after "1977," and inserting before the period a comma and the following: "\$1,500,000 for the fiscal year ending September 30, 1979, and \$1,000,000 for the fiscal year ending September 30, 1980".

(b) (1) Section 203(d) (1) is amended by striking out "and" after "1977," and inserting before the period a comma and the following: "\$34,500,000 for the fiscal year ending September 30, 1979, and \$35,000,000 for the fiscal year ending September 30, 1980".

(2) Section 203(d) (2) is amended (A) by striking out "1978" and inserting in lieu thereof "1980", and (B) by striking out "two fiscal years" and inserting in lieu thereof "four fiscal years".

(c) Section 204(c) is amended by striking out "and" after "1977," and inserting before the period a comma and the following: "\$20,000,000 for the fiscal year ending September 30, 1979, and \$3,000,000 for the fiscal year ending September 30, 1980".

(d) Section 205(c) is amended by striking out "and" after "1977," and inserting before the period a comma and the following: "\$30,000,000 for the fiscal year ending September 30, 1979, and \$25,000,000 for the fiscal year ending September 30, 1980".

(e) Section 212(c) is amended by striking out "three" and inserting in lieu thereof "five".

(f) Section 213 is amended by striking out "and" after "1977," and inserting after "1978," the following: "and \$25,000,000 for the fiscal year ending September 30, 1979,".

(g) Section 231(d) is amended by striking out "and" after "1977," and inserting before the period a comma and the following:

Community
Mental Health
Centers Act,
amendments.
Community
Mental Health
Centers
Extension Act of
1978.
42 USC 2689
note.

42 USC 2689
note.

42 USC 2689a.

42 USC 2689b.

42 USC 2689c.

42 USC 2689d.

42 USC 2689g.

42 USC 2689h.

42 USC 2689q.

“\$8,000,000 for the fiscal year ending September 30, 1979, and \$9,000,000 for the fiscal year ending September 30, 1980”.

USE OF UNOBLIGATED FUNDS

SEC. 103. (a) (1) Subsection (b) (1) of section 203 is amended by adding before the period a comma and the following: “except that if at the end of such period a center or entity has not obligated all the funds received by it under a grant, the center or entity may use the unobligated funds under the grant in the succeeding year for the same purposes for which such grant was made but only if the center or entity is eligible to receive a grant under subsection (a) for such succeeding year”.

Grants.
42 USC 2689b.

(2) Subsection (c) of such section is amended by adding at the end the following: “The amount of a grant prescribed by paragraph (1) or (2) for a community mental health center for any year shall be reduced by the amount of unobligated funds from the preceding year which the center is authorized, under subsection (b) (1), to use in that year. If in a fiscal year the sum of (i) the total of State, local, and other funds, and of the fees, premiums, and third-party reimbursements collected in that year, and (ii) the amount of the grant received under this section, by a center or entity exceeds its costs of operation for that year because such total collected was greater than expected, and if the center or entity is eligible to receive a grant under subsection (a) in the succeeding year, an adjustment in the amount of that grant shall be made in such a manner that the center or entity may retain such an amount (not to exceed 5 per centum of the amount by which such sum exceeded such costs) as the center or entity can demonstrate to the satisfaction of the Secretary will be used to enable the center or entity (I) to expand and improve its services, (II) to increase the number of persons (eligible to receive services from such a center or entity) it is able to serve, (III) to modernize its facilities, (IV) to improve the administration of its service programs, and (V) to establish a financial reserve for the purpose of offsetting the decrease in the percentage of Federal participation in program operations in future years.”.

(b) (1) Paragraph (1) (A) of subsection (e) of such section is amended (A) by striking out “and” at the end of clause (i), (B) by redesignating clause (ii) as clause (iii), and (C) by inserting after clause (i) the following:

“(ii) the amount prescribed for a grant under the applicable repealed section for an entity for any year shall be reduced by the amount of unobligated funds from the preceding fiscal year which the entity is authorized, under subparagraph (B) of this paragraph, to use in that year, and”.

(2) Paragraph (1) (B) of such subsection is amended by inserting before the period a comma and the following: “except that if at the end of any period for which such a grant is made an entity has not obligated all of the funds received by it under the grant, the entity may use the unobligated funds under such grant in the succeeding grant period for the same purposes for which such grant was made but only if the entity is eligible to receive such a grant for such grant period”.

(3) Paragraph (1) of such subsection is amended by adding at the end the following new sentence: “If in a fiscal year the sum of (I) the

total of State, local, and other funds, and of the fees, premiums, and third-party reimbursements collected in that year, and (II) the amount of the grant received under the applicable repealed section, by an entity exceeds its costs of operation for that year because such total collected was greater than expected, and if the entity is eligible to receive a grant under such an applicable repealed section in the succeeding year, an adjustment in the amount of that grant shall be made in such a manner that the entity may retain such an amount (not to exceed 5 per centum of the amount by which such sum exceeded such costs) as the entity can demonstrate to the satisfaction of the Secretary will be used to enable the entity (I) to expand and improve its services, (II) to increase the number of persons (eligible to receive services from such an entity) it is able to serve, (III) to modernize its facilities, (IV) to improve the administration of its service programs, and (V) to establish a financial reserve for the purpose of offsetting the decrease in the percentage of Federal participation in program operations in future years.”

COMMUNITY MENTAL HEALTH CENTERS REQUIREMENTS

42 USC 2689.

SEC. 104. (a) (1) Section 201(b) (1) is amended to read as follows:

“(b) (1) The comprehensive mental health services which shall be provided through a community mental health center are as follows:

“(A) Beginning on the date the community mental health center is established for purposes of this title, the services provided through the center shall include—

“(i) inpatient services, emergency services, and outpatient services;

“(ii) assistance to courts and other public agencies in screening residents of the center’s catchment area who are being considered for referral to a State mental health facility for inpatient treatment to determine if they should be so referred and provision, where appropriate, of treatment for such persons through the center as an alternative to inpatient treatment at such a facility;

“(iii) provision of followup care for residents of its catchment area who have been discharged from inpatient treatment at a mental health facility;

“(iv) consultation and education services which—

“(I) are for a wide range of individuals and entities involved with mental health services, including health professionals, schools, courts, State and local law enforcement and correctional agencies, members of the clergy, public welfare agencies, health services delivery agencies, and other appropriate entities; and

“(II) include a wide range of activities (other than the provision of direct clinical services) designed to develop effective mental health programs in the center’s catchment area, promote the coordination of the provision of mental health services among various entities serving the center’s catchment area, increase the awareness of the residents of the center’s catchment area of the nature of mental health problems and the types of mental health services available, and promote the preven-

tion and control of rape and the proper treatment of the victims of rape; and

“(v) the services described in subparagraph (B) or, in lieu of such services, providing a plan approved by the Secretary under which the center will, during the three-year period beginning on such establishment date, assume in increments the provision of the services described in subparagraph (B) and will upon the expiration of such three-year period provide all the services described in subparagraph (B).

“(B) After the expiration of such three-year period, a community mental health center shall provide, in addition to the services required by subparagraph (A), services which include—

“(i) day care and other partial hospitalization services;

“(ii) a program of specialized services for the mental health of children, including a full range of diagnostic, treatment, liaison, and followup services (as prescribed by the Secretary);

“(iii) a program of specialized services for the mental health of the elderly, including a full range of diagnostic, treatment, liaison, and followup services (as prescribed by the Secretary);

“(iv) a program of transitional half-way house services for mentally ill individuals who are residents of its catchment area and who have been discharged from inpatient treatment in a mental health facility or would without such services require inpatient treatment in such a facility; and

“(v) provision of each of the following service programs (other than a service program for which there is not sufficient need (as determined by the Secretary) in the center's catchment area, or the need for which in the center's catchment area the Secretary determines is currently being met):

“(I) A program for the prevention and treatment of alcoholism and alcohol abuse and for the rehabilitation of alcohol abusers and alcoholics.

Alcohol abuse program.

“(II) A program for the prevention and treatment of drug addiction and abuse and for the rehabilitation of drug addicts, drug abusers, and other persons with drug dependency problems.”

Drug abuse program.
42 USC 2689c.

(2) Section 204 is amended by striking out “section 201(b)(1)(D)” each place it appears and inserting in lieu thereof “section 201(b)(1)(A)(iv)”.

(b) Clause (A) of section 201(b)(2) is amended by inserting after “in the center's catchment area” the following: “, or, with the approval of the Secretary, in the case of inpatient services, emergency services, and transitional half-way house services, through appropriate arrangements with health professionals and others serving the residents of the catchment area”.

42 USC 2689.

(c) (1) Section 201(c)(1) is amended—

(A) by striking out “The governing board of a community mental health center (other than a center described in subparagraph (B))” and inserting in lieu thereof “Except as provided in subparagraph (B), the governing board of a community mental health center”; and

(B) by amending subparagraph (B) to read as follows:

“(B) In the case of a community mental health center which is operated by a governmental agency or a hospital, such center may, in

lieu of meeting the requirements of subparagraph (A), appoint a committee which advises it with respect to the operations of the center and which is composed of individuals who reside in the center's catchment area, who are representative of the residents of the area as to employment, age, sex, place of residence, and other demographic characteristics, and at least one-half of whom are not providers of health care."

42 USC 2689e.

(2) Section 206(e) is amended by inserting "(1)" after "(e)" and by adding at the end the following new paragraph:

42 USC 2689b,
2689c, 2689d.

"(2) (A) Except as provided in subparagraph (B), not more than 5 per centum of the total amount appropriated under sections 203, 204, and 205 for any fiscal year shall be used by the Secretary to provide grants under those sections to community mental health centers which do not meet the governing board requirements of section 201(c)(1)(A).

42 USC 2689.

"(B) Subparagraph (A) shall not apply, during the fiscal year ending September 30, 1979, and during the fiscal year ending September 30, 1980, to any community mental health center which received a grant under this title in a fiscal year beginning before the date of the enactment of the Community Mental Health Centers Amendments of 1975."

42 USC 2689
note.

OPERATIONS GRANTS TECHNICAL ASSISTANCE AND MONITORING

Contract
authority.

SEC. 105. Section 206(e), as amended by section 104(c)(2) of this title, is amended by adding at the end the following new paragraph:

"(3) Not more than 1 per centum of the total amount appropriated under section 203, 204, and 205 for any fiscal year shall be used by the Secretary to enter into contracts with State mental health authorities under which the authorities (A) would monitor activities of community mental health centers (other than centers operated by such authorities) receiving grants under this title to determine if the requirements of this title applicable to the receipt of such grants are being met, and (B) would be provided funds to meet the expenses of conducting such monitoring. The authority of the Secretary to enter into contracts under this paragraph shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts."

APPLICATIONS

SEC. 106. Section 206(c)(2) is amended—

(1) by amending the matter preceding subparagraph (A) to read as follows: "The Secretary may approve an application for a grant under section 203, 204, or 205 only if the application meets the requirements of paragraph (1) and, except as provided in paragraph (3)—";

(2) by inserting "the Secretary" before "determines" in subparagraphs (A) and (B); and

(3) by striking out "and" at the end of clause (iii) of subparagraph (B), by striking out the period at the end of clause (iv) of such subparagraph and inserting in lieu thereof a semicolon, and by adding after such subparagraph the following new subparagraphs:

"(C) in the case of an application for the first grant under section 203, 204, or 205, or an application for a grant under such section which requests a grant in an amount greater than the

National
Advisory Mental
Health Council,
grant approval.

amount specified by the applicant in its plan and budget submitted in accordance with paragraph (1) (A) (i), the application is recommended for approval by the National Advisory Mental Health Council; and

“(D) in the case of an application of a community mental health center which does not meet the governing board requirements of section 201(c) (1) (A), the committee appointed pursuant to section 201(c) (1) (B) has approved the application or, if such committee has not approved the application, the Secretary determines that the committee’s failure to approve the application was unreasonable.” 42 USC 2689.

CATCHMENT AREAS

SEC. 107. Section 238(2) is amended by inserting “health service areas,” after “political subdivisions,” 42 USC 2689u.

RAPE CONTROL

SEC. 108. Section 231(c) is amended by inserting after the first sentence the following: “The recommendations of the committee shall be submitted directly to the Secretary without review or revision by any person without the consent of the committee.” 42 USC 2689q.

STATE MENTAL HEALTH PROGRAMS

SEC. 109. Subsection (g) of section 314 of the Public Health Service Act is amended to read as follows: 42 USC 246.

“STATE MENTAL HEALTH PROGRAMS

“(g) (1) From allotments made pursuant to paragraph (4), the Secretary shall make grants to State mental health authorities to assist them in meeting the costs of carrying out their functions under title XV of this Act and under section 237 of the Community Mental Health Centers Act and, after September 30, 1979, in meeting the costs of providing mental health services. Grants. 42 USC 300k-1. 42 USC 2689t.

“(2) No grant may be made under paragraph (1) unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in such form and manner and shall contain such information as the Secretary may require, and shall contain or be supported by assurances satisfactory to the Secretary that—

“(A) the mental health services provided within the State under the grant applied for will be provided in accordance with the State health plan in effect for such State under section 1524 (c); 42 USC 300m-3.

“(B) funds received under the grant applied for will (i) be used to supplement and, to the extent practical, to increase the level of non-Federal funds that would otherwise be made available for the purposes for which the grant funds are provided, and (ii) not be used to supplant such non-Federal funds;

“(C) the State mental health authority will—

“(i) provide for such fiscal control and fund accounting procedures as may be necessary to assure the proper disbursements of and accounting for funds received under grants under paragraph (1);

Reports.

“(ii) from time to time, but not less often than annually, report to the Secretary (through a uniform national reporting system and by such categories as the Secretary may prescribe) a description of the mental health services provided in the State in the fiscal year for which the grant applied for is made and the amount of funds obligated in such fiscal year for the provision of each such category of services; and

“(iii) make such reports (in such form and containing such information as the Secretary may prescribe) as the Secretary may reasonably require, and keep such records and afford such access thereto as the Secretary may find necessary to assure the correctness of, and to verify, such reports;

“(D) the State mental health authority will—

“(i) perform the duties prescribed by section 237 of the Community Mental Health Centers Act;

“(ii) prescribe and provide for the enforcement of minimum standards for the maintenance and operation of mental health programs and facilities (including community mental health centers) within the State;

“(iii) provide for assistance to courts and other public agencies and to appropriate private agencies to facilitate (I) screening by community mental health centers (or, if there are no such centers, other appropriate entities) of residents of the State who are being considered for inpatient care in a mental health facility to determine if such care is necessary, and (II) provision of followup care by community mental health centers (or, if there are no such centers, by other appropriate entities) for residents of the State who have been discharged from mental health facilities; and

“(iv) establish and carry out a plan which—

“(I) is designed to eliminate inappropriate placement in institutions of persons with mental health problems, to insure the availability of appropriate noninstitutional services for such persons, and to improve the quality of care for those with mental health problems for whom institutional care is appropriate, and

“(II) shall include fair and equitable arrangements (as determined by the Secretary after consultation with the Secretary of Labor) to protect the interests of employees affected by actions described in subclause (I), including arrangements designed to preserve employee rights and benefits and to provide training and retraining of such employees where necessary and arrangements under which maximum effort will be made to guarantee the employment of such employees.

“(3) (A) The Secretary shall review annually the activities undertaken by each State mental health authority with an approved application to determine if it complied with the assurances provided with the application. The Secretary may not approve an application submitted under paragraph (2) if the Secretary determines—

“(i) the State for which the application was submitted did not comply with assurances provided with a prior application under paragraph (2), and

“(ii) he cannot be assured that the State will comply with the assurances provided with the application under consideration.

State mental health authority, duties.
42 USC 2689t.

Consultation with Labor Secretary.

State authority, annual review of activities.

“(B) Whenever the Secretary, after reasonable notice and opportunity for a hearing to the State mental health authority of a State, finds that, with respect to funds paid to the authority under a grant under paragraph (1), there is a failure to comply substantially with assurances provided under paragraph (2) with respect to the receipt of such grant, the Secretary shall notify the authority that further payments will not be made to it under such grant (or, in his discretion, that further payments will not be made to it from such grant for activities in which there is such failure), until he is satisfied that there will no longer be such failure. Until he is so satisfied, the Secretary shall make no payment to such authority from such grant, or shall limit payment under such grant to activities in which there is no such failure.

Grant payments,
termination.

“(4) For the purpose of determining the total amount of grants that may be made to the State mental health authorities of each State, the Secretary shall, in each fiscal year and in accordance with regulations, allot the sums appropriated for such year under paragraph (7) among the States on the basis of the population and the financial need of the respective States. The populations of the States shall be determined on the basis of the latest figures for the population of the States available from the Department of Commerce.

“(5) (A) The Secretary shall determine the amount of any grant under paragraph (1); but the amount of grants made in any fiscal year to the mental health authorities of any State may not exceed the amount of the State's allotment available for obligation in such fiscal year. Payments under such grants may be made in advance or by way of reimbursement, and at such intervals and on such conditions, as the Secretary finds necessary.

“(B) The Secretary, at the request of a State mental health authority, may reduce the amount of the grant to the authority under paragraph (1) by—

“(i) the fair market value of any supplies or equipment furnished the State mental health authority, and

“(ii) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the State mental health authority and the amount of any other costs incurred in connection with the detail of such officer or employee. when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of the State mental health authority and for the purpose of carrying out any project with respect to which its grant under paragraph (1) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the State mental health authority.

“(6) In any fiscal year not less than 70 per centum of the amount of a State's grant shall be available only for the provision of mental health services and for the conduct of mental health planning activities in communities of the State.

“(7) For the purpose of making grants under this subsection there are authorized to be appropriated \$5,000,000 for the fiscal year ending September 30, 1979, \$20,000,000 for the fiscal year ending September 30, 1980, and \$25,000,000 for the fiscal year ending September 30, 1981.

Appropriation
authorization.

“(8) Regulations (including substantive amendments to regula-

Regulations.

tions) under this subsection shall be promulgated by the Secretary after consultation with a conference of State mental health authorities. The Secretary shall consult with such conference before the publication of proposals for such regulations or amendments.”.

MISCELLANEOUS

42 USC 2689f. SEC. 110. (a) Section 211(1)(A) is amended (1) by inserting “for compensation of personnel for its initial operation” after “1975”, and (2) by inserting “for such compensation of personnel” after “under that section”.

42 USC 2689b.
42 USC 2689.
42 USC 2688u. (b) Section 203(e)(1)(A)(i) is amended by striking out “unless it meets the requirements of section 201” and inserting in lieu thereof the following: “(other than section 271) unless it provides at least the comprehensive mental health services described in clauses (i) through (iv) of section 201(b)(1)(A)”.

42 USC 2689m. (c) Effective July 29, 1975, section 225 is amended by striking out “this part” and inserting in lieu thereof “this title”.

42 USC 4588. (d) Section 504(a) of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 is amended by adding after and below paragraph (2) the following: “Insofar as practicable, the Secretary shall approve applications under this subsection in a manner which results in an equitable geographic distribution of Centers.”.

EFFECTIVE DATE

42 USC 2689 note. SEC. 111. The amendments made by this title (other than by section 110(c)) to the Community Mental Health Centers Act shall apply with respect to grants made under the Community Mental Health Centers Act from appropriations for fiscal years ending after September 30, 1978.

Biomedical
Research and
Research
Training
Amendments of
1978.

TITLE II—BIOMEDICAL RESEARCH EXTENSION
AMENDMENTS

SHORT TITLE; REFERENCE TO ACT

42 USC 201 note. SEC. 201. (a) This title may be cited as the “Biomedical Research and Research Training Amendments of 1978”.

42 USC 201 note. (b) Whenever in this title (other than in sections 267 and 268) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act.

PART A—LIBRARIES OF MEDICINE

EXTENSION OF AUTHORIZATIONS

42 USC 280b. SEC. 211. Section 390(c) is amended by striking out “and” after “1976,” and by inserting before the period the following: “, \$15,000,000 for the fiscal year ending September 30, 1979, \$16,500,000 for the fiscal year ending September 30, 1980, and \$18,500,000 for the fiscal year ending September 30, 1981”.

BOARD OF REGENTS' APPOINTMENTS

SEC. 212. Section 383 is amended (1) by striking out "by the President, by and with the advice and consent of the Senate" in the first sentence of subsection (a) and inserting in lieu thereof "by the Secretary", and (2) by striking out "by the President" in the first sentence of subsection (c) and inserting in lieu thereof "by the Secretary". 42 USC 277.

PART B—PROGRAMS OF THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

EXTENSION OF AUTHORIZATIONS

SEC. 221. (a) Section 414(b) is amended by striking out "and" after "1977," and by inserting before the period the following: ", \$40,000,000 for the fiscal year ending September 30, 1979, and \$45,000,000 for the fiscal year ending September 30, 1980". 42 USC 287c.

(b) Section 419B is amended in the first sentence by striking out "and" after "1977," and by inserting before the period the following: ", \$470,000,000 for the fiscal year ending September 30, 1979, and \$515,000,000 for the fiscal year ending September 30, 1980". 42 USC 287i.

SUBMISSION OF REPORTS

SEC. 222. (a) Section 413(b) (2) is amended by striking out "submit to the President for transmittal to the Congress a report" and inserting in lieu thereof "submit a report to the Secretary, for simultaneous transmittal by the Secretary, not later than November 30 of each year, to the President and to the Congress." 42 USC 287b.

(b) Section 418(b) (2) is amended by inserting "by the Secretary" after "transmittal". 42 USC 287g.

INFORMATION PROGRAMS

SEC. 223. (a) Section 412(5) is amended by striking out "make available" and inserting in lieu thereof "make available on a timely basis". 42 USC 287a.

(b) Section 413(d) is amended (1) by striking out "to provide" in the second sentence and inserting in lieu thereof "to provide on a timely basis", and (2) by striking out "diet" in the third sentence and inserting in lieu thereof "diet and nutrition, environmental pollutants". 42 USC 287b.

EDUCATION AND INFORMATION PROGRAMS OF CENTERS

SEC. 224. Section 415(a) (2) is amended by adding after subparagraph (D) the following: 42 USC 287d.

"(E) Programs of continuing education for health and allied health professionals in the diagnosis, prevention, and treatment of such diseases and information programs for the public respecting the prevention and early diagnosis and treatment of such diseases."

PART C—PROGRAMS OF THE NATIONAL CANCER INSTITUTE

Subpart I—Extension of and Substantive Changes in Programs of the National Cancer Institute

EXTENSION OF AUTHORIZATIONS

- 42 USC 286c. SEC. 231. (a) Section 409(b) is amended by striking out “and” after “1977,” and by inserting before the period the following: “, \$90,500,000 for the fiscal year ending September 30, 1979, and \$103,000,000 for the fiscal year ending September 30, 1980”.
- 42 USC 286g. (b) Section 410C is amended by striking out “and” after “1977;” and by inserting before the period the following: “\$924,500,000 for the fiscal year ending September 30, 1979; and \$927,000,000 for the fiscal year ending September 30, 1980”.

NATIONAL CANCER ADVISORY BOARD

- 42 USC 286f. SEC. 232. (a) (1) (A) Subsection (a) of section 410B is amended by striking out “twenty-three” and inserting in lieu thereof “twenty-nine”.
- (B) Paragraph (1) of such subsection is amended by inserting after “Veterans’ Administration” the following: “, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission”.
- (2) The first sentence of such subsection following paragraph (2) is amended (A) by striking out “and not more” and inserting in lieu thereof “, not more”, and (B) by inserting before the period “, and not less than five of the appointed members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors)”.
- (3) The second sentence of such subsection following paragraph (2) is amended by inserting before the period a comma and the following: “and at least two of the physicians appointed to the Board shall be physicians primarily involved in treating individuals who have cancer”.
- (4) Such subsection is amended by adding at the end the following: “The ex officio members of the Board shall be nonvoting members.”
- Reports. (5) Section 410B(g) is amended by striking out “a report to the President for transmittal to the Congress not later than January 31 of each year on the progress” and inserting in lieu thereof “a report to the Secretary, for simultaneous transmittal by the Secretary, not later than November 30 of each year, to the President and to the Congress, on the progress during the preceding fiscal year”.
- 42 USC 286f note. (b) The amendments made by subsection (a) of this section respecting the manner of appointing members of the National Cancer Advisory Board and the composition of such Board shall apply with respect to appointments made to the Board after the date of the enactment of this Act, and the President shall make appointments to such Board

after such date in a manner which will bring about, at the earliest feasible time, the composition prescribed by such amendments.

SUBMISSION OF REPORTS

SEC. 233. Section 410A(b) is amended (1) by striking out "end of each calendar year" and inserting in lieu thereof "end of each fiscal year", (2) by striking out "submit to the President for transmittal to the Congress" and inserting in lieu thereof "submit to the Secretary, for simultaneous transmittal by the Secretary, not later than November 30 of each year, to the President and to the Congress", and (3) by striking out "the preceding calendar year" and inserting in lieu thereof "the preceding fiscal year". 42 USC 286e.

FUNCTIONS OF CENTERS

SEC. 234. (a) Subsections (a) and (b) of section 408 are each amended by striking out "clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to cancer" and inserting in lieu thereof "basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods for cancer". 42 USC 286b.

(b) Clause (3) of the second sentence of section 408(b) is amended by inserting after the comma the following: "continuing education for health professionals and allied health professions personnel, and information programs for the public respecting cancer,".

NATIONAL CANCER PROGRAM

SEC. 235. (a) Paragraph (1) of subsection (b) of section 407 is amended by striking out ", plan and develop" and inserting in lieu thereof "(A) plan and develop", and by inserting before the period the following: "; and (B) implement an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens". 42 USC 286a.

(b) Paragraph (7) of such subsection is amended to read as follows:

"(7) Support appropriate programs of education (including continuing education) and training in fundamental sciences and clinical disciplines for investigators, physicians, and allied health professionals for participation in clinical programs relating to cancer, including the use of training stipends, fellowships, and career awards."

(c) The first sentence of subsection (c)(3) of such section is amended by striking out "twelve times" and inserting in lieu thereof "four times".

CANCER CONTROL PROGRAMS

SEC. 236. (a) Subsection (a) of section 409 is amended to read as follows: 42 USC 286c.

"(a) The Director of the National Cancer Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this subsection shall include—

"(1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research

results and to disseminate information respecting the detection, diagnosis, prevention, and treatment of cancer and rehabilitation and counseling respecting cancer to physicians and other health professionals who provide care to individuals who have cancer;

“(2) the demonstration of and the education of health professionals in—

“(A) effective methods for the early detection of cancer and the identification of individuals with a high risk of developing cancer, and

“(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

“(3) the demonstration of new methods for the dissemination of information to the general public concerning the early detection and treatment of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.”.

Subpart II—Technical Revision of the Authority of the National Cancer Institute

TECHNICAL REVISION

42 USC 281. SEC. 241. (a) (1) Part A of title IV (as amended by subpart I of this part) is amended to read as follows:

“PART A—NATIONAL CANCER INSTITUTE

“A DIVISION OF THE NATIONAL INSTITUTES OF HEALTH

42 USC 281. “SEC. 400. The National Cancer Institute (in this part referred to as the ‘Institute’) is a division of the National Institutes of Health.

“CANCER RESEARCH AND OTHER ACTIVITIES

42 USC 282. “SEC. 401. (a) In carrying out the purposes of section 301 with
42 USC 241. respect to cancer, the Secretary, through the Institute and in cooperation with the National Cancer Advisory Board, shall—

“(1) conduct, assist, and foster research, investigations, experiments, and studies relating to the cause, prevention, and methods of diagnosis and treatment of cancer;

“(2) promote the coordination of research conducted by the Institute and similar research conducted by other agencies and organizations and by individuals;

“(3) provide clinical training and instruction in technical matters relating to the diagnosis and treatment of cancer;

“(4) secure for the Institute consultation services and advice of cancer experts from the United States and abroad;

“(5) cooperate with State health agencies in the prevention, control, and eradication of cancer; and

“(6) procure, use, and lend radium as provided in subsection (b).

“(b) In carrying out subsection (a), all appropriate provisions of section 301 shall be applicable to the authority of the Secretary, and the Secretary is authorized—

41 USC 5. “(1) to purchase radium, from time to time and without regard to section 3709 of the Revised Statutes, and to make such radium

available for the purposes of this part, both to the Service and by loan to other agencies and institutions for such consideration and subject to such conditions as he may prescribe; and

“(2) to provide the necessary facilities where training and instruction may be given in all technical matters relating to the diagnosis and treatment of cancer to persons found by the Secretary to have proper technical qualifications and designated by him for such training or instruction and to fix and pay them a per diem allowance during such training or instruction.

“NATIONAL CANCER PROGRAM

“SEC. 402. The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other research institutes and including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute. 42 USC 283.

“CANCER CONTROL PROGRAMS

“SEC. 403. The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include— 42 USC 284.

“(1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting the detection, diagnosis, prevention, and treatment of cancer and rehabilitation and counseling respecting cancer to physicians and other health professionals who provide care to individuals who have cancer;

“(2) the demonstration of and the education of health professionals in—

“(A) effective methods for the early detection of cancer and the identification of individuals with a high risk of developing cancer, and

“(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

“(3) the demonstration of new methods for the dissemination of information to the general public concerning the early detection and treatment of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

“DUTIES AND FUNCTIONS OF THE DIRECTOR

“SEC. 404. (a) The Director of the Institute in carrying out the National Cancer Program shall— 42 USC 285.

“(1) collect, analyze, and disseminate information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer) useful in the prevention, diagnosis, and treatment of cancer, including the establishment of an international cancer research data bank to collect, catalog, store, and disseminate insofar as feasible the

results of cancer research undertaken in any country for the use of any person involved in cancer research in any country;

“(2) establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for research and set standards of safety and care for persons using such materials;

“(3) support research in the cancer field outside the United States by highly qualified foreign nationals which research can be expected to inure to the benefit of the American people; support collaborative research involving American and foreign participants; and support the training of American scientists abroad and foreign scientists in the United States;

“(4) support appropriate programs of education (including continuing education) and training in fundamental sciences and clinical disciplines for investigators, physicians, and allied health professionals for participation in clinical programs relating to cancer, including the use of training stipends, fellowships, and career awards;

“(5) expeditiously utilize existing research facilities and personnel of the National Institutes of Health for accelerated exploration of opportunities in areas of special promise;

“(6) encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research;

“(7) provide and contract for a program to disseminate and interpret, on a current basis, for practitioners and other health professionals, scientists, and the general public scientific and other information respecting the cause, prevention, diagnosis, and treatment of cancer;

“(8) (A) prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needed for the National Cancer Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the National Cancer Advisory Board; and (B) receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the Institute; and

“(9) as soon as practicable after the end of each fiscal year, prepare in consultation with the National Cancer Advisory Board and submit to the Secretary, for simultaneous transmittal, not later than November 30 of each year, to the President and to the Congress, a report on the activities, progress, and accomplishments under the National Cancer Program during the preceding fiscal year, which shall include a report on the progress, activities, and accomplishments of, and expenditures for, the information services of the Program, and a plan for the Program during the next five years.

“(b) The Director of the Institute (after consultation with the National Cancer Advisory Board) in carrying out his functions in administering the National Cancer Program and without regard to any other provision of this Act is authorized—

“(1) to obtain (in accordance with section 3109 of title 5, United States Code and if authorized by the National Cancer Advisory

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President and
Congress.

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Board, but without regard to the limitation in such section on the number of days or the period of such service) the services of not more than one hundred and fifty-one experts or consultants who have scientific or professional qualifications;

“(2) to acquire, construct, improve, repair, operate, and maintain cancer centers, laboratories, research, and other necessary facilities and equipment, and related accommodations as may be necessary, and such other real or personal property (including patents) as the Director deems necessary; to acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

“(3) to appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments as he deems desirable to advise him with respect to his functions;

“(4) to utilize, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

“(5) to accept voluntary and uncompensated services;

“(6) to accept unconditional gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible;

“(7) to enter into such contracts, leases, cooperative agreements, or other transactions, without regard to sections 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 529, 41 U.S.C. 5), as may be necessary in the conduct of his functions, with any public agency, or with any person, firm, association, corporation, or educational institution;

“(8) to take necessary action to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally;

“(9) to award grants for new construction as well as alterations and renovations for improvement of basic research laboratory facilities, including those related to biohazard control, as deemed necessary for the National Cancer Program; and

Grants.

“(10) to call special meetings of the National Cancer Advisory Board at such times and in such places as the Director deems necessary in order to consult with, obtain advice from, or to secure the approval of projects, programs, or other actions to be undertaken without delay in order to gain maximum benefit from a new scientific or technical finding.

“SCIENTIFIC REVIEW

“SEC. 405. (a) The Director of the Institute shall, by regulation, provide for proper scientific review of all research grants and programs over which he has authority (1) by utilizing, to the maximum extent possible, appropriate peer review groups established within the National Institutes of Health and composed principally of non-Federal scientists and other experts in the scientific and disease fields, 42 USC 286.

and (2) when appropriate, by establishing, with the approval of the National Cancer Advisory Board and the Director of the National Institutes of Health, other formal peer review groups as may be required.

Grants.

“(b) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Cancer Institute may approve grants under this Act for cancer research or training—

“(1) if the direct costs of such research and training do not exceed \$35,000, but only after appropriate review for scientific merit, and

“(2) if the direct costs of such research and training exceed \$35,000, but only after appropriate review for scientific merit and recommendation for approval by the National Cancer Advisory Board under section 407(b)(3).

42 USC 286a.

“NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

Establishment.
42 USC 286a.

“SEC. 406. (a) The Director of the Institute is authorized to provide for the establishment of new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods for cancer. Such centers may be supported under subsection (b) or under any other applicable provision of law.

Cooperative agreements.

“(b) The Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultation with the National Cancer Advisory Board, is authorized to enter into cooperative agreements with public or private nonprofit agencies or institutions to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for existing or new centers (including, but not limited to, centers established under subsection (a)) for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for cancer. Federal payments under this subsection in support of such cooperative agreements may be used for (1) construction (notwithstanding any limitation under section 477), (2) staffing and other basic operating costs, including such patient care costs as are required for research, (3) clinical training (including clinical training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public respecting cancer, and (4) demonstration purposes. The aggregate of payments (other than payments for construction) made to any center in support of such an agreement for its costs (other than indirect costs) described in the first sentence may not exceed \$5,000,000 in any fiscal year, except that if in any fiscal year there is an increase, as reflected in the Consumer Price Index published by the Bureau of Labor Statistics, in the cost of a center for which payments may be made under such an agreement, the aggregate of payments in such year for such center may exceed \$5,000,000 to include such increase and any such increase in any preceding fiscal year for which payments were made to such center under such an agreement to the extent that such increase resulted in payments in excess of \$5,000,000. As used in this section, the term ‘construction’ does not include the acquisition of land, and the term ‘training’ does not include research training for which fellowship support may be provided under section 472. Support of a center under this section may

Post, p. 3432.

42 USC 289-1.

be for a period of not to exceed three years and may be extended by the Director of the Institute for additional periods of not more than three years each, after review of the operations of such center by an appropriate scientific review group established by the Director of the Institute.

“NATIONAL CANCER ADVISORY BOARD

“Sec. 407. (a) (1) There is established in the Institute a National Cancer Advisory Board (hereinafter in this section referred to as the ‘Board’) to be composed of twenty-nine members as follows: Establishment. 42 USC 286b.

“(A) The Secretary, the Director of the Office of Science and Technology Policy, the Director of the National Institutes of Health, the chief medical officer of the Veterans’ Administration, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission (or their designees), and a medical officer designated by the Secretary of Defense shall be ex officio members of the Board.

“(B) Eighteen members appointed by the President.

Not more than twelve of the appointed members of the Board shall be scientists or physicians, not more than eight of the appointed members shall be representatives from the general public, and not less than five of the appointed members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors). The scientists and physicians appointed to the Board shall be appointed from persons who are among the leading scientific or medical authorities outstanding in the study, diagnosis, or treatment of cancer or in fields related thereto, and at least two of the physicians appointed to the Board shall be physicians primarily involved in treating individuals who have cancer. Each appointed member of the Board shall be appointed from among persons who by virtue of their training, experience, and background are especially qualified to appraise the programs of the Institute. The ex officio members of the Board shall be nonvoting members.

“(2) (A) Appointed members shall be appointed for six-year terms, except that of the members first appointed six shall be appointed for a term of two years, and six shall be appointed for a term of four years, as designated by the President at the time of appointment.

“(B) Any member appointed to fill a vacancy occurring prior to expiration of the term for which his predecessor was appointed shall serve only for the remainder of such term. Appointed members shall be eligible for reappointment and may serve after the expiration of their terms until their successors have taken office.

“(C) A vacancy in the Board shall not affect its activities, and twelve members thereof shall constitute a quorum.

“(3) The President shall designate one of the appointed members to serve as Chairman for a term of two years.

“(4) The Board shall meet at the call of the Director of the Institute or the Chairman, but not less often than four times a year and shall advise and assist the Director of the Institute with respect to the National Cancer Program.

“(5) The Director of the Institute shall designate a member of the staff of the Institute to act as Executive Secretary of the Board.

- Hearings. “(6) The Board may hold such hearings, take such testimony, and sit and act at such times and places as the Board deems advisable to investigate programs and activities of the National Cancer Program.
- Reports. “(7) The Board shall submit a report to the Secretary for simultaneous transmittal by the Secretary, not later than November 30 of each year, to the President and the Congress, on the progress during the preceding fiscal year of the National Cancer Program toward the accomplishment of its objectives.
- Compensation. “(8) Members of the Board who are not officers or employees of the United States shall receive for each day they are engaged in the performance of the duties of the Board compensation at rates not to exceed the daily equivalent of the annual rate in effect for GS-18 of the General Schedule, including traveltime; and all members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for persons in the Government service employed intermittently.
- 5 USC 5332 note. “(9) The Director of the Institute shall make available to the Board such staff, information, and other assistance as it may require to carry out its activities.
- Ante, p. 3424. “(b) The Board is authorized—
- “ (1) to review research projects or programs conducted or authorized to be conducted under section 401 relating to the study of the cause, prevention, or methods of diagnosis and treatment of cancer, and recommend to the Secretary any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis and treatment of cancer;
- “ (2) to collect information as to studies which are being carried on in the United States or any other country as to the cause, prevention, and methods of diagnosis and treatment of cancer, by correspondence or by personal investigation of such studies, and with the approval of the Secretary make available such information through the appropriate publications for the benefit of health agencies and organizations (public or private), physicians, or any other scientists, and for the information of the general public;
- Ante, p. 3427. “ (3) to review applications for grants for research projects relating to cancer and to recommend to the Director for approval under section 405(b)(2) those applications which show promise of making valuable contributions to human knowledge with respect to the cause or prevention of cancer or to methods of diagnosis or treatment of cancer;
- 42 USC 219. “ (4) to recommend to the Secretary for acceptance conditional gifts pursuant to section 501 of this Act; and
- “ (5) to make recommendations to the Secretary with respect to carrying out the provisions of this part.

“PRESIDENT’S CANCER PANEL

- Establishment.
42 USC 286c. “SEC. 408. (a) (1) There is established the President’s Cancer Panel (hereinafter in this section referred to as the ‘Panel’) which shall be composed of three persons appointed by the President, who by virtue of their training, experience, and background are exceptionally qual-

ified to appraise the National Cancer Program. At least two of the members of the Panel shall be distinguished scientists or physicians.

“(2) (A) Members of the Panel shall be appointed for three-year terms, except that (i) in the case of two of the members first appointed, one shall be appointed for a term of one year and one shall be appointed for a term of two years, as designated by the President at the time of appointment, and (ii) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term.

“(B) The President shall designate one of the members to serve as Chairman for a term of one year.

“(C) Members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties vested in the Panel, and shall be allowed travel expenses (including a per diem allowance) under section 5703(b) of title 5, United States Code.

“(3) The Panel shall meet at the call of the Chairman, but not less often than four times a year. A transcript shall be kept of the proceedings of each meeting of the Panel, and the Chairman shall make such transcript available to the public.

“(b) The Panel shall monitor the development and execution of the National Cancer Program, and shall report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the Program and annually an evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct.

“GIFTS

“SEC. 409. The Secretary shall recommend acceptance of conditional gifts pursuant to section 501 for study, investigation, or research into the cause, prevention, and methods of diagnosis and treatment of cancer, or for the acquisition of real property or the erection, equipment, or maintenance of premises, buildings, or equipment of the Institute, only after consultation with the National Cancer Advisory Board. Donations of \$50,000 or over in aid of research under this part may be acknowledged by the establishment within the Institute of suitable memorials to the donors.

“AUTHORIZATION OF APPROPRIATIONS

“SEC. 410. (a) For the purpose of carrying out this part (other than section 403), there are authorized to be appropriated \$400,000,000 for the fiscal year ending June 30, 1972; \$500,000,000 for the fiscal year ending June 30, 1973; \$600,000,000 for the fiscal year ending June 30, 1974; \$750,000,000 for the fiscal year ending June 30, 1975; \$830,000,000 for the fiscal year ending June 30, 1976; \$985,000,000 for the fiscal year ending September 30, 1977; \$923,590,000 for the fiscal year ending September 30, 1978; \$924,500,000 for the fiscal year ending September 30, 1979; and \$927,000,000 for the fiscal year ending September 30, 1980.

5 USC 5332
note.

Information
available to
public.

Report to
President.

42 USC 286d.
42 USC 219.

42 USC 286e.

“(b) There are authorized to be appropriated to carry out section 403 \$20,000,000 for the fiscal year ending June 30, 1972; \$30,000,000 for the fiscal year ending June 30, 1973; \$40,000,000 for the fiscal year ending June 30, 1974; \$53,500,000 for the fiscal year ending June 30, 1975; \$68,500,000 for the fiscal year ending June 30, 1976; \$88,500,000 for the fiscal year ending September 30, 1977; \$84,560,000 for the fiscal year ending September 30, 1978; \$90,500,000 for the fiscal year ending September 30, 1979; and \$103,000,000 for the fiscal year ending September 30, 1980.

Contract
authority.
Ante, p. 3425.

42 USC 286b
note.

“(c) The authority of the Secretary to enter into any contract for the conduct of a program under section 404(a)(7) shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.”.

(2) The change in the manner of appointing members of the National Cancer Advisory Board and in the composition of such Board prescribed by the amendment made by paragraph (1) shall apply with respect to appointments made to the Board after the date of the enactment of this Act, and the President shall make appointments to such Board after such date in a manner which will bring about, at the earliest feasible time, the composition prescribed by such amendment.

(b) Part I of title IV is amended by adding at the end the following:

“APPROPRIATIONS

42 USC 289l-6.

“SEC. 477. Appropriations to carry out the purposes of this title shall be available for the acquisition of land or the erection of buildings only if so specified, but in the absence of express limitation therein may be expended in the District of Columbia for personal services, stenographic recording and translating services, by contract if deemed necessary, without regard to section 3709 of the Revised Statutes; traveling expenses (including the expenses of attendance at meetings when specifically authorized by the Secretary); rental, supplies and equipment, purchase and exchange of medical books, books of reference, directories, periodicals, newspapers, and press clippings; purchase, operation, and maintenance of motor-propelled passenger-carrying vehicles; printing and binding (in addition to that otherwise provided by law); and for all other necessary expenses in carrying out the provisions of this title.

41 USC 5.

“OTHER AUTHORITY

42 USC 289l-7.

“SEC. 478. This title shall not be construed as limiting (1) the functions or authority of the Secretary under any other title of this Act, or of any officer or agency of the United States, relating to the study of the prevention, diagnosis, and treatment of any disease or diseases for which a separate institute is established under this Act; or (2) the expenditure of money therefor.”.

CONFORMING AMENDMENTS

42 USC 287d.

SEC. 242. (a) Section 415(b)(1) is amended by striking out “section 405” and inserting in lieu thereof “section 477”.

42 USC 289l.

(b) Section 471 is amended by striking out “section 407(b)(9)” and inserting in lieu thereof “section 404(a)(8)”.

PART D—NATIONAL RESEARCH SERVICE AWARDS

EXTENSION OF AUTHORIZATIONS

SEC. 251. (a) Subsection (d) of section 472 is amended by striking out “and” after “1977,” and by inserting before the period at the end of the first sentence the following: “, \$197,500,000 for the fiscal year ending September 30, 1979, \$210,000,000 for the fiscal year ending September 30, 1980, and \$222,500,000 for the fiscal year ending September 30, 1981”.

42 USC 2891-1.

(b) Subsection (d) of such section is amended (1) by striking out “25 per centum” in the second sentence and inserting in lieu thereof “15 per centum”, and (2) by inserting before the period “and not less than 50 per centum shall be made available for grants under subsection (a) (1) (B) for National Research Service Awards”.

(c) Subsection (d) of such section is amended by adding at the end thereof the following new sentence: “In any fiscal year not more than 4 per centum of the amount obligated to be expended under this section may be obligated for National Research Service Awards for periods of three months or less.”.

APPROVAL OF AWARDS

SEC. 252. Paragraph (2) of subsection (b) of such section is amended by striking out “The award of National Research Service Awards by the Secretary under subsection (a) and the making of grants for such Awards” and inserting in lieu thereof “The making of grants under subsection (a) (1) (B) for National Research Service Awards”.

PERIOD OF AWARDS

SEC. 253. Paragraph (4) of subsection (b) of such section is amended to read as follows:

“(4) The period of any National Research Service Award made to any individual under subsection (a) may not exceed—

“(A) five years in the aggregate for predoctoral training, and

“(B) three years in the aggregate for postdoctoral training, unless the Secretary for good cause shown waives the application of such limit to such individual.”

ADJUSTMENTS IN ALLOWANCES

SEC. 254. The first sentence of subsection (b) (5) of such section is amended by inserting after “dependency allowances)” the following: “, adjusted periodically to reflect increases in the cost of living”.

SERVICE OBLIGATION

SEC. 255. (a) Subparagraph (B) of subsection (c) (1) of such section is amended (1) by inserting “or” in clause (i) after “Corps.”, (2) by striking out clause (ii), and (3) by redesignating clause (iii) as clause (ii).

(b) (1) Paragraph (2) of subsection (c) of such section is amended to read as follows:

“(2) For each month for which an individual receives a National Research Service Award which is made for a period in excess of three months, such individual shall—

“(A) for one month engage in health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment, or, if so authorized, serve as a member of the National Health Service Corps, or

“(B) if authorized under paragraph (1)(B) or (1)(C), for one month serve in the individual’s specialty or engage in a health-related activity.”

(2) Paragraph (4)(A) of such subsection is amended by striking out

$$“A = \phi \left(\frac{t - \frac{1}{2}s}{t} \right)”$$

and inserting in lieu thereof

$$“A = \phi \left(\frac{t - s}{t} \right).”$$

(3) Paragraph (5)(B) of such subsection amended by striking out “extreme hardship” and inserting in lieu thereof “substantial hardship”.

42 USC 289l-1
note.

42 USC 289l-1.

(b) The amendments made by subsection (a) shall apply only with respect to National Research Service Awards made under section 472 of the Public Health Service Act after the date of the enactment of this Act.

REPORTS ON STUDIES

42 USC 289l-2.

SEC. 256. Section 473(c) is amended by striking out “not later than September 30 of each year” and inserting in lieu thereof “at least once every two years”.

PART E—MISCELLANEOUS AMENDMENTS

SUBSTANCES AND ORGANISMS FOR RESEARCH

42 USC 241.

SEC. 261. Effective October 1, 1978, section 301 is amended by adding after and below paragraph (h) the following: “The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.”

EXPANSION OF RESEARCH AND TESTING AUTHORITY

42 USC 241.

SEC. 262. Effective October 1, 1978, section 301 (as amended by section 261 of this title) is amended (1) by striking out “Surgeon General” each place it appears and inserting in lieu thereof “Secretary”, (2) by striking out “Collect” in paragraph (a) and inserting in lieu thereof “collect”, (3) by striking out “Make” in paragraphs (b), (c), and (f) and inserting in lieu thereof “make”, (4) by striking out “Secure” in paragraph (d) and inserting in lieu thereof “secure”, (5) by striking out “For” in paragraph (e) and inserting in lieu thereof “for”, (6) by striking out “Enter” in paragraph (g) and inserting in lieu thereof “enter”, (7) by striking out “Adopt” in paragraph (h) and inserting in lieu thereof “adopt”, (8) by striking out “and” at the end of paragraph (f), (9) by redesignating paragraphs (a)

through (h) as paragraphs (1) through (8), respectively, and (10) by inserting "(a)" after "301." and by adding at the end the following:

"(b) (1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

Grants.

"(2) (A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

Low-level ionizing radiation.

"(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

"(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health, Education, and Welfare and shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

"(4) The Secretary shall publish an annual report which contains—

Annual report, publication.

"(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

"(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

"(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

"(D) a description of (i) each request received during the year involved—

"(I) from a Federal agency outside the Department of Health, Education, and Welfare for the Secretary, or

"(II) from an entity within the Department of Health, Education, and Welfare to any other entity within the Department,

to conduct research into, or testing for, the carcinogenicity of sub-

stances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

Contract
authority.

“(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.”.

NEW ARTHRITIS CENTERS

42 USC 289c-6. SEC. 263. Section 439 (g) is amended by striking out the last sentence.

PEER REVIEW OF RESEARCH GRANTS UNDER THE DIVISION OF NURSING

42 USC 289l-4. SEC. 264. Section 475 (a) is amended (1) by inserting before “, shall by regulation” the following: “and the head of the Division of Nursing of the Health Resources Administration (or the successor to either such entity)”, (2) by inserting after “research” in paragraph (1) the following: “(including research under programs of such Division of Nursing)”, and (3) by striking out “or the” in paragraph (2) and inserting in lieu thereof “the” and by inserting before the period in that paragraph a comma and the following: “or the Division of Nursing of the Health Resources Administration (or the successor to either such entity)”.

EXPERTS AND CONSULTANTS FOR THE INSTITUTES

Ante, p. 3432. SEC. 265. Title IV is amended by inserting after section 478 (as added by section 241 (b) of this title) the following new section:

“EXPERTS AND CONSULTANTS

42 USC 289l-8. “SEC. 479. (a) The Director of the National Institutes of Health may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of service) the services of not more than two hundred experts or consultants who have scientific or professional qualifications, for the National Institutes of Health and for each of the research institutes (other than the National Cancer Institute and the National Heart, Lung, and Blood Institute).

Compensation.
42 USC 284,
287b.

“(b) (1) Experts and consultants whose services are obtained under subsection (a) or under section 404 (b) (1) or 413 (c) (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a (a) (1), 5724a (a) (3), and 5726 (c) of title 5, United States Code.

“(2) Expenses specified in paragraph (1) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under this subsection, unless and until the expert or consultant agrees in writing to complete the entire period of his assignment or 1 year, whichever is shorter, unless separated or reassigned for reasons beyond his control that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for these expenses is recoverable from him as a debt due the United States. The Secretary may waive in whole

or in part a right of recovery under this subsection with respect to an expert or consultant on assignment with the Secretary.”.

PUBLIC HEALTH SERVICE HOSPITALS

SEC. 266. Section 321(a) is amended by striking out “, and tobacco”. 42 USC 248.

EXTENSION OF DEADLINE FOR FINAL REPORT OF NATIONAL COMMISSION ON DIGESTIVE DISEASES

SEC. 267. Section 301(i) (1) of the Arthritis, Diabetes, and Digestive Disease Amendments of 1976 (Public Law 94-562) is amended by striking out “Within eighteen months following its initial meeting (as prescribed by subsection (d)),” and inserting in lieu thereof “Not later than February 1, 1979,”. 42 USC 289a note.

PROGRAMS FOR FAMILIES OF ALCOHOLICS AND ALCOHOL ABUSERS

SEC. 268. (a) Section 2(a) of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 is amended— 42 USC 4541.

- (1) by striking out “and” at the end of paragraph (5),
- (2) by redesignating paragraph (6) as paragraph (7), and
- (3) by inserting after paragraph (5) the following new paragraph:

“(6) alcohol abuse and alcoholism have a substantial impact on the families of alcohol abusers and alcoholics; and”.

(b) Section 303(a) (4) (B) of such Act is amended by inserting “and for education, counseling, and treatment of the families of alcoholic abusers and alcoholics” after “under the age of eighteen”. 42 USC 4573.

(c) Section 501(a) of such Act is amended— 42 USC 4585.

- (1) by striking out “of” each place it appears in paragraphs (1) through (4) and inserting “of” before “alcohol abuse and alcoholism”;

- (2) by striking out “and” at the end of paragraph (3) and inserting “and” after the comma at the end of paragraph (4); and

- (3) by inserting after paragraph (4) the following new paragraph:

“(5) the impact on families;”.

(d) Section 501(b) (5) of such Act is amended by inserting “or those of their families” after “individuals suffering from alcoholism or alcohol abuse”.

TITLE III—PRESIDENT’S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH

PRESIDENT’S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH

SEC. 301. The Public Health Service Act is amended by adding after title XVII the following new title:

"TITLE XVIII—PRESIDENT'S COMMISSION FOR THE
STUDY OF ETHICAL PROBLEMS IN MEDICINE AND
BIOMEDICAL AND BEHAVIORAL RESEARCH

"ESTABLISHMENT OF COMMISSION

42 USC 300v.

"SEC. 1801. (a) ESTABLISHMENT.—(1) There is established the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (hereinafter in this title referred to as the 'Commission') which shall be composed of eleven members appointed by the President. The members of the Commission shall be appointed as follows:

"(A) Three of the members shall be appointed from individuals who are distinguished in biomedical or behavioral research.

"(B) Three of the members shall be appointed from individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care.

"(C) Five of the members shall be appointed from individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than a biomedical or behavioral science), the social sciences, the humanities, health administration, government, and public affairs.

"(2) No individual who is a full-time officer or employee of the United States may be appointed as a member of the Commission. The Secretary of Health, Education, and Welfare, the Secretary of Defense, the Director of Central Intelligence, the Director of the Office of Science and Technology Policy, the Administrator of Veterans' Affairs, and the Director of the National Science Foundation shall each designate an individual to provide liaison with the Commission.

"(3) No individual may be appointed to serve as a member of the Commission if the individual has served for two terms of four years each as such a member.

"(4) A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

"(b) TERMS.—(1) Except as provided in paragraphs (2) and (3), members shall be appointed for terms of four years.

"(2) Of the members first appointed—

"(A) four shall be appointed for terms of three years, and

"(B) three shall be appointed for terms of two years,

as designated by the President at the time of appointment.

"(3) Any member appointed to fill a vacancy occurring before the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term. A member may serve after the expiration of his term until his successor has taken office.

"(c) CHAIRMAN.—The Chairman of the Commission shall be appointed by the President, by and with the advice and consent of the Senate, from members of the Commission.

"(d) MEETINGS.—(1) Seven members of the Commission shall constitute a quorum for business, but a lesser number may conduct hearings.

"(2) The Commission shall meet at the call of the Chairman or at the call of a majority of its members.

“(e) COMPENSATION.—(1) Members of the Commission shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the Commission.

5 USC 5332
note.

“(2) While away from their homes or regular places of business in the performance of services for the Commission, members of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703 of title 5 of the United States Code.

“DUTIES OF THE COMMISSION

“SEC. 1802. (a) STUDIES.—(1) The Commission shall undertake studies of the ethical and legal implications of— 42 USC 300v-1.

“(A) the requirements for informed consent to participation in research projects and to otherwise undergo medical procedures;

“(B) the matter of defining death, including the advisability of developing a uniform definition of death;

“(C) voluntary testing, counseling, and information and education programs with respect to genetic diseases and conditions, taking into account the essential equality of all human beings, born and unborn;

“(D) the differences in the availability of health services as determined by the income or residence of the persons receiving the services;

“(E) current procedures and mechanisms designed (i) to safeguard the privacy of human subjects of behavioral and biomedical research, (ii) to ensure the confidentiality of individually identifiable patient records, and (iii) to ensure appropriate access of patients to information contained in such records, and

“(F) such other matters relating to medicine or biomedical or behavioral research as the President may designate for study by the Commission.

The Commission shall determine the priority and order of the studies required under this paragraph.

“(2) The Commission may undertake an investigation or study of any other appropriate matter which relates to medicine or biomedical or behavioral research (including the protection of human subjects of biomedical or behavioral research) and which is consistent with the purposes of this title on its own initiative or at the request of the head of a Federal agency.

“(3) In order to avoid duplication of effort, the Commission may, in lieu of, or as part of, any study or investigation required or otherwise conducted under this subsection, use a study or investigation conducted by another entity if the Commission sets forth its reasons for such use.

“(4) Upon the completion of each investigation or study undertaken by the Commission under this subsection (including a study or investigation which merely uses another study or investigation), it shall report its findings (including any recommendations for legislation or administrative action) to the President and the Congress and to each Federal agency to which a recommendation in the report applies.

Report to
President and
Congress.

Publication in
Federal Register.

“(b) **RECOMMENDATIONS TO AGENCIES.**—(1) Within 60 days of the date a Federal agency receives a recommendation from the Commission that the agency take any action with respect to its rules, policies, guidelines, or regulations, the agency shall publish such recommendation in the Federal Register and shall provide opportunity for interested persons to submit written data, views, and arguments with respect to adoption of the recommendation.

“(2) Within the 180-day period beginning on the date of such publication, the agency shall determine whether the action proposed by such recommendation is appropriate, and, to the extent that it determines that—

Publication in
Federal Register.

“(A) such action is not appropriate, the agency shall, within such time period, provide the Commission with, and publish in the Federal Register, a notice of such determination (including an adequate statement of the reasons for the determination), or

“(B) such action is appropriate, the agency shall undertake such action as expeditiously as feasible and shall notify the Commission of the determination and the action undertaken.

Report to
President,
Congress, and
Federal agencies.

“(c) **REPORT ON PROTECTION OF HUMAN SUBJECTS.**—The Commission shall biennially report to the President, the Congress, and appropriate Federal agencies on the protection of human subjects of biomedical and behavioral research. Each such report shall include a review of the adequacy and uniformity (1) of the rules, policies, guidelines, and regulations of all Federal agencies regarding the protection of human subjects of biomedical or behavioral research which such agencies conduct or support, and (2) of the implementation of such rules, policies, guidelines, and regulations by such agencies, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

Report to
President,
Congress, and
Federal agencies.

“(d) **ANNUAL REPORT.**—Not later than December 15 of each year (beginning with 1979) the Commission shall report to the President, the Congress, and appropriate Federal agencies on the activities of the Commission during the fiscal year ending in such year. Each such report shall include a complete list of all recommendations described in subsection (b) (1) made to Federal agencies by the Commission during the fiscal year and the actions taken, pursuant to subsection (b) (2), by the agencies upon such recommendations, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

“(e) **PUBLICATIONS.**—The Commission may at any time publish and disseminate to the public reports respecting its activities.

“(b) **DEFINITIONS.**—For purposes of this section:

“(1) The term ‘Federal agency’ means an authority of the government of the United States, but does not include (A) the Congress, (B) the courts of the United States, and (C) the government of the Commonwealth of Puerto Rico, the government of the District of Columbia, or the government of any territory or possession of the United States.

“(2) The term ‘protection of human subjects’ includes the protection of the health, safety, and privacy of individuals.

“ADMINISTRATIVE PROVISIONS

Hearings.
42 USC 300v-2.

“SEC. 1803. (a) **HEARINGS.**—The Commission may for the purpose of carrying out this title hold such hearings, sit and act at such times

and places, take such testimony, and receive such evidence, as the Commission may deem advisable.

“(b) **STAFF.**—(1) The Commission may appoint and fix the pay of such staff personnel as it deems desirable. Such personnel shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

5 USC 5101 *et seq.*, 5331.

“(2) The Commission may procure temporary and intermittent services to the same extent as is authorized by section 3109 (b) of title 5 of the United States Code, but at rates for individuals not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule.

5 USC 5332 note.

“(3) Upon request of the Commission, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Commission to assist it in carrying out its duties under this title.

“(c) **CONTRACTS.**—The Commission, in performing its duties and functions under this title, may enter into contracts with appropriate public or nonprofit private entities. The authority of the Commission to enter into such contracts is effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

“(d) **INFORMATION.**—(1) The Commission may secure directly from any Federal agency information necessary to enable it to carry out this title. Upon request of the Chairman of the Commission, the head of such agency shall furnish such information to the Commission.

“(2) The Commission shall promptly arrange for such security clearances for its members and appropriate staff as are necessary to obtain access to classified information needed to carry out its duties under this title.

“(3) The Commission shall not disclose any information reported to or otherwise obtained by the Commission which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of paragraphs (4) and (6) of subsection (b) of such section.

“(e) **SUPPORT SERVICES.**—The Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

“AUTHORIZATION OF APPROPRIATIONS; TERMINATION OF COMMISSION

“SEC. 1804. (a) **AUTHORIZATIONS.**—To carry out this title there are authorized to be appropriated \$5,000,000 for the fiscal year ending September 30, 1979, \$5,000,000 for the fiscal year ending September 30, 1980, \$5,000,000 for the fiscal year ending September 30, 1981, and \$5,000,000 for the fiscal year ending September 30, 1982.

42 USC 300v-3.

“(b) **FEDERAL ADVISORY COMMITTEE ACT; TERMINATION.**—The Commission shall be subject to the Federal Advisory Committee Act, except that, under section 14(a)(1)(B) of such Act, the Commission shall terminate on December 31, 1982.”

5 USC app.

MISCELLANEOUS PROVISIONS

42 USC 300v
note.

SEC. 302. (a) The President shall initially appoint members to the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (established under the amendment made by section 301) not later than 90 days after the date of the enactment of this title.

Repeal.
42 USC 289l-1
note.
42 USC 218.

(b) Effective November 1, 1978, part A of title II of the National Research Act, section 213 of such Act, and subsection (f) of section 217 of the Public Health Service Act are repealed.

Approved November 9, 1978.

LEGISLATIVE HISTORY:

HOUSE REPORT No. 95-1192 accompanying H.R. 12347 (Comm. on Interstate and Foreign Commerce).

SENATE REPORT No. 95-838 (Comm. on Human Resources).

CONGRESSIONAL RECORD, Vol. 124 (1978):

June 26, considered and passed Senate.

Oct. 15, considered and passed House, amended; Senate concurred in House amendments.