

Public Law 98-551
98th Congress

An Act

To revise and extend provisions of the Public Health Service Act relating to health promotion and disease prevention, to provide for the establishment of centers for research and demonstrations concerning health promotion and disease prevention, and for other purposes.

Oct. 30, 1984
[S. 771]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Health Promotion and Disease Prevention Amendments of 1984".

SEC. 2. (a)(1) Section 1701(a) of the Public Health Service Act (42 U.S.C. 300u(a)) is amended—

(A) by striking out "and" after the semicolon in paragraph (8);

(B) by striking out the period at the end of paragraph (9) and inserting in lieu thereof a semicolon and "and";

(C) by inserting after paragraph (9) the following new paragraph:

"(10) establish in the Office of the Assistant Secretary for Health an Office of Disease Prevention and Health Promotion, which shall—

"(A) coordinate all activities within the Department which relate to disease prevention, health promotion, preventive health services, and health information and education with respect to the appropriate use of health care;

"(B) coordinate such activities with similar activities in the private sector;

"(C) establish a national information clearinghouse to facilitate the exchange of information concerning matters relating to health information and health promotion, preventive health services, and education in the appropriate use of health care, to facilitate access to such information, and to assist in the analysis of issues and problems relating to such matters; and

"(D) support projects, conduct research, and disseminate information relating to preventive medicine, health promotion, and physical fitness and sports medicine.";

(D) by striking out "and with health planning and resource development activities undertaken under titles XV and XVI" in the last sentence; and

(E) by adding at the end thereof the following: "The Secretary shall appoint a Director for the Office of Disease Prevention and Health Promotion established pursuant to paragraph (10) of this subsection. The Secretary shall administer this title in cooperation with health care providers, educators, voluntary organizations, businesses, and State and local health agencies in order to encourage the dissemination of health information and health promotion activities."

(2) Section 1701(b) of such Act is amended to read as follows:

Health
Promotion and
Disease
Prevention
Amendments of
1984.
42 USC 201 note.
Education.

Office of Dis-
ease Prevention
and Health
Promotion,
establishment.

42 USC 300k-1,
300q.

"(b) To carry out this title, there are authorized to be appropriated \$9,000,000 for the fiscal year ending September 30, 1985, \$9,500,000 for the fiscal year ending September 30, 1986, and \$10,000,000 for the fiscal year ending September 30, 1987."

(b) Paragraph (6) of section 1704 of such Act (42 U.S.C. 300u-3(6)) is repealed.

(c) Sections 1706, 1707, 1708, 1709, and 1710 of such Act (42 U.S.C. 300u-5, 300u-6, 300u-7, 300u-8, and 300u-9) are repealed.

(d) Title XVII of such Act is amended by adding at the end thereof the following new sections:

**"CENTERS FOR RESEARCH AND DEMONSTRATION OF HEALTH PROMOTION
AND DISEASE PREVENTION**

42 USC 300u-5.
Grants.

"SEC. 1706. (a) The Secretary shall make grants or enter into contracts with academic health centers for the establishment, maintenance, and operation of centers for research and demonstration with respect to health promotion and disease prevention. Centers established, maintained, or operated under this section shall undertake research and demonstration projects in health promotion, disease prevention, and improved methods of appraising health hazards and risk factors, and shall serve as demonstration sites for the use of new and innovative research in public health techniques to prevent chronic diseases.

"(b) Each center established, maintained, or operated under this section shall—

"(1) be located in an academic health center with—

"(A) a multidisciplinary faculty with expertise in public health and which has working relationships with relevant groups in such fields as medicine, psychology, nursing, social work, education and business;

"(B) graduate training programs relevant to disease prevention;

"(C) a core faculty in epidemiology, biostatistics, social sciences, behavioral and environmental health sciences, and health administration;

"(D) a demonstrated curriculum in disease prevention;

"(E) a capability for residency training in public health or preventive medicine; and

"(F) such other qualifications as the Secretary may prescribe;

"(2) conduct—

"(A) health promotion and disease prevention research, including retrospective studies and longitudinal prospective studies in population groups and communities;

"(B) demonstration projects for the delivery of services relating to health promotion and disease prevention to defined population groups using, as appropriate, community outreach and organization techniques and other methods of educating and motivating communities; and

"(C) evaluation studies on the efficacy of demonstration projects conducted under subparagraph (B) of this paragraph.

Study.

Study.

The design of any evaluation study conducted under subparagraph (C) shall be established prior to the commencement of the demonstration project under subparagraph (B) for which the evaluation will be conducted.

"(c)(1) During fiscal year 1985, the Secretary shall make grants or enter into contracts for the establishment of three centers under this section. During fiscal year 1986, the Secretary shall make grants and enter into contracts for the establishment of five centers under this section and the maintenance and operation of the three centers established under this section in fiscal year 1985. During fiscal year 1987, the Secretary shall make grants and enter into contracts for the establishment of five centers under this section and the operation and maintenance of the eight centers established under this section in fiscal years 1985 and 1986.

Contracts with
U.S.

"(2)(A) In making grants and entering into contracts under this section, the Secretary shall provide for an equitable geographical distribution of centers established, maintained, and operated under this section and for the distribution of such centers among areas containing a wide range of population groups which exhibit incidences of diseases which are most amenable to preventive intervention.

Contracts with
U.S.

"(B) The Secretary, through the Director of the Centers for Disease Control and in consultation with the Director of the National Institutes of Health, shall establish procedures for the appropriate peer review of applications for grants and contracts under this section by peer review groups composed principally of non-Federal experts.

Contracts with
U.S.

"(d) For purposes of this section, the term 'academic health center' means a school of medicine, a school of osteopathy, or a school of public health, as such terms are defined in section 701(4).

"(e) To carry out this section, there are authorized to be appropriated \$3,000,000 for the fiscal year ending September 30, 1985, \$8,000,000 for the fiscal year ending September 30, 1986, and \$13,000,000 for the fiscal year ending September 30, 1987."

Appropriation
authorization.

SEC. 3. Subsection (a) of section 338G of the Public Health Service Act (42 U.S.C. 254r(a)) is amended by inserting "clinical psychologists," after "pharmacists,".

SEC. 4. (a) Section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2)) is amended by striking out "which occurs so infrequently in the United States that" and inserting in lieu thereof "which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which"

(b) Section 5(b)(2) of the Orphan Drug Act (21 U.S.C. 360ee(b)(2)) is amended by striking out "which occurs so infrequently in the United States that" and inserting in lieu thereof "which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which".

SEC. 5. (a) Section 305 of the Public Health Service Act (42 U.S.C. 242c) is amended—

(1) by striking out "National Center for Health Services Research" and inserting in lieu thereof "National Center for Health Services Research and Health Care Technology Assessment";

(2) in subsection (b), by striking out "and" at the end of paragraph (3), by striking out the period at the end of paragraph (4) and inserting in lieu thereof "; and", and by adding after paragraph (4) the following:

"(5) the safety, efficacy, effectiveness, cost effectiveness, economic, and social impacts of health care technologies."; and

Science and
technology.

Grants.
Contracts with
U.S.
Science and
technology.

National
Advisory Council
on Health Care
Technology
Assessment,
establishment.

(3) by redesignating subsection (e) as subsection (i) and by adding after subsection (d) the following:

"(e)(1) The Center shall advise the Secretary respecting health care technology issues and make recommendations with respect to whether specific health care technologies should be reimbursable under federally financed health programs.

"(2) In making recommendations respecting health care technologies, the Center shall consider the safety, efficacy, and effectiveness, and, as appropriate, the cost-effectiveness and appropriate uses of the technology.

"(3) In carrying out its responsibilities under this section respecting health care technologies, the Center shall cooperate and consult with the National Institutes of Health, the Food and Drug Administration, and any other interested Federal departments or agencies.

"(f)(1) The Secretary, acting through the Center, shall undertake and support (by grant or contract) research regarding technology diffusion, methods to assess health care technology, and specific health care technologies.

"(2) Any grant or contract under paragraph (1), the direct cost of which will exceed \$50,000, may be made or entered into only after consultation with the National Advisory Council on Health Care Technology Assessment.

"(g)(1) There is established the National Advisory Council on Health Care Technology Assessment (hereinafter in this section referred to as the 'Council'). The Council shall advise the Secretary and the Director of the Center with respect to the performance of the health care technology assessment functions prescribed by this section. The Council shall assist the Director in developing criteria and methods to be used by the Center in making health care technology coverage recommendations.

"(2) The Council shall consist of—

"(A) the Director of the National Institutes of Health, the Chief Medical Director of the Veterans' Administration, the Assistant Secretary for Health and Environment of the Department of Defense, the head of the Centers for Disease Control, the head of the Health Care Financing Administration, and such other Federal officials as the Secretary may specify, who shall be ex officio members, and

"(B) twelve voting members appointed by the Secretary.

"(3) The Secretary shall make appointments to the Council as follows:

"(A) The Secretary shall appoint six members of the Council from individuals who are distinguished in the fields of medicine, engineering, and science (including social science) and shall appoint four members from individuals who are distinguished in the fields of law, ethics, economics, and management. Of the members appointed under this subparagraph—

"(i) at least two shall be physicians,

"(ii) two shall be selected from individuals who represent business entities engaged in development or production of medical technology,

"(iii) one shall be selected from individuals who represent hospital administrators, and

"(iv) one shall be selected from individuals who represent health insurance companies or self-insured employers.

"(B) The Secretary shall appoint two members from members of the general public who represent the interest of consumers of health care.

"(4)(A) Each appointed member of the Council shall be appointed for a term of three years, except that—

"(i) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and

"(ii) of the members first appointed after the date of the enactment of this subsection, four shall be appointed for a term of three years, four shall be appointed for a term of two years, and four shall be appointed for a term of one year, as designated by the Secretary at the time of appointment.

Appointed members may be appointed for additional terms and may serve after the expiration of their terms until their successors have taken office.

"(B) Members of the Council who are not officers or employees of the United States shall receive for each day they are engaged in the performance of the functions of the Council compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade 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 of title 5, United States Code, for persons in the Government service employed intermittently.

5 USC 5332 note.

"(5) The Council shall annually elect one of its appointed members to serve as Chairman until the next election.

"(6) The Council shall meet at the call of the Chairman, but not less often than three times a year.

"(7) The Director of the Center shall (A) designate a member of the staff of the Center to act as Executive Secretary of the Council, and (B) make available to the Council such staff, information, and other assistance as it may require to carry out its functions.

"(h) In each fiscal year, seven and one-half percent of the amount made available under section 2113 for such fiscal year for evaluations shall be made available to the Assistant Secretary for Health to conduct or support (by both grants and contracts) through the Center, evaluations of health services and health care technology which evaluations are not being conducted or supported under this section or section 304."

Contracts with
U.S.
Grants.
97 Stat. 176.

(b) Subsection (i) of such section (as so redesignated) is amended by striking out "subsections (b), (c), and (d) of".

(c)(1) Section 304 of such Act (42 U.S.C. 242b) is amended by striking out "National Center for Health Services Research" each place it occurs and inserting in lieu thereof "National Center for Health Services Research and Health Care Technology Assessment".

(2) Such section is amended by striking out "the National Center for Health Statistics, and the National Center for Health Care Technology" each place it occurs and inserting in lieu thereof "and the National Center for Health Statistics".

(3) Such section is amended by striking out "the National Center for Health Statistics, or the National Center for Health Care Technology" and inserting in lieu thereof "or the National Center for Health Statistics".

(4) The heading for such section is amended by striking out "and Health Care Technology" and inserting in lieu thereof ", and Health Care Technology Assessment".

42 USC 242c.

SEC. 6. Section 305(c) is amended—

(1) by redesignating paragraphs (1), (2), and (3) as subparagraphs (A), (B), and (C), respectively;

(2) by inserting "(1)" before "The"; and

(3) by adding at the end thereof the following new paragraph:

"(2) In carrying out this section, the Secretary shall assist State and local health agencies through a user liaison program and a technical assistance program."

SEC. 7. (a)(1) The first sentence of paragraph (1) of section 308(i) of such Act (42 U.S.C. 242m(i)) is amended by striking out "and" after "1983," and by inserting before the period a comma and the following: "\$20,500,000 for the fiscal year ending September 30, 1985, \$22,750,000 for the fiscal year ending September 30, 1986, and \$24,750,000 for the fiscal year ending September 30, 1987".

(2) The second sentence of such paragraph is amended (A) by inserting after "Research" the following: "and Health Care Technology Assessment", and (B) by striking out "and at least 5 per centum of such amount or \$1,000,000, whichever is less, shall be available only for dissemination activities directly undertaken through such Center" and inserting in lieu thereof "and at least 10 per centum of such amount or \$1,500,000, whichever is less, shall be available only for the user liaison program and the technical assistance program referred to in section 305(c)(2) and for dissemination activities directly undertaken through such Center".

(3) Such paragraph is amended by adding after the second sentence the following: "For health care technology assessment activities undertaken under subsections (b)(5), (e), (f), and (g) of section 305 the Secretary shall obligate from funds appropriated under this paragraph not less than \$3,000,000 for the fiscal year ending September 30, 1985, \$3,500,000 for the fiscal year ending September 30, 1986, and \$4,000,000 for the fiscal year ending September 30, 1987. For grants under section 309 the Secretary shall obligate from funds appropriated under this paragraph not less than \$500,000 for the fiscal year ending September 30, 1985, \$750,000 for the fiscal year ending September 30, 1986, and \$750,000 for the fiscal year ending September 30, 1987."

(4) The last sentence of such paragraph is amended by striking out "for each" through "1984," and inserting in lieu thereof "for any fiscal year".

(b) Paragraph (2) of such section is amended by striking out "and" after "1983," and by inserting before the period a comma and the following: "\$47,000,000 for the fiscal year ending September 30, 1985, \$49,000,000 for the fiscal year ending September 30, 1986, and \$52,000,000 for the fiscal year ending September 30, 1987".

SEC. 8. Section 309 of the Public Health Service Act (42 U.S.C. 242n) is amended to read as follows:

"COUNCIL ON HEALTH CARE TECHNOLOGY

"SEC. 309. (a)(1) In accordance with this section, the Secretary shall make grants for the planning, development, establishment, and operation of a Council on Health Care Technology. The Council shall comply with the provisions of this section.

Grants.

“(2)(A) The Secretary shall make an initial grant under paragraph (1) to the National Academy of Sciences for the planning, development, and establishment of the Council with the membership prescribed by subsection (d)(1). The amount of such grant may not exceed \$500,000 and may be made for not more than two-thirds of the cost of the planning, development, and establishment of the Council.

“(B) The Secretary may not make a grant for the operation of the Council unless the application submitted to the Secretary for the grant contains written assurances from the applicant that the applicant will expend from non-Federal sources for the operation of the Council an amount equal to at least twice the amount of the grant applied for.

“(b) The purposes of the Council shall include—

“(1) promoting the development and application of appropriate health care technology assessments; and

“(2) the review of existing health care technologies in order to identify obsolete or inappropriately used health care technologies.

“(c)(1) The Council shall—

“(A) serve as a clearinghouse for information on health care technologies and health care technology assessment;

“(B) collect and analyze data concerning specific health care technologies;

“(C) identify needs in the assessment of specific health care technologies and research on assessment methodologies;

“(D) develop and evaluate criteria and methodologies for health care technology assessment;

“(E) promote education, training, and technical assistance in the use of health care technology assessment methodologies and results; and

“(F) stimulate, coordinate, and commission assessments of health care technologies.

“(2) No funds from any grant made by the Secretary under this section for the planning, development, and establishment of the Council may be used to conduct any assessment of a health care technology.

“(d)(1) For purposes of a grant for the planning, development, and establishment of the Council, the Council shall be composed of:

“(A) At least ten members appointed by the National Academy of Sciences from individuals who have education, training, experience, or expertise relating to the quality and cost-effectiveness of health care technologies and who are representatives of organizations of health professionals, hospitals, and other health care providers, health care insurers, employers, consumers, and manufacturers of products for health care.

“(B) Three members appointed by the Secretary of Health and Human Services.

“(C) The Director of the Office of Technology Assessment, who shall be an ex officio member.

“(2) Any vacancy in the Council shall not affect its power and, for purposes of a grant for the planning, development, and establishment of the Council, shall be filled in the manner prescribed by paragraph (1).

“(f) The President of the National Academy of Science shall designate one of the members appointed to the initial Council under subsection (d)(1)(A) as Chairman of the Council for a one-year term.

Science and
technology.

Thereafter, the members of the Council shall elect one of its members as Chairman for such terms as may be determined by the Council.

Report.

"(g) The recipient of a grant under subsection (a) shall submit an annual report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on the Council's activities.

"(h) No grant may be made under this section unless an application is submitted to the Secretary in such form and containing such information as the Secretary shall prescribe."

Approved October 30, 1984.

LEGISLATIVE HISTORY—S. 771:

SENATE REPORT No. 98-158 (Comm. on Labor and Human Resources).
CONGRESSIONAL RECORD:

Vol. 129 (1983): Sept. 21, considered and passed Senate.

Vol. 130 (1984): Oct. 9, considered and passed House, amended.

Oct. 11, Senate concurred in House amendment.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 20, No. 44 (1984):

Oct. 30, Presidential statement.