

Public Law 95-623
95th Congress

An Act

To amend the Public Health Service Act to revise and extend the authorities under that Act relating to health services research and health statistics and to establish a National Center for Health Care Technology, and for other purposes.

Nov. 9, 1978

[S. 2466]

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

Health Services
Research, Health
Statistics, and
Health Care
Technology Act
of 1978.
42 USC 201 note.

SHORT TITLE, REFERENCE TO ACT

SECTION 1. (a) This Act may be cited as the "Health Services Research, Health Statistics, and Health Care Technology Act of 1978".

(b) Whenever in this Act (other than in sections 12 and 13) 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.

42 USC 201 note.

EXTENSION OF AUTHORIZATIONS

SEC. 2. (a) Section 308(i) (1) is amended—

42 USC 242m.

(1) in the first sentence (A) by striking out "and" after "1976," and (B) by inserting before the period a comma and the following: "\$35,000,000 for the fiscal year ending September 30, 1979, \$40,000,000 for the fiscal year ending September 30, 1980, and \$45,000,000 for the fiscal year ending September 30, 1981"; and

(2) by striking out the second sentence and inserting in lieu thereof the following: "At least 20 per centum of the amount appropriated under the preceding sentence for any fiscal year or \$6,000,000, whichever is less, shall be available only for health services research, evaluation and demonstration activities directly undertaken through the National Center for Health Services Research, 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."

(b) Section 308(i) (2) is amended (1) by inserting "and epidemiological" after "statistical", (2) by striking out "and" after "1976," and (3) by inserting before the period a comma and the following: "\$50,000,000 for the fiscal year ending September 30, 1979, \$65,000,000 for the fiscal year ending September 30, 1980, and \$70,000,000 for the fiscal year ending September 30, 1981".

GENERAL AUTHORITY

SEC. 3. (a) Subsection (a) of section 304 is amended to read as follows: 42 USC 242b.

"(a) (1) The Secretary, acting through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology, shall conduct and support research, demonstrations, evaluations, and statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

"(2) In carrying out paragraph (1), the Secretary shall give appropriate emphasis to research, demonstrations, evaluations, and statistical and epidemiological activities respecting—

"(A) the accessibility, acceptability, planning, organization, distribution, utilization, and financing of systems for the delivery of health care,

"(B) alternative methods for measuring and evaluating the quality of systems for the delivery of health care,

"(C) the collection, analysis, and dissemination of health related statistics,

"(D) alternative methods to improve and promote health statistical and epidemiological activities,

"(E) the safety, efficacy, effectiveness, cost effectiveness, and social, economic, and ethical impacts of health care technologies,

"(F) alternative methods for disseminating knowledge concerning health and health related activities,

"(G) the special health problems of low income and minority groups and the elderly to insure that these problems are assessed on a periodic regular basis,

"(H) the prevention of illness, disability, and premature deaths in the United States,

"(I) health care costs, increases in such costs, and the reasons for such increases, and

"(J) the impact of the environment on individual health and on health care.

"(3) The Secretary shall, through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology and using National Research Service Awards and other appropriate authorities, undertake and support training programs to provide for an expanded and continuing supply of individuals qualified to perform the research, evaluation, and demonstration projects set forth in sections 305, 306, and 309."

(b) Paragraph (1) of section 304(b) is amended (1) by inserting " , when appropriate," before "enter into contracts", and (2) by striking out all after "entities and individuals" the second time it appears and inserting in lieu thereof a period.

(c) Subsection (c) of section 304 is amended to read as follows:

"(c) (1) The Secretary shall coordinate all health services research, evaluations, and demonstrations, all health statistical and epidemiological activities, and all research, evaluations, and demonstrations respecting the assessment of health care technology undertaken and supported through units of the Department of Health, Education, and Welfare. To the maximum extent feasible such coordination shall be carried out through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology.

"(2) The Secretary shall coordinate the health services research, evaluations, and demonstrations, the health statistical and (where appropriate) epidemiological activities, and the research, evaluations, and demonstrations respecting the assessment of health care technology authorized by this Act through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology."

(d) Section 304(d)(3) is amended (1) by striking out "experts and", (2) by inserting "but in accordance with section 3109 of title 5,

Training
programs.

42 USC 242c,
242k.
Post, p. 3447.
42 USC 242b.

United States Code" after "advisable", and (3) by adding at the end the following: "The Secretary may for the purpose of carrying out the functions set forth in sections 305, 306, and 309, obtain (in accordance with section 3109 of title 5 of the United States Code, but without regard to the limitation in such section on the number of days or the period of service) for each of the centers the services of not more than fifteen experts who have appropriate scientific or professional qualifications."

42 USC 242c,
242k.
Post, p. 3447.

(e) The heading for section 304 is amended to read as follows:

42 USC 242b.

"GENERAL AUTHORITY RESPECTING RESEARCH, EVALUATIONS, AND DEMONSTRATIONS IN HEALTH STATISTICS, HEALTH SERVICES AND HEALTH CARE TECHNOLOGY".

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

SEC. 4. Subsection (b) of section 305 is amended—

- (1) by striking out "may undertake and support" and inserting in lieu thereof "shall undertake and support";
- (2) by striking out "construction," in paragraph (3);
- (3) striking "and" at the end of paragraph (2);
- (4) striking the period in paragraph (3) and inserting in lieu thereof ", and"; and
- (5) adding at the end thereof the following new paragraph:
"(4) the uses of computer science in health services delivery and medical information systems."

NATIONAL CENTER FOR HEALTH STATISTICS

SEC. 5. (a) Subsection (b) of section 306 is amended (1) by striking out "may", (2) by inserting "shall" after "(1)" and after "(2)", (3) by striking out "and" at the end of paragraph (1), (4) by striking out the period at the end of paragraph (2) and inserting in lieu thereof a semicolon, and (5) by adding after paragraph (2) the following:

"(3) may undertake and support (by grant or contract) epidemiological research, demonstrations, and evaluations on the matters referred to in paragraph (1); and

"(4) may collect, furnish, tabulate, and analyze statistics, and prepare studies, on matters referred to in paragraph (1) upon request of public and nonprofit private entities under arrangements under which the entities will pay the cost of the service provided.

Amounts appropriated to the Secretary from payments made under arrangements made under paragraph (4) shall be available to the Secretary for obligation until expended."

(b) Section 306(c) is amended by—

- (1) inserting "and epidemiological" after "statistical" each place it occurs; and
- (2) striking "Labor and Public Welfare" and inserting in lieu thereof "Human Resources".

(c) (1) Subsection (e) of section 306 is amended to read as follows:

"(e) For the purpose of producing comparable and uniform health information and statistics, there is established the Cooperative Health Statistics System. The Secretary, acting through the Center, shall—

- "(1) coordinate the activities of Federal agencies involved in the design and implementation of the System;

Cooperative
Health Statistics
System,
establishment.

"(2) undertake and support (by grant or contract) research, development, demonstrations, and evaluations respecting the System;

"(3) make grants to and enter into contracts with State and local health agencies to assist them in meeting the costs of data collection carried out under the System; and

"(4) review the statistical activities of the Department of Health, Education, and Welfare to assure that they are consistent with the System.

States participating in the System shall designate a State agency to administer or be responsible for the administration of the statistical activities within the State under the System. The Secretary, acting through the Center, shall prescribe guidelines to assure that statistical activities within States participating in the system produce uniform and timely data and assure appropriate access to such data."

42 USC 242k.

(2) Paragraph (4) (D) of subsection (i) of section 306 is amended by inserting before the semicolon the following: "with respect to the Cooperative Health Statistics System established under subsection (e), and with respect to the standardized means for the collection of health information and statistics to be established by the Secretary under subsection (j) (1)".

(d) The first sentence of subsection (f) of section 306 is amended by inserting "acting through the Center," after "the Secretary".

(e) (1) Section 306(i) (1) is amended by striking out "United States".

(2) Paragraph (2) (A) of section 306(i) is amended by inserting "health planning," after "health statistics,".

(f) Section 306 is amended by redesignating subsection (i) as subsection (k) and by inserting after subsection (h) the following new subsections:

"(i) The Center may provide to public and nonprofit private entities engaged in health planning activities technical assistance in the effective use in such activities of statistics collected or compiled by the Center.

42 USC 242b.

"(j) In carrying out the requirements of section 304(c) and paragraph (1) of subsection (e) of this section, the Secretary shall coordinate health statistical and epidemiological activities of the Department of Health, Education, and Welfare by—

"(1) establishing standardized means for the collection of health information and statistics under laws administered by the Secretary;

"(2) developing, in consultation with the National Committee on Vital and Health Statistics, and maintaining the minimum sets of data needed on a continuing basis to fulfill the collection requirements of subsection (b) (1);

"(3) after consultation with the National Committee on Vital and Health Statistics, establishing standards to assure the quality of health statistical and epidemiological data collection, processing, and analysis;

"(4) in the case of proposed health data collections of the Department which are required to be reviewed by the Director of the Office of Management and Budget under section 3509 of title 44, United States Code, reviewing such proposed collections to determine whether they conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (2)

and (3), and if any such proposed collection is found not to be in conformance, by taking such action as may be necessary to assure that it will conform to such sets of data and standards, and

“(5) periodically reviewing ongoing health data collections of the Department, subject to review under such section 3509, to determine if the collections are being conducted in accordance with the minimum sets of data and the standards promulgated pursuant to paragraphs (2) and (3) and, if any such collection is found not to be in conformance, by taking such action as may be necessary to assure that the collection will conform to such sets of data and standards not later than the ninetieth day after the date of the completion of the review of the collection.”.

NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY; NATIONAL COUNCIL
ON HEALTH CARE TECHNOLOGY

SEC. 6. (a) Section 309 is amended—

42 USC 242n.

(1) by amending the section heading to read as follows:

“HEALTH CONFERENCES AND HEALTH EDUCATION INFORMATION”;

(2) by inserting “(a)” before “A conference”; and

(3) by striking out “309” and inserting in lieu thereof “310”. 42 USC 242o.

(b) Section 310 (as in effect before the date of the enactment of this Act) is amended—

(1) by striking out the section heading; and

(2) by striking out “SEC. 310.” and inserting in lieu thereof

“(b)”.

(c) Part A of title III is amended by adding after section 308 the following new section:

“NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY; NATIONAL COUNCIL
ON HEALTH CARE TECHNOLOGY

“SEC. 309. (a) There is established in the Department of Health, Education, and Welfare the National Center for Health Care Technology (hereinafter in this section referred to as the ‘Center’) which shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Assistant Secretary for Health (or such other officer of the Department as may be designated by the Secretary as the principal adviser to him for health programs).

Establishment.
42 USC 242n.

“(b) (1) The Secretary, acting through the Center, shall undertake and support (by grant or contract) assessments of health care technology. Such assessments shall take into account the safety, effectiveness, and cost effectiveness of, and the social, ethical, and economic impact of health care technologies.

Grants and
contracts.

“(2) The Secretary, acting through the Center, shall encourage, undertake, and support (by grant or contract) research, demonstrations, and evaluations respecting—

“(A) the factors that affect the use of health care technologies in the United States;

“(B) methods for disseminating information on health care technologies; and

“(C) the effectiveness, cost effectiveness, and social, ethical, and economic impacts of particular medical technologies.

"(3) The Secretary, acting through the Center, shall encourage and support (by grant or contract) research, evaluations, and demonstrations respecting the safety and efficacy of particular health care technologies.

"(4) The Secretary, acting through the Center and in consultation with the National Council on Health Care Technology, shall establish priorities for the activities prescribed by paragraphs (1), (2), and (3). In determining if an activity respecting a particular health care technology should be given priority, emphasis shall be placed on—

"(A) the actual or potential risks and the actual or potential benefits to patients associated with the use of the technology,

"(B) the actual or potential cost of the technology,

"(C) the actual or potential rate of its use, and

"(D) the stage of development of the technology.

"(5) The Center may make recommendations to the Secretary respecting health care technology issues in the administration of the laws under the Secretary's jurisdiction, including recommendations with respect to reimbursement policy.

Grants and
contracts.

"(c) (1) The Secretary, acting through the Center, shall, by grant or contract, assist public and private nonprofit entities in meeting the costs of planning and establishing new centers, and operating existing and new centers, for assessments, multidisciplinary research, evaluations, and demonstrations respecting the matters referred to in paragraphs (1) and (2) of subsection (b). To the extent practicable, the Secretary shall take such actions, in accordance with the requirements of this subsection and section 308, to assure that three such centers shall be operational by September 1, 1981.

42 USC 242m.

Limitations.

"(2) (A) No grant or contract may be made under this subsection for planning and establishing a center unless the Secretary, acting through the Center, determines that when it is operational it will meet the requirements listed in subparagraph (B), and no payment shall be made under a grant or contract for operation of a center unless the center meets such requirements.

Requirements.

"(B) Each center shall meet the following requirements:

"(i) There shall be a full-time director of the center who possesses a demonstrated capacity for sustained productivity and leadership in assessments, research, demonstrations, and evaluations respecting the matters referred to in paragraphs (1) and (2) of subsection (b), and there shall be such additional professional staff as may be appropriate.

"(ii) The staff of the center shall have expertise in the various disciplines needed to conduct assessments, multidisciplinary research, evaluations and demonstrations respecting the matters referred to in paragraphs (1) and (2) of subsection (b).

"(iii) The center shall be located within an established academic or research institution with departments and resources appropriate to the programs of the center.

"(iv) Each center shall meet such additional requirements as the Secretary may by regulation prescribe.

Review
requirements for
certain grants and
contracts.

"(d) Any grant or contract under subsection (b) or (c), the direct cost of which will exceed \$35,000, may be made or entered into only after appropriate review for scientific merit by peer review groups composed of experts in the relevant fields and only after the National Council on Health Care Technology has had an opportunity to review

the project with respect to which the grant or contract is to be made or entered into.

“(e) To assist in carrying out this section, the Secretary, acting through the Center, shall cooperate and consult with the National Institutes of Health, the Veterans’ Administration, and any other interested Federal departments or agencies and with State and local health departments and agencies.

“(f) (1) There is established the National Council on Health Care Technology (hereinafter in this subsection referred to as the ‘Council’). The Council shall—

National Council
on Health Care
Technology.
Establishment.

“(A) advise the Secretary and the Director of the Center with respect to the performance of the functions prescribed by this section;

“(B) review applications for grants and contracts under this section in excess of \$35,000 and provide the Secretary its recommendation respecting the approval of such applications;

“(C) after consultation with appropriate public and private entities, advise the Secretary respecting the safety, efficacy, effectiveness, cost effectiveness, and the social and economic impacts of particular health care technologies;

“(D) after consultation with appropriate public and private entities, develop, when appropriate and to the extent practicable, exemplary standards, norms, and criteria concerning the use of particular health care technologies; and

“(E) promptly publish, disseminate, and otherwise make available, through the National Library of Medicine, standards, norms, and criteria developed under subparagraph (D).

“(2) The Council shall consist of—

Membership.

“(A) the Director of the National Institutes of Health, the Chief Medical Officer of the Veterans’ Administration, the Assistant Secretary for Health and Environment of the Department of Defense, the Chairman of the National Professional Standards Review Council, a member of the National Council on Health Planning and Development (established under section 1503), the Director of the Office of Science and Technology Policy, the head of the Food and Drug Administration (or the successor to such entity), the head of the Center for Disease Control (or the successor to such entity), and the head of the Health Care Financing Administration (or the successor to such entity) who (or their designees) shall be ex officio members, and

42 USC 300k-3.

“(B) eighteen members appointed by the Secretary.

The Secretary shall make his initial appointments to the Council within one hundred and twenty days of the date of the enactment of this section. Six of the appointed members shall be selected from individuals who are distinguished in the fields of medicine, engineering, or science (including social science). Of such six members, at least two shall be selected from individuals who are representatives of business entities engaged in the development or production of health care technology. Two of the appointed members shall be physicians, two of the appointed members shall be selected from individuals who are hospital administrators, two of the appointed members shall be selected from individuals who are distinguished in the field of economics, two of the appointed members shall be selected from individuals who are distinguished in the field of law, one of the appointed members shall be selected from individuals who are distinguished in the field of ethics,

and three of the appointed members shall be selected from members of the general public who represent the interests of consumers of health care.

Council
members, terms
of office.

"(3) (A) Each appointed member of the Council shall be appointed for a term of four 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 section, four shall be appointed for a term of four years, 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 serve after the expiration of their terms until their successors have taken office.

Compensation.

"(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.

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

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

"(6) The Director of the Center shall (1) designate a member of the staff of the Center to act as Executive Secretary of the Council, and (2) make available to the Council such staff, information, and other assistance as it may require to carry out its functions.

"(7) The Council shall be subject to the Federal Advisory Committee Act, except that the Council shall terminate September 30, 1981.

"(g) The Director of the National Institutes of Health, the head of the Food and Drug Administration (or the successor to such entity), the head of the Center for Disease Control (or the successor to such entity), the head of the Health Care Financing Administration (or the successor to such entity), and the head of any other entity of the Department of Health, Education, and Welfare designated by the Secretary shall each make available annually to the Center and the Council a listing of all health care technologies of which he is aware that are under development and appear likely to be used in the practice of medicine.

"Health care
technology."

"(h) For purposes of this section, the term 'health care technology' means any discrete and identifiable regimen or modality used to diagnose and treat illness, prevent disease, maintain patient well-being, or facilitate the provision of health care services.

Appropriation
authorization.

"(i) There are authorized to be appropriated to carry out this section \$15,000,000 for the fiscal year ending September 30, 1979,

\$25,000,000 for the fiscal year ending September 30, 1980, and \$33,000,000 for the fiscal year ending September 30, 1981. Not less than 15 per centum of the amount appropriated for the fiscal year ending September 30, 1981, shall be obligated for assessments, research, demonstrations, and evaluations directly undertaken through the Center under paragraph (1) or (2) of subsection (b)."

(d) (1) Subsection (a) (1) of section 308 is amended (A) by inserting "and section 309" after "307", and (B) by striking out "health statistics" and inserting in lieu thereof "health statistics, and health care technology".

42 USC 242m.

(2) Subsection (b) (1) of such section is amended by striking out "or 307" and inserting in lieu thereof "307, or 309".

(3) Subsection (d) of such section is amended (A) by striking out "or 307" and inserting in lieu thereof "307, or 309", and (B) by inserting "or epidemiological" after "statistical" in clause (1).

(4) Subsection (e) of such section is amended by striking out "or 307" each place it occurs and inserting in lieu thereof "307, or 309".

(5) Subsection (f) of such section is amended by striking out "or 306" and inserting in lieu thereof "306, or 309".

(6) Subsection (g) (2) of such section is amended by striking out "and 306" and inserting in lieu thereof "306, and 309".

(7) Subsection (h) (1) of such section is amended by striking out "or 306" each place it occurs and inserting in lieu thereof "306, or 309".

(8) The heading for such section is amended by striking out "AND 307" and inserting in lieu thereof "307, AND 309".

STUDY OF COSTS OF DISEASES AND ADVERSE EFFECTS ON HUMANS WHICH ARE ENVIRONMENTALLY RELATED

SEC. 7. Section 304 (as amended by section 3(d)) is amended by adding at the end the following:

42 USC 242b.

"(e) (1) The Secretary and the National Academy of Sciences (acting through the Institute of Medicine and other appropriate units) shall, jointly and in cooperation with the Administrator of the Environmental Protection Agency, the Secretary of Labor, the Consumer Product Safety Commission, the Council of Economic Advisers, the Council on Wage and Price Stability, the Council on Environmental Quality, and other entities of the Federal Government which the Secretary determines have the expertise in the subject of the study prescribed by this paragraph, conduct, with funds appropriated under section 308(i) (2), an ongoing study of the present and projected future health costs of pollution and other environmental conditions resulting from human activity (including human activity in any place in the indoor or outdoor environment, including places of employment and residence). In conducting the study, the Secretary and the National Academy of Sciences (hereinafter in this subsection referred to as the 'Academy') shall, to the extent feasible—

"(A) identify the pollution (and the pollutants responsible for the pollution) and other environmental conditions which are, or may reasonably be anticipated to be, responsible for causing, contributing to, increasing susceptibility to, or aggravating human diseases and adverse effects on humans;

"(B) identify each such disease and adverse effect on humans

and specifically determine whether cancer, birth defects, genetic damage, emphysema, asthma, bronchitis, and other respiratory diseases, heart disease, stroke, and mental illness and impairment are such a disease or effect;

“(C) identify (on a national, regional, or other geographical basis) the source or sources of such pollutants and conditions and estimate the portion of each pollutant and the extent of each condition which can be traced to a specific type of source;

“(D) ascertain (i) the extent to which the pollutants and conditions identified under subparagraph (A) are, or may reasonably be anticipated to be, responsible, individually or collectively, for causing, contributing to, increasing susceptibility to, or aggravating the diseases and effects identified under subparagraph (B), and (ii) the effect upon the incidence or severity of specific diseases and effects of individual or collective, as appropriate, incremental reductions in the pollutants and changes in such conditions; and

“(E) quantify (i) the present and projected future health costs of the diseases and effects identified under subparagraph (B), and (ii) the reduction in health costs which would result from each incremental reduction and change referred to in subparagraph (D) (ii).

“(2) The Secretary shall enter into appropriate arrangements with the Academy under which the Secretary shall be responsible for expenses incurred by the Academy in connection with the study prescribed by paragraph (1).

“(3) The first report on the study prescribed by paragraph (1) shall be made to the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives by the Secretary and the Academy not later than eighteen months after the date of the enactment of this subsection. Subsequent reports on the study shall be made by the Secretary and the Academy every two years after the date the first report is submitted. Each report shall (A) identify deficiencies and limitations in the data on the matters considered in the study and recommend actions which may be taken to eliminate such deficiencies and limitations, (B) include such recommendations for legislation as the Secretary determines appropriate, (C) include recommendations for facilitating studies of the effects of hazardous substances on humans, and (D) include a description of any administrative action proposed to be taken by the Secretary, the Administrator of the Environmental Protection Agency, the Secretary of Labor, and the Consumer Product Safety Commission to reduce the costs which have been quantified under paragraph (1) (E) (i). In conducting the study, the Secretary and the Academy shall seek assistance from public and private health financing entities in securing the data needed for the study.

“(4) For purposes of paragraph (1), the term ‘health costs of pollution and other environmental conditions’ means the costs of human diseases and other adverse effects on humans which pollution and other environmental conditions are, or may reasonably be anticipated to be, responsible for causing, contributing to, increasing susceptibility to, or aggravating, including the costs of preventing such diseases and effects, the costs of the treatment, cure, convalescence, and rehabilita-

Reports to
congressional
committees.

“Health costs of
pollution and other
environmental
conditions.”

tion of persons afflicted by such diseases, costs reasonably attributable to pain and suffering from such diseases and effects, loss of income and future earnings resulting from such diseases and effects, adverse effects on productivity (and thus increases in production costs and consumer prices) resulting from such diseases and effects, loss of tax revenues resulting from such decreases in earnings and productivity, costs to the welfare and unemployment compensation systems and the programs of health benefits under titles XVIII and XIX of the Social Security Act resulting from such diseases and effects, the overall increases in costs throughout the economy resulting from such diseases and effects, and other related direct and indirect costs.”

42 USC 1395,
1396.

INFORMATION ON EFFECTS ON HEALTH OF THE ENVIRONMENT AND
EMPLOYMENT CONDITIONS

SEC. 8. (a) Section 306 (as amended by section 5) is amended by inserting after subsection (k) the following new subsection:

42 USC 242k.

“(1) (1) The Secretary, acting through the Center, shall develop a plan for the collection and coordination of statistical and epidemiological data on the effects of the environment on health. Such plan shall include a review of the data now available on health effects, deficiencies in such data, and methods by which existing data deficiencies can be corrected. The Secretary shall submit such plan to the Congress not later than January 1, 1980.

Plan.

“(2) (A) The Secretary, acting through the Center, shall establish, not later than two years after the date of the enactment of this subsection, guidelines for the collection, compilation, analysis, publication, and distribution of statistics and information necessary for determining the effects of conditions of employment and indoor and outdoor environmental conditions on the public health. Guidelines established under this subparagraph shall not (i) authorize or require the disclosure of any matter described in section 552(b) (6) of title 5, United States Code, and (ii) authorize or require the disclosure of any statistics or other information which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b) (4) of such section. The guidelines shall be reviewed and, if appropriate, revised at least every three years after the date they are initially established. Guidelines shall take effect on the date of the promulgation of the regulation establishing or revising the guidelines or such later date as may be specified in the guidelines.

Submittal to
Congress.
Guidelines.

“(B) The guidelines shall be designed—

“(i) to improve coordination of environmental and health studies, statistics, and information, and to prevent overlap and unnecessary duplication with respect to such studies, statistics, and information;

“(ii) to assure that such studies, statistics, and information will be available to executive departments responsible for the administration of laws relating to the protection of the public health and safety or the environment;

“(iii) to encourage the more effective use by executive departments of such studies, statistics, and information;

“(iv) to improve the statistical validity and reliability of such studies, statistics, and information; and

"(v) to assure greater responsiveness by the Department of Health, Education, and Welfare and other executive departments in meeting informational and analytical needs for determining the effects of employment and indoor and outdoor environmental conditions on public health.

"(C) In establishing and revising guidelines under subparagraph (A), the Secretary shall take into consideration the plan developed pursuant to paragraph (1).

"(D) The Center shall serve as a clearinghouse for statistics and information with respect to which guidelines have been established under subparagraph (A) and shall assist executive departments in obtaining such statistics and information for purposes of administering laws under their jurisdiction relating to environmental health protection or the safety and health of employees.

Guidelines,
compliance.

"(E) (i) Each executive department shall comply with the substantive and procedural requirements of the guidelines.

"(ii) The President shall by Executive order require each executive department to comply with requests, made in accordance with the guidelines, by the Secretary, the Administrator of the Environmental Protection Agency, the Consumer Product Safety Commission, or the Secretary of Labor for statistics and information.

Exemptions.

"(iii) The President may by Executive order exempt any executive department from compliance with a requirement of the guidelines respecting specific statistics or other information if the President determines that the exemption is necessary in the interest of national security.

"(F) In carrying out his duties under this paragraph, the Secretary, acting through the Center, shall, insofar as practicable, provide for coordination of his activities with those of other Federal agencies and interagency task forces relating to the collection, analysis, publication, or distribution of statistics and information necessary for determining the effects of conditions of employment and indoor and outdoor environmental conditions on the public health.

"Guidelines."

"(G) For purposes of this paragraph, the term 'guidelines' means the guidelines, either as initially established or as revised, in effect under this paragraph.

Study.

"(3) The Secretary, acting through the Center, shall conduct a study of the issues respecting, and the recommendations for, establishing a Federal system to assist, in a manner designed to avoid invasion of personal privacy, Federal, State, and other entities in locating individuals who have been or many have been exposed to hazardous substances to determine the effect on their health of such exposure and to assist them in obtaining appropriate medical care and treatment. In conducting such study, the Secretary may consult with any public and private entity which it determines has expertise on any matter to be considered in the study. Not later than one year after the date of the enactment of this subsection, the Secretary shall complete the study and report to the Congress the results of the study and any recommendations for legislation or administrative action.

Report to
Congress.

"(4) In carrying out paragraphs (1), (2), and (3), the Secretary shall consult with and take into consideration any recommendations of the Task Force on Environmental Cancer and Heart and Lung

Disease, the Administrator of the Environmental Protection Agency, the Secretary of Labor, the Consumer Product Safety Commission, the Council on Environmental Quality, the National Committee on Vital and Health Statistics, and the National Academy of Sciences (including the Institute of Medicine and any other unit of the Academy).".

(b) The first sentence of subsection (d) of section 308 is amended by inserting after "unless authorized" the following: "by guidelines in effect under section 306(1)(2) or".

42 USC 242m.

42 USC 242k.

TASK FORCE ON ENVIRONMENTAL CANCER AND HEART AND LUNG DISEASE

SEC. 9. The Director of the National Center for Health Statistics and the head of the Center for Disease Control (or the successor to such entity) shall each serve as members of the Task Force on Environmental Cancer and Heart and Lung Disease established under section 402 of Public Law 95-95.

42 USC 4362a.

42 USC 4362.

MINE WORKERS STUDY

SEC. 10. The Secretary, acting through the National Center for Health Services Research, shall arrange for the conduct of a study to evaluate the impact upon the utilization of health services by and the health status of members of the United Mine Workers and their dependents as a result of changes in the United Mine Workers' collective-bargaining agreements of March 1978, that require copayments for health services. Such study and a report thereon shall be completed and submitted to the Secretary, the Committee on Human Resources, the Committee on Appropriations, and the Committee on Finance of the Senate, and the Committee on Ways and Means, the Committee on Appropriations, and the Committee on Interstate and Foreign Commerce of the House of Representatives no later than thirty months after the date of enactment of this section. Not more than \$1,000,000 of the sums authorized to be appropriated for health services research, evaluation, and demonstration activities by section 308(i)(1) of the Public Health Service Act shall be made available for such study.

42 USC 242m
note.Report to
congressional
committees.

AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

SEC. 11. (a) Subsection (g) of section 208 is amended (1) by striking out "one hundred and fifty-five" and inserting in lieu thereof "one hundred and seventy-nine", (2) by striking out "and not less than" and inserting in lieu thereof "not less than", and (3) by inserting after "alcoholism," the following: "not less than ten shall be for the National Center for Health Services Research, not less than twelve shall be for the National Center for Health Statistics, and not less than seven shall be for the National Center for Health Care Technology,".

42 USC 210.

(b) Part K of title III is repealed.

Repeal.

(c) Section 453 is amended by adding at the end the following: "The Secretary, through the Institute, may, effective October 1, 1978, and without regard to section 405, carry out a program of grants for public and nonprofit private vision research facilities.".

42 USC 280c.

42 USC 289k.

42 USC 285.

(d) (1) Section 472(a)(1)(A) is amended—

42 USC 289l-1.

(A) by striking out “and” at the end of clause (iii),

(B) by redesignating clause (iv) as clause (vii),

(C) by inserting after clause (iii) the following:

“(iv) research at the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology,

“(v) training at such Centers to undertake such research,

“(vi) research on the matters set forth in section 304(a)

(2) at public institutions and at nonprofit private institutions, and”, and

(D) by striking out “such research” in clause (vii) (as so redesignated) and inserting in lieu thereof “biomedical and behavioral research and the research described in clause (vi)”.

42 USC 289f-1.

(2) Section 472(a)(1)(B) is amended by striking out “such research” and inserting in lieu thereof “biomedical and behavioral research and the research described in subparagraph (A)(vi)”.

42 USC 219.

(e) Title V is amended by adding at the end the following:

“CONTRACT AUTHORITY

42 USC 229c.

“SEC. 514. The authority of the Secretary to enter into contracts under this Act shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.”.

Record
maintenance.

42 USC 292e.

(f)(1) The second sentence of subsection (a) of section 705 is amended to read as follows: “Such records shall include records which fully disclose (A) the amount and disposition by such entity of the funds paid to it under such grant, loan, loan guarantee, interest subsidy, or contract, (B) the total cost of the project or undertaking for which such grant, loan, loan guarantee, interest subsidy, or contract is made, (C) the amount of that portion of the cost of the project or undertaking received by or allocated to such entity from other sources, and (D) such other records as will facilitate an audit conducted in accordance with generally accepted auditing standards.”.

Biennial financial
audit.

(2) Subsection (b) of section 705 is amended to read as follows:

“(b) Each entity which received a grant or entered into a contract under this title shall provide for a biennial financial audit of any books, accounts, financial records, files, and other papers and property which relate to the disposition or use of the funds received under such grant or contract and such other funds received by or allocated to the project or undertaking for which such grant or contract was made. For purposes of assuring accurate, current, and complete disclosure of the disposition or use of the funds received, each such audit shall be conducted in accordance with such requirements concerning the individual or agency which conducts the audit, and such standards applicable to the performance of the audit, as the Secretary may by regulation provide. A report of each such audit shall be filed with the Secretary at such time and in such manner as he may require.”.

Waiver.

42 USC 295f-1.

(g) Section 771(d) is amended by adding at the end the following:

“(5) The Secretary may waive (in whole or in part) application to a school of dentistry of the requirement of any paragraph of this subsection if the Secretary determines, after receiving the written recommendation of the appropriate accreditation body or bodies

(approved for such purpose by the Commissioner of Education) that compliance by such school with such requirement will prevent it from maintaining its accreditation.”.

HEALTH PROFESSIONS REPORTS AND PROGRAMS

SEC. 12. (a) Section 708(d) of the Public Health Service Act is amended (1) by striking out “not later than September 1 of each year”, and (2) by inserting at the end the following: “Such report shall be submitted biennially, and the first such report shall be due not later than October 1, 1979.”. 42 USC 292h.

(b) Section 709(b) of such Act is amended by striking out “January 1, 1979” and inserting in lieu thereof “February 1, 1980”. 42 USC 292i.

(c) Section 751(i) of such Act is amended by striking out “December” and inserting in lieu thereof “March”. 42 USC 294t.

(d) Section 771(b) (2) (B) of such Act is amended by striking out “45 days after the date for which the determination is made” and inserting in lieu thereof “the first December 31 occurring after the date for which the determination is made”. 42 USC 295f-1.

(e) Section 782(c) of such Act is amended by striking out “September 30, 1979” and inserting in lieu thereof “March 1, 1980”. 42 USC 295g-2.

(f) Section 788(b) (6) of such Act is amended by striking out “September 30, 1978” and inserting in lieu thereof “October 1, 1979”. 42 USC 295g-8.

(g) Section 793(c) of such Act is amended (1) by striking out “annually” and inserting in lieu thereof “biennially”, and (2) by striking out “December 1, 1978” and inserting in lieu thereof “October 1, 1979”. 42 USC 295h-2.

(h) Section 951(b) of the Nurse Training Act of 1975 is amended by striking out “Not later than February 1, 1977, and February 1 of each succeeding year” and inserting in lieu thereof “Not later than October 1, 1979, and October 1 of each odd-numbered year thereafter”. 42 USC 296 note.

(i) (1) Section 702(d) of the Health Professions Educational Assistance Act of 1976 is amended by striking out “not later than two years after the date of enactment of this Act” and inserting in lieu thereof “not later than October 1, 1979”. 42 USC 295h-4 note.

(2) Section 903(a) (2) of the Health Professions Educational Assistance Act of 1976 is amended by striking out “January 1, 1979” and inserting in lieu thereof “April 1, 1979”. 42 USC 292h note.

(j) Section 772(e) of the Public Health Service Act is amended by inserting before the period a comma and the following: “except that a student who, for other than academic reasons, withdraws from a year class before the end of an academic year or does not complete an academic year shall not be considered as having been enrolled in a year class in that academic year”. 42 USC 295f-2.

MISCELLANEOUS

SEC. 13. (a) (1) Section 111(h) (42 U.S.C. 7411) of the Act of July 14, 1955, as amended by Public Law 95-95, is amended by adding the following at the end thereof:

“(5) Any design, equipment, work practice, or operational standard, or any combination thereof, described in this subsection shall be treated as a standard of performance for purposes of the provisions of this Act (other than the provisions of subsection (a) and this subsection).”.

(2) Subsections (d) (1) (A) and (g) (4) (B) of such section are each amended by striking out "under subsection (b)" and inserting in lieu thereof "under this section".

(3) Subsection (j) of such section is amended by striking out "subsection (b) of" in paragraphs (1) (A) and (2) (A) thereof.

(b) Section 112(e) of such Act (42 U.S.C. 7412) is amended by adding the following at the end thereof:

"(5) Any design, equipment, work practice, or operational standard, or any combination thereof, described in this subsection shall be treated as an emission standard for purposes of the provisions of this Act (other than the provisions of this subsection)."

(c) Section 117(c) (3) of such Act (42 U.S.C. 7417) is amended by striking out "(b) (1) (B)" in each place it appears.

(d) Section 317(a) (1) of such Act (42 U.S.C. 7617) is amended by striking out "(b)".

Approved November 9, 1978.

LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 95-1190 accompanying H.R. 12584 (Comm. on Interstate and Foreign Commerce) and No. 95-1783 (Comm. of Conference).

SENATE REPORT No. 95-839 (Comm. on Human Resources).

CONGRESSIONAL RECORD, Vol. 124 (1978):

June 26, considered and failed of passage in Senate.

Aug. 9, considered and passed Senate.

Sept. 25, H.R. 12584 considered and passed House; passage vacated, and

S. 2466, amended, passed in lieu.

Oct. 13, House agreed to conference report.

Oct. 15, Senate agreed to conference report.