

Attachment 1

Section 301 of the Public Health Service Act (42 USC 241)

Sec. 301 [Sec. 241] (a) The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to -

- (1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;
- (2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;
- (3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;
- (4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;
- (5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;
- (6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;
- (7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections [2353](#) and [2354](#) of title [10](#), except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and
- (8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

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.

(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 and Human Services, 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.

(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.

(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 and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, 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 a biennial report which contains -

(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 and Human Services for the Secretary, or

(II) from an entity within the Department of Health and Human Services to any other entity within the Department, to conduct research into, or testing for, the carcinogenicity of substances 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.

(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.

(c) The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) Protection of privacy of individuals who are research subjects
The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

Attachment 2

Section 391 of the Public Health Service Act (42 USC 280b)

SEC. 391 [280b] (a) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall –

- (1) conduct, and give assistance to public and nonprofit private entities, scientific institutions, and individuals engaged in the conduct of, research relating to the causes, mechanisms, prevention, diagnosis, treatment of injuries, and rehabilitation from injuries;
- (2) make grants to, or enter into cooperative agreements or contracts with, public and nonprofit private entities (including academic institutions, hospitals, and laboratories) and individuals for the conduct of such research; and
- (3) make grants to, or enter into cooperative agreements or contracts with, academic institutions for the purpose of providing training on the causes, mechanisms, prevention, diagnosis, treatment of injuries, and rehabilitation from injuries.

(b) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall collect and disseminate, through publications and other appropriate means, information concerning the practical applications of research conducted or assisted under subsection (a) of this section. In carrying out the preceding sentence, the Secretary shall disseminate such information to the public, including through elementary and secondary schools.

Attachment 3

Section 42 USC 242(k) and USC 242(m)

Section 42 CSC 242(k)

(a) Establishment; appointment of Director; statistical and epidemiological activities

There is established in the Department of Health and Human Services the National Center for Health Statistics (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. The Secretary, acting through the Center, shall conduct and support statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

(b) Duties

In carrying out subsection (a) of this section, the Secretary, acting through the Center,

(1) shall collect statistics on—

(A) the extent and nature of illness and disability of the population of the United States (or of any groupings of the people included in the population), including life expectancy, the incidence of various acute and chronic illnesses, and infant and maternal morbidity and mortality,

(B) the impact of illness and disability of the population on the economy of the United States and on other aspects of the well-being of its population (or of such groupings),

(C) environmental, social, and other health hazards,

(D) determinants of health,

(E) health resources, including physicians, dentists, nurses, and other health professionals by specialty and type of practice and the supply of services by hospitals, extended care facilities, home health agencies, and other health institutions,

(F) utilization of health care, including utilization of

(i) ambulatory health services by specialties and types of practice of the health professionals providing such services, and

(ii) services of hospitals, extended care facilities, home health agencies, and other institutions,

(G) health care costs and financing, including the trends in health care prices and cost, the sources of payments for health care services, and Federal, State, and local governmental expenditures for health care services, and

(H) family formation, growth, and dissolution;

(2) shall undertake and support (by grant or contract) research, demonstrations, and evaluations respecting new or improved methods for obtaining current data on the matters referred to in paragraph (1);

(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.

(c) Statistical and epidemiological compilations and surveys

The Center shall furnish such special statistical and epidemiological compilations and surveys as the Committee on Labor and Human Resources and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives may request. Such statistical and epidemiological compilations and surveys shall not be made subject to the payment of the actual or estimated cost of the preparation of such compilations and surveys.

(d) Technical aid to States and localities

To insure comparability and reliability of health statistics, the Secretary shall, through the Center, provide adequate technical assistance to assist State and local jurisdictions in the development of model laws dealing with issues of confidentiality and comparability of data.

(e) Cooperative Health Statistics System

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;
- (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 and other activities carried out under the System; and
- (4) review the statistical activities of the Department of Health and Human Services 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 ^[1] produce uniform and timely data and assure appropriate access to such data.

(f) Federal-State cooperation

To assist in carrying out this section, the Secretary, acting through the Center, shall cooperate and consult with the Departments of Commerce and Labor and any other interested Federal departments or agencies and with State and local health departments and agencies. For such purpose he shall utilize insofar as possible the services or facilities of any agency of the Federal Government and, without regard to section 5 of title 41, of any appropriate State or other public agency, and may, without regard to such section, utilize the services or facilities of any private agency, organization, group, or individual, in accordance with written agreements between the head of such agency, organization, or group and the Secretary or between such individual and the Secretary. Payment, if any, for such services or facilities shall be made in such amounts as may be provided in such agreement.

(g) Collection of health data; data collection forms

To secure uniformity in the registration and collection of mortality, morbidity, and other health data, the Secretary shall prepare and distribute suitable and necessary forms for the collection and compilation of such data.

(h) Registration area records

(1) There shall be an annual collection of data from the records of births, deaths, marriages, and divorces in registration areas. The data shall be obtained only from and restricted to such records of the States and municipalities which the Secretary, in his discretion, determines possess records affording satisfactory data in necessary detail and form. The Secretary shall encourage States and registration areas to obtain detailed data on ethnic and racial populations, including subpopulations of Hispanics, Asian Americans, and Pacific Islanders with significant representation in the State or registration area. Each State or registration area shall be paid by the Secretary the Federal share of its reasonable costs (as determined by the Secretary) for collecting and transcribing (at the request of the Secretary and by whatever method authorized by him) its records for such data.

(2) There shall be an annual collection of data from a statistically valid sample concerning the general health, illness, and disability status of the civilian noninstitutionalized population. Specific topics to be addressed under this paragraph, on an annual or periodic basis, shall include the incidence of illness and accidental injuries, prevalence of chronic diseases and impairments, disability, physician visits, hospitalizations, and the relationship between demographic and socioeconomic characteristics and health characteristics.

(i) Technical assistance in effective use of statistics

The Center may provide to public and nonprofit private entities technical assistance in the effective use in such activities of statistics collected or compiled by the Center.

(j) Coordination of health statistical and epidemiological activities

In carrying out the requirements of section [242b \(c\)](#) of this title and paragraph (1) of subsection (e) of this section, the Secretary shall coordinate health statistical and epidemiological activities of the Department of Health and Human Services 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) of this section;
- (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](#) ^[2] of title [44](#), 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](#), ^[2] 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.

(k) National Committee on Vital and Health Statistics; establishment; membership; term of office; compensation; functions; consultations of Secretary with Committee and professional advisory groups

- (1) There is established in the Office of the Secretary a committee to be known as the National Committee on Vital and Health Statistics (hereinafter in this subsection referred to as the "Committee") which shall consist of 18 members.
- (2) The members of the Committee shall be appointed from among persons who have distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Members of the Committee shall be appointed for terms of 4 years.
- (3) Of the members of the Committee—
 - (A) 1 shall be appointed, not later than 60 days after August 21, 1996, by the Speaker of the House of Representatives after consultation with the Minority Leader of the House of Representatives;
 - (B) 1 shall be appointed, not later than 60 days after August 21, 1996, by the President pro tempore of the Senate after consultation with the Minority Leader of the Senate; and
 - (C) 16 shall be appointed by the Secretary.
- (4) Members of the Committee shall be compensated in accordance with section [210 \(c\)](#) of this title.
- (5) The Committee—
 - (A) shall assist and advise the Secretary—
 - (i) to delineate statistical problems bearing on health and health services which are of national or international interest;
 - (ii) to stimulate studies of such problems by other organizations and agencies whenever possible or to make investigations of such problems through subcommittees;
 - (iii) to determine, approve, and revise the terms, definitions, classifications, and guidelines for assessing health status and health services, their distribution and costs, for use

- (I) within the Department of Health and Human Services,
- (II) by all programs administered or funded by the Secretary, including the Federal-State-local cooperative health statistics system referred to in subsection (e) of this section, and
- (III) to the extent possible as determined by the head of the agency involved, by the Department of Veterans Affairs, the Department of Defense, and other Federal agencies concerned with health and health services;
- (iv) with respect to the design of and approval of health statistical and health information systems concerned with the collection, processing, and tabulation of health statistics within the Department of Health and Human Services, with respect to the Cooperative Health Statistics System established under subsection (e) of this section, 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) of this section;
- (v) to review and comment on findings and proposals developed by other organizations and agencies and to make recommendations for their adoption or implementation by local, State, national, or international agencies;
- (vi) to cooperate with national committees of other countries and with the World Health Organization and other national agencies in the studies of problems of mutual interest;
- (vii) to issue an annual report on the state of the Nation's health, its health services, their costs and distributions, and to make proposals for improvement of the Nation's health statistics and health information systems; and
- (viii) in complying with the requirements imposed on the Secretary under part C of title XI of the Social Security Act [[42 U.S.C. 1320d](#) et seq.];
- (B) shall study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information;
- (C) shall report to the Secretary not later than 4 years after August 21, 1996, recommendations and legislative proposals for such standards and electronic exchange; and
- (D) shall be responsible generally for advising the Secretary and the Congress on the status of the implementation of part C of title XI of the Social Security Act [[42 U.S.C. 1320d](#) et seq.].
- (6) In carrying out health statistical activities under this part, the Secretary shall consult with, and seek the advice of, the Committee and other appropriate professional advisory groups.
- (7) Not later than 1 year after August 21, 1996, and annually thereafter, the Committee shall submit to the Congress, and make public, a report regarding the implementation of part C of title XI of the Social Security Act [[42 U.S.C. 1320d](#) et seq.]. Such report shall address the following subjects, to the extent that the Committee determines appropriate:
 - (A) The extent to which persons required to comply with part C of title XI of the Social Security Act are cooperating in implementing the standards adopted under such part.
 - (B) The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for noncompliance with such standards.
 - (C) Whether the Federal and State Governments are receiving information of sufficient quality to meet their responsibilities under such part.
 - (D) Any problems that exist with respect to implementation of such part.
 - (E) The extent to which timetables under such part are being met.
- (I) Data specific to particular ethnic and racial populations**
In carrying out this section, the Secretary, acting through the Center, shall collect and analyze adequate health data that is specific to particular ethnic and racial populations, including data collected under national health surveys. Activities carried out under this subsection shall be in addition to any activities carried out under subsection (m) of this section.
- (m) Grants for assembly and analysis of data on ethnic and racial populations**
 - (1) The Secretary, acting through the Center, may make grants to public and nonprofit private entities for—
 - (A) the conduct of special surveys or studies on the health of ethnic and racial populations

or subpopulations;

(B) analysis of data on ethnic and racial populations and subpopulations; and

(C) research on improving methods for developing statistics on ethnic and racial populations and subpopulations.

(2) The Secretary, acting through the Center, may provide technical assistance, standards, and methodologies to grantees supported by this subsection in order to maximize the data quality and comparability with other studies.

(3) Provisions of section [242m \(d\)](#) of this title do not apply to surveys or studies conducted by grantees under this subsection unless the Secretary, in accordance with regulations the Secretary may issue, determines that such provisions are necessary for the conduct of the survey or study and receives adequate assurance that the grantee will enforce such provisions.

(4)

(A) Subject to subparagraph (B), the Secretary, acting through the Center, shall collect data on Hispanics and major Hispanic subpopulation groups and American Indians, and for developing special area population studies on major Asian American and Pacific Islander populations.

(B) The provisions of subparagraph (A) shall be effective with respect to a fiscal year only to the extent that funds are appropriated pursuant to paragraph (3) of subsection (n) of this section, and only if the amounts appropriated for such fiscal year pursuant to each of paragraphs (1) and (2) of subsection (n) of this section equal or exceed the amounts so appropriated for fiscal year 1997.

(n) Authorization of appropriations

(1) For health statistical and epidemiological activities undertaken or supported under subsections (a) through (l) of this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 2003.

(2) For activities authorized in paragraphs (1) through (3) of subsection (m) of this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through 2003. Of such amounts, the Secretary shall use not more than 10 percent for administration and for activities described in subsection (m)(2) of this section.

(3) For activities authorized in subsection (m)(4) of this section, there are authorized to be appropriated \$1,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

Section 42 USC 242(m)

(a) Reports to Congress and President; preparation; review by Office of Management and Budget

(1) Not later than March 15 of each year, the Secretary shall submit to the President and Congress the following reports:

(A) A report on health care costs and financing. Such report shall include a description and analysis of the statistics collected under section [242k \(b\)\(1\)\(G\)](#) of this title.

(B) A report on health resources. Such report shall include a description and analysis, by geographical area, of the statistics collected under section [242k \(b\)\(1\)\(E\)](#) of this title.

(C) A report on the utilization of health resources. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section [242k \(b\)\(1\)\(F\)](#) of this title.

(D) A report on the health of the Nation's people. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section [242k \(b\)\(1\)\(A\)](#) of this title.

(2) The reports required in paragraph (1) shall be prepared through the National Center for Health Statistics.

(3) The Office of Management and Budget may review any report required by paragraph (1) of this subsection before its submission to Congress, but the Office may not revise any such report or delay its submission beyond the date prescribed for its submission, and may submit to Congress its comments respecting any such report.

(b) Grants or contracts; applications, submittal; application peer review group, findings and recommendations; necessity of favorable recommendation; appointments

(1) No grant or contract may be made under section [242b](#), [242k](#), or [242l](#) of this title unless an application therefor has been submitted to the Secretary in such form and manner, and containing such information, as the Secretary may by regulation prescribe and unless a peer review group referred to in paragraph (2) has recommended the application for approval.

(2)

(A) Each application submitted for a grant or contract under section [242k](#) of this title in an amount exceeding \$50,000 of direct costs and for a health services research, evaluation, or demonstration project, or for a grant under section [242k \(m\)](#) of this title, shall be submitted to a peer review group for an evaluation of the technical and scientific merits of the proposals made in each such application. The Director of the National Center for Health Statistics shall establish such peer review groups as may be necessary to provide for such an evaluation of each such application.

(B) A peer review group to which an application is submitted pursuant to subparagraph (A) shall report its finding and recommendations respecting the application to the Secretary, acting through the Director of the National Center for Health Statistics, in such form and manner as the Secretary shall by regulation prescribe. The Secretary may not approve an application described in such subparagraph unless a peer review group has recommended the application for approval.

(C) The Secretary, acting through the Director of the National Center for Health Statistics, shall make appointments to the peer review groups required in subparagraph (A) from among persons who are not officers or employees of the United States and who possess appropriate technical and scientific qualifications, except that peer review groups regarding grants under section [242k \(m\)](#) of this title may include appropriately qualified such officers and employees.

(c) Development and dissemination of statistics

The Secretary shall take such action as may be necessary to assure that statistics developed under sections [242b](#) and [242k](#) of this title are of high quality, timely, comprehensive as well as specific, standardized, and adequately analyzed and indexed,

and shall publish, make available, and disseminate such statistics on as wide a basis as is practicable.

(d) Information; publication restrictions

No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section [242b](#), [242k](#), or [242l](#) of this title may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose; and in the case of information obtained in the course of health statistical or epidemiological activities under section [242b](#) or [242k](#) of this title, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

(e) Payment procedures; advances or reimbursement; installments; conditions; reductions

(1) Payments of any grant or under any contract under section [242b](#), [242k](#), or [242l](#) of this title may be made in advance or by way of reimbursement, and in such installments and on such conditions, as the Secretary deems necessary to carry out the purposes of such section.

(2) The amounts otherwise payable to any person under a grant or contract made under section [242b](#), [242k](#), or [242l](#) of this title shall be reduced by—

(A) amounts equal to the fair market value of any equipment or supplies furnished to such person by the Secretary for the purpose of carrying out the project with respect to which such grant or contract is made, and

(B) amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the Government in connection with such project, if such officer or employee was assigned or detailed by the Secretary to perform such services, but only if such person requested the Secretary to furnish such equipment or supplies, or such services, as the case may be.

(f) Contracts without regard to section 3324 of title 31 and section 5 of title 41

Contracts may be entered into under section [242b](#) or [242k](#) of this title without regard to section [3324](#) of title [31](#) and section [5](#) of title [41](#).