Division of Overdose Prevention Technical Assistance Hub

OMB #0920-new

Attachment 2. Authorizing Legislation

lations prescribed by the Surgeon General, is dropped from the Track in an affiliated school for deficiency in conduct or studies, or for other reasons, shall be liable to the United States for all tuition and stipend support provided to the student.

SEC. 274. [2391–3] FUNDING.

Beginning with fiscal year 2010, the Secretary shall transfer from the Public Health and Social Services Emergency Fund such sums as may be necessary to carry out this part.

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

IN GENERAL

SEC. 301. [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 title 10, United States Code, sections 2353 and 2354, except

that determination, approval, and certification required thereby shall be by the Secretary of Health, Education, and Welfare; 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.

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

(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, Education, and Welfare and shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish 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 es-

tablished by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

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

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

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

to conduct research into, or testing for, the carcinogenicity of 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)(1)(A) If a person is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary, in coordination with other agencies, as applicable—

(i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and

(ii) may, upon application by a person engaged in research, issue to such person a certificate of confidentiality to protect the privacy of such individuals if the research is not so funded.

(B) Except as provided in subparagraph (C), any person to whom a certificate is issued under subparagraph (A) to protect the privacy of individuals described in such subparagraph shall not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

(C) The disclosure prohibition in subparagraph (B) shall not apply to disclosure or use that is—

(i) required by Federal, State, or local laws, excluding instances described in subparagraph (D);

(ii) necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

(iii) made with the consent of the individual to whom the information, document, or biospecimen pertains; or

(iv) made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

(D) Any person to whom a certificate is issued under subparagraph (A) to protect the privacy of an individual described in such subparagraph shall not, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, disclose or provide the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, except in the circumstance described in subparagraph (C)(iii).

(E) Identifiable, sensitive information protected under subparagraph (A), and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

(F) Identifiable, sensitive information collected by a person to whom a certificate has been issued under subparagraph (A), and all copies thereof, shall be subject to the protections afforded by this section for perpetuity.

(G) The Secretary shall take steps to minimize the burden to researchers, streamline the process, and reduce the time it takes to comply with the requirements of this subsection.

(2) The Secretary shall coordinate with the heads of other applicable Federal agencies to ensure that such departments have policies in place with respect to the issuance of a certificate of confidentiality pursuant to paragraph (1) and other requirements of this subsection.

(3) Nothing in this subsection shall be construed to limit the access of an individual who is a subject of research to information about himself or herself collected during such individual's participation in the research.

(4) For purposes of this subsection, the term "identifiable, sensitive information" means information that is about an individual and that is gathered or used during the course of research described in paragraph (1)(A) and—

(A) through which an individual is identified; or

(B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

(e) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand, intensify, and coordinate the activities of the Centers for Disease Control and Prevention with respect to preterm labor and delivery and infant mortality.

(f)(1) The Secretary may exempt from disclosure under section 552(b)(3) of title 5, United States Code, biomedical information that

is about an individual and that is gathered or used during the course of biomedical research if—

(A) an individual is identified; or

(B) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual.

(2)(A) Each determination of the Secretary under paragraph (1) to exempt information from disclosure shall be made in writing and accompanied by a statement of the basis for the determination.

(B) Each such determination and statement of basis shall be available to the public, upon request, through the Office of the Chief FOIA Officer of the Department of Health and Human Services.

(3) Nothing in this subsection shall be construed to limit a research participant's access to information about such participant collected during the participant's participation in the research.

(g) Subchapter I of chapter 35 of title 44, United States Code, shall not apply to the voluntary collection of information during the conduct of research by the National Institutes of Health.

(h)(1) 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.

(2) Where research substances and living organisms are made available under paragraph (1) through contractors, the Secretary may direct such contractors to collect payments on behalf of the Secretary for the costs incurred to make available such substances and organisms and to forward amounts so collected to the Secretary, in the time and manner specified by the Secretary.

(3) Amounts collected under paragraph (2) shall be credited to the appropriations accounts that incurred the costs to make available the research substances and living organisms involved, and shall remain available until expended for carrying out activities under such accounts.

NARCOTICS

SEC. 302. [242] (a) In carrying out the purposes of section 301 with respect to drugs the use or misuse of which might result in drug abuse or dependency, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives, and preparations, and other drugs subject to control under the Controlled Substances Act and Controlled Substances Import and Export Act, together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary

EFFECTS OF FOLIC ACID IN PREVENTION OF BIRTH DEFECTS

SEC. 317J. [247b–11] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand and intensify programs (directly or through grants or contracts) for the following purposes:

(1) To provide education and training for health professionals and the general public for purposes of explaining the effects of folic acid in preventing birth defects and for purposes of encouraging each woman of reproductive capacity (whether or not planning a pregnancy) to consume on a daily basis a dietary supplement that provides an appropriate level of folic acid.

(2) To conduct research with respect to such education and training, including identifying effective strategies for increasing the rate of consumption of folic acid by women of reproductive capacity.

(3) To conduct research to increase the understanding of the effects of folic acid in preventing birth defects, including understanding with respect to cleft lip, cleft palate, and heart defects.

(4) To provide for appropriate epidemiological activities regarding folic acid and birth defects, including epidemiological activities regarding neural tube defects.

(b) CONSULTATIONS WITH STATES AND PRIVATE ENTITIES.—In carrying out subsection (a), the Secretary shall consult with the States and with other appropriate public or private entities, including national nonprofit private organizations, health professionals, and providers of health insurance and health plans.

(c) TECHNICAL ASSISTANCE.—The Secretary may (directly or through grants or contracts) provide technical assistance to public and nonprofit private entities in carrying out the activities described in subsection (a).

(d) EVALUATIONS.—The Secretary shall (directly or through grants or contracts) provide for the evaluation of activities under subsection (a) in order to determine the extent to which such activities have been effective in carrying out the purposes of the program under such subsection, including the effects on various demographic populations. Methods of evaluation under the preceding sentence may include surveys of knowledge and attitudes on the consumption of folic acid and on blood folate levels. Such methods may include complete and timely monitoring of infants who are born with neural tube defects.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

SAFE MOTHERHOOD

SEC. 317K. [247b–12] (a) SURVEILLANCE.—

(1) PURPOSE.—The purpose of this subsection is to develop surveillance systems at the local, State, and national level to better understand the burden of maternal complications and

mortality and to decrease the disparities among population at risk of death and complications from pregnancy.

(2) ACTIVITIES.—For the purpose described in paragraph (1), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may carry out the following activities:

(A) The Secretary may establish and implement a national surveillance program to identify and promote the investigation of deaths and severe complications that occur during pregnancy.

(B) The Secretary may expand the Pregnancy Risk Assessment Monitoring System to provide surveillance and collect data in each State.

(C) The Secretary may expand the Maternal and Child Health Epidemiology Program to provide technical support, financial assistance, or the time-limited assignment of senior epidemiologists to maternal and child health programs in each State.

(b) PREVENTION RESEARCH.—

(1) PURPOSE.—The purpose of this subsection is to provide the Secretary with the authority to further expand research concerning risk factors, prevention strategies, and the roles of the family, health care providers and the community in safe motherhood.

(2) RESEARCH.—The Secretary may carry out activities to expand research relating to—

(A) encouraging preconception counseling, especially for at risk populations such as diabetics;

(B) the identification of critical components of prenatal delivery and postpartum care;

(C) the identification of outreach and support services, such as folic acid education, that are available for pregnant women;

(D) the identification of women who are at high risk for complications;

(E) preventing preterm delivery;

(F) preventing urinary tract infections;

(G) preventing unnecessary caesarean sections;

(H) an examination of the higher rates of maternal mortality among African American women;

(I) an examination of the relationship between domestic violence and maternal complications and mortality;

(J) preventing and reducing adverse health consequences that may result from smoking, alcohol and illegal drug use before, during and after pregnancy;

(K) preventing infections that cause maternal and infant complications; and

(L) other areas determined appropriate by the Secretary.

(c) PREVENTION PROGRAMS.—

(1) [13] IN GENERAL.—The Secretary may carry out activities to promote safe motherhood, including—

(A) public education campaigns on healthy pregnancies and the building of partnerships with outside organizations concerned about safe motherhood;

(B) education programs for physicians, nurses and other health care providers; and

(C) activities to promote community support services for pregnant women.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

PRENATAL AND POSTNATAL HEALTH

SEC. 317L. [247b–13] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out programs—

(1) to collect, analyze, and make available data on prenatal smoking, alcohol and illegal drug use, including data on the implications of such activities and on the incidence and prevalence of such activities and their implications;

(2) to conduct applied epidemiological research on the prevention of prenatal and postnatal smoking, alcohol and illegal drug use;

(3) to support, conduct, and evaluate the effectiveness of educational and cessation programs; and

(4) to provide information and education to the public on the prevention and implications of prenatal and postnatal smoking, alcohol and illegal drug use.

(b) GRANTS.—In carrying out subsection (a), the Secretary may award grants to and enter into contracts with States, local governments, scientific and academic institutions, federally qualified health centers, and other public and nonprofit entities, and may provide technical and consultative assistance to such entities.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 317L–1. [247b–13a] SCREENING AND TREATMENT FOR MATERNAL DEPRESSION.

(a) GRANTS.—The Secretary shall make grants to States to establish, improve, or maintain programs for screening, assessment, and treatment services, including culturally and linguistically appropriate services, as appropriate, for women who are pregnant, or who have given birth within the preceding 12 months, for maternal depression.

(b) APPLICATION.—To seek a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may re-

[13] So in law. Subsection (c) does not contain a paragraph (2). See section 901 of Public Law 106–310 (114 Stat. 1126).