

# **BioSense – Request for Revision**

## **Attachment 1**

**Public Health Service Act  
(42 U.S.C 241, 247b and 247d-4)**

**Pandemic and All-Hazards Preparedness Act  
(Public Law 109-417)**

# **Public Health Service Act**

## **42 U.S.C. 241, 247b and 247d-4**

Excerpted from: U.S. Code TITLE 42--THE PUBLIC HEALTH AND WELFARE; CHAPTER 6A--PUBLIC HEALTH SERVICE; SUBCHAPTER II--GENERAL POWERS AND DUTIES; Part A--Research and Investigations

### **Sec. 241. Research and investigations generally**

#### **(a) Authority of Secretary**

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) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation

(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) Diseases not significantly occurring in United States

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.

Excerpted from: U.S. Code TITLE 42--THE PUBLIC HEALTH AND WELFARE; CHAPTER 6A--PUBLIC HEALTH SERVICE; SUBCHAPTER II--GENERAL POWERS AND DUTIES; Part B—Federal-State Cooperation

**Section 247b. Project grants for preventive health services**

(a) Grant authority

The Secretary may make grants to States, and in consultation with State health authorities, to political subdivisions of States and to other public entities to assist them in meeting the costs of establishing and maintaining preventive health service programs.

(b) Application

No grant may be made under subsection (a) of this section unless an application therefore has been submitted to, and approved by, the Secretary. Such an application shall be in such form and be submitted in such manner as the Secretary shall by regulation prescribe and shall provide –

(1) a complete description of the type and extent of the program for which the applicant is seeking a grant under subsection (a) of this section;

(2) with respect to each such program

(A) the amount of Federal, State, and other funds obligated by the applicant in its latest annual accounting period for the provision of such program, (B) a description of the services provided by the applicant in such program in such period,

(C) the amount of Federal funds needed by the applicant to continue providing such services in such program, and

- (D) if the applicant proposes changes in the provision of the services in such program, the priorities of such proposed changes, reasons for such changes, and the amount of Federal funds needed by the applicant to make such changes;
- (3) assurances satisfactory to the Secretary that the program which will be provided with funds under a grant under subsection (a) of this section will be provided in a manner consistent with the State health plan in effect under section 300m-3(c) (!1) of this title and in those cases where the applicant is a State, that such program will be provided, where appropriate, in a manner consistent with any plans in effect under an application approved under section 247 (!1) of this title;
- (4) assurances satisfactory to the Secretary that the applicant will provide for such fiscal control and fund accounting procedures as the Secretary by regulation prescribes to assure the proper disbursement of and accounting for funds received under grants under subsection (a) of this section;
- (5) assurances satisfactory to the Secretary that the applicant will provide for periodic evaluation of its program or programs;
- (6) assurances satisfactory to the Secretary that the applicant will make such reports (in such form and containing such information as the Secretary may by regulation prescribe) as the Secretary may reasonably require and keep such records and afford such access thereto as the Secretary may find necessary to assure the correctness of, and to verify, such reports;
- (7) assurances satisfactory to the Secretary that the applicant will comply with any other conditions imposed by this section with respect to grants; and
- (8) such other information as the Secretary may by regulation prescribe.

(c) Approval; annual project review

- (1) The Secretary shall not approve an application submitted under subsection (b) of this section for a grant for a program for which a grant was previously made under subsection (a) of this section unless the Secretary determines -
  - (A) the program for which the application was submitted is operating effectively to achieve its stated purpose,
  - (B) the applicant complied with the assurances provided the Secretary when applying for such previous grant, and
  - (C) the applicant will comply with the assurances provided with the application.
- (2) The Secretary shall review annually the activities undertaken by each recipient of a grant under subsection (a) of this section to determine if the program assisted by such grant is operating effectively to achieve its stated purposes and if the recipient is in compliance with the assurances provided the Secretary when applying for such grant.

(d) Amount of grant; payment

The amount of a grant under subsection (a) of this section shall be determined by the Secretary. Payments under such grants may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

(e) Reduction

The Secretary, at the request of a recipient of a grant under subsection (a) of this section, may reduce the amount of such grant by -

(1) the fair market value of any supplies (including vaccines and other preventive agents) or equipment furnished the grant recipient, and

(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee, when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) of this section is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(f) Recordkeeping; audit authority

(1) Each recipient of a grant under subsection (a) of this section shall keep such records as the Secretary shall by regulation prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the undertaking in connection with which such grant was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of grants under subsection (a) of this section that are pertinent to such grants.

(g) Use of grant funds; mandatory treatment prohibited

(1) Nothing in this section shall limit or otherwise restrict the use of funds which are granted to a State or to an agency or a political subdivision of a State under provisions of Federal law (other than this section) and which are available for the conduct of preventive health service programs from being used in connection with programs assisted through grants under subsection (a) of this section.

(2) Nothing in this section shall be construed to require any State or any agency or political subdivision of a State to have a preventive health service program which would require any person, who objects to any treatment provided under such a program, to be treated or to have any child or ward treated under such program.

(h) Reports

The Secretary shall include, as part of the report required by section 300u-4 of this title, a report on the extent of the problems presented by the diseases and conditions referred to in subsection (j) of this section; on the amount of funds obligated under grants under subsection (a) of this section in the preceding fiscal year for each of the programs listed in subsection (j) of this section; and on the effectiveness of the activities assisted under grants under subsection (a) of this section in controlling such diseases and conditions.

(i) Technical assistance

The Secretary may provide technical assistance to States, State health authorities, and other public entities in connection with the operation of their preventive health service programs.

(j) Authorization of appropriations

(1) Except for grants for immunization programs the authorization of appropriations for which are established in paragraph (2), for grants under subsections (a) and (k)(1) of this section for preventive health service programs to immunize without charge children, adolescents, and adults against vaccine-preventable diseases, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1998 through 2005. Not more than 10 percent of the total amount appropriated under the preceding sentence for any fiscal year shall be available for grants under subsection (k)(1) of this section for such fiscal year.

(2) For grants under subsection (a) of this section for preventive health service programs for the provision without charge of immunizations with vaccines approved for use, and recommended for routine use, after October 1, 1997, there are authorized to be appropriated such sums as may be necessary.

(k) Additional grants to States, political subdivisions, and other public and nonprofit private entities

(1) The Secretary may make grants to States, political subdivisions of States, and other public and nonprofit private entities for -

(A) research into the prevention and control of diseases that may be prevented through vaccination;

(B) demonstration projects for the prevention and control of such diseases;

(C) public information and education programs for the prevention and control of such diseases; and

(D) education, training, and clinical skills improvement activities in the prevention and control of such diseases for health professionals (including allied health personnel).

(2) The Secretary may make grants to States, political subdivisions of States, and other public and nonprofit private entities for -

(A) research into the prevention and control of diseases and conditions;

(B) demonstration projects for the prevention and control of such diseases and conditions;

(C) public information and education programs for the prevention and control of such diseases and conditions; and

(D) education, training, and clinical skills improvement activities in the prevention and control of such diseases and conditions for health professionals (including allied health personnel).

(3) No grant may be made under this subsection unless an application therefore is submitted to the Secretary in such form, at such time, and containing such information as the Secretary may by regulation prescribe.

(4) Subsections (d), (e), and (f) of this section shall apply to grants under this subsection in the same manner as such subsections apply to grants under subsection (a) of this section.

Excerpted from: U.S. Code TITLE 42--THE PUBLIC HEALTH AND WELFARE; CHAPTER 6A--PUBLIC HEALTH SERVICE; SUBCHAPTER II--GENERAL POWERS AND DUTIES; Part B--Federal-State Cooperation

#### **Section 247d-4. Revitalizing the Centers for Disease Control and Prevention**

(a) Facilities; capacities

(1) Findings

Congress finds that the Centers for Disease Control and Prevention has an essential role in defending against and combating public health threats and requires secure and modern facilities, and expanded and improved capabilities related to bioterrorism and other public health emergencies, sufficient to enable such Centers to conduct this important mission.

(2) Facilities

(A) In general

The Director of the Centers for Disease Control and Prevention may design, construct, and equip new facilities, renovate existing facilities (including laboratories, laboratory support buildings, scientific communication facilities, transshipment complexes, secured and isolated parking structures, office buildings, and other facilities and infrastructure), and upgrade security of such facilities, in order to better conduct the capacities described in section 247d-1 of this title, and for supporting public health activities.

(B) Multiyear contracting authority

For any project of designing, constructing, equipping, or renovating any facility under subparagraph (A), the Director of the Centers for Disease Control and Prevention may enter into a single contract or related contracts that collectively include the full scope of the project, and the solicitation and contract shall contain the clause "availability of funds" found at section 52.232-18 of title 48, Code of Federal Regulations.

(3) Improving the capacities of the Centers for Disease Control and Prevention

The Secretary, taking into account evaluations under section 247d-2(a) of this title shall expand, enhance, and improve the capabilities of the Centers for Disease Control and Prevention relating to preparedness for and responding effectively to bioterrorism and other public health emergencies. Activities that may be carried out under the preceding sentence include -

(A) expanding or enhancing the training of personnel;

(B) improving communications facilities and networks, including delivery of necessary information to rural areas;

(C) improving capabilities for public health surveillance and reporting activities, taking into account the integrated system or systems of public health alert communications and surveillance networks under subsection (b) of this section; and



(D) improving laboratory facilities related to bioterrorism and other public health emergencies, including increasing the security of such facilities.

(b) National communications and surveillance networks

(1) In general

The Secretary, directly or through awards of grants, contracts, or cooperative agreements, shall provide for the establishment of an integrated system or systems of public health alert communications and surveillance networks between and among -

(A) Federal, State, and local public health officials;

(B) public and private health-related laboratories, hospitals, and other health care facilities; and

(C) any other entities determined appropriate by the Secretary.

(2) Requirements

The Secretary shall ensure that networks under paragraph (1) allow for the timely sharing and discussion, in a secure manner, of essential information concerning bioterrorism or another public health emergency, or recommended methods for responding to such an attack or emergency.

(3) Standards

Not later than one year after June 12, 2002, the Secretary, in cooperation with health care providers and State and local public health officials, shall establish any additional technical and reporting standards (including standards for interoperability) for networks under paragraph (1).

(c) Authorization of appropriations

(1) Facilities; capacities

(A) Facilities

For the purpose of carrying out subsection (a)(2) of this section, there are authorized to be appropriated \$300,000,000 for each of the fiscal years 2002 and 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006.

(B) Mission; improving capacities

For the purposes of achieving the mission of the Centers for Disease Control and Prevention described in subsection (a)(1) of this section, for carrying out subsection (a)(3) of this section, for better conducting the capacities described in section 247d-1 of this title, and for supporting public health activities, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

(2) National communications and surveillance networks

For the purpose of carrying out subsection (b) of this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

# Pandemic and All-Hazards Preparedness Act (Public Law 109-417)

PUBLIC LAW 109-417—DEC. 19, 2006

120 STAT. 2831

Public Law 109-417  
109th Congress

## An Act

To amend the Public Health Service Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

Dec. 19, 2006  
[S. 3678]

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

Pandemic and  
All-Hazards  
Preparedness  
Act.  
42 USC 201 note.

### SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Pandemic and All-Hazards Preparedness Act”.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

#### TITLE I—NATIONAL PREPAREDNESS AND RESPONSE, LEADERSHIP, ORGANIZATION, AND PLANNING

- Sec. 101. Public health and medical preparedness and response functions of the Secretary of Health and Human Services.
- Sec. 102. Assistant Secretary for Preparedness and Response.
- Sec. 103. National Health Security Strategy.

#### TITLE II—PUBLIC HEALTH SECURITY PREPAREDNESS

- Sec. 201. Improving State and local public health security.
- Sec. 202. Using information technology to improve situational awareness in public health emergencies.
- Sec. 203. Public health workforce enhancements.
- Sec. 204. Vaccine tracking and distribution.
- Sec. 205. National Science Advisory Board for Biosecurity.
- Sec. 206. Revitalization of Commissioned Corps.

#### TITLE III—ALL-HAZARDS MEDICAL SURGE CAPACITY

- Sec. 301. National disaster medical system.
- Sec. 302. Enhancing medical surge capacity.
- Sec. 303. Encouraging health professional volunteers.
- Sec. 304. Core education and training.
- Sec. 305. Partnerships for State and regional hospital preparedness to improve surge capacity.
- Sec. 306. Enhancing the role of the Department of Veterans Affairs.

#### TITLE IV—PANDEMIC AND BIODEFENSE VACCINE AND DRUG DEVELOPMENT

- Sec. 401. Biomedical Advanced Research and Development Authority.
- Sec. 402. National Biodefense Science Board.
- Sec. 403. Clarification of countermeasures covered by Project BioShield.
- Sec. 404. Technical assistance.
- Sec. 405. Collaboration and coordination.
- Sec. 406. Procurement.