can be linked with the identification cards under section 300hh–15 of this title.

(e) Confidentiality

The Secretary shall establish and require the application of and compliance with measures to ensure the effective security of, integrity of, and access to the data included in the verification network.

(f) Coordination

The Secretary shall coordinate with the Secretary of Veterans Affairs and the Secretary of Homeland Security to assess the feasibility of integrating the verification network under this section with the VetPro system of the Department of Veterans Affairs and the National Emergency Responder Credentialing System of the Department of Homeland Security. The Secretary shall, if feasible, integrate the verification network under this section with such VetPro system and the National Emergency Responder Credentialing System.

(g) Updating of information

The States that are participants in the verification network shall, on at least a quarterly basis, work with the Director to provide for the updating of the information contained in the verification network.

(h) Clarification

Inclusion of a health professional in the verification network shall not constitute appointment of such individual as a Federal employee for any purpose, either under section 300hh–11(c) of this title or otherwise. Such appointment may only be made under section 300hh–11 or 300hh–15 of this title.

(i) Health care provider licenses

The Secretary shall encourage States to establish and implement mechanisms to waive the application of licensing requirements applicable to health professionals, who are seeking to provide medical services (within their scope of practice), during a national, State, local, or tribal public health emergency upon verification that such health professionals are licensed and in good standing in another State and have not been disciplined by any State health licensing or disciplinary board.

(j) Rule of construction

This section may not be construed as authorizing the Secretary to issue requirements regarding the provision by the States of credentials, licenses, accreditations, or hospital privileges.

(k) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2011.

(July 1, 1944, ch. 373, title III, § 319I, as added Pub. L. 107–188, title I, § 107, June 12, 2002, 116 Stat. 608; amended Pub. L. 109–417, title III, § 303(b), Dec. 19, 2006, 120 Stat. 2857.)

AMENDMENTS

2006—Subsecs. (a), (b). Pub. L. 109–417, § 303(b)(2), added subsecs. (a) and (b) and struck out former subsecs. (a) and (b) which related to establishment of a verification system and provisions regarding its promptness and efficiency.

Subsec. (c). Pub. L. 109–417, § 303(b)(3), substituted ''network'' for ''system''.

Subsecs. (d) to (k). Pub. L. 109–417, § 303(b)(1), (4), (5), added subsecs. (d) to (i), redesignated former subsecs. (e) and (f) as (j) and (k), respectively, substituted ''2011'' for ''2006'' in subsec. (k), and struck out heading and text of former subsec. (d). Text read as follows: ''The Secretary may encourage each State to provide legal authority during a public health emergency for health professionals authorized in another State to provide certain health services to provide such health services in the State.''

§ 247d–7c. Supplies and services in lieu of award funds

(a) In general

Upon the request of a recipient of an award under any of sections 247d through 247d–7b of this title or section 247d–7d of this title, the Secretary may, subject to subsection (b) of this section, provide supplies, equipment, and services for the purpose of aiding the recipient in carrying out the purposes for which the award is made and, for such purposes, may detail to the recipient any officer or employee of the Department of Health and Human Services.

(b) Corresponding reduction in payments

With respect to a request described in subsection (a) of this section, the Secretary shall reduce the amount of payments under the award involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(July 1, 1944, ch. 373, title III, § 319J, as added Pub. L. 107–188, title I, § 110, June 12, 2002, 116 Stat. 611.)

§ 247d–7d. Security for countermeasure development and production

(a) In general

The Secretary, in consultation with the Attorney General and the Secretary of Defense, may provide technical or other assistance to provide security to persons or facilities that conduct development, production, distribution, or storage of priority countermeasures (as defined in section 247d–6(h)(4) of this title).

(b) Guidelines

The Secretary may develop guidelines to enable entities eligible to receive assistance under subsection (a) of this section to secure their facilities against potential terrorist attack.

(July 1, 1944, ch. 373, title III, § 319K, as added Pub. L. 107–188, title I, § 124, June 12, 2002, 116 Stat. 614.)

§ 247d–7e. Biomedical Advanced Research and Development Authority

(a) Definitions

In this section:

(1) BARDA

The term ''BARDA'' means the Biomedical Advanced Research and Development Authority.

(2) Fund

The term ''Fund'' means the Biodefense Medical Countermeasure Development Fund established under subsection (d).

(3) Other transactions

The term ''other transactions'' means transactions, other than procurement contracts, grants, and cooperative agreements, such as the Secretary of Defense may enter into under section 2371 of title 10.

(4) Qualified countermeasure

The term ''qualified countermeasure'' has the meaning given such term in section 247d–6a of this title.

(5) Qualified pandemic or epidemic product

The term ''qualified pandemic or epidemic product'' has the meaning given the term in section 247d–6d of this title.

(6) Advanced research and development

(A) In general

The term ''advanced research and development'' means, with respect to a product that is or may become a qualified countermeasure or a qualified pandemic or epidemic product, activities that predominantly—

(i) are conducted after basic research and preclinical development of the product; and

(ii) are related to manufacturing the product on a commercial scale and in a form that satisfies the regulatory requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or under section 262 of this title.

(B) Activities included

The term under subparagraph (A) includes—

(i) testing of the product to determine whether the product may be approved, cleared, or licensed under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or under section 262 of this title for a use that is or may be the basis for such product becoming a qualified countermeasure or qualified pandemic or epidemic product, or to help obtain such approval, clearance, or license;

(ii) design and development of tests or models, including animal models, for such testing;

(iii) activities to facilitate manufacture of the product on a commercial scale with consistently high quality, as well as to improve and make available new technologies to increase manufacturing surge capacity;

(iv) activities to improve the shelf-life of the product or technologies for administering the product; and

(v) such other activities as are part of the advanced stages of testing, refinement, improvement, or preparation of the product for such use and as are specified by the Secretary.

(7) Security countermeasure

The term ''security countermeasure'' has the meaning given such term in section 247d–6b of this title.

(8) Research tool

The term ''research tool'' means a device, technology, biological material (including a cell line or an antibody), reagent, animal model, computer system, computer software, or analytical technique that is developed to assist in the discovery, development, or manufacture of qualified countermeasures or qualified pandemic or epidemic products.

(9) Program manager

The term ''program manager'' means an individual appointed to carry out functions under this section and authorized to provide project oversight and management of strategic initiatives.

(10) Person

The term ''person'' includes an individual, partnership, corporation, association, entity, or public or private corporation, and a Federal, State, or local government agency or department.

(b) Strategic plan for countermeasure research, development, and procurement

(1) In general

Not later than 6 months after December 19, 2006, the Secretary shall develop and make public a strategic plan to integrate biodefense and emerging infectious disease requirements with the advanced research and development, strategic initiatives for innovation, and the procurement of qualified countermeasures and qualified pandemic or epidemic products. The Secretary shall carry out such activities as may be practicable to disseminate the information contained in such plan to persons who may have the capacity to substantially contribute to the activities described in such strategic plan. The Secretary shall update and incorporate such plan as part of the National Health Security Strategy described in section 300hh–1 of this title.

(2) Content

The strategic plan under paragraph (1) shall guide—

(A) research and development, conducted or supported by the Department of Health and Human Services, of qualified countermeasures and qualified pandemic or epidemic products against possible biological, chemical, radiological, and nuclear agents and to emerging infectious diseases;

(B) innovation in technologies that may assist advanced research and development of qualified countermeasures and qualified pandemic or epidemic products (such research and development referred to in this section as ''countermeasure and product advanced research and development''); and

(C) procurement of such qualified countermeasures and qualified pandemic or epidemic products by such Department.

(c) Biomedical Advanced Research and Development Authority

(1) Establishment

There is established within the Department of Health and Human Services the Biomedical Advanced Research and Development Authority.

(2) In general

Based upon the strategic plan described in subsection (b), the Secretary shall coordinate the acceleration of countermeasure and product advanced research and development by—

(A) facilitating collaboration between the Department of Health and Human Services and other Federal agencies, relevant industries, academia, and other persons, with respect to such advanced research and development;

(B) promoting countermeasure and product advanced research and development;

(C) facilitating contacts between interested persons and the offices or employees authorized by the Secretary to advise such persons regarding requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and under section 262 of this title; and

(D) promoting innovation to reduce the time and cost of countermeasure and product advanced research and development.

(3) Director

The BARDA shall be headed by a Director (referred to in this section as the ''Director'') who shall be appointed by the Secretary and to whom the Secretary shall delegate such functions and authorities as necessary to implement this section.

(4) Duties

(A) Collaboration

To carry out the purpose described in paragraph (2)(A), the Secretary shall—

(i) facilitate and increase the expeditious and direct communication between the Department of Health and Human Services and relevant persons with respect to countermeasure and product advanced research and development, including by—

(I) facilitating such communication regarding the processes for procuring such advanced research and development with respect to qualified countermeasures and qualified pandemic or epidemic products of interest; and

(II) soliciting information about and data from research on potential qualified countermeasures and qualified pandemic or epidemic products and related technologies;

(ii) at least annually—

(I) convene meetings with representatives from relevant industries, academia, other Federal agencies, international agencies as appropriate, and other interested persons;

(II) sponsor opportunities to demonstrate the operation and effectiveness of relevant biodefense countermeasure technologies; and

(III) convene such working groups on countermeasure and product advanced research and development as the Secretary may determine are necessary to carry out this section; and

(iii) carry out the activities described in section 405 of the Pandemic and All-Hazards Preparedness Act.

(B) Support advanced research and development

To carry out the purpose described in paragraph (2)(B), the Secretary shall—

(i) conduct ongoing searches for, and support calls for, potential qualified countermeasures and qualified pandemic or epidemic products;

(ii) direct and coordinate the countermeasure and product advanced research and development activities of the Department of Health and Human Services;

(iii) establish strategic initiatives to accelerate countermeasure and product advanced research and development and innovation in such areas as the Secretary may identify as priority unmet need areas; and

(iv) award contracts, grants, cooperative agreements, and enter into other transactions, for countermeasure and product advanced research and development.

(C) Facilitating advice

To carry out the purpose described in paragraph (2)(C) the Secretary shall—

(i) connect interested persons with the offices or employees authorized by the Secretary to advise such persons regarding the regulatory requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and under section 262 of this title related to the approval, clearance, or licensure of qualified countermeasures or qualified pandemic or epidemic products; and

(ii) with respect to persons performing countermeasure and product advanced research and development funded under this section, enable such offices or employees to provide to the extent practicable such advice in a manner that is ongoing and that is otherwise designed to facilitate expeditious development of qualified countermeasures and qualified pandemic or epidemic products that may achieve such approval, clearance, or licensure.

(D) Supporting innovation

To carry out the purpose described in paragraph (2)(D), the Secretary may award contracts, grants, and cooperative agreements, or enter into other transactions, such as prize payments, to promote—

(i) innovation in technologies that may assist countermeasure and product advanced research and development;

(ii) research on and development of research tools and other devices and technologies; and

(iii) research to promote strategic initiatives, such as rapid diagnostics, broad spectrum antimicrobials, and vaccine manufacturing technologies.

(5) Transaction authorities

(A) Other transactions

(i) In general

The Secretary shall have the authority to enter into other transactions under this subsection in the same manner as the Sec-

retary of Defense enters into such transactions under section 2371 of title 10.

(ii) Limitations on authority

(I) In general

Subsections (b), (c), and (h) of section 845 of the National Defense Authorization Act for Fiscal Year 1994 (10 U.S.C. 2371 note) shall apply to other transactions under this subparagraph as if such transactions were for prototype projects described by subsection (a) of such section 845.

(II) Written determinations required

The authority of this subparagraph may be exercised for a project that is expected to cost the Department of Health and Human Services in excess of $20,000,000 only upon a written determination by the senior procurement executive for the Department (as designated for purpose of section 1702(c) of title 41), that the use of such authority is essential to promoting the success of the project. The authority of the senior procurement executive under this subclause may not be delegated.

(iii) Guidelines

The Secretary shall establish guidelines regarding the use of the authority under clause (i). Such guidelines shall include auditing requirements.

(B) Expedited authorities

(i) In general

In awarding contracts, grants, and cooperative agreements, and in entering into other transactions under subparagraph (B) or (D) of paragraph (4), the Secretary shall have the expedited procurement authorities, the authority to expedite peer review, and the authority for personal services contracts, supplied by subsections (b), (c), and (d) of section 247d–6a of this title.

(ii) Application of provisions

Provisions in such section 247d–6a of this title that apply to such authorities and that require institution of internal controls, limit review, provide for Federal Tort Claims Act coverage of personal services contractors, and commit decisions to the discretion of the Secretary shall apply to the authorities as exercised pursuant to this paragraph.

(iii) Authority to limit competition

For purposes of applying section 247d–6a(b)(1)(D) of this title to this paragraph, the phrase ''BioShield Program under the Project BioShield Act of 2004'' shall be deemed to mean the countermeasure and product advanced research and development program under this section.

(iv) Availability of data

The Secretary shall require that, as a condition of being awarded a contract, grant, cooperative agreement, or other transaction under subparagraph (B) or (D) of paragraph (4), a person make available to the Secretary on an ongoing basis, and submit upon request to the Secretary, all data related to or resulting from countermeasure and product advanced research and development carried out pursuant to this section.

(C) Advance payments; advertising

The Secretary may waive the requirements of section 3324(a) of title 31 or section 6101 of title 41 upon the determination by the Secretary that such waiver is necessary to obtain countermeasures or products under this section.

(D) Milestone-based payments allowed

In awarding contracts, grants, and cooperative agreements, and in entering into other transactions, under this section, the Secretary may use milestone-based awards and payments.

(E) Foreign nationals eligible

The Secretary may under this section award contracts, grants, and cooperative agreements to, and may enter into other transactions with, highly qualified foreign national persons outside the United States, alone or in collaboration with American participants, when such transactions may inure to the benefit of the American people.

(F) Establishment of research centers

The Secretary may assess the feasibility and appropriateness of establishing, through contract, grant, cooperative agreement, or other transaction, an arrangement with an existing research center in order to achieve the goals of this section. If such an agreement is not feasible and appropriate, the Secretary may establish one or more federally-funded research and development centers, or university-affiliated research centers, in accordance with section 3304(a)(3) of title 41.

(6) At-risk individuals

In carrying out the functions under this section, the Secretary may give priority to the advanced research and development of qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to children, pregnant women, elderly, and other at-risk individuals.

(7) Personnel authorities

(A) Specially qualified scientific and professional personnel

(i) In general

In addition to any other personnel authorities, the Secretary may—

(I) without regard to those provisions of title 5 governing appointments in the competitive service, appoint highly qualified individuals to scientific or professional positions in BARDA, such as program managers, to carry out this section; and

(II) compensate them in the same manner and subject to the same terms and

conditions in which individuals appointed under section 9903 of such title are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(ii) Manner of exercise of authority

The authority provided for in this subparagraph shall be exercised subject to the same limitations described in section 247d–6a(e)(2) of this title.

(iii) Term of appointment

The term limitations described in section 9903(c) of title 5 shall apply to appointments under this subparagraph, except that the references to the ''Secretary'' and to the ''Department of Defense's national security missions'' shall be deemed to be to the Secretary of Health and Human Services and to the mission of the Department of Health and Human Services under this section.

(B) Special consultants

In carrying out this section, the Secretary may appoint special consultants pursuant to section 209(f) of this title.

(C) Limitation

(i) In general

The Secretary may hire up to 100 highly qualified individuals, or up to 50 percent of the total number of employees, whichever is less, under the authorities provided for in subparagraphs (A) and (B).

(ii) Report

The Secretary shall report to Congress on a biennial basis on the implementation of this subparagraph.

(d) Fund

(1) Establishment

There is established the Biodefense Medical Countermeasure Development Fund, which shall be available to carry out this section in addition to such amounts as are otherwise available for this purpose.

(2) Funding

To carry out the purposes of this section, there are authorized to be appropriated to the Fund—

(A) $1,070,000,000 for fiscal years 2006 through 2008, the amounts to remain available until expended; and

(B) such sums as may be necessary for subsequent fiscal years, the amounts to remain available until expended.

(e) Inapplicability of certain provisions

(1) Disclosure

(A) In general

The Secretary shall withhold from disclosure under section 552 of title 5 specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and development carried out under subsection (c) that reveals significant and not otherwise publicly known vulnerabilities of existing medical or public health defenses against biological, chemical, nuclear, or radiological threats. Such information shall be deemed to be information described in section 552(b)(3) of title 5.

(B) Review

Information subject to nondisclosure under subparagraph (A) shall be reviewed by the Secretary every 5 years, or more frequently as determined necessary by the Secretary, to determine the relevance or necessity of continued nondisclosure.

(C) Sunset

This paragraph shall cease to have force or effect on the date that is 7 years after December 19, 2006.

(2) Review

Notwithstanding section 14 of the Federal Advisory Committee Act, a working group of BARDA under this section and the National Biodefense Science Board under section 247d–7f of this title shall each terminate on the date that is 5 years after the date on which each such group or Board, as applicable, was established. Such 5-year period may be extended by the Secretary for one or more additional 5-year periods if the Secretary determines that any such extension is appropriate.

(July 1, 1944, ch. 373, title III, § 319L, as added Pub. L. 109–417, title IV, § 401, Dec. 19, 2006, 120 Stat. 2865.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a)(6)(A)(ii), (B)(i) and (c)(2)(C), (4)(C)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Section 405 of the Pandemic and All-Hazards Preparedness Act, referred to in subsec. (c)(4)(A)(iii), is section 405 of Pub. L. 109–417, which is set out as a note under section 247d–6a of this title.

Section 845 of the National Defense Authorization Act for Fiscal Year 1994, referred to in subsec. (c)(5)(A)(ii)(I), is section 845 of Pub. L. 103–160, which is set out as a note under section 2371 of Title 10, Armed Forces.

The Federal Tort Claims Act, referred to in subsec. (c)(5)(B)(ii), is title IV of act Aug. 2, 1946, ch. 753, 60 Stat. 842, which was classified principally to chapter 20 (§§ 921, 922, 931–934, 941–946) of former Title 28, Judicial Code and Judiciary. Title IV of act Aug. 2, 1946, was substantially repealed and reenacted as sections 1346(b) and 2671 et seq. of Title 28, Judiciary and Judicial Procedure, by act June 25, 1948, ch. 646, 62 Stat. 992, the first section of which enacted Title 28. The Federal Tort Claims Act is also commonly used to refer to chapter 171 of Title 28, Judiciary and Judicial Procedure. For complete classification of title IV to the Code, see Tables. For distribution of former sections of Title 28 into the revised Title 28, see Table at the beginning of Title 28.

Section 14 of the Federal Advisory Committee Act, referred to in subsec. (e)(2), is section 14 of Pub. L. 92–463, which is set out in the Appendix to Title 5, Government Organization and Employees.

CODIFICATION

In subsec. (c)(5)(A)(ii)(II), ''section 1702(c) of title 41'' substituted for ''section 16(c) of the Office of Federal

Procurement Policy Act (41 U.S.C. 414(c))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(5)(C), ''section 6101 of title 41'' substituted for ''section 3709 of the Revised Statutes of the United States (41 U.S.C. 5)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(5)(F), ''section 3304(a)(3) of title 41'' substituted for ''section 303(c)(3) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(3))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

§ 247d–7f. National Biodefense Science Board and working groups

(a) In general

(1) Establishment and function

The Secretary shall establish the National Biodefense Science Board (referred to in this section as the ''Board'') to provide expert advice and guidance to the Secretary on scientific, technical and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.

(2) Membership

The membership of the Board shall be comprised of individuals who represent the Nation's preeminent scientific, public health, and medical experts, as follows—

(A) such Federal officials as the Secretary may determine are necessary to support the functions of the Board;

(B) four individuals representing the pharmaceutical, biotechnology, and device industries;

(C) four individuals representing academia; and

(D) five other members as determined appropriate by the Secretary, of whom—

(i) one such member shall be a practicing healthcare professional; and

(ii) one such member shall be an individual from an organization representing healthcare consumers.

(3) Term of appointment

A member of the Board described in subparagraph (B), (C), or (D) of paragraph (2) shall serve for a term of 3 years, except that the Secretary may adjust the terms of the initial Board appointees in order to provide for a staggered term of appointment for all members.

(4) Consecutive appointments; maximum terms

A member may be appointed to serve not more than 3 terms on the Board and may serve not more than 2 consecutive terms.

(5) Duties

The Board shall—

(A) advise the Secretary on current and future trends, challenges, and opportunities presented by advances in biological and life sciences, biotechnology, and genetic engineering with respect to threats posed by naturally occurring infectious diseases and chemical, biological, radiological, and nuclear agents;

(B) at the request of the Secretary, review and consider any information and findings received from the working groups established under subsection (b); and

(C) at the request of the Secretary, provide recommendations and findings for expanded, intensified, and coordinated biodefense research and development activities.

(6) Meetings

(A) Initial meeting

Not later than one year after December 19, 2006, the Secretary shall hold the first meeting of the Board.

(B) Subsequent meetings

The Board shall meet at the call of the Secretary, but in no case less than twice annually.

(7) Vacancies

Any vacancy in the Board shall not affect its powers, but shall be filled in the same manner as the original appointment.

(8) Chairperson

The Secretary shall appoint a chairperson from among the members of the Board.

(9) Powers

(A) Hearings

The Board may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Board considers advisable to carry out this subsection.

(B) Postal services

The Board may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

(10) Personnel

(A) Employees of the Federal Government

A member of the Board that is an employee of the Federal Government may not receive additional pay, allowances, or benefits by reason of the member's service on the Board.

(B) Other members

A member of the Board that is not an employee of the Federal Government may be compensated at a rate not to exceed the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5 for each day (including travel time) during which the member is engaged in the actual performance of duties as a member of the Board.

(C) Travel expenses

Each member of the Board shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions under subchapter I of chapter 57 of title 5.

(D) Detail of Government employees

Any Federal Government employee may be detailed to the Board with the approval for