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 (which may include advanced research and development for purposes of fulfilling requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or section 262 of this title) 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, vaccine-manufacturing technologies, dose-sparing technologies, efficacy-increasing technologies, and platform 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 Secretary 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[1] 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

[1] See References in Text note below.

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.

(G) Government purpose

In awarding contracts, grants, and cooperative agreements under this section, the Secretary shall provide a clear statement of defined Government purpose related to activities included in subsection (a)(6)(B) for a qualified countermeasure or qualified pandemic or epidemic product.

(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 is authorized to be appropriated to the Fund $415,000,000 for each of fiscal years 2014 through 2018, such 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 12 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.

(f) Independent evaluation

(1) In general

Not later than 180 days after March 13, 2013, the Comptroller General of the United States shall conduct an independent evaluation of the activities carried out to facilitate flexible manufacturing capacity pursuant to this section.

(2) Report

Not later than 1 year after March 13, 2013, the Comptroller General of the United States shall submit to the appropriate committees of Congress a report concerning the results of the evaluation conducted under paragraph (1). Such report shall review and assess—

(A) the extent to which flexible manufacturing capacity under this section is dedicated to chemical, biological, radiological, and nuclear threats;

(B) the activities supported by flexible manufacturing initiatives; and

(C) the ability of flexible manufacturing activities carried out under this section to—

(i) secure and leverage leading technical expertise with respect to countermeasure advanced research, development, and manufacturing processes; and

(ii) meet the surge manufacturing capacity needs presented by novel and emerging threats, including chemical, biological, radiological, and nuclear agents.

(July 1, 1944, ch. 373, title III, § 319L, as added Pub. L. 109–417, title IV, § 401, Dec. 19, 2006, 120 Stat. 2865; amended Pub. L. 113–5, title IV, § 402(a)–(d), (f), Mar. 13, 2013, 127 Stat. 194, 195.)

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)(B)(iii), (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 was formerly set out as a note under section 2371 of Title 10, Armed Forces, prior to repeal by Pub. L. 114–92, div. A, title VIII, § 815(c), Nov. 25, 2015, 129 Stat. 896. See section 2371b of Title 10.

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.

AMENDMENTS

2013—Subsec. (c)(4)(B)(iii). Pub. L. 113–5, § 402(a)(1), inserted ''(which may include advanced research and development for purposes of fulfilling requirements under the Federal Food, Drug, and Cosmetic Act or section 262 of this title)'' after ''research and development''.

Subsec. (c)(4)(D)(iii). Pub. L. 113–5, § 402(a)(2), substituted ''vaccine-manufacturing technologies, dose-sparing technologies, efficacy-increasing technologies, and platform technologies'' for ''and vaccine manufacturing technologies''.

Subsec. (c)(5)(G). Pub. L. 113–5, § 402(b), added subpar. (G).

Subsec. (d)(2). Pub. L. 113–5, § 402(c), amended par. (2) generally. Prior to amendment, text read as follows: ''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.''

Subsec. (e)(1)(C). Pub. L. 113–5, § 402(d), substituted ''12 years'' for ''7 years''.

Subsec. (f). Pub. L. 113–5, § 402(f), added subsec. (f).

§ 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.