

a contingency basis, to a community in the event of a public health emergency;

(2) integrating the practice of telemedicine within the National Disaster Medical System; and

(3) other strategies to improve such capacity as determined appropriate by the Secretary.

(b) Authority to acquire and operate mobile medical assets

In addition to any other authority to acquire, deploy, and operate mobile medical assets, the Secretary may acquire, deploy, and operate mobile medical assets if, taking into consideration the evaluation conducted under subsection (a), such acquisition, deployment, and operation is determined to be beneficial and feasible in improving the capacity of the Department of Health and Human Services to provide additional medical surge capacity to local communities in the event of a public health emergency.

(c) Using Federal facilities to enhance medical surge capacity

(1) Analysis

The Secretary shall conduct an analysis of whether there are Federal facilities which, in the event of a public health emergency, could practicably be used as facilities in which to provide health care.

(2) Memoranda of understanding

If, based on the analysis conducted under paragraph (1), the Secretary determines that there are Federal facilities which, in the event of a public health emergency, could be used as facilities in which to provide health care, the Secretary shall, with respect to each such facility, seek to conclude a memorandum of understanding with the head of the Department or agency that operates such facility that permits the use of such facility to provide health care in the event of a public health emergency.

(July 1, 1944, ch. 373, title XXVIII, §2803, as added Pub. L. 109-417, title III, §302(a), Dec. 19, 2006, 120 Stat. 2855.)

PART B—ALL-HAZARDS EMERGENCY
PREPAREDNESS AND RESPONSE

AMENDMENTS

2006—Pub. L. 109-417, title I, §102(a)(1), Dec. 19, 2006, 120 Stat. 2832, inserted “All-Hazards” before “Emergency Preparedness” in heading.

§ 300hh-10. Coordination of preparedness for and response to all-hazards public health emergencies

(a) In general

There is established within the Department of Health and Human Services the position of the Assistant Secretary for Preparedness and Response. The President, with the advice and consent of the Senate, shall appoint an individual to serve in such position. Such Assistant Secretary shall report to the Secretary.

(b) Duties

Subject to the authority of the Secretary, the Assistant Secretary for Preparedness and Response shall carry out the following functions:

(1) Leadership

Serve as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies.

(2) Personnel

Register, credential, organize, train, equip, and have the authority to deploy Federal public health and medical personnel under the authority of the Secretary, including the National Disaster Medical System, and coordinate such personnel with the Medical Reserve Corps and the Emergency System for Advance Registration of Volunteer Health Professionals.

(3) Countermeasures

Oversee advanced research, development, and procurement of qualified countermeasures (as defined in section 247d-6a of this title), security countermeasures (as defined in section 247d-6b of this title), and qualified pandemic or epidemic products (as defined in section 247d-6d of this title).

(4) Coordination

(A) Federal integration

Coordinate with relevant Federal officials to ensure integration of Federal preparedness and response activities for public health emergencies.

(B) State, local, and tribal integration

Coordinate with State, local, and tribal public health officials, the Emergency Management Assistance Compact, health care systems, and emergency medical service systems to ensure effective integration of Federal public health and medical assets during a public health emergency.

(C) Emergency medical services

Promote improved emergency medical services medical direction, system integration, research, and uniformity of data collection, treatment protocols, and policies with regard to public health emergencies.

(D) Policy coordination and strategic direction

Provide integrated policy coordination and strategic direction with respect to all matters related to Federal public health and medical preparedness and execution and deployment of the Federal response for public health emergencies and incidents covered by the National Response Plan developed pursuant to section 314(a)(6)¹ of title 6, or any successor plan, before, during, and following public health emergencies.

(E) Identification of inefficiencies

Identify and minimize gaps, duplication, and other inefficiencies in medical and public health preparedness and response activities and the actions necessary to overcome these obstacles.

(F) Coordination of grants and agreements

Align and coordinate medical and public health grants and cooperative agreements as

¹ See References in Text note below.

applicable to preparedness and response activities authorized under this chapter, to the extent possible, including program requirements, timelines, and measurable goals, and in consultation with the Secretary of Homeland Security, to—

- (i) optimize and streamline medical and public health preparedness and response capabilities and the ability of local communities to respond to public health emergencies; and
- (ii) gather and disseminate best practices among grant and cooperative agreement recipients, as appropriate.

(G) Drill and operational exercises

Carry out drills and operational exercises, in consultation with the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and other applicable Federal departments and agencies, as necessary and appropriate, to identify, inform, and address gaps in and policies related to all-hazards medical and public health preparedness and response, including exercises based on—

- (i) identified threats for which countermeasures are available and for which no countermeasures are available; and
- (ii) unknown threats for which no countermeasures are available.

(H) National security priority

On a periodic basis consult with, as applicable and appropriate, the Assistant to the President for National Security Affairs, to provide an update on, and discuss, medical and public health preparedness and response activities pursuant to this chapter and the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], including progress on the development, approval, clearance, and licensure of medical countermeasures.

(5) Logistics

In coordination with the Secretary of Veterans Affairs, the Secretary of Homeland Security, the General Services Administration, and other public and private entities, provide logistical support for medical and public health aspects of Federal responses to public health emergencies.

(6) Leadership

Provide leadership in international programs, initiatives, and policies that deal with public health and medical emergency preparedness and response.

(7) Countermeasures budget plan

Develop, and update on an annual basis, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d). Each such plan shall—

- (A) include consideration of the entire medical countermeasures enterprise, including—
 - (i) basic research and advanced research and development;
 - (ii) approval, clearance, licensure, and authorized uses of products; and
 - (iii) procurement, stockpiling, maintenance, and replenishment of all products in the Strategic National Stockpile;

- (B) inform prioritization of resources and include measurable outputs and outcomes to allow for the tracking of the progress made toward identified priorities;

- (C) identify medical countermeasure life-cycle costs to inform planning, budgeting, and anticipated needs within the continuum of the medical countermeasure enterprise consistent with section 247d-6b of this title; and

- (D) be made available to the appropriate committees of Congress upon request.

(c) Functions

The Assistant Secretary for Preparedness and Response shall—

- (1) have lead responsibility within the Department of Health and Human Services for emergency preparedness and response policy coordination and strategic direction;

- (2) have authority over and responsibility for—

- (A) the National Disaster Medical System pursuant to section 300hh-11 of this title;

- (B) the Hospital Preparedness Cooperative Agreement Program pursuant to section 247d-3b of this title;

- (C) the Biomedical Advanced Research and Development Authority pursuant to section 247d-7e of this title;

- (D) the Medical Reserve Corps pursuant to section 300hh-15 of this title;

- (E) the Emergency System for Advance Registration of Volunteer Health Professionals pursuant to section 247d-7b of this title; and

- (F) administering grants and related authorities related to trauma care under parts A through C of subchapter X, such authority to be transferred by the Secretary from the Administrator of the Health Resources and Services Administration to such Assistant Secretary;

- (3) exercise the responsibilities and authorities of the Secretary with respect to the coordination of—

- (A) the Public Health Emergency Preparedness Cooperative Agreement Program pursuant to section 247d-3a of this title;

- (B) the Strategic National Stockpile pursuant to section 247d-6b of this title; and

- (C) the Cities Readiness Initiative; and

- (4) assume other duties as determined appropriate by the Secretary.

(d) Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan

(1) In general

Not later than 180 days after March 13, 2013, and every year thereafter, the Assistant Secretary for Preparedness and Response shall develop and submit to the appropriate committees of Congress a coordinated strategy and accompanying implementation plan for medical countermeasures to address chemical, biological, radiological, and nuclear threats. In developing such a plan, the Assistant Secretary for Preparedness and Response shall consult with the Director of the Biomedical

Advanced Research and Development Authority, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs. Such strategy and plan shall be known as the “Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan”.

(2) Requirements

The plan under paragraph (1) shall—

(A) describe the chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation and the corresponding efforts to develop qualified countermeasures (as defined in section 247d-6a of this title), security countermeasures (as defined in section 247d-6b of this title), or qualified pandemic or epidemic products (as defined in section 247d-6d of this title) for each threat;

(B) evaluate the progress of all activities with respect to such countermeasures or products, including research, advanced research, development, procurement, stockpiling, deployment, distribution, and utilization;

(C) identify and prioritize near-, mid-, and long-term needs with respect to such countermeasures or products to address a chemical, biological, radiological, and nuclear threat or threats;

(D) identify, with respect to each category of threat, a summary of all awards and contracts, including advanced research and development and procurement, that includes—

(i) the time elapsed from the issuance of the initial solicitation or request for a proposal to the adjudication (such as the award, denial of award, or solicitation termination); and

(ii) an identification of projected timelines, anticipated funding allocations, benchmarks, and milestones for each medical countermeasure priority under subparagraph (C), including projected needs with regard to replenishment of the Strategic National Stockpile;

(E) be informed by the recommendations of the National Biodefense Science Board pursuant to section 247d-7f of this title;

(F) evaluate progress made in meeting timelines, allocations, benchmarks, and milestones identified under subparagraph (D)(ii);

(G) report on the amount of funds available for procurement in the special reserve fund as defined in section 247d-6b(h) of this title and the impact this funding will have on meeting the requirements under section 247d-6b of this title;

(H) incorporate input from Federal, State, local, and tribal stakeholders;

(I) identify the progress made in meeting the medical countermeasure priorities for at-risk individuals (as defined in² 300hh-1(b)(4)(B) of this title), as applicable under subparagraph (C), including with regard to the projected needs for related

stockpiling and replenishment of the Strategic National Stockpile, including by addressing the needs of pediatric populations with respect to such countermeasures and products in the Strategic National Stockpile, including—

(i) a list of such countermeasures and products necessary to address the needs of pediatric populations;

(ii) a description of measures taken to coordinate with the Office of Pediatric Therapeutics of the Food and Drug Administration to maximize the labeling, dosages, and formulations of such countermeasures and products for pediatric populations;

(iii) a description of existing gaps in the Strategic National Stockpile and the development of such countermeasures and products to address the needs of pediatric populations; and

(iv) an evaluation of the progress made in addressing priorities identified pursuant to subparagraph (C);

(J) identify the use of authority and activities undertaken pursuant to sections 247d-6a(b)(1), 247d-6a(b)(2), 247d-6a(b)(3), 247d-6a(c), 247d-6a(d), 247d-6a(e), 247d-6b(c)(7)(C)(iii), 247d-6b(c)(7)(C)(iv), and 247d-6b(c)(7)(C)(v) of this title, and subsections (a)(1), (b)(1), and (e) of section 564 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb-3], by summarizing—

(i) the particular actions that were taken under the authorities specified, including, as applicable, the identification of the threat agent, emergency, or the biomedical countermeasure with respect to which the authority was used;

(ii) the reasons underlying the decision to use such authorities, including, as applicable, the options that were considered and rejected with respect to the use of such authorities;

(iii) the number of, nature of, and other information concerning the persons and entities that received a grant, cooperative agreement, or contract pursuant to the use of such authorities, and the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, except that the report need not disclose the identity of any such person or entity;

(iv) whether, with respect to each procurement that is approved by the President under section 247d-6b(c)(6) of this title, a contract was entered into within one year after such approval by the President; and

(v) with respect to section 247d-6a(d) of this title, for the one-year period for which the report is submitted, the number of persons who were paid amounts totaling \$100,000 or greater and the number of persons who were paid amounts totaling at least \$50,000 but less than \$100,000; and

(K) be made publicly available.

² So in original. The word “section” probably should appear.

(3) GAO report**(A) In general**

Not later than 1 year after the date of the submission to the Congress of the first Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate committees of Congress a report, concerning such Strategy and Implementation Plan.

(B) Content

The report described in subparagraph (A) shall review and assess—

- (i) the near-term, mid-term, and long-term medical countermeasure needs and identified priorities of the Federal Government pursuant to paragraph (2)(C);
- (ii) the activities of the Department of Health and Human Services with respect to advanced research and development pursuant to section 247d-7e of this title; and
- (iii) the progress made toward meeting the timelines, allocations, benchmarks, and milestones identified in the Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan under this subsection.

(e) Protection of national security

In carrying out subsections (b)(7) and (d), the Secretary shall ensure that information and items that could compromise national security, contain confidential commercial information, or contain proprietary information are not disclosed.

(July 1, 1944, ch. 373, title XXVIII, §2811, as added Pub. L. 109-417, title I, §102(a)(3), Dec. 19, 2006, 120 Stat. 2833; amended Pub. L. 113-5, title I, §102(a), Mar. 13, 2013, 127 Stat. 163.)

REFERENCES IN TEXT

Section 314(a)(6) of title 6, referred to in subsec. (b)(4)(D), was in the original “section 504(6) of the Homeland Security Act of 2002” and was translated as meaning section 504(a)(6) of the Homeland Security Act of 2002 to reflect the probable intent of Congress.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(4)(H), is act June 25, 1938, ch. 675, 52 Stat. 1040, 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 301 of the Pandemic and All-Hazards Preparedness Act, referred to in subsec. (c)(1)(A), is section 301 of Pub. L. 109-417, title III, Dec. 19, 2006, 120 Stat. 2853, which amended sections 247d-6 and 300hh-11 of this title and sections 313 and 314 of Title 6, Domestic Security, and enacted provisions set out as notes under section 300hh-11 of this title and section 313 of Title 6.

PRIOR PROVISIONS

A prior section 2811 of act July 1, 1944, was renumbered section 2812 and is classified to section 300hh-11 of this title.

AMENDMENTS

2013—Subsec. (b)(3). Pub. L. 113-5, §102(a)(1)(A), inserted “, security countermeasures (as defined in section 247d-6b of this title),” after “qualified countermeasures (as defined in section 247d-6a of this title)”.

Subsec. (b)(4)(D) to (H). Pub. L. 113-5, §102(a)(1)(B), added subpars. (D) to (H).

Subsec. (b)(7). Pub. L. 113-5, §102(a)(1)(C), added par. (7).

Subsec. (c). Pub. L. 113-5, §102(a)(2), added subsec. (c) and struck out former subsec. (c) which directed that the Assistant Secretary would have authority over and responsibility for the National Disaster Medical System and the Hospital Preparedness Cooperative Agreement Program, would exercise the responsibilities and authorities of the Secretary with respect to the coordination of the Medical Reserve Corps, the Emergency System for Advance Registration of Volunteer Health Professionals, the Strategic National Stockpile, and the Cities Readiness Initiative, and would assume other duties as determined appropriate by the Secretary.

Subsecs. (d), (e). Pub. L. 113-5, §102(a)(3), added subsecs. (d) and (e).

TRANSFER OF FUNCTIONS

Pub. L. 109-417, title I, §102(b), Dec. 19, 2006, 120 Stat. 2834, provided that:

“(1) TRANSFER OF FUNCTIONS.—There shall be transferred to the Office of the Assistant Secretary for Preparedness and Response the functions, personnel, assets, and liabilities of the Assistant Secretary for Public Health Emergency Preparedness as in effect on the day before the date of enactment of this Act [Dec. 19, 2006].

“(2) REFERENCES.—Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or pertaining to the Assistant Secretary for Public Health Emergency Preparedness as in effect the day before the date of enactment of this Act, shall be deemed to be a reference to the Assistant Secretary for Preparedness and Response.”

INTERAGENCY COORDINATION PLAN

Pub. L. 113-5, title I, §102(b), Mar. 13, 2013, 127 Stat. 168, provided that: “In the first Public Health Emergency [Medical] Countermeasures Enterprise Strategy and Implementation Plan submitted under subsection (d) of section 2811 of the Public Health Service Act (42 U.S.C. 300hh-10) (as added by subsection (a)(3)), the Secretary of Health and Human Services, in consultation with the Secretary of Defense, shall include a description of the manner in which the Department of Health and Human Services is coordinating with the Department of Defense regarding countermeasure activities to address chemical, biological, radiological, and nuclear threats. Such report shall include information with respect to—

- “(1) the research, advanced research, development, procurement, stockpiling, and distribution of countermeasures to meet identified needs; and
- “(2) the coordination of efforts between the Department of Health and Human Services and the Department of Defense to address countermeasure needs for various segments of the population.”

§ 300hh-10a. National Advisory Committee on Children and Disasters**(a) Establishment**

The Secretary, in consultation with the Secretary of Homeland Security, shall establish an advisory committee to be known as the “National Advisory Committee on Children and Disasters” (referred to in this section as the “Advisory Committee”).

(b) Duties

The Advisory Committee shall—

- (1) provide advice and consultation with respect to the activities carried out pursuant to section 300hh-16 of this title, as applicable and appropriate;
- (2) evaluate and provide input with respect to the medical and public health needs of chil-