

and Human Services, and Defense, and the Attorney General, in coordination with the U.S. Postal Service, and in consultation with State and local public health, emergency management, and law enforcement officials, within 180 days of the date of this order, shall develop an accompanying plan for supplementing local law enforcement personnel, as necessary and appropriate, with local Federal law enforcement, as well as other appropriate personnel, to escort U.S. Postal workers delivering medical countermeasures.

SEC. 3. *Federal Rapid Response.* (a) The Federal Government must develop the capacity to anticipate and immediately supplement the capabilities of affected jurisdictions to rapidly distribute medical countermeasures following a biological attack. Implementation of a Federal strategy to rapidly dispense medical countermeasures requires establishment of a Federal rapid response capability.

(b) The Secretaries of Homeland Security and Health and Human Services, in coordination with the Secretary of Defense, within 90 days of the date of this order, shall develop a concept of operations and establish requirements for a Federal rapid response to dispense medical countermeasures to an affected population following a large-scale biological attack.

SEC. 4. *Continuity of Operations.* (a) The Federal Government must establish mechanisms for the provision of medical countermeasures to personnel performing mission-essential functions to ensure that mission-essential functions of Federal agencies continue to be performed following a biological attack.

(b) The Secretaries of Health and Human Services and Homeland Security, within 180 days of the date of this order, shall develop a plan for the provision of medical countermeasures to ensure that mission-essential functions of executive branch departments and agencies continue to be performed following a large-scale biological attack.

SEC. 5. *General Provisions.*

(a) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to a department or agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

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§ 300hh-2. Enhancing medical surge capacity

(a) Study of enhancing medical surge capacity

As part of the joint review described in section 300hh-11(b) of this title, the Secretary shall evaluate the benefits and feasibility of 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. Such study shall include an assessment of the need for and feasibility of improving surge capacity through—

(1) acquisition and operation of mobile medical assets by the Secretary to be deployed, on 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

CODIFICATION

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 utilize experience related to public health emergency preparedness and response, biodefense, medical countermeasures, and other relevant topics to 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, before, during, and following public health emergencies, 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 described in section 314(a)(6) of title 6, or any successor plan; and such Federal responses covered by the National Cybersecurity Incident Response Plan developed under section 660(c)¹ of title 6, including public health emergencies or incidents related to cybersecurity threats that present a threat to national health security.

(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 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.

(I) Threat awareness

Coordinate with the Director of the Centers for Disease Control and Prevention, the Director of National Intelligence, the Secretary of Homeland Security, the Assistant to the President for National Security Affairs, the Secretary of Defense, and other relevant Federal officials, such as the Secretary of Agriculture, to maintain a current assessment of national security threats and inform preparedness and response capabilities based on the range of the threats that have the potential to result in a public health emergency.

(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. Such logistical support shall include working with other relevant Federal, State, local, Tribal, and territorial public

¹ See References in Text note below.

health officials and private sector entities to identify the critical infrastructure assets, systems, and networks needed for the proper functioning of the health care and public health sectors that need to be maintained through any emergency or disaster, including entities capable of assisting with, responding to, and mitigating the effect of a public health emergency, including a public health emergency determined by the Secretary pursuant to section 247d(a) of this title or an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act or the National Emergencies Act, including by establishing methods to exchange critical information and deliver products consumed or used to preserve, protect, or sustain life, health, or safety, and sharing of specialized expertise.

(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 not later than March 15 of each year, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d), including with respect to chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation, including such agents that are novel or emerging infectious diseases, 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), and qualified pandemic or epidemic products (as defined in section 247d-6d of this title) for each such threat. 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;

(iii) procurement, stockpiling, maintenance, and potential replenishment (including manufacturing capabilities) of all products in the Strategic National Stockpile;

(iv) the availability of technologies that may assist in the advanced research and development of countermeasures and opportunities to use such technologies to accelerate and navigate challenges unique to countermeasure research and development; and

(v) potential deployment, distribution, and utilization of medical countermeasures; development of clinical guidance and emergency use instructions for the use of medical countermeasures; and, as applicable, potential postdeployment activities related to medical countermeasures;

(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;

(D) identify the full range of anticipated medical countermeasure needs related to research and development, procurement, and stockpiling, including the potential need for indications, dosing, and administration technologies, and other countermeasure needs as applicable and appropriate;

(E) be made available, not later than March 15 of each year, to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives; and

(F) not later than March 15 of each year, be made publicly available in a manner that does not compromise national security.

(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 March 15, 2020, and biennially 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 Public Health Emergency Medical Countermeasures Enterprise established under section 300hh-10a of this title. 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, and ancillary medical supplies to assist with the utilization of 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-7g 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 Presi-

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

dent 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 2-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.

(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.

(f) Protection of national security from threats

(1) In general

In carrying out subsection (b)(3), the Assistant Secretary for Preparedness and Response shall implement strategic initiatives or activities to address threats, including pandemic influenza and which may include a chemical, biological, radiological, or nuclear agent (including any such agent with a significant potential to become a pandemic), that pose a significant level of risk to public health and national security based on the characteristics of such threat. Such initiatives shall include activities to—

(A) accelerate and support the advanced research, development, manufacturing capacity, procurement, and stockpiling of countermeasures, including initiatives under section 247d-7e(c)(4)(F) of this title;

(B) support the development and manufacturing of virus seeds, clinical trial lots, and stockpiles of novel virus strains; and

(C) maintain or improve preparedness activities, including for pandemic influenza.

(2) Authorization of appropriations

(A) In general

To carry out this subsection, there is authorized to be appropriated \$250,000,000 for each of fiscal years 2019 through 2023.

(B) Supplement, not supplant

Amounts appropriated under this paragraph shall be used to supplement and not supplant funds provided under sections 247d-7e(d) and 247d-6b(g) of this title.

(C) Documentation required

The Assistant Secretary for Preparedness and Response, in accordance with subsection (b)(7), shall document amounts expended for purposes of carrying out this subsection, including amounts appropriated under the heading “Public Health and Social Services Emergency Fund” under the heading “Office of the Secretary” under title II of division H of the Consolidated Appropriations Act, 2018 (Public Law 115-141) and allocated to carrying out section 247d-7e(c)(4)(F) of this title.

(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; Pub. L. 114-255, div. A, title III, §3083, Dec. 13, 2016, 130 Stat. 1141; Pub. L. 116-22, title III, §302(a), (b), title IV, §§401, 402(b), 404(b), title V, §501, title VII, §703(b), June 24, 2019, 133 Stat. 934, 942, 943, 948, 950, 963.)

REFERENCES IN TEXT

Section 660(c) of title 6, referred to in subsec. (b)(4)(D), was in the original “section 228(c) of the Homeland Security Act of 2002”, and was translated as meaning section 2210(c) of the Homeland Security Act of 2002 to reflect the probable intent of Congress. Section 228 of the Homeland Security Act of 2002, meaning section 228 of Pub. L. 107-296, was renumbered section 2210 of Pub. L. 107-296 by Pub. L. 115-278, §2(g)(2)(I), Nov. 16, 2018, 132 Stat. 4178, and transferred to section 660 of Title 6, Domestic Security. Pub. L. 107-296 no longer contains a section 228.

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.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act, referred to in subsec. (b)(5), is Pub. L. 93-288, May 22, 1974, 88 Stat. 143, which is classified principally to chapter 68 (§5121 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 5121 of this title and Tables.

The National Emergencies Act, referred to in subsec. (b)(5), is Pub. L. 94-412, Sept. 14, 1976, 90 Stat. 1255, which is classified principally to chapter 34 (§1601 et seq.) of Title 50, War and National Defense. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 50 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.

The Consolidated Appropriations Act, 2018, referred to in subsec. (f)(2)(C), is Pub. L. 115-141, Mar. 23, 2018, 132 Stat. 348. Title II of division H of the Act is title II of div. H of Pub. L. 115-141, Mar. 23, 2018, 132 Stat. 714, which is not classified to the Code. For complete classification of this Act to the Code, see Tables.

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

2019—Subsec. (b). Pub. L. 116-22, § 401(1), inserted “utilize experience related to public health emergency preparedness and response, biodefense, medical countermeasures, and other relevant topics to” after “shall” in introductory provisions.

Subsec. (b)(4)(D). Pub. L. 116-22, § 703(b), amended subpar. (D) generally. Prior to amendment, text read as follows: “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) of title 6, or any successor plan, before, during, and following public health emergencies.”

Subsec. (b)(4)(I). Pub. L. 116-22, § 401(2), added subpar. (I).

Subsec. (b)(5). Pub. L. 116-22, § 302(a), inserted at end “Such logistical support shall include working with other relevant Federal, State, local, Tribal, and territorial public health officials and private sector entities to identify the critical infrastructure assets, systems, and networks needed for the proper functioning of the health care and public health sectors that need to be maintained through any emergency or disaster, including entities capable of assisting with, responding to, and mitigating the effect of a public health emergency, including a public health emergency determined by the Secretary pursuant to section 247d(a) of this title or an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act or the National Emergencies Act, including by establishing methods to exchange critical information and deliver products consumed or used to preserve, protect, or sustain life, health, or safety, and sharing of specialized expertise.”

Subsec. (b)(7). Pub. L. 116-22, § 501(1), substituted “March 15” for “March 1” in introductory provisions.

Subsec. (b)(7)(A)(iii) to (v). Pub. L. 116-22, § 501(2), added cls. (iii) to (v) and struck out former cl. (iii) which read as follows: “procurement, stockpiling, maintenance, and replenishment of all products in the Strategic National Stockpile.”

Subsec. (b)(7)(D) to (F). Pub. L. 116-22, § 501(3), (4), added subpar. (D) and redesignated former subpars. (D) and (E) as (E) and (F), respectively.

Subsec. (d)(1). Pub. L. 116-22, § 402(b)(1), substituted “Not later than March 15, 2020, and biennially thereafter” for “Not later than 180 days after March 13, 2013, and every year thereafter” and “Public Health Emergency Medical Countermeasures Enterprise established under section 300hh-10a of this title” for “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”.

Subsec. (d)(2)(C). Pub. L. 116-22, § 302(b), inserted “, and ancillary medical supplies to assist with the utilization of such countermeasures or products,” after “products”.

Subsec. (d)(2)(J)(v). Pub. L. 116-22, § 402(b)(2), substituted “2-year period” for “one-year period”.

Subsec. (f). Pub. L. 116-22, § 404(b), added subsec. (f).

2016—Subsec. (b)(7). Pub. L. 114-255, § 3083(1), in introductory provisions, substituted “Develop, and update not later than March 1 of each year, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d), including with respect to chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation, including such agents that are novel or emerging infectious diseases, 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), and qualified pandemic or epidemic products (as defined in section 247d-6d of this title) for each such threat.” for “Develop, and update on an annual basis, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d).”

Subsec. (b)(7)(D). Pub. L. 114-255, § 3083(3), substituted “, not later than March 15 of each year, to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives; and” for “to the appropriate committees of Congress upon request.”

Subsec. (b)(7)(E). Pub. L. 114-255, § 3083(2), (4), added subpar. (E).

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. Public Health Emergency Medical Countermeasures Enterprise

(a) In general

The Secretary shall establish the Public Health Emergency Medical Countermeasures Enterprise (referred to in this section as the “PHEMCE”). The Assistant Secretary for Preparedness and Response shall serve as chair of the PHEMCE.

(b) Members

The PHEMCE shall include each of the following members, or the designee of such members:

(1) The Assistant Secretary for Preparedness and Response.

(2) The Director of the Centers for Disease Control and Prevention.

(3) The Director of the National Institutes of Health.

(4) The Commissioner of Food and Drugs.

(5) The Secretary of Defense.

(6) The Secretary of Homeland Security.

(7) The Secretary of Agriculture.

(8) The Secretary of Veterans Affairs.

(9) The Director of National Intelligence.

(10) Representatives of any other Federal agency, which may include the Director of the Biomedical Advanced Research and Development Authority, the Director of the Strategic National Stockpile, the Director of the National Institute of Allergy and Infectious Diseases, and the Director of the Office of Public Health Preparedness and Response, as the Secretary determines appropriate.

(c) Functions

(1) In general

The functions of the PHEMCE shall include the following:

(A) Utilize a process to make recommendations to the Secretary regarding research, advanced research, development, procurement, stockpiling, deployment, distribution, and utilization with respect to countermeasures, as defined in section 247d-6b(c) of this title, including prioritization based on the health security needs of the United States. Such recommendations shall be informed by, when available and practicable, the National Health Security Strategy pursuant to section 300hh-1 of this title, the Strategic National Stockpile needs pursuant to section 247d-6b of this title, and assessments of current national security threats, including chemical, biological, radiological, and nuclear threats, including emerging infectious diseases. In the event that members of the PHEMCE do not agree upon a recommendation, the Secretary shall provide a de-

termination regarding such recommendation.

(B) Identify national health security needs, including gaps in public health preparedness and response related to countermeasures and challenges to addressing such needs (including any regulatory challenges), and support alignment of countermeasure procurement with recommendations to address such needs under subparagraph (A).

(C) Assist the Secretary in developing strategies related to logistics, deployment, distribution, dispensing, and use of countermeasures that may be applicable to the activities of the strategic national stockpile under section 247d-6b(a) of this title.

(D) Provide consultation for the development of the strategy and implementation plan under section 300hh-10(d) of this title.

(2) Input

In carrying out subparagraphs (B) and (C) of paragraph (1), the PHEMCE shall solicit and consider input from State, local, Tribal, and territorial public health departments or officials, as appropriate.

(July 1, 1944, ch. 373, title XXVIII, §2811-1, as added Pub. L. 116-22, title IV, §402(a), June 24, 2019, 133 Stat. 942.)

PRIOR PROVISIONS

A prior section 300hh-10a, act July 1, 1944, ch. 373, title XXVIII, §2811A, as added Pub. L. 113-5, title I, §103, Mar. 13, 2013, 127 Stat. 168; amended Pub. L. 116-22, title III, §305(a), June 24, 2019, 133 Stat. 936, which related to the National Advisory Committee on Children and Disasters, was transferred to section 300hh-10b of this title.

§ 300hh-10b. 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, mental and behavioral, and public health needs of children as they relate to preparation for, response to, and recovery from all-hazards emergencies; and

(3) provide advice and consultation with respect to State emergency preparedness and response activities and children, including related drills and exercises pursuant to the preparedness goals under section 300hh-1(b) of this title.

(c) Additional duties

The Advisory Committee may provide advice and recommendations to the Secretary with respect to children and the medical and public health grants and cooperative agreements as ap-