

studies, analyses, and related services with public or private entities, as applicable and appropriate; and

(2) may hold such hearings in various parts of the United States as necessary to determine the views of the entities and individuals referred to in paragraph (1) and of the general public, concerning national needs and trends in pandemic preparedness and response.

(h) Staffing and detailees

In carrying out functions under this section, the Director may—

(1) appoint not more than 25 individuals to serve as employees of the Office as necessary to carry out this section;

(2) fix the compensation of such personnel at a rate to be determined by the Director, up to the amount of annual compensation (excluding expenses) specified in section 102 of title 3;

(3) utilize the services of consultants, which may include by obtaining services described under section 3109(b) of title 5, at rates not to exceed the rate of basic pay for level IV of the Executive Schedule; and

(4) direct, with the concurrence of the Secretary of a department or head of an agency, the temporary reassignment within the Federal Government of personnel employed by such department or agency, in order to carry out the functions of the Office.

(i) Preparedness review and report

The Director, in consultation with the heads of applicable Federal departments, agencies, and offices, shall—

(1) not later than 1 year after December 29, 2022, conduct a review of applicable Federal strategies, policies, procedures, and after-action reports to identify gaps and inefficiencies related to pandemic preparedness and response;

(2) not later than 18 months after December 29, 2022, and every 2 years thereafter, submit to the President and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing—

(A) current and emerging pandemic and other biological threats that pose a significant level of risk to national security;

(B) the roles and responsibilities of the Federal Government in preparing for, and responding to, such threats;

(C) the findings of the review conducted under paragraph (1);

(D) any barriers or limitations related to addressing such findings;

(E) current and planned activities to update Federal strategies, policies, and procedures to address such findings, consistent with applicable laws and the National Response Framework;

(F) current and planned activities to support the development of expertise within the Federal Government pursuant to subsection (b)(3); and

(G) opportunities to improve Federal preparedness and response capacities and capabilities through the use of current and emerging technologies.

(j) Nonduplication of effort

The Director shall ensure that activities carried out under this section do not unnecessarily duplicate the efforts of other Federal departments, agencies, and offices.

(Pub. L. 117-328, div. FF, title II, §2104, Dec. 29, 2022, 136 Stat. 5715.)

Editorial Notes

REFERENCES IN TEXT

Level IV of the Executive Schedule, referred to in subsec. (h)(3), is set out in section 5315 of Title 5, Government Organization and Employees.

CODIFICATION

Section was enacted as part of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, also known as the PREVENT Pandemics Act, and also as part of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, and not as part of the Public Health Service Act which comprises this chapter.

Section is comprised of section 2104 of div. FF of Pub. L. 117-328. Subsec. (k) of section 2104 of div. FF of Pub. L. 117-328 amended sections 300hh-10a, 6614, and 6651 of this title and section 3021 of Title 50, War and National Defense.

PART B—ALL-HAZARDS EMERGENCY
PREPAREDNESS AND RESPONSE

Editorial Notes

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 and, consistent with the National Response Framework and other applicable provisions of law, assist the Secretary in carrying out the functions under section 300hh of this title.

(2) Personnel

Register, credential, organize, train, equip, and have the authority to deploy Federal pub-

lic 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(b) 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 recommend actions necessary to overcome these obstacles, such as—

- (i) improving coordination with relevant Federal officials;
- (ii) partnering with other public or private entities to leverage capabilities maintained by such entities, as appropriate and consistent with this subsection; and
- (iii) coordinating efforts to support or establish new capabilities, as appropriate.

(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 each year, including national-level and State-level full-scale exercises not less than once every 4 years, 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—

(i) based on¹

(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;

(ii) that assess the ability of the Strategic National Stockpile, as appropriate, to provide medical countermeasures, medical products, and other supplies, including ancillary medical supplies, to support the response to a public health emergency or potential public health emergency, including a threat that requires the large-scale and simultaneous deployment of stockpiles and a long-term public health and medical response; and

(iii) conducted in coordination with State and local health officials.

(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 Af-

¹ So in original. Probably should be followed by a dash.

fairs, 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.

(J) Medical product and supply capacity planning

Coordinate efforts within the Department of Health and Human Services to support—

(i) preparedness for medical product and medical supply needs directly related to responding to chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, and incidents covered by the National Response Framework, including—

(I) sharing information, including with appropriate stakeholders, related to the anticipated need for, and availability of, such products and supplies during such responses;

(II) supporting activities, which may include public-private partnerships, to maintain capacity of medical products and medical supplies, as applicable and appropriate; and

(III) planning for potential surges in medical supply needs for purposes of a response to such a threat; and

(ii) situational awareness with respect to anticipated need for, and availability of, such medical products and medical supplies within the United States during a response to such a threat.

(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 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

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

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 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.

(g) Appearances before Congress

(1) In general

Each fiscal year, the Assistant Secretary for Preparedness and Response shall appear before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives at hearings, on topics such as—

(A) coordination of Federal activities to prepare for, and respond to, public health emergencies;

(B) activities and capabilities of the Strategic National Stockpile, including whether, and the degree to which, recommendations made pursuant to section 300hh-10a(c)(1)(A) of this title have been met;

(C) support for State, local, and Tribal public health and medical preparedness;

(D) activities implementing the countermeasures budget plan described under subsection (b)(7), including—

(i) any challenges in meeting the full range of identified medical countermeasure needs; and

(ii) progress in supporting advanced research, development, and procurement of medical countermeasures, pursuant to subsection (b)(3);

(E) the strategic direction of, and activities related to, the sustainment of manufacturing surge capacity and capabilities for medical countermeasures pursuant to section 247d-7e of this title and the distribution and deployment of such countermeasures;

(F) any additional objectives, activities, or initiatives that have been carried out or are planned by the Assistant Secretary for Preparedness and Response and associated challenges, as appropriate;

(G) the specific all-hazards threats that the Assistant Secretary for Preparedness and Response is preparing to address, or that are being addressed, through the activities described in subparagraphs (A) through (F); and

(H) objectives, activities, or initiatives related to the coordination and consultation required under subsections (b)(4)(H) and (b)(4)(I), in a manner consistent with paragraph (3), as appropriate.

(2) Clarifications

(A) Waiver authority

The Chair of the Committee on Health, Education, Labor, and Pensions of the Senate or the Chair of the Committee on Energy and Commerce of the House of Representatives may waive the requirements of paragraph (1) for the applicable fiscal year with respect to the applicable Committee.

(B) Scope of requirements

The requirements of this subsection shall not be construed to impact the appearance of other Federal officials or the Assistant

Secretary at hearings of either Committee described in paragraph (1) at other times and for purposes other than the times and purposes described in paragraph (1)³

(3) Closed hearings

Information that is not appropriate for disclosure during an open hearing under paragraph (1) in order to protect national security may instead be discussed in a closed hearing that immediately follows such open hearing.

(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; Pub. L. 117-263, div. G, title LXXI, §7143(d)(4), Dec. 23, 2022, 136 Stat. 3663; Pub. L. 117-328, div. FF, title II, §2103(b)(2), (c), Dec. 29, 2022, 136 Stat. 5712, 5713.)

Editorial Notes

REFERENCES IN TEXT

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.

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

2022—Subsec. (b)(1). Pub. L. 117-328, §2103(b)(2)(A), inserted “and, consistent with the National Response Framework and other applicable provisions of law, assist the Secretary in carrying out the functions under section 300hh of this title” after “emergencies”.

Subsec. (b)(4)(D). Pub. L. 117-263 substituted “section 660(b) of title 6” for “section 228(c) of the Homeland Security Act of 2002 (6 U.S.C. 149(c))”.

Subsec. (b)(4)(E). Pub. L. 117-328, §2103(b)(2)(B)(i), substituted “recommend actions necessary to overcome these obstacles, such as—” and cls. (i) to (iii) for “the actions necessary to overcome these obstacles.”

Subsec. (b)(4)(G). Pub. L. 117-328, §2103(b)(2)(B)(ii), inserted “each year, including national-level and State-

³ So in original. Probably should be followed by a period.

level full-scale exercises not less than once every 4 years” after “operational exercises”, substituted “exercises—” and “(i) based on” for “exercises based on—”, added cls. (ii) and (iii), and redesignated former cls. (i) and (ii) as subcls. (I) and (II), respectively, of cl. (i).

Subsec. (b)(4)(J). Pub. L. 117-328, §2103(b)(2)(B)(iii), added subpar. (J).

Subsec. (g). Pub. L. 117-328, §2103(c), added subsec. (g). 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).

Statutory Notes and Related Subsidiaries

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 and the Director of the Office of Pandemic Preparedness and Response Policy shall serve as co-chairs 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) The Director of the Office of Pandemic Preparedness and Response Policy.

(11) 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 determination regarding such recommendation.

(B) Identify national health security needs, including gaps in public health pre-

paredness 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; amended Pub. L. 117-328, div. FF, title II, §2104(k)(1), Dec. 29, 2022, 136 Stat. 5719.)

Editorial Notes

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.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117-328, §2104(k)(1)(A), substituted “and the Director of the Office of Pandemic Preparedness and Response Policy shall serve as co-chairs” for “shall serve as chair”.

Subsec. (b)(10), (11). Pub. L. 117-328, §2104(k)(1)(B), added par. (10) and redesignated former par. (10) as (11).

§ 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, behavioral, developmental, and public health needs of children as they relate to preparation for, response to, and recovery from all-hazards emergencies;

(3) provide advice and consultation with respect to State emergency preparedness and response activities and children, including related drills and exercises pursuant to the pre-