(d), and (f) of section 32 of the Office of Federal Procurement Policy Act (41 U.S.C. 428)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2019—Subsec. (a)(1), (5). Pub. L. 116–22 substituted ''section 247d–6(e) of this title'' for ''section 247d–6(h) of this title''.

2013—Subsec. (a)(2)(A). Pub. L. 113–5 struck out ''to'' before dash at end of introductory provisions, inserted ''to'' before ''diagnose'' in cls. (i) and (ii), and added cl. (iii).

2006—Subsec. (a)(2). Pub. L. 109–417 added par. (2) and struck out heading and text of former par. (2). Text read as follows: ''For purposes of this section, the term 'qualified countermeasure' means a drug (as that term is defined by section 321(g)(1) of title 21), biological product (as that term is defined by section 262(i) of this title), or device (as that term is defined by section 321(h) of title 21) that the Secretary determines to be a priority (consistent with sections 182(2) and 184(a) of title 6) to—

''(A) treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security; or

''(B) treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in subparagraph (A).''

Statutory Notes and Related Subsidiaries

RULE OF CONSTRUCTION

Pub. L. 108–276, § 2(e), July 21, 2004, 118 Stat. 842, provided that: ''Nothing in this section [enacting this section and amending sections 247d–6, 287a–2, and 300aa–6 of this title] has any legal effect on sections 302(2), 302(4), 304(a), or 304(b) of the Homeland Security Act of 2002 [6 U.S.C. 182(2), (4), 184(a), (b)].''

COLLABORATION AND COORDINATION

Pub. L. 109–417, title IV, § 405, Dec. 19, 2006, 120 Stat. 2875, as amended by Pub. L. 113–5, § 402(e)(1), Mar. 13, 2013, 127 Stat. 195; Pub. L. 116–22, title VII, § 701(e)(1)(A), (B), June 24, 2019, 133 Stat. 961, which authorized the Secretary of Health and Human Services, in coordination with the Attorney General and the Secretary of Homeland Security, to conduct meetings with persons engaged in the development of a security countermeasure, a qualified countermeasure, or a qualified pandemic or epidemic product, in such a manner to ensure that no national security, confidential commercial, or proprietary information is disclosed outside the meeting, and exempted from antitrust laws conduct pursuant to a written agreement executed at such a meeting approved by the Attorney General and the Chairman of the Federal Trade Commission, was redesignated as section 319L–1 of act July 1, 1944, ch. 373, known as the Public Health Service Act, by Pub. L. 116–22, title VII, § 701(e)(1)(C), (D), June 24, 2019, 133 Stat. 961, and editorially reclassified as section 247d–7f of this title.

OUTREACH

Pub. L. 108–276, § 6, July 21, 2004, 118 Stat. 862, provided that: ''The Secretary of Health and Human Services shall develop outreach measures to ensure to the extent practicable that diverse institutions, including Historically Black Colleges and Universities and those serving large proportions of Black or African Americans, American Indians, Appalachian Americans, Alaska Natives, Asians, Native Hawaiians, other Pacific Islanders, Hispanics or Latinos, or other underrepresented populations, are meaningfully aware of available research and development grants, contracts, cooperative agreements, and procurements conducted under sections 2 and 3 of this Act [enacting this section and section 320 of Title 6, Domestic Security, amending sections 247d–6, 247d–6b, 287a–2, and 300aa–6 of this title and sections 312 and 313 of Title 6, renumbering section 300hh–12 of this title as section 247d–6b of this title, and enacting provisions set out as notes under this section and section 247d–6b of this title].''

RECOMMENDATION FOR EXPORT CONTROLS ON CERTAIN BIOMEDICAL COUNTERMEASURES

Pub. L. 108–276, § 7, July 21, 2004, 118 Stat. 863, provided that: ''Upon the award of any grant, contract, or cooperative agreement under section 2 or 3 of this Act [enacting this section and section 320 of Title 6, Domestic Security, amending sections 247d–6, 247d–6b, 287a–2, and 300aa–6 of this title and sections 312 and 313 of Title 6, renumbering section 300hh–12 of this title as section 247d–6b of this title, and enacting provisions set out as notes under this section and section 247d–6b of this title] for the research, development, or procurement of a qualified countermeasure or a security countermeasure (as those terms are defined in this Act [see Short Title of 2004 Amendments note set out under section 201 of this title]), the Secretary of Health and Human Services shall, in consultation with the heads of other appropriate Federal agencies, determine whether the countermeasure involved in such grant, contract, or cooperative agreement is subject to existing export-related controls and, if not, may make a recommendation to the appropriate Federal agency or agencies that such countermeasure should be included on the list of controlled items subject to such controls.''

ENSURING COORDINATION, COOPERATION AND THE ELIMINATION OF UNNECESSARY DUPLICATION IN PROGRAMS DESIGNED TO PROTECT THE HOMELAND FROM BIOLOGICAL, CHEMICAL, RADIOLOGICAL, AND NUCLEAR AGENTS

Pub. L. 108–276, § 8, July 21, 2004, 118 Stat. 863, provided that:

''(a) ENSURING COORDINATION OF PROGRAMS.—The Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Defense shall ensure that the activities of their respective Departments coordinate, complement, and do not unnecessarily duplicate programs to identify potential domestic threats from biological, chemical, radiological or nuclear agents, detect domestic incidents involving such agents, analyze such incidents, and develop necessary countermeasures. The aforementioned Secretaries shall further ensure that information and technology possessed by the Departments relevant to these activities are shared with the other Departments.

''(b) DESIGNATION OF AGENCY COORDINATION OFFICER.—The Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Defense shall each designate an officer or employee of their respective Departments who shall coordinate, through regular meetings and communications, with the other aforementioned Departments such programs and activities carried out by their Departments.''

§ 247d–6b. Strategic National Stockpile and security countermeasure procurements

(a) Strategic National Stockpile

(1) In general

The Secretary, in collaboration with the Assistant Secretary for Preparedness and Response and the Director of the Centers for Disease Control and Prevention, and in coordination with the Secretary of Homeland Security (referred to in this section as the ''Homeland Security Secretary''), shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other

supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile) in such numbers, types, and amounts as are determined consistent with section 300hh–10 of this title by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for and optimize the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency and, as informed by existing recommendations of, or consultations with, the Public Health Emergency Medical Countermeasure Enterprise established under section 300hh–10a of this title, make necessary additions or modifications to the contents of such stockpile or stockpiles based on the review conducted under paragraph (2).

(2) Threat-based review

(A) In general

The Secretary shall conduct an annual threat-based review (taking into account at-risk individuals) of the contents of the stockpile under paragraph (1), including non-pharmaceutical supplies, and, in consultation with the Public Health Emergency Medical Countermeasures Enterprise established under section 300hh–10a of this title, review contents within the stockpile and assess whether such contents are consistent with the recommendations made pursuant to section 300hh–10a(c)(1)(A) of this title. Such review shall be submitted on June 15, 2019, and on March 15 of each year thereafter, to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, in a manner that does not compromise national security.

(B) Additions, modifications, and replenishments

Each annual threat-based review under subparagraph (A) shall, for each new or modified countermeasure procurement or replenishment, provide—

(i) information regarding—

(I) the quantities of the additional or modified countermeasure procured for, or contracted to be procured for, the stockpile;

(II) planning considerations for appropriate manufacturing capacity and capability to meet the goals of such additions or modifications (without disclosing proprietary information), including—

(aa) consideration of the effect such additions or modifications may have on the availability of such products and ancillary medical supplies on the health care system; and

(bb) an assessment of the current supply chain for such products, including information on supply chain redundancies, any known domestic manufacturing capacity for such products, and any related vulnerabilities;

(III) the presence or lack of a commercial market for the countermeasure at the time of procurement;

(IV) the emergency health security threat or threats such countermeasure procurement is intended to address, including whether such procurement is consistent with meeting emergency health security needs associated with such threat or threats;

(V) an assessment of whether the emergency health security threat or threats described in subclause (IV) could be addressed in a manner that better utilizes the resources of the stockpile and permits the greatest possible increase in the level of emergency preparedness to address such threats;

(VI) whether such countermeasure is replenishing an expiring or expired countermeasure, is a different countermeasure with the same indication that is replacing an expiring or expired countermeasure, or is a new addition to the stockpile;

(VII) a description of how such additions or modifications align with projected investments under previous countermeasures budget plans under section 300hh–10(b)(7) of this title, including expected life-cycle costs, expenditures related to countermeasure procurement to address the threat or threats described in subclause (IV), replenishment dates (including the ability to extend the maximum shelf life of a countermeasure), and the manufacturing capacity required to replenish such countermeasure; and

(VIII) appropriate protocols and processes for the deployment, distribution, or dispensing of the countermeasure at the State and local level, including plans for relevant capabilities of State and local entities to dispense, distribute, and administer the countermeasure; and

(ii) an assurance, which need not be provided in advance of procurement, that for each countermeasure procured or replenished under this subsection, the Secretary completed a review addressing each item listed under this subsection in advance of such procurement or replenishment.

(3) Procedures

The Secretary, in managing the stockpile under paragraph (1), shall—

(A) consult with the working group under section 247d–6(a) of this title and the Public Health Emergency Medical Countermeasures Enterprise established under section 300hh–10a of this title;

(B) ensure that adequate procedures are followed, regularly reviewed, and updated with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

(C) in consultation with Federal, State, local, and Tribal officials, take into consideration the timing and location of special events, and the availability, deployment, dispensing, and administration of countermeasures;

(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that—

(i) emerging threats, advanced technologies, and new countermeasures are adequately considered;

(ii) the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment; and

(iii) such contents are in working condition or usable, as applicable, and are ready for deployment, which may include conducting maintenance services on such contents of the stockpile and disposing of such contents that are no longer in working condition, or usable, as applicable;

(E) devise plans for effective and timely supply-chain management of the stockpile, in consultation with the Director of the Centers for Disease Control and Prevention, the Assistant Secretary for Preparedness and Response, the Secretary of Transportation, the Secretary of Homeland Security, the Secretary of Veterans Affairs, and the heads of other appropriate Federal agencies; State, local, Tribal, and territorial agencies; and the public and private health care infrastructure, as applicable, taking into account the manufacturing capacity and other available sources of products and appropriate alternatives to supplies in the stockpile;

(F) deploy the stockpile at the discretion of the Secretary, in consultation with, or at the request of, the Secretary of Homeland Security, to respond to an actual or potential emergency;

(G) deploy the stockpile at the discretion of the Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety;

(H) ensure the adequate physical security of the stockpile;

(I) ensure that each countermeasure or product under consideration for procurement pursuant to this subsection receives the same consideration regardless of whether such countermeasure or product receives or had received funding under section 247d–7e of this title, including with respect to whether the countermeasure or product is most appropriate to meet the emergency health security needs of the United States;

(J) provide assistance, including technical assistance, to maintain and improve State[1] local, and Tribal public health preparedness capabilities to distribute and dispense medical countermeasures and products from the stockpile, as appropriate; and

(K) convene meetings, not less than once per year, with representatives from State, local, and Tribal health departments or officials, relevant industries, other Federal agencies, and other appropriate stakeholders, in a manner that does not compromise national security, to coordinate and share information related to maintenance and use of the stockpile, including a description of future countermeasure needs and additions, modifications, and replenishments of the contents of the stockpile, and considerations related to the manufacturing and procurement of products consistent with the requirements of the with the requirements of[2] chapter 83 of title 41 (commonly referred to as the ''Buy American Act''), as appropriate.

(4) Utilization guidelines

The Secretary shall ensure timely and accurate recommended utilization guidelines for qualified countermeasures (as defined in section 247d–6a of this title), qualified pandemic and epidemic products (as defined in section 247d–6d of this title), and security countermeasures (as defined in subsection (c)), including for such products in the stockpile.

(5) Vendor-managed inventory and warm-base surge capacity

(A) In general

For the purposes of maintaining the stockpile under paragraph (1) and carrying out procedures under paragraph (3), the Secretary may enter into contracts or cooperative agreements with vendors, which may include manufacturers or distributors of medical products, with respect to medical products intended to be delivered to the ownership of the Federal Government. Each such contract or cooperative agreement shall be subject to such terms and conditions as the Secretary may specify, including terms and conditions with respect to—

(i) procurement, maintenance, storage, and delivery of products, in alignment with inventory management and other applicable best practices, under such contract or cooperative agreement, which may consider, as appropriate, costs of transporting and handling such products; or

(ii) maintenance of domestic manufacturing capacity and capabilities of such products to ensure additional reserved production capacity and capabilities are available, and that such capacity and capabilities are able to support the rapid manufacture, purchase, storage, and delivery of such products, as required by the Secretary to prepare for, or respond to, an existing or potential public health emergency.

(B) Report

Not later than 2 years after December 29, 2022, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Com-

[1] So in original. Probably should be followed by a comma.

[2] So in original.

merce and the Committee on Appropriations of the House of Representatives a report on any contracts or cooperative agreements entered into under subparagraph (A) for purposes of establishing and maintaining vendor-managed inventory or reserve manufacturing capacity and capabilities for products intended for the stockpile, including a description of—

(i) the amount of each award;

(ii) the recipient of each award;

(iii) the product or products covered through each award; and

(iv) how the Secretary works with each recipient to ensure situational awareness related to the manufacturing capacity for, or inventory of, such products and coordinates the distribution and deployment of such products, as appropriate and applicable.

(6) GAO report

(A) In general

Not later than 3 years after June 24, 2019, and every 5 years thereafter, the Comptroller General of the United States shall conduct a review of any changes to the contents or management of the stockpile since January 1, 2015. Such review shall include—

(i) an assessment of the comprehensiveness and completeness of each annual threat-based review under paragraph (2), including whether all newly procured or replenished countermeasures within the stockpile were described in each annual review, and whether, consistent with paragraph (2)(B), the Secretary conducted the necessary internal review in advance of such procurement or replenishment;

(ii) an assessment of whether the Secretary established health security and science-based justifications, and a description of such justifications for procurement decisions related to health security needs with respect to the identified threat, for additions or modifications to the stockpile based on the information provided in such reviews under paragraph (2)(B), including whether such review was conducted prior to procurement, modification, or replenishment;

(iii) an assessment of the plans developed by the Secretary for the deployment, distribution, and dispensing of countermeasures procured, modified, or replenished under paragraph (1), including whether such plans were developed prior to procurement, modification, or replenishment;

(iv) an accounting of countermeasures procured, modified, or replenished under paragraph (1) that received advanced research and development funding from the Biomedical Advanced Research and Development Authority;

(v) an analysis of how such procurement decisions made progress toward meeting emergency health security needs related to the identified threats for countermeasures added, modified, or replenished under paragraph (1);

(vi) a description of the resources expended related to the procurement of countermeasures (including additions, modifications, and replenishments) in the stockpile, and how such expenditures relate to the ability of the stockpile to meet emergency health security needs;

(vii) an assessment of the extent to which additions, modifications, and replenishments reviewed under paragraph (2) align with previous relevant reports or reviews by the Secretary or the Comptroller General;

(viii) with respect to any change in the Federal organizational management of the stockpile, an assessment and comparison of the processes affected by such change, including planning for potential countermeasure deployment, distribution, or dispensing capabilities and processes related to procurement decisions, use of stockpiled countermeasures, and use of resources for such activities;

(ix) an assessment of whether the processes and procedures described by the Secretary pursuant to section 403(b) of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 are sufficient to ensure countermeasures and products under consideration for procurement pursuant to subsection (a) receive the same consideration regardless of whether such countermeasures and products receive or had received funding under section 247d–7e of this title, including with respect to whether such countermeasures and products are most appropriate to meet the emergency health security needs of the United States; and

(x) with respect to reports issued in 2027 or any subsequent year, an assessment of selected contracts or cooperative agreements entered into pursuant to paragraph (5).

(B) Submission

Not later than 6 months after completing a classified version of the review under subparagraph (A), the Comptroller General shall submit an unclassified version of the review to the congressional committees of jurisdiction.

(7) Reimbursement for certain supplies

(A) In general

The Secretary may, at appropriate intervals, make available for purchase excess contents procured for, and maintained within, the stockpile under paragraph (1) to any Federal agency or State, local, or Tribal government. The Secretary shall make such contents available for purchase only if—

(i) such contents are in excess of what is required for appropriate maintenance of such stockpile;

(ii) the Secretary determines that the costs for maintaining such excess contents are not appropriate to expend to meet the needs of the stockpile; and

(iii) the Secretary determines that such action does not compromise national security and is in the national interest.

(B) Reimbursement and collection

The Secretary may require reimbursement for contents that are made available under subparagraph (A), in an amount that reflects the cost of acquiring and maintaining such contents and the costs incurred to make available such contents in the time and manner specified by the Secretary. Amounts collected under this subsection shall be credited to the appropriations account or fund that incurred the costs to procure such contents, and shall remain available, without further appropriation, until expended, for the purposes of the appropriation account or fund so credited.

(C) Rule of construction

This paragraph shall not be construed to preclude transfers of contents in the stockpile under other authorities.

(D) Report

Not later than 2 years after December 29, 2022, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report on the use of the authority provided under this paragraph, including details of each action taken pursuant to this paragraph, the account or fund to which any collected amounts have been credited, and how the Secretary has used such amounts.

(E) Sunset

The authority under this paragraph shall terminate on September 30, 2028.

(b) Smallpox vaccine development

(1) In general

The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by such Secretary to be sufficient to meet the health security needs of the United States.

(2) Rule of construction

Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

(c) Additional authority regarding procurement of certain countermeasures; availability of special reserve fund

(1) In general

(A) Use of fund

A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund as defined in subsection (h).

(B) Security countermeasure

For purposes of this subsection, the term ''security countermeasure'' means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 262(i) of this title), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))) that—

(i)(I) the Secretary determines to be a priority (consistent with sections 182(2) and 184(a) of title 6) to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent;

(II) the Secretary determines under paragraph (2)(B)(ii) to be a necessary countermeasure; and

(III)(aa) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351 et seq.] or licensed under section 262 of this title; or

(bb) is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within 10 years after the date of a determination under paragraph (5); or

(ii) is authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3].

(2) Determination of material threats

(A) Material threat

The Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—

(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and

(ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.

(B) Public health impact; necessary countermeasures

The Secretary shall on an ongoing basis—

(i) assess the potential public health consequences for the United States population of exposure to agents identified under subparagraph (A)(ii); and

(ii) determine, on the basis of such assessment, the agents identified under subparagraph (A)(ii) for which countermeasures are necessary to protect the public health.

(C) Notice to Congress

The Secretary and the Secretary of Homeland Security shall send to Congress, not later than March 15 of each year, all current material threat determinations and shall promptly notify the Committee on Health,

Education, Labor, and Pensions and the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives that a determination has been made pursuant to subparagraph (A) or (B).

(D) Assuring access to threat information

In making the assessment and determination required under subparagraph (A), the Homeland Security Secretary shall use all relevant information to which such Secretary is entitled under section 122 of title 6, including but not limited to information, regardless of its level of classification, relating to current and emerging threats of chemical, biological, radiological, and nuclear agents.

(3) Assessment of availability and appropriateness of countermeasures

(A) In general

The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).

(B) Information

The Secretary shall institute a process for making publicly available the results of assessments under subparagraph (A) while withholding such information as—

(i) would, in the judgment of the Secretary, tend to reveal public health vulnerabilities; or

(ii) would otherwise be exempt from disclosure under section 552 of title 5.

(4) Call for development of countermeasures; commitment for recommendation for procurement

(A) Proposal to the President

If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently not developed or unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to—

(i) issue a call for the development of such countermeasure; and

(ii) make a commitment that, upon the first development of such countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, and subject to the availability of appropriations, make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure, as applicable.

(B) Countermeasure specifications

The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—

(i) estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of dosage form);

(ii) necessary measures of minimum safety and effectiveness;

(iii) estimated price for each dose or effective course of treatment regardless of dosage form; and

(iv) other information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(C) Presidential approval

If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall make known to persons who may respond to a call for the countermeasure involved—

(i) the call for the countermeasure;

(ii) specifications for the countermeasure under subparagraph (B); and

(iii) the commitment described in subparagraph (A)(ii).

(5) Secretary's determination of countermeasures appropriate for funding from special reserve fund

(A) In general

The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) pursuant to procurements made with amounts in the special reserve fund as defined in subsection (h) (referred to in this subsection individually as a ''procurement under this subsection'').

(B) Requirements

In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following:

(i) The quantities of the product that will be needed to meet the stockpile needs.

(ii) The feasibility of production and delivery within 10 years of sufficient quantities of the product.

(iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

(6) Recommendations for procurement

(A) Notice to appropriate congressional committees

The Secretary shall notify 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 of each decision to make available the special reserve fund as defined in subsection (h) for procurement of a security counter-

measure, including, where available, the number of, the nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons for each such rejection.

(B) Subsequent specific countermeasures

Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

(7) Procurement

(A) Payments from special reserve fund

The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for procurement of a security countermeasure in accordance with the provisions of this paragraph.

(B) Procurement

(i) In general

The Secretary shall be responsible for—

(I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, including advanced research and development, in accordance with the provisions of this subparagraph; and

(II) promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.

(ii) Contract terms

A contract for procurements under this subsection shall (or, as specified below, may) include the following terms:

(I) Payment conditioned on delivery

The contract shall provide that no payment may be made until delivery of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment, partial payment for significant milestones, or payment to increase manufacturing capacity is necessary to ensure success of a project, the Secretary shall pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The Secretary shall, to the extent practicable, make the determination of advance payment at the same time as the issuance of a solicitation. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. The contract may also provide for additional advance payments of 5 percent each for meeting the milestones specified in such contract, except that such payments shall not exceed 50 percent of the total contract amount. If the specified milestones are reached, the advanced payments of 5 percent shall not be required to be repaid. Nothing in this subclause shall be construed as affecting the rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government.

(II) Discounted payment

The contract may provide for a discounted price per unit of a product that is not licensed, cleared, or approved as described in paragraph (1)(B)(i)(III)(aa) at the time of delivery, and may provide for payment of an additional amount per unit if the product becomes so licensed, cleared, or approved before the expiration date of the contract (including an additional amount per unit of product delivered before the effective date of such licensing, clearance, or approval).

(III) Contract duration

The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding 10 years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be renewable for additional periods, none of which shall exceed five years. The Secretary shall notify the vendor within 90 days of a determination by the Secretary to renew, extend, or terminate such contract.

(IV) Storage by vendor

The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the special reserve fund as defined in subsection (h) shall be available for costs of shipping, handling, storage, and related costs for such product.

(V) Product approval

The contract shall provide that the vendor seek approval, clearance, or li-

censing of the product from the Secretary; for a timetable for the development of data and other information to support such approval, clearance, or licensing; and that the Secretary may waive part or all of this contract term on request of the vendor or on the initiative of the Secretary.

(VI) Non-stockpile transfers of security countermeasures

The contract shall provide that the vendor will comply with all applicable export-related controls with respect to such countermeasure.

(VII) Sales exclusivity

The contract may provide that the vendor is the exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed the term of the contract, on the condition that the vendor is able to satisfy the needs of the Government. During the agreed period of sales exclusivity, the vendor shall not assign its rights of sales exclusivity to another entity or entities without approval by the Secretary. Such a sales exclusivity provision in such a contract shall constitute a valid basis for a sole source procurement under section 3304(a)(1) of title 41.

(VIII) Warm based surge capacity

The contract may provide that the vendor establish domestic manufacturing capacity of the product to ensure that additional production of the product is available in the event that the Secretary determines that there is a need to quickly purchase additional quantities of the product. Such contract may provide a fee to the vendor for establishing and maintaining such capacity in excess of the initial requirement for the purchase of the product. Additionally, the cost of maintaining the domestic manufacturing capacity shall be an allowable and allocable direct cost of the contract.

(IX) Contract terms

The Secretary, in any contract for procurement under this section—

(aa) may specify—

(AA) the dosing and administration requirements for the countermeasure to be developed and procured;

(BB) the amount of funding that will be dedicated by the Secretary for advanced research, development, and procurement of the countermeasure; and

(CC) the specifications the countermeasure must meet to qualify for procurement under a contract under this section; and

(bb) shall provide a clear statement of defined Government purpose limited to uses related to a security countermeasure, as defined in paragraph (1)(B).

(iii) Availability of simplified acquisition procedures

(I) In general

If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection shall be deemed to be below the threshold amount specified in section 134 of title 41, for purposes of application to such procurement, pursuant to section 3101(b)(1)(A) of title 41, of—

(aa) section 3305(a)(1) of title 41 and its implementing regulations; and

(bb) section 3101(b)(1)(B) of title 41 and its implementing regulations.

(II) Application of certain provisions

Notwithstanding subclause (I) and the provision of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

(aa) Chapter 37 of title 40 (relating to contract work hours and safety standards).

(bb) Section 8703(a) of title 41.

(cc) Section 4706 of title 41 (relating to the examination of contractor records).

(dd) Section 3131 of title 40 (relating to bonds of contractors of public buildings or works).

(ee) Section 3901 of title 41 (relating to contingent fees to middlemen).

(ff) Section 6962 of this title.

(gg) Section 1354 of title 31 (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements).

(III) Internal controls to be established

The Secretary shall establish appropriate internal controls for procurements made under this clause, including requirements with respect to documentation of the justification for the use of the authority provided under this paragraph with respect to the procurement involved.

(IV) Authority to limit competition

In conducting a procurement under this subparagraph, the Secretary may not use the authority provided for under subclause (I) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the mission of the BioShield Program under the Project BioShield Act of 2004 would be seriously impaired without such a limitation.

(iv) Procedures other than full and open competition

(I) In general

In using the authority provided in section 3304(a)(1) of title 41 to use proce-

dures other than competitive procedures in the case of a procurement under this subsection, the phrase ''available from only one responsible source'' in such section 3304(a)(1) shall be deemed to mean ''available from only one responsible source or only from a limited number of responsible sources''.

(II) Relation to other authorities

The authority under subclause (I) is in addition to any other authority to use procedures other than competitive procedures.

(III) Applicable government-wide regulations

The Secretary shall implement this clause in accordance with government-wide regulations implementing such section 3304(a)(1) (including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source or only from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

(v) Premium provision in multiple award contracts

(I) In general

If, under this subsection, the Secretary enters into contracts with more than one vendor to procure a security countermeasure, such Secretary may, notwithstanding any other provision of law, include in each of such contracts a provision that—

(aa) identifies an increment of the total quantity of security countermeasure required, whether by percentage or by numbers of units; and

(bb) promises to pay one or more specified premiums based on the priority of such vendors' production and delivery of the increment identified under item (aa), in accordance with the terms and conditions of the contract.

(II) Determination of Government's requirement not reviewable

If the Secretary includes in each of a set of contracts a provision as described in subclause (I), such Secretary's determination of the total quantity of security countermeasure required, and any amendment of such determination, is committed to agency discretion.

(vi) Extension of closing date for receipt of proposals not reviewable

A decision by the Secretary to extend the closing date for receipt of proposals for a procurement under this subsection is committed to agency discretion.

(vii) Limiting competition to sources responding to request for information

In conducting a procurement under this subsection, the Secretary may exclude a source that has not responded to a request for information under section 3306(a)(1)(B) of title 41 if such request has given notice that the Secretary may so exclude such a source.

(viii) Flexibility

In carrying out this section, the Secretary may, consistent with the applicable provisions of this section, enter into contracts and other agreements that are in the best interest of the Government in meeting identified security countermeasure needs, including with respect to reimbursement of the cost of advanced research and development as a reasonable, allowable, and allocable direct cost of the contract involved.

(8) Interagency cooperation

(A) In general

In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government. Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures.

(B) Limitation

An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section to the Homeland Security Secretary or to the Secretary.

(d) Disclosures

No Federal agency may disclose under section 552 of title 5 any information identifying the location at which materials in the stockpile described in subsection (a) are stored, or other information regarding the contents or deployment capability of the stockpile that could compromise national security.

(e) Definition

For purposes of subsection (a), the term ''stockpile'' includes—

(1) a physical accumulation (at one or more locations) of the supplies described in subsection (a); or

(2) a contractual agreement between the Secretary and a vendor or vendors under

which such vendor or vendors agree to provide to such Secretary supplies described in subsection (a).

(f) Authorization of appropriations

(1) Strategic National Stockpile

For the purpose of carrying out subsection (a), there are authorized to be appropriated $610,000,000 for each of fiscal years 2019 through 2021, and $750,000,000 for each of fiscal years 2022 and 2023, to remain available until expended. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (h).

(2) Smallpox vaccine development

For the purpose of carrying out subsection (b), there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(g) Special reserve fund

(1) Authorization of appropriations

In addition to amounts appropriated to the special reserve fund prior to March 13, 2013, there is authorized to be appropriated, for the procurement of security countermeasures under subsection (c) and for carrying out section 247d–7e of this title (relating to the Biomedical Advanced Research and Development Authority), $7,100,000,000 for the period of fiscal years 2019 through 2028, to remain available until expended.

(2) Use of special reserve fund for advanced research and development

The Secretary may utilize not more than 50 percent of the amounts authorized to be appropriated under paragraph (1) to carry out section 247d–7e of this title (related to the Biomedical Advanced Research and Development Authority). Amounts authorized to be appropriated under this subsection to carry out section 247d–7e of this title are in addition to amounts otherwise authorized to be appropriated to carry out such section.

(3) Restrictions on use of funds

Amounts in the special reserve fund shall not be used to pay costs other than payments made by the Secretary to a vendor for advanced development (under section 247d–7e of this title) or for procurement of a security countermeasure under subsection (c)(7).

(4) Report on security countermeasure procurement

Not later than March 1 of each year in which the Secretary determines that the amount of funds available for procurement of security countermeasures is less than $1,500,000,000, the Secretary shall submit 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 a report detailing the amount of such funds available for procurement and the impact such amount of funding will have—

(A) in meeting the security countermeasure needs identified under this section; and

(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 300hh–10(d) of this title).

(5) Clarification on contracting authority

The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, shall carry out the programs funded by the special reserve fund (for the procurement of security countermeasures under subsection (c) and for carrying out section 247d–7e of this title), including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section and section 247d–7e of this title.

(h) Definitions

In this section:

(1) The term ''advanced research and development'' has the meaning given such term in section 247d–7e(a) of this title.

(2) The term ''special reserve fund'' means the ''Biodefense Countermeasures'' appropriations account, any appropriation made available pursuant to section 321j(a) of title 6, and any appropriation made available pursuant to subsection (g)(1).

(i) Pilot program to support State medical stockpiles

(1) In general

The Secretary, in consultation with the Assistant Secretary for Preparedness and Response and the Director of the Centers for Disease Control and Prevention, shall award grants or cooperative agreements to not fewer than 5 States, or consortia of States, with consideration given to distribution among the geographical regions of the United States, to establish, expand, or maintain a stockpile of appropriate drugs, vaccines and other biological products, medical devices, and other medical supplies determined by the State to be necessary to respond to a public health emergency declared by the Governor of a State or by the Secretary under section 247d of this title, or a major disaster or emergency declared by the President under section 5170 or 5191, respectively, of this title, in order to support the preparedness goals described in paragraphs (2) through (6) and (8) of section 300hh–1(b) of this title. A recipient of such an award may not use award funds to support the stockpiling of security countermeasures (as defined in subsection (c)(1),[3] unless the eligible entity provides justification for maintaining such countermeasures and the Secretary determines such justification is appropriate and applicable.

(2) Requirements

(A) Application

To be eligible to receive an award under paragraph (1), an entity shall prepare, in consultation with appropriate health care entities and health officials within the jurisdiction of such State or States, and submit to the Secretary an application that con-

[3] So in original. Another closing parenthesis probably should precede the comma.

tains such information as the Secretary may require, including—

(i) a plan for such stockpile, consistent with paragraph (4), including—

(I) a description of the activities such entity will carry out under the agreement;

(II) an assurance that such entity will use funds under such award in alignment with the requirements of chapter 83 of title 41 (commonly referred to as the ''Buy American Act''); and

(III) an outline of proposed expenses; and

(ii) a description of how such entity will coordinate with relevant entities in receipt of an award under section 247d–3a or 247d–3b of this title pursuant to paragraph (4), including through promoting alignment between the stockpile plan established pursuant to clause (i) and applicable plans that are established by such entity pursuant to section 247d–3a or 247d–3b of this title.

(B) Matching funds

(i) Subject to clause (ii), the Secretary may not make an award under this subsection unless the applicant agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in this subsection, to make available non-Federal contributions toward such costs in an amount equal to—

(I) for each of fiscal years 2023 and 2024, not less than $1 for each $20 of Federal funds provided in the award; and

(II) for fiscal year 2025 and each fiscal year thereafter, not less than $1 for each $10 of Federal funds provided in the award.

(ii) WAIVER.—The Secretary may, upon the request of a State, waive the requirement under clause (i), in whole or in part, if the Secretary determines that extraordinary economic conditions in the State in the fiscal year involved or in the previous fiscal year justify the waiver. A waiver provided by the Secretary under this subparagraph shall apply only to the fiscal year involved.

(C) Administrative expenses

Not more than 10 percent of amounts received by an entity pursuant to an award under this subsection may be used for administrative expenses.

(3) Lead entity

An entity in receipt of an award under paragraph (1) may designate a lead entity, which may be a public or private entity, as appropriate, to manage the stockpile at the direction of the State or consortium of States.

(4) Use of funds

An entity in receipt of an award under paragraph (1) shall use such funds to—

(A) purchase, store, and maintain a stockpile of appropriate drugs, vaccines and other biological products, medical devices, and other medical supplies to be used during a public health emergency, major disaster, or emergency described in paragraph (1), in such numbers, types, and amounts as the entity determines necessary, consistent with such entity's stockpile plan established pursuant to paragraph (2)(A)(i);

(B) deploy the stockpile as required by the entity to respond to an actual or potential public health emergency, major disaster, or other emergency described in paragraph (1);

(C) replenish and make necessary additions or modifications to the contents of such stockpile, including to address potential depletion;

(D) in consultation with Federal, State, and local officials, take into consideration the availability, deployment, dispensing, and administration requirements of medical products within the stockpile;

(E) ensure that procedures are followed for inventory management and accounting, and for the physical security of the stockpile, as appropriate;

(F) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that, to the extent practicable, new technologies and medical products are considered;

(G) carry out exercises, drills, and other training for purposes of stockpile deployment, dispensing, and administration of medical products, and for purposes of assessing the capability of such stockpile to address the medical supply needs of public health emergencies, major disasters, or other emergencies described in paragraph (1) of varying types and scales, which may be conducted in accordance with requirements related to exercises, drills, and other training for recipients of awards under section 247d–3a or 247d–3b of this title, as applicable; and

(H) carry out other activities related to the State strategic stockpile as the entity determines appropriate, to support State efforts to prepare for, and respond to, public health threats.

(5) Supplement not supplant

Awards under paragraph (1) shall supplement, not supplant, the maintenance and use of the Strategic National Stockpile by the Secretary under subsection (a).

(6) Guidance for States

Not later than 180 days after December 29, 2022, the Secretary, in consultation with States, health officials, and other relevant stakeholders, as appropriate, shall issue guidance, and update such guidance as appropriate, for States related to maintaining and replenishing a stockpile of medical products, which may include strategies and best practices related to—

(A) types of medical products and medical supplies that are critical to respond to public health emergencies, and may be appropriate for inclusion in a stockpile by States, with consideration of threats that require the large-scale and simultaneous deployment of stockpiles, including the stockpile maintained by the Secretary pursuant to subsection (a), and long-term public health and medical response needs;

(B) appropriate management of the contents of a stockpile, including management by vendors of reserve amounts of medical products and supplies intended to be delivered to the ownership of the State and appropriate disposition of excess products, as applicable; and

(C) the procurement of medical products and medical supplies consistent with the requirements of chapter 83 of title 41 (commonly referred to as the ''Buy American Act'').

(7) Technical assistance

The Secretary shall provide assistance to States, including technical assistance, as appropriate, in establishing, maintaining, improving, and utilizing a medical stockpile, including appropriate inventory management and disposition of products.

(8) Reporting

(A) State reports

Each entity receiving an award under paragraph (1) shall update, as appropriate, the plan established pursuant to paragraph (2)(A)(i) and submit to the Secretary an annual report on implementation of such plan, including any changes to the contents of the stockpile supported under such award. The Secretary shall use information obtained from such reports to inform the maintenance and management of the Strategic National Stockpile pursuant to subsection (a).

(B) Reports to Congress

Not later than 1 year after the initial issuance of awards pursuant to paragraph (1), and annually thereafter for the duration of the program established under this subsection, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report on such program, including—

(i) Federal and State expenditures to support stockpiles under such program;

(ii) activities conducted pursuant to paragraph (4); and

(iii) any additional information from the States that the Secretary determines relevant.

(9) Authorization of appropriations

To carry out this subsection, there is authorized to be appropriated $3,500,000,000 for each of fiscal years 2023 and 2024, to remain available until expended.

(July 1, 1944, ch. 373, title III, § 319F–2, formerly Pub. L. 107–188, title I, § 121, June 12, 2002, 116 Stat. 611; Pub. L. 107–296, title XVII, § 1705(a), Nov. 25, 2002, 116 Stat. 2316; renumbered § 319F–2 of act July 1, 1944, and amended Pub. L. 108–276, § 3(a), July 21, 2004, 118 Stat. 842; Pub. L. 109–417, title I, § 102(c), title IV, §§ 403(b), 406, Dec. 19, 2006, 120 Stat. 2834, 2874, 2879; Pub. L. 113–5, title IV, §§ 401, 403, Mar. 13, 2013, 127 Stat. 192, 196; Pub. L. 114–255, div. A, title III, §§ 3081, 3082(a), 3085, Dec. 13, 2016, 130 Stat. 1140, 1144; Pub. L. 116–22, title IV, § 403(a), (c), title V, §§ 502, 504(a), title VII, § 702, June 24, 2019, 133 Stat. 943, 947, 950, 951, 962; Pub. L. 116–136, div. A, title III, § 3102, Mar. 27, 2020, 134 Stat. 361; Pub. L. 117–58, div. G, title IX, § 70953(f)(3), Nov. 15, 2021, 135 Stat. 1316; Pub. L. 117–328, div. FF, title II, §§ 2402, 2403, 2404(b)–2406, 2408(a), 2409(a), Dec. 29, 2022, 136 Stat. 5785–5787, 5789.)

Editorial Notes

REFERENCES IN TEXT

Section 403(b) of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, referred to in subsec. (a)(6)(A)(ix), is section 403(b) of Pub. L. 116–22, title IV, June 24, 2019, 133 Stat. 947, which is not classified to the Code.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(1)(B)(i)(III)(aa), is act June 25, 1938, ch. 675, 52 Stat. 1040. Chapter V of the Act is classified generally to subchapter V (§ 351 et seq.) of chapter 9 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Project BioShield Act of 2004, referred to in subsec. (c)(7)(B)(iii)(IV), is Pub. L. 108–276, July 21, 2004, 118 Stat. 835. For complete classification of this Act to the Code, see Short Title of 2004 Amendments note set out under section 201 of this title and Tables.

CODIFICATION

In subsec. (c)(7)(B)(ii)(VII), ''section 3304(a)(1) of title 41'' substituted for ''section 303(c)(1) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(I), ''section 134 of title 41'' substituted for ''section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11))'' and ''section 3101(b)(1)(A) of title 41'' substituted for ''section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(I)(aa), ''section 3305(a)(1) of title 41'' substituted for ''section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(I)(bb), ''section 3101(b)(1)(B) of title 41'' substituted for ''section 302A(b) of such Act (41 U.S.C. 252a(b))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(II)(bb), ''Section 8703(a) of title 41'' substituted for ''Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(II)(cc), ''Section 4706 of title 41'' substituted for ''Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(II)(ee), ''Section 3901 of title 41'' substituted for ''Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iv)(I), ''section 3304(a)(1) of title 41'' substituted for ''section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1))'' and ''such section 3304(a)(1)'' substituted for ''such section 303(c)(1)'' on authority of

Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iv)(III), ''such section 3304(a)(1)'' substituted for ''such section 303(c)(1)'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(vii), ''section 3306(a)(1)(B) of title 41'' substituted for ''section 303A(a)(1)(B) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253a(a)(1)(B))'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

Section was formerly classified to section 300hh–12 of this title prior to renumbering by Pub. L. 108–276.

AMENDMENTS

2022—Subsec. (a)(2)(B)(i)(II). Pub. L. 117–328, §2402, amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: ''planning considerations for appropriate manufacturing capacity and capability to meet the goals of such additions or modifications (without disclosing proprietary information), including consideration of the effect such additions or modifications may have on the availability of such products and ancillary medical supplies in the health care system;''.

Subsec. (a)(3)(B). Pub. L. 117–328, §2403(1), inserted '', regularly reviewed, and updated'' after ''followed''.

Subsec. (a)(3)(C). Pub. L. 117–328, §2408(a)(1), substituted ''local, and Tribal'' for ''and local''.

Subsec. (a)(3)(D). Pub. L. 117–328, §2403(2), amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: ''review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered and that the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment;''.

Subsec. (a)(3)(F). Pub. L. 117–328, §2405(a)(1)(A), substituted ''at the discretion of the Secretary, in consultation with, or at the request of, the Secretary of Homeland Security,'' for ''as required by the Secretary of Homeland Security''.

Subsec. (a)(3)(J). Pub. L. 117–328, §2408(a)(2), substituted ''local, and Tribal'' for ''and local''.

Subsec. (a)(3)(K). Pub. L. 117–328, §2404(b), added subpar. (K).

Subsec. (a)(5). Pub. L. 117–328, §2405(a)(1)(C), added par. (5). Former par. (5) redesignated (6).

Subsec. (a)(6). Pub. L. 117–328, §2405(a)(1)(B), redesignated par. (5) as (6). Former par. (6) redesignated (7).

Subsec. (a)(6)(A)(x). Pub. L. 117–328, §2405(a)(1)(D), added cl. (x).

Subsec. (a)(7). Pub. L. 117–328, §2406, amended par. (7) generally. Prior to amendment, text read as follows: ''The Secretary, in coordination with the Secretary of Homeland Security, may sell drugs, vaccines and other biological products, medical devices, or other supplies maintained in the stockpile under paragraph (1) to a Federal agency or private, nonprofit, State, local, tribal, or territorial entity for immediate use and distribution, provided that any such items being sold are—

''(A) within 1 year of their expiration date; or

''(B) determined by the Secretary to no longer be needed in the stockpile due to advances in medical or technical capabilities.''

Pub. L. 117–328, §2405(a)(1)(B), redesignated par. (6) as (7).

Subsec. (c)(2)(C). Pub. L. 117–328, §2405(a)(2), substituted ''not later than March 15 of each year'' for ''on an annual basis''.

Subsec. (f)(1). Pub. L. 117–328, §2405(b), substituted ''$610,000,000 for each of fiscal years 2019 through 2021, and $750,000,000 for each of fiscal years 2022 and 2023'' for ''$610,000,000 for each of fiscal years 2019 through 2023''.

Subsec. (i). Pub. L. 117–328, §2409(a), added subsec. (i).

2021—Subsec. (a)(6). Pub. L. 117–58 added par. (6).

2020—Subsec. (a)(1). Pub. L. 116–136 inserted ''(including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile)'' after ''other supplies''.

2019—Subsec. (a)(1). Pub. L. 116–22, §403(a)(2), inserted ''the Assistant Secretary for Preparedness and Response and'' after ''collaboration with'', ''and optimize'' after ''provide for'' and ''and, as informed by existing recommendations of, or consultations with, the Public Health Emergency Medical Countermeasure Enterprise established under section 300hh–10a of this title, make necessary additions or modifications to the contents of such stockpile or stockpiles based on the review conducted under paragraph (2)'' after ''public health emergency'', and struck out at end ''The Secretary shall conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review and shall submit such review annually to the appropriate congressional committees of jurisdiction to the extent that disclosure of such information does not compromise national security.''

Subsec. (a)(2). Pub. L. 116–22, §403(a)(3), added par. (2). Former par. (2) redesignated (3).

Subsec. (a)(3). Pub. L. 116–22, §403(a)(1), redesignated par. (2) as (3). Former par. (3) redesignated (4).

Subsec. (a)(3)(A). Pub. L. 116–22, §403(a)(4)(A), inserted before semicolon at end ''and the Public Health Emergency Medical Countermeasures Enterprise established under section 300hh–10a of this title''.

Subsec. (a)(3)(C). Pub. L. 116–22, §403(a)(4)(B), inserted before semicolon at end '', and the availability, deployment, dispensing, and administration of countermeasures''.

Subsec. (a)(3)(E). Pub. L. 116–22, §403(a)(4)(C), amended subpar. (E) generally. Prior to amendment, subpar. (E) read as follows: ''devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure;''.

Subsec. (a)(3)(I), (J). Pub. L. 116–22, §403(a)(4)(D)–(F), added subpars. (I) and (J).

Subsec. (a)(4). Pub. L. 116–22, §403(a)(1), redesignated par. (3) as (4).

Subsec. (a)(5). Pub. L. 116–22, §403(a)(5), added par. (5).

Subsec. (c)(2)(C). Pub. L. 116–22, §502(a), substituted ''The Secretary and the Secretary of Homeland Security shall send to Congress, on an annual basis, all current material threat determinations and shall promptly notify the Committee on Health, Education, Labor, and Pensions and the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives'' for ''The Secretary and the Homeland Security Secretary shall promptly notify the appropriate committees of Congress''.

Subsec. (c)(7)(B)(ii)(III). Pub. L. 116–22, §502(b), inserted at end ''The Secretary shall notify the vendor within 90 days of a determination by the Secretary to renew, extend, or terminate such contract.''

Subsec. (d). Pub. L. 116–22, §702, amended subsec. (d) generally. Prior to amendment, text read as follows: ''No Federal agency shall disclose under section 552 of title 5 any information identifying the location at which materials in the stockpile under subsection (a) are stored.''

Subsec. (f)(1). Pub. L. 116–22, §403(c), substituted ''$610,000,000 for each of fiscal years 2019 through 2023, to remain available until expended'' for ''$533,800,000 for each of fiscal years 2014 through 2018''.

Subsec. (g)(1). Pub. L. 116–22, §504(a), substituted ''$7,100,000,000 for the period of fiscal years 2019 through 2028, to remain available until expended'' for ''$2,800,000,000 for the period of fiscal years 2014 through 2018'' and struck out at end ''Amounts appropriated pursuant to the preceding sentence are authorized to remain available until September 30, 2019.''

2016—Subsec. (a)(3). Pub. L. 114–255, §3081(1), added par. (3).

Subsec. (c)(4)(A)(ii). Pub. L. 114–255, § 3085(1), substituted ''and subject to the availability of appropriations, make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure, as applicable'' for ''make a recommendation under paragraph (6) that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure''.

Subsec. (c)(6). Pub. L. 114–255, § 3085(2)(D), substituted ''Recommendations for procurement'' for ''Recommendation for President's approval'' in heading.

Subsec. (c)(6)(A). Pub. L. 114–255, § 3085(2)(C), amended subpar. (A) generally. Prior to amendment, text read as follows: ''The Secretary and the Homeland Security Secretary shall notify the appropriate congressional committees of each decision of the President to approve a recommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the special reserve fund as defined in subsection (h) for procurement of such a countermeasure, including, where available, the number of, nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefor.''

Pub. L. 114–255, § 3085(2)(A), (B), redesignated subpar. (C) as (A) and struck out former subpar. (A). Text of former subpar. (A) read as follows: ''In the case of a security countermeasure that the Secretary has, in accordance with paragraphs (3) and (5), determined to be appropriate for procurement under this subsection, the Homeland Security Secretary and the Secretary shall jointly submit to the President, in coordination with the Director of the Office of Management and Budget, a recommendation that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure.''

Subsec. (c)(6)(B). Pub. L. 114–255, § 3085(2)(A), (B), redesignated subpar. (D) as (B) and struck out former subpar. (B). Text of former subpar. (B) read as follows: ''The special reserve fund as defined in subsection (h) is available for a procurement of a security countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure.''

Subsec. (c)(6)(C), (D). Pub. L. 114–255, § 3085(2)(B), redesignated subpars. (C) and (D) as (A) and (B), respectively.

Subsec. (c)(6)(E). Pub. L. 114–255, § 3085(2)(A), struck out subpar. (E). Text read as follows: ''Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund as defined in subsection (h) will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.''

Subsec. (c)(7)(A). Pub. L. 114–255, § 3085(3)(A), added subpar. (A) and struck out former subpar. (A). Text of former subpar. (A) read as follows: ''For purposes of a procurement under this subsection that is approved by the President under paragraph (6), the Homeland Security Secretary and the Secretary shall have responsibilities in accordance with subparagraphs (B) and (C).''

Subsec. (c)(7)(B), (C). Pub. L. 114–255, § 3085(3), redesignated subpar. (C) as (B) and struck out former subpar. (B). Text of former subpar. (B) read as follows: ''The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in accordance with the provisions of this paragraph. The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for such procurement.''

Subsec. (g)(4). Pub. L. 114–255, § 3081(2), amended par. (4) generally. Prior to amendment, text read as follows: ''Not later than 30 days after any date on which the Secretary determines that the amount of funds in the special reserve fund available for procurement is less than $1,500,000,000, the Secretary shall submit to the appropriate committees of Congress a report detailing the amount of such funds available for procurement and the impact such reduction in funding will have—

''(A) in meeting the security countermeasure needs identified under this section; and

''(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 300hh–10(d) of this title).''

Subsec. (g)(5). Pub. L. 114–255, § 3082(a), added par. (5).

2013—Subsec. (a)(1). Pub. L. 113–5, § 403(1)(A), inserted ''consistent with section 300hh–10 of this title'' after ''amounts as are determined'' and ''and shall submit such review annually to the appropriate congressional committees of jurisdiction to the extent that disclosure of such information does not compromise national security'' after ''based on such review''.

Subsec. (a)(2)(D). Pub. L. 113–5, § 403(1)(B), inserted ''and that the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment'' before semicolon at end.

Subsec. (c). Pub. L. 113–5, § 401(b)(1)(A), substituted ''special reserve fund as defined in subsection (h)'' for ''special reserve fund under paragraph (10)'' wherever appearing.

Subsec. (c)(1)(B)(i)(III)(bb). Pub. L. 113–5, § 401(a)(1), substituted ''10 years'' for ''eight years''.

Subsec. (c)(2)(C). Pub. L. 113–5, § 401(a)(2), substituted ''the appropriate committees of Congress'' for ''the designated congressional committees (as defined in paragraph (10))''.

Subsec. (c)(5)(B)(ii). Pub. L. 113–5, § 401(a)(3), substituted ''10 years'' for ''eight years''.

Subsec. (c)(6)(C). Pub. L. 113–5, § 401(a)(4), substituted ''appropriate congressional committees'' for ''designated congressional committees'' in heading and in text.

Subsec. (c)(7)(C)(i)(I). Pub. L. 113–5, § 401(a)(5)(A), inserted ''including advanced research and development,'' after ''as may reasonably be required,''.

Subsec. (c)(7)(C)(ii)(III). Pub. L. 113–5, § 401(a)(5)(B)(i), substituted ''10 years'' for ''eight years''.

Subsec. (c)(7)(C)(ii)(IX). Pub. L. 113–5, § 401(a)(5)(B)(ii), added subcl. (IX) and struck out former subcl. (IX). Prior to amendment, text read as follows: ''The Secretary, in any contract for procurement under this section, may specify—

''(aa) the dosing and administration requirements for countermeasures to be developed and procured;

''(bb) the amount of funding that will be dedicated by the Secretary for development and acquisition of the countermeasure; and

''(cc) the specifications the countermeasure must meet to qualify for procurement under a contract under this section.''

Subsec. (c)(7)(C)(viii). Pub. L. 113–5, § 401(a)(5)(C), added cl. (viii).

Subsec. (c)(9), (10). Pub. L. 113–5, § 401(b)(1)(B), struck out pars. (9) and (10) which described restrictions on the use of funds and defined ''special reserve fund'' and ''designated congressional committees''.

Subsec. (f)(1). Pub. L. 113–5, § 403(2), substituted ''$533,800,000 for each of fiscal years 2014 through 2018. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (h).'' for ''$640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (c)(10)(A) of this section.''

Subsecs. (g), (h). Pub. L. 113–5, § 401(b)(2), added subsecs. (g) and (h).

2006—Pub. L. 109–417, § 406(1), inserted ''and security countermeasure procurements'' after ''Stockpile'' in section catchline.

Subsec. (a)(1). Pub. L. 109–417, § 102(c), inserted ''in collaboration with the Director of the Centers for Disease Control and Prevention, and'' after ''The Secretary,'' and inserted at end ''The Secretary shall con-

duct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review.''

Subsec. (c). Pub. L. 109–417, §406(2)(A), struck out ''biomedical'' before ''countermeasures'' in heading.

Subsec. (c)(1)(B)(i)(I). Pub. L. 109–417, §403(b), which directed amendment of section 319F–2(c)(1)(B) by substituting ''diagnose, mitigate, prevent, or treat'' for ''treat, identify, or prevent'' wherever appearing, was executed by making the substitution in two places in subsec. (c)(1)(B)(i)(I) of this section, which is section 319F–2 of the Public Health Service Act, to reflect the probable intent of Congress.

Subsec. (c)(3). Pub. L. 109–417, §406(2)(B), designated existing provisions as subpar. (A), inserted heading, and added subpar. (B).

Subsec. (c)(4)(A). Pub. L. 109–417, §406(2)(C), inserted ''not developed or'' after ''currently'' in introductory provisions.

Subsec. (c)(5)(B)(i). Pub. L. 109–417, §406(2)(D), substituted ''to meet the stockpile needs'' for ''to meet the needs of the stockpile''.

Subsec. (c)(7)(B). Pub. L. 109–417, §406(2)(E), substituted ''cost'' for ''costs'' in subpar. heading, struck out cl. (i) designation and heading before ''The Homeland'', and struck out heading and text of cl. (ii). Text read as follows: ''The actual costs to the Secretary under this section, other than the costs described in clause (i), shall be paid from the appropriation provided for under subsection (f)(1) of this section.''

Subsec. (c)(7)(C)(ii)(I). Pub. L. 109–417, §406(2)(F)(i), amended heading and text of subcl. (I) generally. Prior to amendment, text read as follows: ''The contract shall provide that no payment may be made until delivery has been made of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment is necessary to ensure success of a project, the Secretary may pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. Nothing in this subclause may be construed as affecting rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to termination of contracts for the convenience of the Government.''

Subsec. (c)(7)(C)(ii)(VII) to (IX). Pub. L. 109–417, §406(2)(F)(ii), added subcls. (VII) to (IX).

Subsec. (c)(8)(A). Pub. L. 109–417, §406(2)(G), inserted at end ''Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures.''

2004—Pub. L. 108–276, §3(a)(2), amended section generally. Prior to amendment, text related in subsec. (a) to Strategic National Stockpile, in subsec. (b) to smallpox vaccine development, in subsec. (c) to disclosures, in subsec. (d) to definition of ''stockpile'', and in subsec. (e) to authorization of appropriations.

2002—Subsec. (a)(1). Pub. L. 107–296, §1705(a)(1), substituted ''The Secretary of Homeland Security'' for ''The Secretary of Health and Human Services'' and inserted ''the Secretary of Health and Human Services and'' after ''in coordination with'' and ''of Health and Human Services'' after ''as are determined by the Secretary''.

Subsecs. (a)(2), (b)(1). Pub. L. 107–296, §1705(a)(2), inserted ''of Health and Human Services'' after ''Secretary'' wherever appearing.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–296, title XVII, §1705(b), Nov. 25, 2002, 116 Stat. 2316, provided that: ''The amendments made by this section [amending this section] shall take effect on the date of transfer of the Strategic National Stockpile of the Department of Health and Human Services to the Department [of Homeland Security].''

IMPROVING TRANSPARENCY AND PREDICTABILITY OF PROCESSES OF THE STRATEGIC NATIONAL STOCKPILE

Pub. L. 117–328, div. FF, title II, §2404(a), Dec. 29, 2022, 136 Stat. 5785, provided that: ''Not later than 60 days after the date of enactment of this Act [Dec. 29, 2022], the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall issue guidance describing the processes by which the Secretary deploys the contents of the Strategic National Stockpile under section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)), or otherwise distributes medical countermeasures, as applicable, to States, territories, Indian Tribes and Tribal organizations (as such terms are defined under section 4 of the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5304]), and other applicable entities. Such guidance shall include information related to processes by which to request access to the contents of the Strategic National Stockpile, factors considered by the Secretary when making deployment or distribution decisions, and processes and points of contact through which entities may contact the Secretary to address any issues related to products requested or received by such entity from the stockpile, and on other relevant topics.''

INCREASED MANUFACTURING CAPACITY FOR CERTAIN CRITICAL ANTIBIOTIC DRUGS

Pub. L. 117–328, div. FF, title II, §2411, Dec. 29, 2022, 136 Stat. 5793, provided that:

''(a) PROGRAM.—

''(1) IN GENERAL.—The Secretary, in consultation with the Assistant Secretary for Preparedness and Response and Commissioner of Food and Drugs, may award contracts to increase the domestic manufacturing capacity of certain antibiotic drugs with identified supply chain vulnerabilities, or the active pharmaceutical ingredient or key starting material of such antibiotic drugs.

''(2) ELIGIBLE ENTITIES.—To be eligible to receive an award under this subsection, an entity shall—

''(A) be a manufacturer that is in compliance with, or demonstrates capability to comply with, the relevant requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

''(B) prepare and submit to the Secretary an application at such time, and in such manner, and containing such information as the Secretary may require, including—

''(i) a description of proposed activities to be supported by an award under this subsection to increase manufacturing capacity for such antibiotic drug or drugs;

''(ii) the antibiotic drug or drugs, or related active pharmaceutical ingredients or key starting materials for such drug or drugs, that such entity intends to manufacture with any increased manufacturing capacity supported by an award under this subsection;

''(iii) any additional products such increased manufacturing capacity could be used to manufacture;

''(iv) a description of the current supply chain for such antibiotic drugs, including any existing and applicable manufacturing facilities, known vulnerabilities in the supply chain, known or po-

tential supply limitations, such as foreign export restrictions, or subsidies from foreign governments, as applicable;

''(v) a description of how such entity may use advanced or flexible manufacturing in carrying out the terms of an award under this subsection; and

''(vi) a strategic plan regarding the maintenance, operation, and sustainment of such increased manufacturing capacity following the expiration of a contract under this subsection.

''(3) USE OF FUNDS.—A recipient of an award under this subsection shall use such funds to build, expand, upgrade, modify, or recommission a facility located in the United States, which may include the purchase or upgrade of equipment, as applicable, to support increased manufacturing capacity of certain antibiotic drugs for which supply chain vulnerabilities exist, or the active pharmaceutical ingredient or key starting material of such antibiotic drugs.

''(4) REPORTS.—An entity in receipt of an award under this subsection shall submit to the Secretary such reports as the Secretary may require related to increasing domestic manufacturing capacity of antibiotic drugs pursuant to a contract under this subsection, including actions taken to implement the strategic plan required under paragraph (2)(B)(vi).

''(5) CONTRACT TERMS.—The following shall apply to a contract to support increased domestic manufacturing capacity under this subsection:

''(A) MILESTONE-BASED PAYMENTS.—The Secretary may provide payment, including advance payment or partial payment for significant milestones, if the Secretary makes a determination that such payment is necessary and appropriate.

''(B) REPAYMENT.—The contract shall provide that such payment is required to be repaid if there is a failure to perform by the manufacturer under the contract; if the specified milestones are reached, an advance or partial payment shall not be required to be repaid.

''(C) CONTRACT DURATION.—

''(i) IN GENERAL.—Each contract shall be for a period not to exceed 5 years.

''(ii) NON-RENEWABILITY.—A contract shall not be renewable.

''(iii) NOTIFICATIONS OF EXTENSIONS AND TERMINATIONS.—If the Secretary decides to terminate a contract prior to its expiration, the Secretary shall notify the manufacturer within 90 days of such determination.

''(D) ADDITIONAL TERMS.—The Secretary, in any contract under this subsection—

''(i) may specify—

''(I) the amount of funding that will be dedicated by the Secretary for supporting increased manufacturing capacity under such contract; and

''(II) the amount of manufacturing capacity that such eligible entity must meet; and

''(ii) shall provide a clear statement of defined Federal Government purpose limited to uses related to increasing domestic manufacturing capacity for antibiotic drugs to address identified supply chain vulnerabilities and challenges to establishing and maintaining domestic manufacturing capacity.

''(E) SUSTAINMENT.—Each contract shall provide for the eligible entity to update the strategic plan required under paragraph (2)(B)(vi) throughout the duration of such contract, as required by the Secretary.

''(b) REPORT.—Not later than 2 years after the date of enactment of this Act [Dec. 29, 2022] and every year thereafter until the termination or expiration of all such contracts, the Secretary shall submit to 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 on any activities supported under subsection (a), including—

''(1) the antibiotic drugs for which the Secretary prioritized awards under subsection (a), including a description of how the Secretary consulted with stakeholders to inform such prioritization;

''(2) information regarding each contract awarded pursuant to subsection (a), including—

''(A) the recipient of each such contract, including any recipients of a subaward;

''(B) the milestone and performance requirements pursuant to each such contract;

''(C) the duration of each such contract;

''(D) the amount of funding provided by the Secretary pursuant to each such contract, including any advanced or partial payments;

''(E) the antibiotic drugs supported through each such contract, including a description of the medical necessity of each such antibiotic drug and any supply chain vulnerabilities, limitations, and related characteristics identified pursuant to subsection (a)(2)(B)(iv) for each such antibiotic drug; and

''(F) the amount of increased manufacturing capacity for such antibiotic drug that each such contract supports; and

''(3) a description of how such contracts address supply chain vulnerabilities, including increasing manufacturing capacity of antibiotic drugs in the United States; and

''(4) a description of the strategic plan submitted pursuant to subsection (a)(2)(B)(vi) by each recipient of an award under subsection (a).

''(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

''(1) to limit, directly or indirectly, or otherwise impact the private distribution, purchase, or sale of antibiotic drugs or active pharmaceutical ingredients or key starting materials; or

''(2) to authorize the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

''(d) DEFINITIONS.—For purposes of this section:

''(1) ACTIVE PHARMACEUTICAL INGREDIENT.—The term 'active pharmaceutical ingredient' has the meaning given such term in section 744A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41).

''(2) ANTIBIOTIC DRUG.—The term 'antibiotic drug' means an antibacterial or antifungal drug approved by the Food and Drug Administration under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that is of significant priority to providing health care and is medically necessary to have available at all times in an amount adequate to serve patient needs.

''(3) KEY STARTING MATERIAL.—The term 'key starting material' means any component of a drug that the Secretary determines to be necessary to the safety and effectiveness of the drug.

''(4) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services.

''(e) SUNSET.—The authority to enter into new contracts under this section shall cease to be effective 3 years after the date of enactment of this Act [Dec. 29, 2022], and, beginning on the date that is 8 years after the date of enactment of this Act, this section shall have no force or effect.''

FIRST RESPONDER ANTHRAX PREPAREDNESS

Pub. L. 114–268, Dec. 14, 2016, 130 Stat. 1387, provided that:

''SECTION 1. SHORT TITLE.

''This Act may be cited as the 'First Responder Anthrax Preparedness Act'.

''SEC. 2. VOLUNTARY PRE-EVENT ANTHRAX VACCINATION PILOT PROGRAM FOR EMERGENCY RESPONSE PROVIDERS.

''(a) PILOT PROGRAM.—

''(1) ESTABLISHMENT.—The Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, shall carry out a pilot program to provide eligible anthrax vaccines from the Strategic National Stockpile under section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)) that will be nearing the end of their labeled dates of use at the time such vaccines are made available to States for administration to emergency response providers who would be at high risk of exposure to anthrax if such an attack should occur and who voluntarily consent to such administration.

''(2) DETERMINATION.—The Secretary of Health and Human Services shall determine whether an anthrax vaccine is eligible to be provided to the Secretary of Homeland Security for the pilot program described in paragraph (1) based on—

''(A) a determination that the vaccine is not otherwise allotted for other purposes;

''(B) a determination that the provision of the vaccine will not reduce, or otherwise adversely affect, the capability to meet projected requirements for this product during a public health emergency, including a significant reduction of available quantities of vaccine in the Strategic National Stockpile; and

''(C) such other considerations as determined appropriate by the Secretary of Health and Human Services.

''(3) PRELIMINARY REQUIREMENTS.—Before implementing the pilot program required under this subsection, the Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, shall—

''(A) establish a communication platform for the pilot program;

''(B) develop and deliver education and training for the pilot program;

''(C) conduct economic analysis of the pilot program, including a preliminary estimate of total costs and expected benefits;

''(D) create a logistical platform for the anthrax vaccine request process under the pilot program;

''(E) establish goals and desired outcomes for the pilot program; and

''(F) establish a mechanism to reimburse the Secretary of Health and Human Services for—

''(i) the costs of shipment and transportation of such vaccines provided to the Secretary of Homeland Security from the Strategic National Stockpile under such pilot program, including staff time directly supporting such shipment and transportation; and

''(ii) the amount, if any, by which the warehousing costs of the Strategic National Stockpile are increased in order to operate such pilot program.

''(4) LOCATION.—

''(A) IN GENERAL.—In carrying out the pilot program required under this subsection, the Secretary of Homeland Security shall select not fewer than 2 nor more than 5 States for voluntary participation in the pilot program.

''(B) REQUIREMENT.—Each State that participates in the pilot program under this subsection shall ensure that such participation is consistent with the All-Hazards Public Health Emergency Preparedness and Response Plan of the State developed under section 319C–1 of the Public Health Service Act (42 U.S.C. 247d–3a).

''(5) GUIDANCE FOR SELECTION.—To ensure that participation in the pilot program under this subsection strategically increases State and local response readiness in the event of an anthrax release, the Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, shall provide guidance to participating States and units of local government on identifying emergency response providers who are at high risk of exposure to anthrax.

''(6) DISTRIBUTION OF INFORMATION.—The Secretary of Homeland Security shall require that each State that participates in the pilot program under this subsection submit a written certification to the Secretary of Homeland Security stating that each emergency response provider within the State that participates in the pilot program is provided with disclosures and educational materials designated by the Secretary of Health and Human Services, which may include—

''(A) materials regarding the associated benefits and risks of any vaccine provided under the pilot program, and of exposure to anthrax;

''(B) additional material consistent with the Centers for Disease Control and Prevention's clinical guidance; and

''(C) notice that the Federal Government is not obligated to continue providing anthrax vaccine after the date on which the pilot program ends.

''(7) MEMORANDUM OF UNDERSTANDING.—Before implementing the pilot program under this subsection, the Secretary of Homeland Security shall enter into a memorandum of understanding with the Secretary of Health and Human Services to—

''(A) define the roles and responsibilities of each Department for the pilot program; and

''(B) establish other performance metrics and policies for the pilot program, as appropriate.

''(8) REPORT.—

''(A) IN GENERAL.—Notwithstanding subsection (c), not later than 1 year after the date on which the initial vaccines are administered under this section, and annually thereafter until 1 year after the completion of the pilot program under this section, the Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, shall submit to the Committee on Homeland Security and the Committee on Energy and Commerce of the House of Representatives and the Committee on Homeland Security and Governmental Affairs and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the progress and results of the pilot program, including—

''(i) a detailed tabulation of the costs to administer the program, including—

''(I) total costs for management and administration;

''(II) total costs to ship vaccines;

''(III) total number of full-time equivalents allocated to the program; and

''(IV) total costs to the Strategic National Stockpile;

''(ii) the number and percentage of eligible emergency response providers, as determined by each pilot location, that volunteer to participate;

''(iii) the degree to which participants complete the vaccine regimen;

''(iv) the total number of doses of vaccine administered; and

''(v) recommendations to improve initial and recurrent participation in the pilot program.

''(B) FINAL REPORT.—The final report required under subparagraph (A) shall—

''(i) consider whether the pilot program required under this subsection should continue after the date described in subsection (c); and

''(ii) include—

''(I) an analysis of the costs and benefits of continuing the program to provide anthrax vaccines to emergency response providers;

''(II) an explanation of the economic, health, and other risks and benefits of administering vaccines through the pilot program rather than post-event treatment; and

''(III) in the case of a recommendation under clause (i) to continue the pilot program after the date described in subsection (c), a plan under which the pilot program could be continued.

''(b) DEADLINE FOR IMPLEMENTATION.—Not later than 1 year after the date of enactment of this Act [Dec. 14,

2016], the Secretary of Homeland Security shall begin implementing the pilot program under this section.

''(c) SUNSET.—The authority to carry out the pilot program under this section shall expire on the date that is 5 years after the date of enactment of this Act [Dec. 14, 2016].''

STOCKPILE FUNCTIONS TRANSFERRED

Pub. L. 108–276, §3(c)(1), (2), July 21, 2004, 118 Stat. 853, provided that:

''(1) IN GENERAL.—Except as provided in paragraph (2), there shall be transferred to the Secretary of Health and Human Services the functions, personnel, assets, unexpended balances, and liabilities of the Strategic National Stockpile, including the functions of the Secretary of Homeland Security relating thereto.

''(2) EXCEPTIONS.—

''(A) FUNCTIONS.—The transfer of functions pursuant to paragraph (1) shall not include such functions as are explicitly assigned to the Secretary of Homeland Security by this Act [see Short Title of 2004 Amendments note set out under section 201 of this title] (including the amendments made by this Act).

''(B) ASSETS AND UNEXPENDED BALANCES.—The transfer of assets and unexpended balances pursuant to paragraph (1) shall not include the funds appropriated under the heading 'BIODEFENSE COUNTERMEASURES' in the Department of Homeland Security Appropriations Act, 2004 (Public Law 108–90 [117 Stat. 1148]).''

POTASSIUM IODIDE

Pub. L. 107–188, title I, §127, June 12, 2002, 116 Stat. 615, provided that:

''(a) IN GENERAL.—Through the national stockpile under section 121 [now section 319F–2 of act July 1, 1944, 42 U.S.C. 247d–6b], the President, subject to subsections (b) and (c), shall make available to State and local governments potassium iodide tablets for stockpiling and for distribution as appropriate to public facilities, such as schools and hospitals, in quantities sufficient to provide adequate protection for the population within 20 miles of a nuclear power plant.

''(b) STATE AND LOCAL PLANS.—

''(1) IN GENERAL.—Subsection (a) applies with respect to a State or local government, subject to paragraph (2), if the government involved meets the following conditions:

''(A) Such government submits to the President a plan for the stockpiling of potassium iodide tablets, and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident.

''(B) The plan is accompanied by certifications by such government that the government has not already received sufficient quantities of potassium iodide tablets from the Federal Government.

''(2) LOCAL GOVERNMENTS.—Subsection (a) applies with respect to a local government only if, in addition to the conditions described in paragraph (1), the following conditions are met:

''(A) The State in which the locality involved is located—

''(i) does not have a plan described in paragraph (1)(A); or

''(ii) has a plan described in such paragraph, but the plan does not address populations at a distance greater than 10 miles from the nuclear power plant involved.

''(B) The local government has petitioned the State to modify the State plan to address such populations, not exceeding 20 miles from such plant, and 60 days have elapsed without the State modifying the State plan to address populations at the full distance sought by the local government through the petition.

''(C) The local government has submitted its local plan under paragraph (1)(A) to the State, and the State has approved the plan and certified that the plan is not inconsistent with the State emergency plan.

''(c) GUIDELINES.—Not later than one year after the date of the enactment of this Act [June 12, 2002], the President, in consultation with individuals representing appropriate Federal, State, and local agencies, shall establish guidelines for the stockpiling of potassium iodide tablets, and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident. Such tablets may not be made available under subsection (a) until such guidelines have been established.

''(d) INFORMATION.—The President shall carry out activities to inform State and local governments of the program under this section.

''(e) REPORTS.—

''(1) PRESIDENT.—Not later than six months after the date on which the guidelines under subsection (c) are issued, the President shall submit to the Congress a report—

''(A) on whether potassium iodide tablets have been made available under subsection (a) or other Federal, State, or local programs, and the extent to which State and local governments have established stockpiles of such tablets; and

''(B) the measures taken by the President to implement this section.

''(2) NATIONAL ACADEMY OF SCIENCES.—

''(A) IN GENERAL.—The President shall request the National Academy of Sciences to enter into an agreement with the President under which the Academy conducts a study to determine what is the most effective and safe way to distribute and administer potassium iodide tablets on a mass scale. If the Academy declines to conduct the study, the President shall enter into an agreement with another appropriate public or nonprofit private entity to conduct the study.

''(B) REPORT.—The President shall ensure that, not later than six months after the date of the enactment of this Act [June 12, 2002], the study required in subparagraph (A) is completed and a report describing the findings made in the study is submitted to the Congress.

''(f) APPLICABILITY.—Subsections (a) and (d) cease to apply as requirements if the President determines that there is an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants.''

[Memorandum of President of the United States, July 3, 2007, 72 F.R. 37627, provided:

[Memorandum for the Secretary of Health and Human Services[,] the Secretary of Energy[,] the Secretary of Homeland Security[,] the Chairman of the Nuclear Regulatory Commission[, and] the Director of the Office of Science and Technology Policy

[By the authority vested in me as President by the Constitution and the laws of the United States, including section 301 of title 3, United States Code, and section 204(b) of the National Science and Technology Policy, Organization, and Priorities Act of 1976, as amended (42 U.S.C. 6613(b)), the functions of the President under section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188) (42 U.S.C. 247d–6b note) are assigned as follows:

[(1) the function of making a determination under subsection 127(f) of Public Law 107–188 is assigned to the Director of the Office of Science and Technology Policy; and

[(2) the functions of the President under section 127 of Public Law 107–188 other than that assigned under subsection 127(f) are assigned to the Chairman of the Nuclear Regulatory Commission.

[In the performance of such functions the Chairman and the Director should consult each other and the Secretaries of Health and Human Services, Energy, and Homeland Security, as appropriate.

[The Director is authorized and directed to publish this memorandum in the Federal Register.]

Executive Documents

EX. ORD. NO. 13944. COMBATING PUBLIC HEALTH EMERGENCIES AND STRENGTHENING NATIONAL SECURITY BY ENSURING ESSENTIAL MEDICINES, MEDICAL COUNTERMEASURES, AND CRITICAL INPUTS ARE MADE IN THE UNITED STATES

Ex. Ord. No. 13944, Aug. 6, 2020, 85 F.R. 49929, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. The United States must protect our citizens, critical infrastructure, military forces, and economy against outbreaks of emerging infectious diseases and chemical, biological, radiological, and nuclear (CBRN) threats. To achieve this, the United States must have a strong Public Health Industrial Base with resilient domestic supply chains for Essential Medicines, Medical Countermeasures, and Critical Inputs deemed necessary for the United States. These domestic supply chains must be capable of meeting national security requirements for responding to threats arising from CBRN threats and public health emergencies, including emerging infectious diseases such as COVID–19. It is critical that we reduce our dependence on foreign manufacturers for Essential Medicines, Medical Countermeasures, and Critical Inputs to ensure sufficient and reliable long-term domestic production of these products, to minimize potential shortages, and to mobilize our Nation's Public Health Industrial Base to respond to these threats. It is therefore the policy of the United States to:

(a) accelerate the development of cost-effective and efficient domestic production of Essential Medicines and Medical Countermeasures and have adequate redundancy built into the domestic supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs;

(b) ensure long-term demand for Essential Medicines, Medical Countermeasures, and Critical Inputs that are produced in the United States;

(c) create, maintain, and maximize domestic production capabilities for Critical Inputs, Finished Drug Products, and Finished Devices that are essential to protect public safety and human health and to provide for the national defense; and

(d) combat the trafficking of counterfeit Essential Medicines, Medical Countermeasures, and Critical Inputs over e-commerce platforms and from third-party online sellers involved in the government procurement process.

I am therefore directing each executive department and agency involved in the procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs (agency) to consider a variety of actions to increase their domestic procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs, and to identify vulnerabilities in our Nation's supply chains for these products. Under this order, agencies will have the necessary flexibility to increase their domestic procurement in appropriate and responsible ways, while protecting our Nation's service members, veterans, and their families from increases in drug prices and without interfering with our Nation's ability to respond to the spread of COVID–19.

SEC. 2. *Maximizing Domestic Production in Procurement*. (a) Agencies shall, as appropriate, to the maximum extent permitted by applicable law, and in consultation with the Commissioner of Food and Drugs (FDA Commissioner) with respect to Critical Inputs, use their respective authorities under section 2304(c) of title 10, United States Code [now 10 U.S.C. 3204(a)]; section 3304(a) of title 41, United States Code; and subpart 6.3 of the Federal Acquisition Regulation, title 48, Code of Federal Regulations, to conduct the procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs by:

(i) using procedures to limit competition to only those Essential Medicines, Medical Countermeasures, and Critical Inputs that are produced in the United States; and

(ii) dividing procurement requirements among two or more manufacturers located in the United States, as appropriate.

(b) Within 90 days of the date of this order [Aug. 6, 2020], the Director of the Office of Management and Budget (OMB), in consultation with appropriate agency heads, shall:

(i) review the authority of each agency to limit the online procurement of Essential Medicines and Medical Countermeasures to e-commerce platforms that have:

(A) adopted, and certified their compliance with, the applicable best practices published by the Department of Homeland Security in its Report to the President on ''Combating Trafficking in Counterfeit and Pirated Goods,'' dated January 24, 2020; and

(B) agreed to permit the Department of Homeland Security's National Intellectual Property Rights Coordination Center to evaluate and confirm their compliance with such best practices; and

(ii) report its findings to the President.

(c) Within 90 days of the date of this order, the head of each agency shall, in consultation with the FDA Commissioner, develop and implement procurement strategies, including long-term contracts, consistent with law, to strengthen and mobilize the Public Health Industrial Base in order to increase the manufacture of Essential Medicines, Medical Countermeasures, and Critical Inputs in the United States.

(d) No later than 30 days after the FDA Commissioner has identified, pursuant to section 3(c) of this order, the initial list of Essential Medicines, Medical Countermeasures, and Critical Inputs, the United States Trade Representative shall, to the extent permitted by law, take all appropriate action to modify United States Federal procurement product coverage under all relevant Free Trade Agreements and the World Trade Organization Agreement on Government Procurement to exclude coverage of Essential Medicines, Medical Countermeasures, and Critical Inputs. The United States Trade Representative shall further modify United States Federal procurement product coverage, as appropriate, to reflect updates by the FDA Commissioner. After the modifications to United States Federal procurement coverage take effect, the United States Trade Representative shall make any necessary, corresponding modifications of existing waivers under section 301 of the Trade Agreements Act of 1979 [19 U.S.C. 2511]. The United States Trade Representative shall notify the President, through the Director of OMB, once it has taken the actions described in this subsection.

(e) No later than 60 days after the FDA Commissioner has identified, pursuant to section 3(c) of this order, the initial list of Essential Medicines, Medical Countermeasures, and Critical Inputs, and notwithstanding the public interest exception in subsection (f)(i)(1) of this section, the Secretary of Defense shall, to the maximum extent permitted by applicable law, use his authority under section 225.872–1(c) of the Defense Federal Acquisition Regulation Supplement to restrict the procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs to domestic sources and to reject otherwise acceptable offers of such products from sources in Qualifying Countries in instances where considered necessary for national defense reasons.

(f) Subsections (a), (d), and (e) of this section shall not apply:

(i) where the head of the agency determines in writing, with respect to a specific contract or order, that (1) their application would be inconsistent with the public interest; (2) the relevant Essential Medicines, Medical Countermeasures, and Critical Inputs are not produced in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality; or (3) their application would cause the cost of the procurement to increase by more than 25 percent, unless applicable law requires a higher percentage, in which case such higher percentage shall apply;

(ii) with respect to the procurement of items that are necessary to respond to any public health emergency

declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), any major disaster or emergency declared under the Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.), or any national emergency declared under the National Emergencies Act (50 U.S.C. 1601 et seq.).

(g) To the maximum extent permitted by law, any public interest determination made pursuant to section 2(f)(i)(1) of this order shall be construed to maximize the procurement and use of Essential Medicines and Medical Countermeasures produced in the United States.

(h) The head of an agency who makes any determination pursuant to section 2(f)(i) of this order shall submit an annual report to the President, through the Director of OMB and the Assistant to the President for Trade and Manufacturing Policy, describing the justification for each such determination.

SEC. 3. *Identifying Vulnerabilities in Supply Chains.* (a) Within 180 days of the date of this order, the Secretary of Health and Human Services, through the FDA Commissioner and in consultation with the Director of OMB, shall take all necessary and appropriate action, consistent with law, to identify vulnerabilities in the supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs and to mitigate those vulnerabilities, including by:

(i) considering proposing regulations or revising guidance on the collection of the following information from manufacturers of Essential Medicines and Medical Countermeasures as part of the application and regulatory approval process:

(A) the sources of Finished Drug Products, Finished Devices, and Critical Inputs;

(B) the use of any scarce Critical Inputs; and

(C) the date of the last FDA inspection of the manufacturer's regulated facilities and the results of such inspection;

(ii) entering into written agreements, pursuant to section 20.85 of title 21, Code of Federal Regulations, with the National Security Council, Department of State, Department of Defense, Department of Veterans Affairs, and other interested agencies, as appropriate, to disclose records regarding the security and vulnerabilities of the supply chains for Essential Medicines, Medical Countermeasures, and Critical Inputs;

(iii) recommending to the President any changes in applicable law that may be necessary to accomplish the objectives of this subsection; and

(iv) reviewing FDA regulations to determine whether any of those regulations may be a barrier to domestic production of Essential Medicines, Medical Countermeasures, and Critical Inputs, and by advising the President whether such regulations should be repealed or amended.

(b) The Secretary of Health and Human Services, through the FDA Commissioner, shall take all appropriate action, consistent with applicable law, to:

(i) accelerate FDA approval or clearance, as appropriate, for domestic producers of Essential Medicines, Medical Countermeasures, and Critical Inputs, including those needed for infectious disease and CBRN threat preparedness and response;

(ii) issue guidance with recommendations regarding the development of Advanced Manufacturing techniques;

(iii) negotiate with countries to increase site inspections and increase the number of unannounced inspections of regulated facilities manufacturing Essential Medicines, Medical Countermeasures, and Critical Inputs; and

(iv) refuse admission, as appropriate, to imports of Essential Medicines, Medical Countermeasures, and Critical Inputs if the facilities in which they are produced refuse or unreasonably delay an inspection.

(c) Within 90 days of the date of this order, and periodically updated as appropriate, the FDA Commissioner, in consultation with the Director of OMB, the Assistant Secretary for Preparedness and Response in the Department of Health and Human Services, the Assistant to the President for Economic Policy, and the Director of the Office of Trade and Manufacturing Policy, shall identify the list of Essential Medicines, Medical Countermeasures, and their Critical Inputs that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms.

(d) Within 180 days of the date of this order, the Secretary of Defense, in consultation with the Director of OMB, shall take all necessary and appropriate action, consistent with law, to identify vulnerabilities in the supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs necessary to meet the unique needs of the United States Armed Forces and to mitigate the vulnerabilities identified in subsection (a) of this section. The Secretary of Defense shall provide to the Secretary of Health and Human Services, the FDA Commissioner, the Director of OMB, and the Director of the Office of Trade and Manufacturing Policy a list of defense-specific Essential Medicines, Medical Countermeasures, and Critical Inputs that are medically necessary to have available for defense use in adequate amounts and in appropriate dosage forms. The Secretary of Defense shall, as appropriate, periodically update this list.

SEC. 4. *Streamlining Regulatory Requirements.* Consistent with law, the Administrator of the Environmental Protection Agency shall take all appropriate action to identify relevant requirements and guidance documents that can be streamlined to provide for the development of Advanced Manufacturing facilities and the expeditious domestic production of Critical Inputs, including by accelerating siting and permitting approvals.

SEC. 5. *Priorities and Allocation of Essential Medicines, Medical Countermeasures, and Critical Inputs.* The Secretary of Health and Human Services shall, as appropriate and in accordance with the delegation of authority under Executive Order 13603 of March 16, 2012 (National Defense Resources Preparedness) [50 U.S.C. 4553 note], use the authority under section 101 of the Defense Production Act of 1950, as amended (50 U.S.C. 4511), to prioritize the performance of Federal Government contracts or orders for Essential Medicines, Medical Countermeasures, or Critical Inputs over performance of any other contracts or orders, and to allocate such materials, services, and facilities as the Secretary deems necessary or appropriate to promote the national defense.

SEC. 6. *Reporting.* (a) No later than December 15, 2021, and annually thereafter, the head of each agency shall submit a report to the President, through the Director of OMB and the Assistant to the President for Trade and Manufacturing Policy, detailing, for the preceding three fiscal years:

(i) the Essential Medicines, Medical Countermeasures, and Critical Inputs procured by the agency;

(ii) the agency's annual itemized and aggregated expenditures for all Essential Medicines, Medical Countermeasures, and Critical Inputs;

(iii) the sources of these products and inputs; and

(iv) the agency's plan to support domestic production of such products and inputs in the next fiscal year.

(b) Within 180 days of the date of this order, the Secretary of Commerce shall submit a report to the Director of OMB, the Assistant to the President for National Security Affairs, the Director of the National Economic Council, and the Director of the Office of Trade and Manufacturing Policy, describing any change in the status of the Public Health Industrial Base and recommending initiatives to strengthen the Public Health Industrial Base.

(c) To the maximum extent permitted by law, and with the redaction of any information protected by law from disclosure, each agency's report shall be published in the Federal Register and on each agency's official website.

SEC. 7. *Definitions.* As used in this order:

(a) ''Active Pharmaceutical Ingredient'' has the meaning set forth in section 207.1 of title 21, Code of Federal Regulations.

(b) ''Advanced Manufacturing'' means any new medical product manufacturing technology that can improve drug quality, address shortages of medicines, and speed time to market, including continuous manufacturing and 3D printing.

(c) ''API Starting Material'' means a raw or intermediate material that is used in the manufacturing of an API, that is incorporated as a significant structural fragment into the structure of the API, and that is determined by the FDA Commissioner to be relevant in assessing the safety and effectiveness of Essential Medicines and Medical Countermeasures.

(d) ''Critical Inputs'' means API, API Starting Material, and other ingredients of drugs and components of medical devices that the FDA Commissioner determines to be critical in assessing the safety and effectiveness of Essential Medicines and Medical Countermeasures.

(e) ''Essential Medicines'' are those Essential Medicines deemed necessary for the United States pursuant to section 3(c) of this order.

(f) ''Finished Device'' has the meaning set forth in section 820.3(l) of title 21, Code of Federal Regulations.

(g) ''Finished Drug Product'' has the meaning set forth in section 207.1 of title 21, Code of Federal Regulations.

(h) ''Healthcare and Public Health Sector'' means the critical infrastructure sector identified in Presidential Policy Directive 21 of February 12, 2013 (Critical Infrastructure Security and Resilience), and the National Infrastructure Protection Plan of 2013.

(i) An Essential Medicine or Medical Countermeasure is ''produced in the United States'' if the Critical Inputs used to produce the Essential Medicine or Medical Countermeasures are produced in the United States and if the Finished Drug Product or Finished Device, are manufactured, prepared, propagated, compounded, or processed, as those terms are defined in section 360(a)(1) of title 21, United States Code, in the United States.

(j) ''Medical Countermeasures'' means items that meet the definition of ''qualified countermeasure'' in section 247d–6a(a)(2)(A) of title 42, United States Code; ''qualified pandemic or epidemic product'' in section 247d–6d(i)(7) of title 42, United States Code; ''security countermeasure'' in section 247d–6b(c)(1)(B) of title 42, United States Code; or personal protective equipment described in part 1910 of title 29, Code of Federal Regulations.

(k) ''Public Health Industrial Base'' means the facilities and associated workforces within the United States, including research and development facilities, that help produce Essential Medicines, Medical Countermeasures, and Critical Inputs for the Healthcare and Public Health Sector.

(l) ''Qualifying Countries'' has the meaning set forth in section 225.003, Defense Federal Acquisition Regulation Supplement.

SEC. 8. *Rule of Construction*. Nothing in this order shall be construed to impair or otherwise affect:

(a) the ability of State, local, tribal, or territorial governments to timely procure necessary resources to respond to any public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), any major disaster or emergency declared under the Stafford Act (42 U.S.C. 5121 et seq.), or any national emergency declared under the National Emergencies Act (50 U.S.C. 1601 et seq.);

(b) the ability or authority of any agency to respond to the spread of COVID–19; or

(c) the authority of the Secretary of Veterans Affairs to take all necessary steps, including those necessary to implement the policy set forth in section 1 of this order, to ensure that service members, veterans, and their families continue to have full access to Essential Medicines at reasonable and affordable prices.

SEC. 9. *Severability*. If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of any of its other provisions to any other persons or circumstances shall not be affected thereby.

SEC. 10. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

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

(ii) the functions of the Director of OMB 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.

DONALD J. TRUMP.

EX. ORD. NO. 13962. ENSURING ACCESS TO UNITED STATES GOVERNMENT COVID–19 VACCINES

Ex. Ord. No. 13962, Dec. 8, 2020, 85 F.R. 79777, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Purpose*. Through unprecedented collaboration across the United States Government, industry, and international partners, the United States expects to soon have safe and effective COVID–19 vaccines available for the American people. To ensure the health and safety of our citizens, to strengthen our economy, and to enhance the security of our Nation, we must ensure that Americans have priority access to COVID–19 vaccines developed in the United States or procured by the United States Government (''United States Government COVID–19 Vaccines'').

SEC. 2. *Policy*. It is the policy of the United States to ensure Americans have priority access to free, safe, and effective COVID–19 vaccines. After ensuring the ability to meet the vaccination needs of the American people, it is in the interest of the United States to facilitate international access to United States Government COVID–19 Vaccines.

SEC. 3. *American Access to COVID–19 Vaccines*. (a) The Secretary of Health and Human Services, through Operation Warp Speed and with the support of the Secretary of Defense, shall ensure safe and effective COVID–19 vaccines are available to the American people, coordinating with public and private entities—including State, territorial, and tribal governments, where appropriate—to enable the timely distribution of such vaccines.

(b) The Secretary of Health and Human Services, in consultation with the Secretary of Defense and the heads of other executive departments and agencies (agencies), as appropriate, shall ensure that Americans have priority access to United States Government COVID–19 Vaccines, and shall ensure that the most vulnerable United States populations have first access to such vaccines.

(c) The Secretary of Health and Human Services shall ensure that a sufficient supply of COVID–19 vaccine doses is available for all Americans who choose to be vaccinated in order to safeguard America from COVID–19.

SEC. 4. *International Access to United States Government COVID–19 Vaccines*. After determining that there exists a sufficient supply of COVID–19 vaccine doses for all Americans who choose to be vaccinated, as required by section 3(b) of this order, the Secretary of Health and Human Services and the Secretary of State, in coordination with the Administrator of the United States Agency for International Development, the Chief Executive Officer of the United States International Development Finance Corporation, the Chairman and President of the Export-Import Bank of the United States, and the heads of other agencies, shall facilitate international access to United States Government COVID–19 Vaccines for allies, partners, and others, as appropriate and consistent with applicable law.

SEC. 5. *Coordination of International Access to United States Government COVID–19 Vaccines.* Within 30 days of the date of this order [Dec. 8, 2020], the Assistant to the President for National Security Affairs shall coordinate development of an interagency strategy for the implementation of section 4 of this order.

SEC. 6. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

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

(ii) the 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.

DONALD J. TRUMP.

EX. ORD. NO. 14001. A SUSTAINABLE PUBLIC HEALTH SUPPLY CHAIN

Ex. Ord. No. 14001, Jan. 21, 2021, 86 F.R. 7219, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Defense Production Act of 1950, as amended (50 U.S.C. 4501 *et seq.*), sections 319 and 361 of the Public Health Service Act (42 U.S.C. 247d and 264), sections 306 and 307 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5149 and 5150), and section 301 of title 3, United States Code, it is hereby ordered as follows:

SECTION 1. *Purpose.* The Federal Government must act urgently and effectively to combat the coronavirus disease 2019 (COVID–19) pandemic. To that end, this order directs immediate actions to secure supplies necessary for responding to the pandemic, so that those supplies are available, and remain available, to the Federal Government and State, local, Tribal, and territorial authorities, as well as to America's health care workers, health systems, and patients. These supplies are vital to the Nation's ability to reopen its schools and economy as soon and safely as possible.

SEC. 2. *Immediate Inventory of Response Supplies and Identification of Emergency Needs.* (a) The Secretary of State, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Homeland Security, and the heads of appropriate executive departments and agencies (agencies), in coordination with the COVID–19 Response Coordinator, shall:

(i) immediately review the availability of critical materials, treatments, and supplies needed to combat COVID–19 (pandemic response supplies), including personal protective equipment (PPE) and the resources necessary to effectively produce and distribute tests and vaccines at scale; and

(ii) assess, including by reviewing prior such assessments, whether United States industry can be reasonably expected to provide such supplies in a timely manner.

(b) Where a review and assessment described in section 2(a)(i) of this order identifies shortfalls in the provision of pandemic response supplies, the head of the relevant agency shall:

(i) promptly revise its operational assumptions and planning factors being used to determine the scope and prioritization, acquisition, and distribution of such supplies; and

(ii) take appropriate action using all available legal authorities, including the Defense Production Act, to fill those shortfalls as soon as practicable by acquiring additional stockpiles, improving distribution systems, building market capacity, or expanding the industrial base.

(c) Upon completing the review and assessment described in section 2(a)(i) of this order, the Secretary of Health and Human Services shall provide to the President, through the COVID–19 Response Coordinator, a report on the status and inventory of the Strategic National Stockpile.

(d) The Secretary of State, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Homeland Security, and the heads of any other agencies relevant to inventorying pandemic response supplies shall, as soon as practicable, provide to the President, through the COVID–19 Response Coordinator, a report consisting of:

(i) an assessment of the need for, and an inventory of current supplies of, key pandemic response supplies;

(ii) an analysis of their agency's capacity to produce, provide, and distribute pandemic response supplies;

(iii) an assessment of their agency's procurement of pandemic response supplies on the availability of such supplies on the open market;

(iv) an account of all existing or ongoing agency actions, contracts, and investment agreements regarding pandemic response supplies;

(v) a list of any gaps between the needs identified in section 2(a)(i) of this order and supply chain delivery, and recommendations on how to close such gaps; and

(vi) a compilation and summary of their agency's existing distribution and prioritization plans for pandemic response supplies, which shall include any assumptions or planning factors used to determine such needs and any recommendations for changes to such assumptions or factors.

(e) The COVID–19 Response Coordinator, in coordination with the heads of appropriate agencies, shall review the report described in section 2(d) of this order and submit recommendations to the President that address:

(i) whether additional use of the Defense Production Act, by the President or agencies exercising delegated authority under the Act, would be helpful; and

(ii) the extent to which liability risk, regulatory requirements, or other factors impede the development, production, and procurement of pandemic response supplies, and any actions that can be taken, consistent with law, to remove those impediments.

(f) The heads of agencies responsible for completing the requirements of this section, as appropriate and in coordination with the COVID–19 Response Coordinator, shall consult with State, local, Tribal, and territorial authorities, as well as with other entities critical to assessing the availability of and need for pandemic response supplies.

SEC. 3. *Pricing.* To take steps to address the pricing of pandemic response supplies:

(a) The Secretary of Health and Human Services shall promptly recommend to the President, through the COVID–19 Response Coordinator, whether any changes should be made to the authorities delegated to the Secretary by Executive Order 13910 of March 23, 2020 (Preventing Hoarding of Health and Medical Resources To Respond to the Spread of COVID–19) [50 U.S.C. 4512 note], with respect to scarce materials or materials the supply of which would be threatened by accumulation for the purpose of hoarding or price gouging.

(b) The Secretary of Defense, the Secretary of Health and Human Services, and the Secretary of Homeland Security shall promptly review and provide to the President, through the COVID–19 Response Coordinator, recommendations for how to address the pricing of pandemic response supplies, including whether and how to direct the use of reasonable pricing clauses in Federal contracts and investment agreements, or other related vehicles, and whether to use General Services Administration Schedules to facilitate State, local, Tribal, and territorial government buyers and compacts in purchasing pandemic response supplies using Federal supply schedules.

SEC. 4. *Pandemic Supply Chain Resilience Strategy.* Within 180 days of the date of this order [Jan. 21, 2021], the Secretary of Defense, the Secretary of Health and Human Services, and the Secretary of Homeland Security, in coordination with the Assistant to the Presi-

dent for National Security Affairs (APNSA), the Assistant to the President for Domestic Policy, the COVID–19 Response Coordinator, and the heads of any agencies or entities selected by the APNSA and COVID–19 Response Coordinator, shall provide to the President a strategy to design, build, and sustain a long-term capability in the United States to manufacture supplies for future pandemics and biological threats. This strategy shall include:

(a) mechanisms to respond to emergency supply needs of State, local, Tribal, and territorial authorities, which should include standards and processes to prioritize requests and delivery and to ensure equitable distribution based on public health criteria;

(b) an analysis of the role of foreign supply chains in America's pandemic supply chain, America's role in the international public health supply chain, and options for strengthening and better coordinating global supply chain systems in future pandemics;

(c) mechanisms to address points of failure in the supply chains and to ensure necessary redundancies;

(d) the roles of the Strategic National Stockpile and other Federal and military stockpiles in providing pandemic supplies on an ongoing or emergency basis, including their roles in allocating supplies across States, localities, tribes, and territories, sustaining supplies during a pandemic, and in contingency planning to ensure adequate preparedness for future pandemics and public health emergencies;

(e) approaches to assess and maximize the value and efficacy of public/private partnerships and the value of Federal investments in latent manufacturing capacity; and

(f) an approach to develop a multi-year implementation plan for domestic production of pandemic supplies.

SEC. 5. *Access to Strategic National Stockpile.* The Secretary of Health and Human Services shall consult with Tribal authorities and take steps, as appropriate and consistent with applicable law, to facilitate access to the Strategic National Stockpile for federally recognized Tribal governments, Indian Health Service healthcare providers, Tribal health authorities, and Urban Indian Organizations.

SEC. 6. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

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

(ii) the 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.

J.R. BIDEN, JR.

DESIGNATION AND AUTHORIZATION TO PERFORM FUNCTIONS UNDER SECTION 319F–2 OF THE PUBLIC HEALTH SERVICE ACT

Memorandum of President of the United States, Oct. 21, 2004, 69 F.R. 70349, provided:

Memorandum for the Director of the Office of Management and Budget

By the authority vested in me by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby direct you to perform the functions vested in the President under section 319F–2(c)(6) of the Public Health Service Act, 42 U.S.C. 247d–6b(c)(6).

Any reference in this memorandum to the provision of any Act shall be deemed to include references to any hereafter-enacted provision of law that is the same or substantially the same as such provision.

You are authorized and directed to publish this memorandum in the Federal Register.

GEORGE W. BUSH.

§ 247d–6c. Repealed. Pub. L. 113–5, title II, § 205, Mar. 13, 2013, 127 Stat. 179

Section, Pub. L. 108–276, § 5, July 21, 2004, 118 Stat. 860, related to reports regarding authorities under the Project BioShield Act of 2004.

§ 247d–6d. Targeted liability protections for pandemic and epidemic products and security countermeasures

(a) Liability protections

(1) In general

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

(2) Scope of claims for loss

(A) Loss

For purposes of this section, the term ''loss'' means any type of loss, including—

(i) death;

(ii) physical, mental, or emotional injury, illness, disability, or condition;

(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

(B) Scope

The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

(3) Certain conditions

Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if—

(A) the countermeasure was administered or used during the effective period of the declaration that was issued under subsection (b) with respect to the countermeasure;

(B) the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration; and

(C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the administration or use of the countermeasure, the countermeasure was administered to or used by an individual who—