
42 U.S. Code § 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 Commerce 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.

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