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 on—

"(1) the deployment of the contents of the stockpile in response to State, local, and Tribal requests;

"(2) the amount of such products that remain within the stockpile following such deployment; and

"(3) plans to replenish such products, as appropriate, including related timeframes and any barriers or limitations to replenishment.". Plans.

SEC. 2408. PROVISION OF MEDICAL COUNTERMEASURES TO INDIAN PROGRAMS AND FACILITIES.

(a) CLARIFICATION.—Section 319F–2(a)(3) of the Public Health Service Act (42 U.S.C. 247d–6b(a)(3)) is amended—

(1) in subparagraph (C), by striking "and local" and inserting "local, and Tribal"; and

(2) in subparagraph (J), by striking "and local" and inserting "local, and Tribal".

(b) DISTRIBUTION OF MEDICAL COUNTERMEASURES TO INDIAN TRIBES.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by inserting after section 319F–4 the following:

"SEC. 319F–5. PROVISION OF MEDICAL COUNTERMEASURES TO INDIAN PROGRAMS AND FACILITIES. 42 USC 247d–6f.

"In the event that the Secretary deploys the contents of the Strategic National Stockpile under section 319F–2(a), or otherwise distributes medical countermeasures to States to respond to a public health emergency declared by the Secretary under section 319, the Secretary shall, in consultation with the applicable States, make such contents or countermeasures directly available to Indian Tribes and Tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304), which may include through health programs or facilities operated by the Indian Health Service, that are affected by such public health emergency.".

SEC. 2409. GRANTS FOR STATE STRATEGIC STOCKPILES.

(a) Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended by adding at the end the following:

"(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 319, or a major disaster or emergency declared by the President under section 401 or 501, respectively, of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, in order to support the preparedness goals described in paragraphs (2) through (6) and (8) of section 2802(b). A recipient Contracts. Determination.

of such an award may not use award funds to support the stockpiling of security countermeasures (as defined in subsection (c)(1), 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 contains such information as the Secretary may require, including—

Plan.

"(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, United States Code (commonly referred to as the 'Buy American Act'); and

Outline.

"(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 319C–1 or 319C–2 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 319C–1 or 319C–2.

"(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.

Determination.

"(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.

Applicability.

"(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; Review. Revision.

"(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 319C–1 or 319C–2, 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 the date of enactment of this subsection, 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— Deadline. Update.

"(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, United States Code (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.—

Update.

"(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.

Time periods.

"(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.".

(b) GAO REPORT.—Not later than 3 years after the date on which awards are first issued pursuant to subsection (i)(1) of section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b), as added by subsection (a), the Comptroller General of the United States 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 the State

stockpiles established or maintained pursuant to this section. Such report shall include an assessment of— Assessments.

(1) coordination and communication between the Secretary of Health and Human Services and entities in receipt of an award under this section, or a lead entity designated by such entity;

(2) technical assistance provided by the Secretary of Health and Human Services to such entities; and

(3) the impact of such stockpiles on the ability of the State to prepare for and respond to a public health emergency, major disaster, or other emergency described in subsection (i)(1) of section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b), as added by subsection (a), including the availability and distribution of items from such State stockpile to health care entities and other applicable entities.

SEC. 2410. STUDY ON INCENTIVES FOR DOMESTIC PRODUCTION OF GENERIC MEDICINES.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services shall—

(1) conduct a study on the feasibility, including related to sustainment, and potential effectiveness, and utility of providing incentives for increased domestic production and capacity of specified generic medicines and their active pharmaceutical ingredients, which may include through applicable nonprofit or for-profit private entities; and

(2) not later than 1 year after the date of enactment of this Act, submit a report on such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Reports.

(b) SPECIFIED GENERIC MEDICINE.—In this section, the term "specified generic medicine" means a generic drug approved under section 505(j) of the Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that is — Definition.

(1) used to prevent, mitigate, or treat a serious or life-threatening disease or condition, or used in a common procedure that could be life-threatening without such medicine;

(2) an antibiotic or antifungal used to treat a serious or life threatening infectious disease;

(3) critical to the public health during a public health emergency; or

(4) life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition.

SEC. 2411. INCREASED MANUFACTURING CAPACITY FOR CERTAIN CRITICAL ANTIBIOTIC DRUGS. 42 USC 247d–6b note.

(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. Contracts.