117TH CONGRESS
1ST SESSION

H. R. 3635

IN THE SENATE OF THE UNITED STATES

OCTOBER 21, 2021

Received; read twice and referred to the Committee on Health, Education, Labor, and Pensions

AN ACT

To amend the Public Health Service Act with respect to the Strategic National Stockpile, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Strengthening America's Strategic National Stockpile Act of 2021''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. REIMBURSABLE TRANSFERS.

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

''(6) TRANSFERS AND REIMBURSEMENTS.—

''(A) IN GENERAL.—Without regard to chapter 5 of title 40, United States Code, the Secretary may transfer to any Federal department or agency, on a reimbursable basis, any drugs, vaccines and other biological products, medical devices, and other supplies in the stockpile if—

''(i) the transferred supplies are less than one year from expiry;

"(ii) the stockpile is able to replenish the supplies, as appropriate; and

"(iii) the Secretary decides the transfer is in the best interest of the United States Government.

"(B) USE OF REIMBURSEMENT.—Reimbursement derived from the transfer of supplies pursuant to subparagraph (A) may, to the extent and in the amounts made available in advance in appropriations Acts, be used by the Secretary to carry out this section. Funds made available pursuant to the preceding sentence are in addition to any other funds that may be made available for such purpose.

"(C) RULE OF CONSTRUCTION.—This paragraph shall not be construed to preclude transfers of products in the stockpile under other authorities.

"(D) REPORT.—Not later than September 30, 2023, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on each transfer made

under this paragraph and the amount received by the Secretary in exchange for that transfer.

''(E) SUNSET.—The authority to make transfers under this paragraph shall cease to be effective on September 30, 2024.''.

SEC. 3. EQUIPMENT MAINTENANCE.

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

(1) in subsection (a)(3)—

(A) in subparagraph (I), by striking ''; and'' and inserting a semicolon;

(B) in subparagraph (J), by striking the period at the end and inserting a semicolon; and

(C) by inserting the following new subparagraph at the end:

''(K) ensure contents of the stockpile remain in good working order and, as appropriate, conduct maintenance services on contents of the stockpile; and''; and

(2) in subsection (c)(7)(B), by adding at the end the following new clause:

''(ix) EQUIPMENT MAINTENANCE SERVICE.—In carrying out this section, the Secretary may enter into contracts for the

procurement of equipment maintenance services.''.

SEC. 4. SUPPLY CHAIN FLEXIBILITY MANUFACTURING PILOT.

(a) IN GENERAL.—Section 319F–2(a)(3) of the Public Health Service Act (42 U.S.C. 247d–6b(a)(3)), as amended by section 3, is further amended by adding at the end the following new subparagraph:

''(L) enhance medical supply chain elasticity and establish and maintain domestic reserves of critical medical supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, and other medical devices (including diagnostic tests)) by—

''(i) increasing emergency stock of critical medical supplies;

''(ii) geographically diversifying domestic production of such medical supplies, as appropriate;

''(iii) entering into cooperative agreements or partnerships with respect to manufacturing lines, facilities, and equipment

for the domestic production of such medical supplies; and

''(iv) managing, either directly or through cooperative agreements with manufacturers and distributors, domestic reserves established under this subparagraph by refreshing and replenishing stock of such medical supplies.''.

(b) REPORTING; SUNSET.—Section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)), as amended by section 2, is further amended by adding at the end the following:

''(7) REPORTING.—Not later than September 30, 2023, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on the details of each cooperative agreement or partnership entered into under paragraph (3)(L), including the amount expended by the Secretary on each such cooperative agreement or partnership.

''(8) SUNSET.—The authority to enter into cooperative agreements or partnerships pursuant to paragraph (3)(L) shall cease to be effective on September 30, 2024.''.

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

''(3) SUPPLY CHAIN ELASTICITY.—

''(A) IN GENERAL.—For the purpose of carrying out subsection (a)(3)(L), there is authorized to be appropriated $500,000,000 for each of fiscal years 2022 through 2024, to remain available until expended.

''(B) RELATION TO OTHER AMOUNTS.—The amount authorized to be appropriated by subparagraph (A) for the purpose of carrying out subsection (a)(3)(L) is in addition to any other amounts available for such purpose.''.

SEC. 5. GAO STUDY ON THE FEASIBILITY AND BENEFITS OF A USER FEE AGREEMENT.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study to investigate the feasibility of establishing user fees to offset certain Federal costs attributable to the procurement of single-source materials for the Strategic National Stockpile under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) and distributions of such materials from the Stockpile. In conducting this study, the Comptroller General shall consider, to the extent information is available—

(1) whether entities receiving such distributions generate profits from those distributions;

(2) any Federal costs attributable to such distributions;

(3) whether such user fees would provide the Secretary with funding to potentially offset procurement costs of such materials for the Strategic National Stockpile; and

(4) any other issues the Comptroller General identifies as relevant.

(b) REPORT.—Not later than February 1, 2024, the Comptroller General of the United States shall submit to the Congress a report on the findings and conclusions of the study under subsection (a).

SEC. 6. GRANTS FOR STATE STRATEGIC STOCKPILES.

Title III of the Public Health Service Act is amended by inserting after section 319F–4 of such Act (42 U.S.C. 247d–6e) the following new section:

"SEC. 319F–5. GRANTS FOR STATE STRATEGIC STOCKPILES.

''(a) IN GENERAL.—The Secretary may establish a pilot program consisting of awarding grants to States to expand or maintain a strategic stockpile of commercially available drugs, devices, personal protective equipment, and other products deemed by the State to be essential in the event of a public health emergency.

''(b) ALLOWABLE USE OF FUNDS.—

''(1) USES.—A State receiving a grant under this section may use the grant funds to—

''(A) acquire commercially available products listed pursuant to paragraph (2) for inclusion in the State's strategic stockpile;

''(B) store, maintain, and distribute products in such stockpile; and

''(C) conduct planning in connection with such activities.

''(2) LIST.—The Secretary shall develop and publish a list of the products that are eligible, as described in subsection (a), for inclusion in a State's strategic stockpile using funds received under this section.

''(3) CONSULTATION.—In developing the list under paragraph (2) and otherwise determining the allowable uses of grant funds under this section, the Secretary shall consult with States and relevant stakeholders, including public health organizations.

''(c) FUNDING REQUIREMENT.—The Secretary may not obligate or expend any funds to award grants or fund any previously awarded grants under this section for a fiscal year unless the total amount made available to carry out section 319F–2 for such fiscal year is equal to or

greater than the total amount of funds made available to carry out section 319F–2 for fiscal year 2022.

''(d) MATCHING FUNDS.—

''(1) IN GENERAL.—With respect to the costs of expanding and maintaining a strategic stockpile through a grant under this section, as a condition on receipt of the grant, a State shall make available (directly) non-Federal contributions in cash toward such costs in an amount that is equal to not less than the amount of Federal funds provided through the grant.

''(2) WAIVER.—The Secretary may waive the requirement of paragraph (1) with respect to a State for the first two years of the State receiving a grant under this section if the Secretary determines that such waiver is needed for the State to establish a strategic stockpile described in subsection (a).

''(e) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to States in establishing, expanding, and maintaining a stockpile described in subsection (a).

''(f) DEFINITION.—In this section, the term 'drug' has the meaning given to that term in section 201 of the Federal Food, Drug, and Cosmetic Act.

''(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $3,500,000,000 for each of fiscal years 2022 through 2024, to remain available until expended.

''(h) SUNSET.—The authority vested by this section terminates at the end of fiscal year 2024.''.

SEC. 7. ACTION REPORTING.

(a) IN GENERAL.—The Secretary of Health and Human Services or the Assistant Secretary for Preparedness and Response, in consultation with the Administrator of the Federal Emergency Management Agency, shall—

(1) not later than 30 days after the date of enactment of this Act, issue a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate regarding all State, local, Tribal, and territorial requests for supplies from the Strategic National Stockpile related to COVID–19; and

(2) not less than every 30 days thereafter through the end of the emergency period (as such term is defined in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B))), submit to such committees an updated version of such report.

(b) REPORTING PERIOD.—

(1) INITIAL REPORT.—The initial report under subsection (a) shall address all requests described in such subsection made during the period—

(A) beginning on January 31, 2022; and

(B) ending on the date that is 30 days before the date of submission of the report.

(2) UPDATES.—Each update to the report under subsection (a) shall address all requests described in such subsection made during the period—

(A) beginning at the end of the previous reporting period under this section; and

(B) ending on the date that is 30 days before the date of submission of the updated report.

(c) CONTENTS OF REPORT.—The report under subsection (a) (and updates thereto) shall include—

(1) the details of each request described in such subsection, including—

(A) the specific medical countermeasures, devices, personal protective equipment, and other materials requested; and

(B) the amount of such materials requested; and

(2) the outcomes of each request described in subsection (a), including—

(A) whether the request was wholly fulfilled, partially fulfilled, or denied;

(B) if the request was wholly or partially fulfilled, the fulfillment amount; and

(C) if the request was partially fulfilled or denied, a rationale for such outcome.

SEC. 8. IMPROVED, TRANSPARENT PROCESSES.

(a) IN GENERAL.—Not later than January 1, 2022, the Secretary of Health and Human Services shall develop and implement improved, transparent processes for the use and distribution 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 Strategic National Stockpile under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) (in this section referred to as the ''Stockpile'').

(b) PROCESSES.—The processes developed under subsection (a) shall include—

(1) the form and manner in which States, localities, Tribes, and territories are required to submit requests for supplies from the Stockpile;

(2) the criteria used by the Secretary of Health and Human Services in responding to such requests, including the reasons for fulfilling or denying such requests;

(3) what circumstances result in prioritization of distribution of supplies from the Stockpile to States, localities, Tribes, or territories;

(4) clear plans for future, urgent communication between the Secretary and States, localities, Tribes, and territories regarding the outcome of such requests; and

(5) any differences in the processes developed under subsection (a) for geographically related emergencies, such as weather events, and national emergencies, such as pandemics.

(c) CLASSIFICATION.—The processes developed under subsection (a) shall be unclassified to the greatest extent possible consistent with national security. The Secretary of Health and Human Services may classify portions of such processes as necessary to protect national security.

(d) REPORT TO CONGRESS.—Not later than January 1, 2022, the Secretary of Health and Human Services shall—

(1) submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate regarding the improved, transparent processes developed under this section;

(2) include in such report recommendations for opportunities for communication (by telebriefing, phone calls, or in-person meetings) between the Secretary and States, localities, Tribes, and territories regarding such improved, transparent processes; and

(3) submit such report in unclassified form to the greatest extent possible, except that the Secretary may include a classified appendix if necessary to protect national security.

SEC. 9. AUTHORIZATION OF APPROPRIATIONS.

Section 319F–2(f)(1) of the Public Health Service Act (42 U.S.C. 247d–6b(f)(1)) is amended by striking ''$610,000,000 for each of fiscal years 2019 through

2023'' and inserting ''$705,000,000 for each of fiscal years 2022 through 2024''.

Passed the House of Representatives October 20, 2021.

Attest: CHERYL L. JOHNSON,

Clerk.