

117TH CONGRESS
1ST SESSION

H. R. 3635

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

IN THE HOUSE OF REPRESENTATIVES

MAY 28, 2021

Ms. SLOTKIN (for herself, Mr. HUDSON, Ms. SCHRIER, Mr. MCKINLEY, Ms. DEGETTE, Mr. CARTER of Georgia, Mr. BUTTERFIELD, Mrs. WALORSKI, Mr. NEGUSE, Mr. UPTON, Mr. MALINOWSKI, Mr. BURGESS, Mrs. DINGELL, Mr. VAN DREW, Mr. SOTO, and Mr. FITZPATRICK) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Strengthening America’s Strategic National Stockpile
6 Act of 2021”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Reimbursable transfers.
- Sec. 3. Equipment maintenance.
- Sec. 4. Supply chain flexibility manufacturing pilot.
- Sec. 5. GAO study on the feasibility and benefits of a user fee agreement.
- Sec. 6. Grants for State strategic stockpiles.
- Sec. 7. Action reporting.
- Sec. 8. Improved, transparent processes.
- Sec. 9. Authorization of appropriations.

1 **SEC. 2. REIMBURSABLE TRANSFERS.**

2 Section 319F–2(a) of the Public Health Service Act
 3 (42 U.S.C. 247d–6b(a)) is amended by adding at the end
 4 the following:

5 “(6) TRANSFERS AND REIMBURSEMENTS.—

6 “(A) IN GENERAL.—Without regard to
 7 chapter 5 of title 40, United States Code, the
 8 Secretary may transfer to any Federal depart-
 9 ment or agency, on a reimbursable basis, any
 10 drugs, vaccines and other biological products,
 11 medical devices, and other supplies in the stock-
 12 pile if—

13 “(i) the transferred supplies are less
 14 than one year from expiry;

15 “(ii) the stockpile is able to replenish
 16 the supplies, as appropriate; and

17 “(iii) the Secretary decides the trans-
 18 fer is in the best interest of the United
 19 States Government.

20 “(B) USE OF REIMBURSEMENT.—Reim-
 21 bursement derived from the transfer of supplies

1 pursuant to subparagraph (A) may, to the ex-
2 tent and in the amounts made available in ad-
3 vance in appropriations Acts, be used by the
4 Secretary to carry out this section. Funds made
5 available pursuant to the preceding sentence are
6 in addition to any other funds that may be
7 made available for such purpose.

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

12 “(D) REPORT.—Not later than September
13 30, 2023, the Secretary shall submit to the
14 Committee on Energy and Commerce of the
15 House of Representatives and the Committee
16 on Health, Education, Labor, and Pensions of
17 the Senate a report on each transfer made
18 under this paragraph and the amount received
19 by the Secretary in exchange for that transfer.

20 “(E) SUNSET.—The authority to make
21 transfers under this paragraph shall cease to be
22 effective on September 30, 2024.”.

23 **SEC. 3. EQUIPMENT MAINTENANCE.**

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

1 (1) in subsection (a)(3)—

2 (A) in subparagraph (I), by striking “;
3 and” and inserting a semicolon;

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

7 (C) by inserting the following new subpara-
8 graph at the end:

9 “(K) ensure contents of the stockpile re-
10 main in good working order and, as appro-
11 priate, conduct maintenance services on con-
12 tents of the stockpile; and”; and

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

15 “(ix) EQUIPMENT MAINTENANCE
16 SERVICE.—In carrying out this section, the
17 Secretary may enter into contracts for the
18 procurement of equipment maintenance
19 services.”.

20 **SEC. 4. SUPPLY CHAIN FLEXIBILITY MANUFACTURING**
21 **PILOT.**

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

1 “(L) enhance medical supply chain elas-
2 ticity and establish and maintain domestic re-
3 serves of critical medical supplies (including
4 personal protective equipment, ancillary medical
5 supplies, and other applicable supplies required
6 for the administration of drugs, vaccines and
7 other biological products, and other medical de-
8 vices (including diagnostic tests)) by—

9 “(i) increasing emergency stock of
10 critical medical supplies;

11 “(ii) geographically diversifying do-
12 mestic production of such medical supplies,
13 as appropriate;

14 “(iii) entering into cooperative agree-
15 ments or partnerships with respect to man-
16 ufacturing lines, facilities, and equipment
17 for the domestic production of such med-
18 ical supplies; and

19 “(iv) managing, either directly or
20 through cooperative agreements with man-
21 ufacturers and distributors, domestic re-
22 serves established under this subparagraph
23 by refreshing and replenishing stock of
24 such medical supplies.”.

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

5 “(7) REPORTING.—Not later than September
6 30, 2023, the Secretary shall submit to the Com-
7 mittee on Energy and Commerce of the House of
8 Representatives and the Committee on Health, Edu-
9 cation, Labor and Pensions of the Senate a report
10 on the details of each cooperative agreement or part-
11 nership entered into under paragraph (3)(L), includ-
12 ing the amount expended by the Secretary on each
13 such cooperative agreement or partnership.

14 “(8) SUNSET.—The authority to enter into co-
15 operative agreements or partnerships pursuant to
16 paragraph (3)(L) shall cease to be effective on Sep-
17 tember 30, 2024.”.

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

21 “(3) SUPPLY CHAIN ELASTICITY.—

22 “(A) IN GENERAL.—For the purpose of
23 carrying out subsection (a)(3)(L), there is au-
24 thorized to be appropriated \$500,000,000 for

1 each of fiscal years 2022 through 2024, to re-
2 main available until expended.

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

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

10 (a) IN GENERAL.—The Comptroller General of the
11 United States shall conduct a study to investigate the fea-
12 sibility of establishing user fees to offset certain Federal
13 costs attributable to the procurement of single-source ma-
14 terials for the Strategic National Stockpile under section
15 319F–2 of the Public Health Service Act (42 U.S.C.
16 247d–6b) and distributions of such materials from the
17 Stockpile. In conducting this study, the Comptroller Gen-
18 eral shall consider, to the extent information is available—

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

21 (2) any Federal costs attributable to such dis-
22 tributions;

23 (3) whether such user fees would provide the
24 Secretary with funding to potentially offset procure-

1 ment costs of such materials for the Strategic Na-
2 tional Stockpile; and

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

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

9 **SEC. 6. GRANTS FOR STATE STRATEGIC STOCKPILES.**

10 Title III of the Public Health Service Act is amended
11 by inserting after section 319F–4 of such Act (42 U.S.C.
12 247d–6e) the following new section:

13 **“SEC. 319F-5. GRANTS FOR STATE STRATEGIC STOCKPILES.**

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

20 “(b) ALLOWABLE USE OF FUNDS.—

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

23 “(A) acquire commercially available prod-
24 ucts listed pursuant to paragraph (2) for inclu-
25 sion in the State’s strategic stockpile;

1 “(B) store, maintain, and distribute prod-
2 ucts in such stockpile; and

3 “(C) conduct planning in connection with
4 such activities.

5 “(2) LIST.—The Secretary shall develop and
6 publish a list of the products that are eligible, as de-
7 scribed in subsection (a), for inclusion in a State’s
8 strategic stockpile using funds received under this
9 section.

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

15 “(c) FUNDING REQUIREMENT.—The Secretary may
16 not obligate or expend any funds to award grants or fund
17 any previously awarded grants under this section for a fis-
18 cal year unless the total amount made available to carry
19 out section 319F–2 for such fiscal year is equal to or
20 greater than the total amount of funds made available to
21 carry out section 319F–2 for fiscal year 2022.

22 “(d) MATCHING FUNDS.—

23 “(1) IN GENERAL.—With respect to the costs of
24 expanding and maintaining a strategic stockpile
25 through a grant under this section, as a condition on

1 receipt of the grant, a State shall make available (di-
2 rectly) non-Federal contributions in cash toward
3 such costs in an amount that is equal to not less
4 than the amount of Federal funds provided through
5 the grant.

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

12 “(e) TECHNICAL ASSISTANCE.—The Secretary shall
13 provide technical assistance to States in establishing, ex-
14 panding, and maintaining a stockpile described in sub-
15 section (a).

16 “(f) DEFINITION.—In this section, the term ‘drug’
17 has the meaning given to that term in section 201 of the
18 Federal Food, Drug, and Cosmetic Act.

19 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
20 carry out this section, there is authorized to be appro-
21 priated \$3,500,000,000 for each of fiscal years 2022
22 through 2024, to remain available until expended.

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

1 **SEC. 7. ACTION REPORTING.**

2 (a) IN GENERAL.—The Secretary of Health and
3 Human Services or the Assistant Secretary for Prepared-
4 ness and Response, in consultation with the Administrator
5 of the Federal Emergency Management Agency, shall—

6 (1) not later than 30 days after the date of en-
7 actment of this Act, issue a report to the Committee
8 on Energy and Commerce of the House of Rep-
9 resentatives and the Committee on Health, Edu-
10 cation, Labor, and Pensions of the Senate regarding
11 all State, local, Tribal, and territorial requests for
12 supplies from the Strategic National Stockpile re-
13 lated to COVID–19; and

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

20 (b) REPORTING PERIOD.—

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

24 (A) beginning on January 31, 2022; and

25 (B) ending on the date that is 30 days be-
26 fore the date of submission of the report.

1 (2) UPDATES.—Each update to the report
2 under subsection (a) shall address all requests de-
3 scribed in such subsection made during the period—

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

6 (B) ending on the date that is 30 days be-
7 fore the date of submission of the updated re-
8 port.

9 (c) CONTENTS OF REPORT.—The report under sub-
10 section (a) (and updates thereto) shall include—

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

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

16 (B) the amount of such materials re-
17 quested; and

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

20 (A) whether the request was wholly ful-
21 filled, partially fulfilled, or denied;

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

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

1 **SEC. 8. IMPROVED, TRANSPARENT PROCESSES.**

2 (a) IN GENERAL.—Not later than January 1, 2022,
3 the Secretary of Health and Human Services shall develop
4 and implement improved, transparent processes for the
5 use and distribution of drugs, vaccines and other biological
6 products, medical devices, and other supplies (including
7 personal protective equipment, ancillary medical supplies,
8 and other applicable supplies required for the administra-
9 tion of drugs, vaccines and other biological products, med-
10 ical devices, and diagnostic tests) in the Strategic National
11 Stockpile under section 319F–2 of the Public Health Serv-
12 ice Act (42 U.S.C. 247d–6b) (in this section referred to
13 as the “Stockpile”).

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

16 (1) the form and manner in which States, local-
17 ities, Tribes, and territories are required to submit
18 requests for supplies from the Stockpile;

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

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

1 (4) clear plans for future, urgent communica-
2 tion between the Secretary and States, localities,
3 Tribes, and territories regarding the outcome of
4 such requests; and

5 (5) any differences in the processes developed
6 under subsection (a) for geographically related emer-
7 gencies, such as weather events, and national emer-
8 gencies, such as pandemics.

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

14 (d) REPORT TO CONGRESS.—Not later than January
15 1, 2022, the Secretary of Health and Human Services
16 shall—

17 (1) submit a report to the Committee on En-
18 ergy and Commerce of the House of Representatives
19 and the Committee on Health, Education, Labor,
20 and Pensions of the Senate regarding the improved,
21 transparent processes developed under this section;

22 (2) include in such report recommendations for
23 opportunities for communication (by telebriefing,
24 phone calls, or in-person meetings) between the Sec-

1 retary and States, localities, Tribes, and territories
2 regarding such improved, transparent processes; and
3 (3) submit such report in unclassified form to
4 the greatest extent possible, except that the Sec-
5 retary may include a classified appendix if necessary
6 to protect national security.

7 **SEC. 9. AUTHORIZATION OF APPROPRIATIONS.**

8 Section 319F-2(f)(1) of the Public Health Service
9 Act (42 U.S.C. 247d-6b(f)(1)) is amended by striking
10 “\$610,000,000 for each of fiscal years 2019 through
11 2023” and inserting “\$705,000,000 for each of fiscal
12 years 2022 through 2024”.

○