

117TH CONGRESS
1ST SESSION

H. R. 3635

AN ACT

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,*

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

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

5 (b) TABLE OF CONTENTS.—The table of contents for
 6 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.

7 **SEC. 2. REIMBURSABLE TRANSFERS.**

8 Section 319F–2(a) of the Public Health Service Act
 9 (42 U.S.C. 247d–6b(a)) is amended by adding at the end
 10 the following:

11 “(6) TRANSFERS AND REIMBURSEMENTS.—

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

19 “(i) the transferred supplies are less
 20 than one year from expiry;

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

3 “(iii) the Secretary decides the trans-
4 fer is in the best interest of the United
5 States Government.

6 “(B) USE OF REIMBURSEMENT.—Reim-
7 bursement derived from the transfer of supplies
8 pursuant to subparagraph (A) may, to the ex-
9 tent and in the amounts made available in ad-
10 vance in appropriations Acts, be used by the
11 Secretary to carry out this section. Funds made
12 available pursuant to the preceding sentence are
13 in addition to any other funds that may be
14 made available for such purpose.

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

19 “(D) REPORT.—Not later than September
20 30, 2023, the Secretary shall submit to the
21 Committee on Energy and Commerce of the
22 House of Representatives and the Committee
23 on Health, Education, Labor, and Pensions of
24 the Senate a report on each transfer made

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

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

6 **SEC. 3. EQUIPMENT MAINTENANCE.**

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

9 (1) in subsection (a)(3)—

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

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

15 (C) by inserting the following new subpara-
 16 graph at the end:

17 “(K) ensure contents of the stockpile re-
 18 main in good working order and, as appro-
 19 priate, conduct maintenance services on con-
 20 tents of the stockpile; and”; and

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

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

1 procurement of equipment maintenance
2 services.”.

3 **SEC. 4. SUPPLY CHAIN FLEXIBILITY MANUFACTURING**
4 **PILOT.**

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

9 “(L) enhance medical supply chain elas-
10 ticity and establish and maintain domestic re-
11 serves of critical medical supplies (including
12 personal protective equipment, ancillary medical
13 supplies, and other applicable supplies required
14 for the administration of drugs, vaccines and
15 other biological products, and other medical de-
16 vices (including diagnostic tests)) by—

17 “(i) increasing emergency stock of
18 critical medical supplies;

19 “(ii) geographically diversifying do-
20 mestic production of such medical supplies,
21 as appropriate;

22 “(iii) entering into cooperative agree-
23 ments or partnerships with respect to man-
24 ufacturing lines, facilities, and equipment

1 for the domestic production of such med-
2 ical supplies; and

3 “(iv) managing, either directly or
4 through cooperative agreements with man-
5 ufacturers and distributors, domestic re-
6 serves established under this subparagraph
7 by refreshing and replenishing stock of
8 such medical supplies.”.

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

13 “(7) REPORTING.—Not later than September
14 30, 2023, the Secretary shall submit to the Com-
15 mittee on Energy and Commerce of the House of
16 Representatives and the Committee on Health, Edu-
17 cation, Labor and Pensions of the Senate a report
18 on the details of each cooperative agreement or part-
19 nership entered into under paragraph (3)(L), includ-
20 ing the amount expended by the Secretary on each
21 such cooperative agreement or partnership.

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

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

4 “(3) SUPPLY CHAIN ELASTICITY.—

5 “(A) IN GENERAL.—For the purpose of
 6 carrying out subsection (a)(3)(L), there is au-
 7 thorized to be appropriated \$500,000,000 for
 8 each of fiscal years 2022 through 2024, to re-
 9 main available until expended.

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

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

17 (a) IN GENERAL.—The Comptroller General of the
 18 United States shall conduct a study to investigate the fea-
 19 sibility of establishing user fees to offset certain Federal
 20 costs attributable to the procurement of single-source ma-
 21 terials for the Strategic National Stockpile under section
 22 319F–2 of the Public Health Service Act (42 U.S.C.
 23 247d–6b) and distributions of such materials from the
 24 Stockpile. In conducting this study, the Comptroller Gen-
 25 eral shall consider, to the extent information is available—

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

3 (2) any Federal costs attributable to such dis-
4 tributions;

5 (3) whether such user fees would provide the
6 Secretary with funding to potentially offset procure-
7 ment costs of such materials for the Strategic Na-
8 tional Stockpile; and

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

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

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

16 Title III of the Public Health Service Act is amended
17 by inserting after section 319F–4 of such Act (42 U.S.C.
18 247d–6e) the following new section:

19 **“SEC. 319F–5. GRANTS FOR STATE STRATEGIC STOCKPILES.**

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

1 “(b) ALLOWABLE USE OF FUNDS.—

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

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

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

9 “(C) conduct planning in connection with
10 such activities.

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

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

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

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

3 “(d) MATCHING FUNDS.—

4 “(1) IN GENERAL.—With respect to the costs of
5 expanding and maintaining a strategic stockpile
6 through a grant under this section, as a condition on
7 receipt of the grant, a State shall make available (di-
8 rectly) non-Federal contributions in cash toward
9 such costs in an amount that is equal to not less
10 than the amount of Federal funds provided through
11 the grant.

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

18 “(e) TECHNICAL ASSISTANCE.—The Secretary shall
19 provide technical assistance to States in establishing, ex-
20 panding, and maintaining a stockpile described in sub-
21 section (a).

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

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

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

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

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

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

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

1 (b) REPORTING PERIOD.—

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

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

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

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

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

13 (B) ending on the date that is 30 days be-
14 fore the date of submission of the updated re-
15 port.

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

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

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

23 (B) the amount of such materials re-
24 quested; and

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

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

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

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

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

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

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

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

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

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

11 (4) clear plans for future, urgent communica-
12 tion between the Secretary and States, localities,
13 Tribes, and territories regarding the outcome of
14 such requests; and

15 (5) any differences in the processes developed
16 under subsection (a) for geographically related emer-
17 gencies, such as weather events, and national emer-
18 gencies, such as pandemics.

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

1 (d) REPORT TO CONGRESS.—Not later than January
2 1, 2022, the Secretary of Health and Human Services
3 shall—

4 (1) submit a report to the Committee on En-
5 ergy and Commerce of the House of Representatives
6 and the Committee on Health, Education, Labor,
7 and Pensions of the Senate regarding the improved,
8 transparent processes developed under this section;

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

14 (3) submit such report in unclassified form to
15 the greatest extent possible, except that the Sec-
16 retary may include a classified appendix if necessary
17 to protect national security.

18 **SEC. 9. AUTHORIZATION OF APPROPRIATIONS.**

19 Section 319F–2(f)(1) of the Public Health Service
20 Act (42 U.S.C. 247d–6b(f)(1)) is amended by striking
21 “\$610,000,000 for each of fiscal years 2019 through

1 2023” and inserting “\$705,000,000 for each of fiscal
2 years 2022 through 2024”.

Passed the House of Representatives October 20,
2021.

Attest:

Clerk.

117TH CONGRESS
1ST SESSION

H. R. 3635

AN ACT

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