

116TH CONGRESS
2D SESSION

H. R. 7574

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

IN THE HOUSE OF REPRESENTATIVES

JULY 13, 2020

Ms. SLOTKIN (for herself, Mrs. BROOKS of Indiana, Ms. ESHOO, Mr. CARTER of Georgia, Mrs. DINGELL, Mrs. WALORSKI, Ms. DEGETTE, Mr. MCKINLEY, Mr. BUTTERFIELD, Mr. VAN DREW, Mr. SOTO, Mr. UPTON, Mr. MALINOWSKI, Mr. HUDSON, Ms. SCHRIER, Mr. GIANFORTE, Mr. CISNEROS, Mr. NEGUSE, and Mr. BURGESS) 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 2020”.

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 six months 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 be used by
2 the Secretary, without further appropriation
3 and without fiscal year limitation, to carry out
4 this section.

5 “(C) REPORT.—Not later than September
6 30, 2022, the Secretary shall submit to the
7 Committee on Energy and Commerce of the
8 House of Representatives and the Committee
9 on Health, Education, Labor, and Pensions of
10 the Senate a report on each transfer made
11 under this paragraph and the amount received
12 by the Secretary in exchange for that transfer.

13 “(D) SUNSET.—The authority to make
14 transfers under this paragraph shall cease to be
15 effective on September 30, 2023.”.

16 **SEC. 3. EQUIPMENT MAINTENANCE.**

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

19 (1) in subsection (a)(3)—

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

22 (B) by inserting the following new sub-
23 paragraph at the end:

24 “(K) ensure contents of the stockpile re-
25 main in good working order and, as appro-

1 appropriate, conduct maintenance services on con-
2 tents of the stockpile; and”;

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

5 “(ix) EQUIPMENT MAINTENANCE
6 SERVICE.—In carrying out this section, the
7 Secretary may enter into contracts for the
8 procurement of equipment maintenance
9 services.”.

10 **SEC. 4. SUPPLY CHAIN FLEXIBILITY MANUFACTURING**
11 **PILOT.**

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

16 “(L) enhance medical supply chain elas-
17 ticity and establish and maintain domestic re-
18 serves of critical medical supplies (including
19 personal protective equipment, ancillary medical
20 supplies, and other applicable supplies required
21 for the administration of drugs, vaccines and
22 other biological products, and other medical de-
23 vices (including diagnostic tests)) by—

24 “(i) increasing emergency stock of
25 critical medical supplies;

1 “(ii) geographically diversifying pro-
2 duction of such medical supplies;

3 “(iii) purchasing, leasing, or entering
4 into joint ventures with respect to facilities
5 and equipment for the production of such
6 medical supplies; and

7 “(iv) working with distributors of
8 such medical supplies to manage the do-
9 mestic reserves established under this sub-
10 paragraph by refreshing and replenishing
11 stock of such medical supplies.”.

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

16 “(7) REPORTING.—Not later than September
17 30, 2022, the Secretary shall submit to the Com-
18 mittee on Energy and Commerce of the House of
19 Representatives and the Committee on Health, Edu-
20 cation, Labor, and Pensions of the Senate a report
21 on the details of each purchase, lease, or joint ven-
22 ture entered into under paragraph (3)(L), including
23 the amount expended by the Secretary on each such
24 purchase, lease, or joint venture.

1 “(8) SUNSET.—The authority to make pur-
2 chases, leases, or joint ventures pursuant to para-
3 graph (3)(L) shall cease to be effective on Sep-
4 tember 30, 2023.”.

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

8 “(3) SUPPLY CHAIN ELASTICITY.—

9 “(A) IN GENERAL.—For the purpose of
10 carrying out subsection (a)(3)(L), there is au-
11 thorized to be appropriated \$500,000,000 for
12 each of fiscal years 2020 through 2023, to re-
13 main available until expended.

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

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

21 (a) IN GENERAL.—The Comptroller General of the
22 United States shall conduct a study to investigate the fea-
23 sibility of establishing user fees to offset certain Federal
24 costs attributable to the procurement of single-source ma-
25 terials for the Strategic National Stockpile under section

1 319F–2 of the Public Health Service Act (42 U.S.C.
2 247d–6b) and distributions of such materials from the
3 Stockpile. In conducting this study, the Comptroller Gen-
4 eral shall consider, to the extent information is available—

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

7 (2) any Federal costs attributable to such dis-
8 tributions;

9 (3) whether such user fees would provide the
10 Secretary with funding to potentially offset procure-
11 ment costs of such materials for the Strategic Na-
12 tional Stockpile; and

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

15 (b) REPORT.—Not later than February 1, 2023, the
16 Comptroller General of the United States shall submit to
17 the Congress a report on the findings and conclusions of
18 the study under subsection (a).

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

20 Title III of the Public Health Service Act is amended
21 by inserting after section 319F–4 of such Act (42 U.S.C.
22 247d–6e) the following new section:

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

24 “(a) IN GENERAL.—The Secretary may establish a
25 pilot program consisting of awarding grants to States to

1 expand or maintain a strategic stockpile of commercially
2 available drugs, medical equipment, personal protective
3 equipment, and other products deemed by the State to be
4 essential in the event of a public health emergency.

5 “(b) ALLOWABLE USE OF FUNDS.—

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

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

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

13 “(C) conduct planning in connection with
14 such activities.

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

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

1 “(c) FUNDING REQUIREMENT.—The Secretary may
2 not obligate or expend any funds to award grants or fund
3 any previously awarded grants under this section for a fis-
4 cal year unless the total amount made available to carry
5 out section 319F–2 for such fiscal year is equal to or
6 greater than the total amount of funds made available to
7 carry out section 319F–2 for fiscal year 2020.

8 “(d) MATCHING FUNDS.—

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

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

23 “(e) TECHNICAL ASSISTANCE.—The Secretary shall
24 provide technical assistance to States in establishing, ex-

1 panding, and maintaining a stockpile described in sub-
2 section (a).

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

6 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
7 carry out this section, there is authorized to be appro-
8 priated \$3,500,000,000 for each of fiscal years 2020
9 through 2023, to remain available until expended.

10 “(h) SUNSET.—The authority vested by this section
11 terminates at the end of fiscal year 2023.”.

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

13 (a) IN GENERAL.—The Assistant Secretary for Pre-
14 paredness and Response (in this section referred to as the
15 “Assistant Secretary”), in coordination with the Adminis-
16 trator of the Federal Emergency Management Agency,
17 shall—

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

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

7 (b) REPORTING PERIOD.—

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

11 (A) beginning on January 31, 2020; and

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

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

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

19 (B) ending on the date that is 30 days be-
20 fore the date of submission of the updated re-
21 port.

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

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

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

4 (B) the amount of such materials re-
5 quested; and

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

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

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

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

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

15 (a) IN GENERAL.—Not later than January 1, 2021,
16 the Secretary of Health and Human Services, in collabora-
17 tion with the Assistant Secretary for Preparedness and
18 Response and the Director of the Centers for Disease Con-
19 trol and Prevention, shall develop and implement im-
20 proved, transparent processes for the use and distribution
21 of drugs, vaccines and other biological products, medical
22 devices, and other supplies (including personal protective
23 equipment, ancillary medical supplies, and other applicable
24 supplies required for the administration of drugs, vaccines
25 and other biological products, medical devices, and diag-

1 nostic tests) in the Strategic National Stockpile under sec-
2 tion 319F–2 of the Public Health Service Act (42 U.S.C.
3 247d–6b) (in this section referred to as the “Stockpile”).

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

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

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

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

16 (4) clear plans for future, urgent communica-
17 tion between the Secretary and States, localities,
18 Tribes, and territories regarding the outcome of
19 such requests; and

20 (5) any differences in the processes developed
21 under subsection (a) for geographically related emer-
22 gencies, such as weather events, and national emer-
23 gencies, such as pandemics.

24 (c) CLASSIFICATION.—The processes developed under
25 subsection (a) shall be unclassified to the greatest extent

1 possible consistent with national security. The Secretary
2 of Health and Human Services may classify portions of
3 such processes as necessary to protect national security.

4 (d) REPORT TO CONGRESS.—Not later than January
5 1, 2021, the Secretary of Health and Human Services
6 shall—

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

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

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

21 **SEC. 9. AUTHORIZATION OF APPROPRIATIONS.**

22 Section 319F–2(f)(1) of the Public Health Service
23 Act (42 U.S.C. 247d–6b(f)(1)) is amended by striking
24 “\$610,000,000 for each of fiscal years 2019 through

1 2023” and inserting “\$705,000,000 for each of fiscal
2 years 2020 through 2023”.

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