

Union Calendar No. 418

116TH CONGRESS
2^D SESSION

H. R. 7574

[Report No. 116–518]

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

SEPTEMBER 18, 2020

Additional sponsors: Mr. LUJÁN and Mr. FITZPATRICK

SEPTEMBER 18, 2020

Reported with an amendment; committed to the Committee of the Whole
House on the State of the Union and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on July 13, 2020]

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 Act*
 6 *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.

9 **SEC. 2. REIMBURSABLE TRANSFERS.**

10 *Section 319F–2(a) of the Public Health Service Act*
 11 *(42 U.S.C. 247d–6b(a)) is amended by adding at the end*
 12 *the following:*

13 “(6) *TRANSFERS AND REIMBURSEMENTS.*—

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

1 “(i) the transferred supplies are less
2 than one year from expiry;

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

5 “(iii) the Secretary decides the transfer
6 is in the best interest of the United States
7 Government.

8 “(B) *USE OF REIMBURSEMENT.*—Reim-
9 bursement derived from the transfer of supplies
10 pursuant to subparagraph (A) may be used by
11 the Secretary, without further appropriation and
12 without fiscal year limitation, to carry out this
13 section.

14 “(C) *RULE OF CONSTRUCTION.*—This para-
15 graph shall not be construed to preclude transfers
16 of products in the stockpile under other authori-
17 ties.

18 “(D) *REPORT.*—Not later than September
19 30, 2022, the Secretary shall submit to the Com-
20 mittee on Energy and Commerce of the House of
21 Representatives and the Committee on Health,
22 Education, Labor, and Pensions of the Senate a
23 report on each transfer made under this para-
24 graph and the amount received by the Secretary
25 in exchange for that transfer.

1 “(E) *SUNSET.*—*The authority to make*
 2 *transfers under this paragraph shall cease to be*
 3 *effective on September 30, 2023.*”.

4 **SEC. 3. EQUIPMENT MAINTENANCE.**

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

7 *(1) in subsection (a)(3)—*

8 *(A) in subparagraph (I), by striking “;*
 9 *and” and inserting a semicolon;*

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

12 *(C) by inserting the following new subpara-*
 13 *graph at the end:*

14 *“(K) ensure contents of the stockpile remain*
 15 *in good working order and, as appropriate, con-*
 16 *duct maintenance services on contents of the*
 17 *stockpile; and”; and*

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

20 *“(ix) EQUIPMENT MAINTENANCE SERV-*
 21 *ICE.—In carrying out this section, the Sec-*
 22 *retary may enter into contracts for the pro-*
 23 *curement of equipment maintenance serv-*
 24 *ices.”.*

1 **SEC. 4. SUPPLY CHAIN FLEXIBILITY MANUFACTURING**
2 **PILOT.**

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

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

15 “(i) increasing emergency stock of crit-
16 ical medical supplies;

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

20 “(iii) entering into cooperative agree-
21 ments or partnerships with respect to man-
22 ufacturing lines, facilities, and equipment
23 for the domestic production of such medical
24 supplies; and

25 “(iv) managing, either directly or
26 through cooperative agreements with manu-

1 *facturers and distributors, domestic reserves*
 2 *established under this subparagraph by re-*
 3 *freshing and replenishing stock of such med-*
 4 *ical supplies.”.*

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

9 “(7) *REPORTING.*—Not later than September 30,
 10 2022, the Secretary shall submit to the Committee on
 11 *Energy and Commerce of the House of Representa-*
 12 *tives and the Committee on Health, Education, Labor*
 13 *and Pensions of the Senate a report on the details of*
 14 *each cooperative agreement or partnership entered*
 15 *into under paragraph (3)(L), including the amount*
 16 *expended by the Secretary on each such cooperative*
 17 *agreement or partnership.*

18 “(8) *SUNSET.*—The authority to enter into coop-
 19 *erative agreements or partnerships pursuant to para-*
 20 *graph (3)(L) shall cease to be effective on September*
 21 *30, 2023.”.*

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

25 “(3) *SUPPLY CHAIN ELASTICITY.*—

1 “(A) *IN GENERAL.*—For the purpose of car-
 2 rying out subsection (a)(3)(L), there is author-
 3 ized to be appropriated \$500,000,000 for each of
 4 fiscal years 2020 through 2023, to remain avail-
 5 able until expended.

6 “(B) *RELATION TO OTHER AMOUNTS.*—The
 7 amount authorized to be appropriated by sub-
 8 paragraph (A) for the purpose of carrying out
 9 subsection (a)(3)(L) is in addition to any other
 10 amounts available for such purpose.”.

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

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

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

24 (2) *any Federal costs attributable to such dis-*
 25 *tributions;*

1 (3) *whether such user fees would provide the Sec-*
 2 *retary with funding to potentially offset procurement*
 3 *costs of such materials for the Strategic National*
 4 *Stockpile; and*

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

7 (b) *REPORT.*—*Not later than February 1, 2023, the*
 8 *Comptroller General of the United States shall submit to*
 9 *the Congress a report on the findings and conclusions of*
 10 *the study under subsection (a).*

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

12 *Title III of the Public Health Service Act is amended*
 13 *by inserting after section 319F–4 of such Act (42 U.S.C.*
 14 *247d–6e) the following new section:*

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

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

22 “(b) *ALLOWABLE USE OF FUNDS.*—

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

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

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

6 “(C) conduct planning in connection with
7 such activities.

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

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

18 “(c) *FUNDING REQUIREMENT.*—The Secretary may
19 not obligate or expend any funds to award grants or fund
20 any previously awarded grants under this section for a fis-
21 cal year unless the total amount made available to carry
22 out section 319F–2 for such fiscal year is equal to or greater
23 than the total amount of funds made available to carry out
24 section 319F–2 for fiscal year 2020.

25 “(d) *MATCHING FUNDS.*—

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

8 “(2) *WAIVER.*—*The Secretary may waive the re-*
9 *quirement of paragraph (1) with respect to a State*
10 *for the first two years of the State receiving a grant*
11 *under this section if the Secretary determines that*
12 *such waiver is needed for the State to establish a stra-*
13 *tegic stockpile described in subsection (a).*

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

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

21 “(g) *AUTHORIZATION OF APPROPRIATIONS.*—*To carry*
22 *out this section, there is authorized to be appropriated*
23 *\$3,500,000,000 for each of fiscal years 2020 through 2023,*
24 *to remain available until expended.*

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

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

4 (a) *IN GENERAL.*—*The Assistant Secretary for Pre-*
5 *paredness and Response (in this section referred to as the*
6 *“Assistant Secretary”), in coordination with the Adminis-*
7 *trator of the Federal Emergency Management Agency,*
8 *shall—*

9 (1) *not later than 30 days after the date of en-*
10 *actment of this Act, issue a report to the Committee*
11 *on Energy and Commerce of the House of Representa-*
12 *tives and the Committee on Health, Education,*
13 *Labor, and Pensions of the Senate regarding all*
14 *State, local, Tribal, and territorial requests for sup-*
15 *plies from the Strategic National Stockpile related to*
16 *COVID–19; and*

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

22 (b) *REPORTING PERIOD.*—

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

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

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

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

7 (A) beginning at the end of the previous re-
8 porting period under this section; and

9 (B) ending on the date that is 30 days be-
10 fore the date of submission of the updated report.

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

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

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

18 (B) the amount of such materials requested;
19 and

20 (2) the outcomes of each request described in sub-
21 section (a), including—

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

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

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

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

4 (a) *IN GENERAL.*—Not later than January 1, 2021,
5 the Secretary of Health and Human Services, in collabora-
6 tion with the Assistant Secretary for Preparedness and Re-
7 sponse and the Director of the Centers for Disease Control
8 and Prevention, shall develop and implement improved,
9 transparent processes for the use and distribution of drugs,
10 vaccines and other biological products, medical devices, and
11 other supplies (including personal protective equipment,
12 ancillary medical supplies, and other applicable supplies
13 required for the administration of drugs, vaccines and other
14 biological products, medical devices, and diagnostic tests)
15 in the Strategic National Stockpile under section 319F–2
16 of the Public Health Service Act (42 U.S.C. 247d–6b) (in
17 this section referred to as the “Stockpile”).

18 (b) *PROCESSES.*—The processes developed under sub-
19 section (a) shall include—

20 (1) the form and manner in which States, local-
21 ities, Tribes, and territories are required to submit re-
22 quests for supplies from the Stockpile;

23 (2) the criteria used by the Secretary of Health
24 and Human Services in responding to such requests,

1 *including the reasons for fulfilling or denying such*
2 *requests;*

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

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

10 *(5) any differences in the processes developed*
11 *under subsection (a) for geographically related emer-*
12 *gencies, such as weather events, and national emer-*
13 *gencies, such as pandemics.*

14 *(c) CLASSIFICATION.—The processes developed under*
15 *subsection (a) shall be unclassified to the greatest extent pos-*
16 *sible consistent with national security. The Secretary of*
17 *Health and Human Services may classify portions of such*
18 *processes as necessary to protect national security.*

19 *(d) REPORT TO CONGRESS.—Not later than January*
20 *1, 2021, the Secretary of Health and Human Services*
21 *shall—*

22 *(1) submit a report to the Committee on Energy*
23 *and Commerce of the House of Representatives and*
24 *the Committee on Health, Education, Labor, and*

1 *Pensions of the Senate regarding the improved, trans-*
2 *parent processes developed under this section;*

3 *(2) include in such report recommendations for*
4 *opportunities for communication (by telebriefing,*
5 *phone calls, or in-person meetings) between the Sec-*
6 *retary and States, localities, Tribes, and territories*
7 *regarding such improved, transparent processes; and*
8 *(3) submit such report in unclassified form to*
9 *the greatest extent possible, except that the Secretary*
10 *may include a classified appendix if necessary to pro-*
11 *tect national security.*

12 **SEC. 9. AUTHORIZATION OF APPROPRIATIONS.**

13 *Section 319F–2(f)(1) of the Public Health Service Act*
14 *(42 U.S.C. 247d-6b(f)(1)) is amended by striking*
15 *“\$610,000,000 for each of fiscal years 2019 through 2023”*
16 *and inserting “\$705,000,000 for each of fiscal years 2020*
17 *through 2023”.*

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[Report No. 116-518]

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