

117TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Ms. HASSAN (for herself and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on

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. Equipment maintenance.
- Sec. 3. Supply chain flexibility manufacturing pilot.
- Sec. 4. GAO study on the feasibility and benefits of a user fee agreement.

- Sec. 5. Grants for State strategic stockpiles.
- Sec. 6. Action reporting.
- Sec. 7. Improved, transparent processes.
- Sec. 8. Authorization of appropriations.

1 **SEC. 2. EQUIPMENT MAINTENANCE.**

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

4 (1) in subsection (a)(3)—

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

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

10 (C) by inserting the following new subpara-
11 graph at the end:

12 “(K) ensure contents of the stockpile re-
13 main in good working order and, as appro-
14 priate, conduct maintenance services on con-
15 tents of the stockpile and dispose of contents
16 that are no longer in working order; and”;

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

19 “(ix) EQUIPMENT MAINTENANCE
20 SERVICE.—In carrying out this section, the
21 Secretary may enter into contracts for the
22 procurement of equipment maintenance
23 services.”.

1 **SEC. 3. SUPPLY CHAIN FLEXIBILITY MANUFACTURING**
2 **PILOT.**

3 (a) IN GENERAL.—Section 319F–2(a)(3) of the Pub-
4 lic Health Service Act (42 U.S.C. 247d–6b(a)(3)), as
5 amended by section 2, is further amended by adding at
6 the end the 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
10 such personal protective equipment, ancillary
11 medical supplies, and other applicable supplies
12 required for the administration of drugs, vac-
13 cines and other biological products, and other
14 medical devices (including diagnostic tests) as
15 the Secretary, in consultation with the Public
16 Health Emergency Medical Countermeasures
17 Enterprise, determines appropriate) by—

18 “(i) increasing or contracting emer-
19 gency stock of critical medical supplies, as
20 appropriate;

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

24 “(iii) entering into cooperative agree-
25 ments or partnerships with respect to man-
26 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)) is
11 amended by adding at the end the following:

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

21 “(7) SUNSET.—The authority to enter into co-
22 operative agreements or partnerships pursuant to
23 paragraph (3)(L) shall cease to be effective on Sep-
24 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. 4. 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, including an analysis of an overall
9 estimate of such annual procurement costs;

10 (4) whether funding certainty through regular
11 appropriations would facilitate more appropriate
12 long term investments and contracts related to the
13 Strategic National Stockpile; and

14 (5) any other issues the Comptroller General
15 identifies as relevant.

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

20 **SEC. 5. GRANTS FOR STATE STRATEGIC STOCKPILES.**

21 Title III of the Public Health Service Act is amended
22 by inserting after section 319F–4 of such Act (42 U.S.C.
23 247d–6e) the following new section:

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

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

8 “(b) ALLOWABLE USE OF FUNDS.—

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

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

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

16 “(C) conduct planning in connection with
17 such activities.

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

23 “(3) CONSULTATION.—In developing the list
24 under paragraph (2) and otherwise determining the
25 allowable uses of grant funds under this section, the

1 Secretary shall consult with States and relevant
2 stakeholders, including public health organizations.

3 “(c) FUNDING REQUIREMENT.—The Secretary may
4 not obligate or expend any funds to award grants or fund
5 any previously awarded grants under this section for a fis-
6 cal year unless the total amount made available to carry
7 out section 319F–2 for such fiscal year is equal to or
8 greater than the total amount of funds made available to
9 carry out section 319F–2 for fiscal year 2021.

10 “(d) MATCHING FUNDS.—

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

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

1 “(e) TECHNICAL ASSISTANCE.—The Secretary shall
2 provide technical assistance to States in establishing, ex-
3 panding, and maintaining a stockpile described in sub-
4 section (a).

5 “(f) ANNUAL REPORTS.—Each State receiving a
6 grant under this section shall submit to the Secretary an
7 annual report on the contents of its State stockpile, in-
8 cluding any expansions or contractions in such contents
9 over the past year.

10 “(g) DEFINITION.—In this section, the term ‘drug’
11 has the meaning given to that term in section 201 of the
12 Federal Food, Drug, and Cosmetic Act.

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

17 “(i) SUNSET.—The authority vested by this section
18 terminates at the end of fiscal year 2024.”.

19 **SEC. 6. ACTION REPORTING.**

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

24 (1) not later than 30 days after the date of en-
25 actment of this Act, issue a report to the Committee

1 on Health, Education, Labor, and Pensions of the
2 Senate and the Committee on Energy and Com-
3 merce of the House of Representatives regarding all
4 State, local, Tribal, and territorial requests for sup-
5 plies from the Strategic National Stockpile related to
6 COVID-19; and

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

13 (b) REPORTING PERIOD.—

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

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

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

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

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

1 (B) ending on the date that is 30 days be-
2 fore the date of submission of the updated re-
3 port.

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

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

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

11 (B) the amount of such materials re-
12 quested; and

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

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

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

19 (C) if the request was partially fulfilled or
20 denied, a rationale and public health assess-
21 ment for such outcome.

22 **SEC. 7. IMPROVED, TRANSPARENT PROCESSES.**

23 (a) IN GENERAL.—Not later than January 1, 2022,
24 the Secretary of Health and Human Services shall develop
25 and implement improved, transparent processes for the

1 use and distribution of drugs, vaccines and other biological
2 products, medical devices, and other supplies (including
3 personal protective equipment, ancillary medical supplies,
4 and other applicable supplies required for the administra-
5 tion of drugs, vaccines and other biological products, med-
6 ical devices, and diagnostic tests) in the Strategic National
7 Stockpile under section 319F–2 of the Public Health Serv-
8 ice Act (42 U.S.C. 247d–6b) (in this section referred to
9 as the “Stockpile”).

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

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

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

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

22 (4) clear plans for future, urgent communica-
23 tion between the Secretary and States, localities, In-
24 dian Tribes, and territories regarding the outcome of
25 such requests; and

1 (5) any differences in the processes developed
2 under subsection (a) for geographically related emer-
3 gencies, such as weather events, and national emer-
4 gencies, such as pandemics.

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

10 (d) REPORT TO CONGRESS.—Not later than January
11 1, 2022, the Secretary of Health and Human Services
12 shall—

13 (1) submit a report to the Committee on
14 Health, Education, Labor, and Pensions of the Sen-
15 ate and the Committee on Energy and Commerce of
16 the House of Representatives regarding the im-
17 proved, transparent processes developed under this
18 section;

19 (2) include in such report recommendations for
20 opportunities for communication (by telebriefing,
21 phone calls, or in-person meetings) between the Sec-
22 retary and States, localities, Indian Tribes, and ter-
23 ritories regarding such improved, transparent proc-
24 esses; and

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

5 **SEC. 8. AUTHORIZATION OF APPROPRIATIONS.**

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