

116TH CONGRESS  
2D SESSION

# S. 4231

To strengthen and sustain on-shore manufacturing capacity and State stockpiles, and to improve the Strategic National Stockpile.

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IN THE SENATE OF THE UNITED STATES

JULY 20, 2020

Mr. ALEXANDER introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To strengthen and sustain on-shore manufacturing capacity and State stockpiles, and to improve the Strategic National Stockpile.

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.**

4       This Act may be cited as the “Preparing for the Next  
5       Pandemic Act”.

6       **SEC. 2. SUSTAINED ON-SHORE MANUFACTURING CAPACITY**  
7                               **FOR PUBLIC HEALTH EMERGENCIES.**

8       (a) IN GENERAL.—Section 319L of the Public  
9       Health Service Act (42 U.S.C. 247d–7e) is amended—

10                       (1) in subsection (a)(6)(B)—

1 (A) by redesignating clauses (iv) and (v) as  
 2 clauses (v) and (vi), respectively;

3 (B) by inserting after clause (iii), the fol-  
 4 lowing:

5 “(iv) activities to support domestic  
 6 manufacturing surge capacity of products  
 7 or platform technologies, including manu-  
 8 facturing capacity and capabilities to uti-  
 9 lize platform technologies to provide for  
 10 flexible manufacturing initiatives;”; and

11 (C) in clause (vi) (as so redesignated), by  
 12 inserting “manufacture,” after “improvement,”;  
 13 (2) in subsection (b)—

14 (A) in the first sentence of paragraph (1),  
 15 by inserting “support for domestic manufac-  
 16 turing surge capacity,” after “initiatives for in-  
 17 novation,”; and

18 (B) in paragraph (2)—

19 (i) in subparagraph (B), by striking  
 20 “and” at the end;

21 (ii) by redesignating subparagraph  
 22 (C) as subparagraph (D); and

23 (iii) by inserting after subparagraph  
 24 (B), the following:

“(C) activities to support manufacturing surge capacities and capabilities to increase the availability of existing medical countermeasures and utilize existing novel platforms to manufacture new medical countermeasures to meet manufacturing demands to address threats that pose a significant level of risk to national security; and”;

(3) in subsection (c)—

(A) in paragraph (2)—

(i) in subparagraph (C), by striking “and” at the end;

(ii) in subparagraph (D), by striking the period and inserting “; and”; and

(iii) by adding at the end the following:

“(E) promoting domestic manufacturing surge capacity and capabilities for countermeasure advanced research and development, including facilitating contracts to support flexible or surge manufacturing.”;

(B) in paragraph (4)—

(i) in subparagraph (B)—

(I) in clause (iii), by striking “and” at the end;

1 (II) in clause (iv), by striking the  
 2 period and inserting “; and”; and

3 (III) by adding at the end the  
 4 following:

5 “(v) support and maintain domestic  
 6 manufacturing surge capacity and capabili-  
 7 ties, including through contracts to sup-  
 8 port flexible or surge manufacturing, to en-  
 9 sure that additional production of counter-  
 10 measures is available in the event that the  
 11 Secretary determines there is such a need  
 12 for additional production.”;

13 (ii) in subparagraph (D)—

14 (I) in clause (ii), by striking  
 15 “and” at the end;

16 (II) by redesignating clause (iii)  
 17 as clause (iv); and

18 (III) by inserting after clause (ii)  
 19 the following:

20 “(iii) research to advance manufac-  
 21 turing capacities and capabilities for med-  
 22 ical countermeasures and platform tech-  
 23 nologies that may be utilized for medical  
 24 countermeasures; and”; and

1 (iii) in subparagraph (E), by striking  
2 clause (ix); and

3 (C) in paragraph (7)(C)(i), by striking “up  
4 to 100 highly qualified individuals, or up to 50  
5 percent of the total number of employees,  
6 whichever is less,” and inserting “75 percent of  
7 the total number of employees”;

8 (4) in subsection (d), by adding at the end the  
9 following:

10 “(3) ADDITIONAL FUNDING.—For necessary ex-  
11 penses to improve and expand manufacturing surge  
12 capacity and capabilities, there is authorized to be  
13 appropriated to the Fund \$5,000,000,000, to remain  
14 available until September 30, 2030.

15 “(4) ADVANCE APPROPRIATION.—

16 “(A) IN GENERAL.—There is appropriated,  
17 out of amounts in the Treasury not otherwise  
18 appropriated for the fiscal year ending Sep-  
19 tember 30, 2021, for necessary expenses to im-  
20 prove and expand manufacturing surge capacity  
21 and capabilities pursuant to subsection  
22 (c)(4)(B)(v), \$5,000,000,000, to remain avail-  
23 able until September 30, 2030.

24 “(B) EMERGENCY DESIGNATION.—

“(i) IN GENERAL.—The amounts provided by this paragraph are designated as an emergency requirement pursuant to section 4(g) of the Statutory Pay-As-You-Go Act of 2010 (2 U.S.C. 933(g)).

“(ii) DESIGNATION IN SENATE.—In the Senate, this paragraph is designated as an emergency requirement pursuant to section 4112(a) of H. Con. Res. 71 (115th Congress), the concurrent resolution on the budget for fiscal year 2018.

“(C) APPLICATION OF PROVISIONS.—Amounts appropriated pursuant to this paragraph for fiscal year 2021 shall be subject to the requirements contained in Public Law 116–94 for funds for programs authorized under section 319L of this Act.”;

(5) in subsection (e)(1)—

(A) by redesignating subparagraphs (B) through (D) as subparagraphs (C) through (E), respectively; and

(B) by inserting after subparagraph (A), the following:

“(B) TEMPORARY FLEXIBILITY.—During a public health emergency under section 319, the

Secretary shall be provided with an additional 60 business days to comply with information requests for the disclosure of information under section 552 of title 5, United States Code, related to the activities under this section (unless such activities are otherwise exempt under subparagraph (A)).”; and  
(6) in subsection (f)—

(A) in paragraph (1), by striking “Not later than 180 days after the date of enactment of this subsection” and inserting “Not later than 180 days after the date of enactment of the Preparing for the Next Pandemic Act”; and

(B) in paragraph (2), by striking “Not later than 1 year after the date of enactment of this subsection” and inserting “Not later than 1 year after the date of enactment of the Preparing for the Next Pandemic Act”.

(b) MEDICAL COUNTERMEASURE INNOVATION PARTNER.—The restrictions under section 202 of division A of the Further Consolidated Appropriations Act, 2020 (Public Law 116–94), or any other provision of law imposing a restriction on salaries of individuals related to a previous appropriation to the Department of Health and Human Services, shall not apply with respect to salaries paid pur-

1 suant to an agreement under the medical countermeasure  
 2 innovation partner program under section 319L(c)(4)(E)  
 3 of the Public Health Service Act (42 U.S.C. 247d–  
 4 7e(c)(4)(E)).

5 **SEC. 3. IMPROVING AND SUSTAINING STATE MEDICAL**  
 6 **STOCKPILES.**

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

10 “(i) IMPROVING AND MAINTAINING STATE MEDICAL  
 11 STOCKPILES.—

12 “(1) IN GENERAL.—The Secretary, acting  
 13 through the Assistant Secretary for Preparedness  
 14 and Response, shall award grants, contracts, or co-  
 15 operative agreements to eligible entities to maintain  
 16 a stockpile of appropriate drugs, vaccines and other  
 17 biological products, medical devices, and other med-  
 18 ical supplies (including personal protective equip-  
 19 ment, ancillary medical supplies, and other applica-  
 20 ble supplies required for the administration of drugs,  
 21 vaccines and other biological products, medical de-  
 22 vices, and diagnostic tests) to be used during a pub-  
 23 lic health emergency declared by the Governor of a  
 24 State or by the Secretary under section 319, or a  
 25 major disaster or emergency declared by the Presi-

1       dent under section 401 or 501, respectively, of the  
2       Robert T. Stafford Disaster Relief and Emergency  
3       Assistance Act, in order to support the preparedness  
4       goals described in paragraphs (2), (3), and (8) of  
5       section 2802(b).

6               “(2) ELIGIBLE ENTITIES.—

7               “(A) IN GENERAL.—To be eligible to re-  
8       ceive an award under paragraph (1), an entity  
9       shall—

10              “(i) be a State or consortium of  
11       States that is a recipient of an award  
12       under section 319C–1(b); and

13              “(ii) prepare, in consultation with ap-  
14       propriate health care providers and health  
15       officials within the State or consortium of  
16       States, and submit to the Secretary an ap-  
17       plication that contains such information as  
18       the Secretary may require, including a  
19       plan for the State stockpile and a descrip-  
20       tion of the activities such entity will carry  
21       out under the agreement, consistent with  
22       the requirements of paragraph (3).

23              “(B) LIMITATION.—The Secretary may  
24       make an award under this subsection to not  
25       more than one eligible entity in each State.

1           “(C) SUPPLEMENT NOT SUPPLANT.—  
2           Awards, contracts, or grants awarded under  
3           this subsection shall supplement, not supplant,  
4           the reserve amounts of medical supplies pro-  
5           cured by and for the Strategic National Stock-  
6           pile under subsection (a).

7           “(D) ADMINISTRATIVE EXPENSES.—Not  
8           more than 5 percent of amounts received by an  
9           entity pursuant to an award under this sub-  
10          section may be used for administrative ex-  
11          penses.

12          “(E) CLARIFICATION.—An eligible entity  
13          receiving an award under this subsection may  
14          assign a lead entity to manage the State stock-  
15          pile, which may be a recipient of an award  
16          under section 319C–2(b).

17          “(F) REQUIREMENT OF MATCHING  
18          FUNDS.—

19                 “(i) IN GENERAL.—Subject to clause  
20                 (ii), the Secretary may not make an award  
21                 under this subsection unless the applicant  
22                 agrees, with respect to the costs to be in-  
23                 curred by the applicant in carrying out the  
24                 purpose described in this subsection, to

1 make available non-Federal contributions  
2 toward such costs in an amount equal to—

3 “(I) for each of fiscal years 2023  
4 and 2024, not less than \$1 for each  
5 \$10 of Federal funds provided in the  
6 award;

7 “(II) for each of fiscal years  
8 2025 and 2026, not less than \$1 for  
9 each \$5 of Federal funds provided in  
10 the award; and

11 “(III) for fiscal year 2027 and  
12 each fiscal year thereafter, not less  
13 than \$1 for each \$3 of Federal funds  
14 provided in the award.

15 “(ii) WAIVER.—

16 “(I) IN GENERAL.—The Sec-  
17 retary may, upon the request of a  
18 State, waive the requirement under  
19 clause (i) in whole or in part if the  
20 Secretary determines that extraor-  
21 dinary economic conditions in the  
22 State in the fiscal year involved or in  
23 the previous fiscal year justify the  
24 waiver.

1                   “(II) APPLICABILITY OF WAIV-  
2                   ER.—A waiver provided by the Sec-  
3                   retary under this subparagraph shall  
4                   apply only to the fiscal year involved.

5                   “(3) STOCKPILING ACTIVITIES AND REQUIRE-  
6                   MENTS.—A recipient of a grant, contract, or cooper-  
7                   ative agreement under this subsection shall use such  
8                   funds to carry out the following:

9                   “(A) Maintaining a stockpile of appro-  
10                  priate drugs, vaccines and other biological prod-  
11                  ucts, medical devices, and other supplies (in-  
12                  cluding personal protective equipment, ancillary  
13                  medical supplies, and other applicable supplies  
14                  required for the administration of drugs, vac-  
15                  cines and other biological products, medical de-  
16                  vices, and diagnostic tests) to be used during a  
17                  public health emergency in such numbers,  
18                  types, and amounts as the State determines  
19                  necessary, consistent with such State’s stockpile  
20                  plan. Such a recipient may not use funds to  
21                  support the stockpiling of countermeasures as  
22                  defined under subsection (c), unless the eligible  
23                  entity provides justification for maintaining  
24                  such products and the Secretary determines  
25                  such appropriate and applicable.

1           “(B) Deploying the stockpile as required  
2           by the State to respond to an actual or poten-  
3           tial public health emergency.

4           “(C) Replenishing and making necessary  
5           additions or modifications to the contents of  
6           such stockpile or stockpiles, including to ad-  
7           dress potential depletion.

8           “(D) In consultation with Federal, State,  
9           and local officials, take into consideration the  
10          availability, deployment, dispensing, and admin-  
11          istration requirements of medical products with-  
12          in the stockpile.

13          “(E) Ensuring that procedures are fol-  
14          lowed for inventory management and account-  
15          ing, and for the physical security of the stock-  
16          pile, as appropriate.

17          “(F) Reviewing and revising, as appro-  
18          priate, the contents of the stockpile on a reg-  
19          ular basis to ensure that to the extent prac-  
20          ticable, advanced technologies and medical  
21          products are considered.

22          “(G) Carrying out exercises, drills, and  
23          other training for purposes of stockpile deploy-  
24          ment, dispensing, and administration of medical  
25          products, and for purposes of assessing the ca-

1           pability of such stockpile to address the medical  
2           supply needs of public health emergencies of  
3           varying types and scales, which may be con-  
4           ducted in accordance with requirements related  
5           to exercises, drills, and other training for recipi-  
6           ents of awards under section 319C–1 or 319C–  
7           2, as applicable.

8           “(H) Carrying out other activities as the  
9           State determines appropriate, to support State  
10          efforts to prepare for, and respond to, public  
11          health threats.

12          “(4) STATE PLAN COORDINATION.—The eligible  
13          entity under this subsection shall ensure appropriate  
14          coordination of the State stockpile plan developed  
15          pursuant to paragraph (2)(A)(ii) and the plans re-  
16          quired pursuant to section 319C–1.

17          “(5) GUIDANCE FOR STATES.—Not later than  
18          180 days after the date of enactment of this sub-  
19          section, the Secretary, acting through the Assistant  
20          Secretary for Preparedness and Response, shall  
21          issue guidance for States related to maintaining and  
22          replenishing a stockpile of medical products. The  
23          Secretary shall update such guidance as appropriate.

24          “(6) ASSISTANCE TO STATES.—The Secretary  
25          shall provide assistance to States, including technical

1 assistance, as appropriate, to maintain and improve  
2 State and local public health preparedness capabilities  
3 to distribute and dispense medical products  
4 from a State stockpile.

5 “(7) COORDINATION WITH THE STRATEGIC NA-  
6 TIONAL STOCKPILE.—Each recipient of an award  
7 under this subsection shall ensure that the State  
8 stockpile plan developed pursuant to paragraph  
9 (2)(A)(ii) contains such information as the Secretary  
10 may require related to current inventory of supplies  
11 maintained pursuant to paragraph (3), and any  
12 plans to replenish such supplies, or procure new or  
13 alternative supplies. The Secretary shall use infor-  
14 mation obtained from State stockpile plans to inform  
15 the maintenance and management of the Strategic  
16 National Stockpile pursuant to subsection (a).

17 “(8) PERFORMANCE AND ACCOUNTABILITY.—

18 “(A) IN GENERAL.—The Secretary, acting  
19 through the Assistant Secretary for Prepared-  
20 ness and Response, shall develop and implement  
21 a process to review and audit entities in receipt  
22 of an award under this subsection, including by  
23 establishing metrics to ensure that each entity  
24 receiving such an award is carrying out activi-  
25 ties in accordance with the applicable State

1 stockpile plan. The Secretary may require enti-  
2 ties to—

3 “(i) measure progress toward achiev-  
4 ing the outcome goals; and

5 “(ii) at least annually, test, exercise,  
6 and rigorously evaluate the stockpile ca-  
7 pacity and response capabilities of the enti-  
8 ty, and report to the Secretary on the re-  
9 sults of such test, exercise, and evaluation,  
10 and on progress toward achieving outcome  
11 goals, based on criteria established by the  
12 Secretary.

13 “(B) NOTIFICATION OF FAILURE.—The  
14 Secretary shall develop and implement a proc-  
15 ess to notify entities that are determined by the  
16 Secretary to have failed to meet the require-  
17 ments of the terms of an award under this sub-  
18 section. Such process shall provide such entities  
19 with the opportunity to correct such noncompli-  
20 ance. An entity that fails to correct such non-  
21 compliance shall be subject to subparagraph  
22 (C).

23 “(C) WITHHOLDING OF CERTAIN AMOUNTS  
24 FROM ENTITIES THAT FAIL TO ACHIEVE  
25 BENCHMARKS OR SUBMIT STATE STOCKPILE

PLAN.—Beginning with fiscal year 2022, and in each succeeding fiscal year, the Secretary shall withhold from each entity that has failed substantially to meet the terms of an award under this subsection for at least 1 of the 2 immediately preceding fiscal years (beginning with fiscal year 2022), the amount allowed for administrative expenses described in described in paragraph (2)(D).

“(9) AUTHORIZATION OF APPROPRIATIONS.—

For the purpose of carrying out this subsection, there are authorized to be appropriated \$1,000,000,000 for each of fiscal years 2021 through 2030, to remain available until expended.

“(10) ADVANCE APPROPRIATION.—

“(A) IN GENERAL.—There is appropriated, out of amounts in the Treasury not otherwise appropriated, for fiscal year 2021, for necessary expenses to establish and maintain State medical stockpiles pursuant to this subsection, \$10,000,000,000, to remain available until September 30, 2030.

“(B) EMERGENCY DESIGNATION.—

“(i) IN GENERAL.—The amounts provided by this paragraph are designated as

1 an emergency requirement pursuant to sec-  
 2 tion 4(g) of the Statutory Pay-As-You-Go  
 3 Act of 2010 (2 U.S.C. 933(g)).

4 “(ii) DESIGNATION IN SENATE.—In  
 5 the Senate, this paragraph is designated as  
 6 an emergency requirement pursuant to sec-  
 7 tion 4112(a) of H. Con. Res. 71 (115th  
 8 Congress), the concurrent resolution on the  
 9 budget for fiscal year 2018.

10 “(C) APPLICATION OF PROVISIONS.—  
 11 Amounts appropriated pursuant to this para-  
 12 graph for fiscal year 2021 shall be subject to  
 13 the requirements contained in Public Law 116–  
 14 94 for funds for programs authorized under  
 15 section 319F–2 of this Act.”.

16 **SEC. 4. STRENGTHENING THE STRATEGIC NATIONAL**  
 17 **STOCKPILE.**

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

20 (1) in subsection (a)—

21 (A) in paragraph (2)(A), by adding “and  
 22 the contracts issued under paragraph (5)” after  
 23 “paragraph (1)”;

24 (B) in paragraph (3)(F), by striking “Sec-  
 25 retary of Homeland Security” and inserting

1 “Secretary of Health and Human Services, in  
2 coordination with or at the request of, the Sec-  
3 retary of Homeland Security,”;

4 (C) by redesignating paragraph (5) as  
5 paragraph (6);

6 (D) by inserting after paragraph (4) the  
7 following:

8 “(5) SURGE CAPACITY.—The Secretary, in  
9 maintaining the stockpile under paragraph (1) and  
10 carrying out procedures under paragraph (3), may—

11 “(A) enter into contracts or cooperative  
12 agreements with vendors for procurement,  
13 maintenance, and storage of reserve amounts of  
14 drugs, vaccines and other biological products,  
15 medical devices, and other medical supplies (in-  
16 cluding personal protective equipment, ancillary  
17 medical supplies, and other applicable supplies  
18 required for the administration of drugs, vac-  
19 cines and other biological products, medical de-  
20 vices, and diagnostic tests in the stockpile),  
21 under such terms and conditions (including  
22 quantity, production schedule, maintenance  
23 costs, and price of product) as the Secretary  
24 may specify, including for purposes of—

1 “(i) maintenance and storage of re-  
2 serve amounts of products intended to be  
3 delivered to the ownership of the Federal  
4 Government under the contract, which may  
5 consider costs of shipping, or otherwise  
6 transporting, handling, storage, and re-  
7 lated costs for such product or products;  
8 and

9 “(ii) maintaining domestic manufac-  
10 turing capacity of such products to ensure  
11 additional reserved production capacity of  
12 such products is available, and that such  
13 products are provided in a timely manner,  
14 to be delivered to the ownership of the  
15 Federal Government under the contract  
16 and deployed in the event that the Sec-  
17 retary determines that there is a need to  
18 quickly purchase additional quantities of  
19 such product; and

20 “(B) promulgate such regulations as the  
21 Secretary determines necessary to implement  
22 this paragraph.”; and

23 (E) in subparagraph (A) of paragraph (6),  
24 as so redesignated—

- 1 (i) in clause (viii), by striking “; and”  
2 and inserting a semicolon;  
3 (ii) in clause (ix), by striking the pe-  
4 riod and inserting “; and”; and  
5 (iii) by adding at the end the fol-  
6 lowing:  
7 “(x) an assessment of the contracts or  
8 cooperative agreements entered into pursu-  
9 ant to paragraph (5).”; and  
10 (2) in subsection (c)(2)(C), by striking “on an  
11 annual basis” and inserting “not later than March  
12 15 of each year”.

○