

117TH CONGRESS
1ST SESSION

S. 2925

To provide for a strategic plan for the domestic manufacture of necessary medical supplies or supplies needed to facilitate emergency or medical response, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 4, 2021

Ms. ROSEN (for herself and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for a strategic plan for the domestic manufacture of necessary medical supplies or supplies needed to facilitate emergency or medical response, 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.**

4 This Act may be cited as the “Strategic Planning for
5 Emergency Medical Manufacturing Act”.

1 **SEC. 2. DOMESTIC BACK-UP MANUFACTURING NETWORK.**

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

5 **“SEC. 319F–5. DOMESTIC BACK-UP MANUFACTURING NET-**
6 **WORK.**

7 “(a) IN GENERAL.—The Secretary, acting through
8 the Assistant Secretary for Preparedness and Response
9 (referred to in this section as the ‘Assistant Secretary’),
10 shall develop and maintain a network of manufacturers—

11 “(1) whose manufacturing facilities are in the
12 United States (including small business concerns, as
13 defined in section 3 of the Small Business Act);

14 “(2) who manufacture certain items identified
15 by the Assistant Secretary, which shall primarily be
16 medical supplies or supplies needed to facilitate
17 emergency or medical response; and

18 “(3) that have voluntarily opted in for inclusion
19 in such network, in order to provide for the domestic
20 manufacture of necessary supplies during times of
21 emergency or disruption of the usual supply chain.

22 “(b) DISTRIBUTION OF NETWORK.—The Assistant
23 Secretary shall make information about the network de-
24 scribed in subsection (a) available to States, local govern-
25 mental entities, Indian Tribes, Tribal organizations, and
26 urban Indian organizations, medical suppliers, hospitals,

1 and other health care providers, as the Assistant Secretary
2 determines appropriate, when critical supply shortfalls are
3 anticipated.

4 “(c) PLANS DEVELOPED IN CONJUNCTION WITH
5 PARTICIPATING MANUFACTURERS.—Domestic manufac-
6 turers opting to participate as described in subsection (a)
7 shall develop, in coordination with the Assistant Secretary,
8 a comprehensive plan that identifies—

9 “(1) the items that the manufacturer could
10 produce, which may include—

11 “(A) items such manufacturer has current
12 capacity to produce, or the ability to rapidly ex-
13 pand capacity to produce; and

14 “(B) information about the manufacturer’s
15 general capacity and equipment and willingness
16 to work with the Assistant Secretary to identify
17 other products likely to be needed during an
18 emergency that fit within the manufacturer’s
19 operational capabilities;

20 “(2) manufacturing capacity, including options
21 for partial operations and full capacity operations,
22 and the time needed to switch from standard prod-
23 uct manufacturing to the needed emergency supply;

24 “(3) technical assistance needed for production
25 of items needed during times of emergency, such as

1 equipment, staff training, and regulatory compli-
2 ance, including scope, duration, and the appropriate
3 Federal agency to provide assistance; and

4 “(4) the frequency of testing by the manufac-
5 turer to ensure that the plan is operational and
6 meets quality metrics and other obligations under
7 Federal purchasing contracts (including with respect
8 to contracts for supplies for the Strategic National
9 Stockpile under section 319F–2) or to meet other
10 requirements determined by the Assistant Secretary.

11 “(d) GUIDANCE.—The Secretary shall issue guidance
12 on the quality standards for items identified by the Assist-
13 ant Secretary as described in subsection (a)(2), by product
14 type or category, that apply with respect to such items
15 produced by manufacturers included in the network.

16 “(e) COORDINATION WITH OTHER AGENCIES.—The
17 Secretary shall coordinate with other Federal agencies to
18 provide contracting opportunities for Federal purchasing
19 of items identified by the Assistant Secretary as described
20 in subsection (a)(2), as such items are needed, provided
21 that such items meet all quality standards and other re-
22 quirements and are produced as part of an agreement with
23 the Federal Government.

24 “(f) LIMITS ON PARTICIPATION; OPPORTUNITIES
25 FOR CONSIDERATION.—

1 “(1) LIMITS.—The Secretary may limit the
2 number of manufacturers that have active manufac-
3 turing plans under subsection (c) and manufacturers
4 that are active participants in the network described
5 in subsection (a), taking into account diversity of
6 product and geography of production facilities.

7 “(2) OPPORTUNITIES FOR FUTURE CONSIDER-
8 ATION.—All manufacturers wishing to participate in
9 such network shall have access to a point of contact
10 within the Office of the Assistant Secretary for Pre-
11 paredness and Response and, if not included in such
12 network, shall have the option to add their name to
13 a simplified list for future consideration for such
14 participation, unless the Assistant Secretary deter-
15 mines there to be any substantial cause for removal
16 of the manufacturer from such list.”.

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