

118TH CONGRESS
2D SESSION

S. 5368

To amend the Federal Food, Drug, and Cosmetic Act to expand drug shortage notification practices to include surges in demand for a drug, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 21, 2024

Mr. KAINE (for himself and Mr. COTTON) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to expand drug shortage notification practices to include surges in demand for a drug, 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 “End Drug Shortages
5 Act”.

6 **SEC. 2. DRUG SHORTAGE NOTIFICATION PRACTICES.**

7 Section 506C of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 356c) is amended—

1 (1) in the section heading, by inserting “**OR**
 2 **SURGE IN DEMAND FOR**” after “**PRODUCTION**
 3 **OF**”;

4 (2) in subsection (a), in the matter following
 5 paragraph (2)—

6 (A) by striking “or an interruption of the
 7 manufacture of the drug” and inserting “, an
 8 interruption of the manufacture of the drug, or
 9 a surge in demand for the drug”;

10 (B) by striking “such discontinuance or
 11 interruption” and inserting “such discontinu-
 12 ance, interruption, or surge in demand”;

13 (C) by striking “the discontinuation or
 14 interruption” and inserting “the discontinu-
 15 ation, interruption, or surge in demand”; and

16 (D) by striking “such discontinuation or
 17 interruption; the expected duration of the inter-
 18 ruption;” and inserting “such discontinuation,
 19 interruption, or surge in demand; the expected
 20 duration of the interruption or surge in de-
 21 mand”;

22 (3) in subsection (b), by striking paragraphs
 23 (1) and (2) and inserting the following:

24 “(1) in the case of a notice of a discontinuance
 25 or interruption in the manufacture of a drug—

1 “(A) at least 6 months prior to the date of
2 the discontinuance or interruption; or

3 “(B) if compliance with subparagraph (A)
4 is not possible, as soon as practicable; or

5 “(2) in the case of a notice of a surge in de-
6 mand for a drug, as soon as practicable.”;

7 (4) in subsection (c)—

8 (A) by striking “discontinuance or inter-
9 ruption” and inserting “discontinuance, inter-
10 ruption, or surge in demand”; and

11 (B) by inserting “and outsourcing facilities
12 (as defined in section 503B(d))” after “patient
13 organizations”; and

14 (5) in subsection (h)—

15 (A) in paragraph (1), by striking “and
16 that is subject to section 503(b)(1)” and insert-
17 ing “or the active pharmaceutical ingredient of
18 such a drug”;

19 (B) by amending paragraph (2), to read as
20 follows:

21 “(2) the term ‘drug shortage’ or ‘shortage’,
22 with respect to a drug, means a period of time with
23 the demand or projected demand for the drug within
24 the United States exceeds the supply of the drug,
25 taking into consideration—

1 “(A) how the drug is prepared or dis-
 2 pensed, including the route of administration
 3 and dosage form; and

4 “(B) information reported by manufactur-
 5 ers, health care professionals, and patients;”;

6 (C) in paragraph (3)(B), by striking the
 7 period and inserting “; and”; and

8 (D) by adding at the end the following:

9 “(4) the term ‘surge’ means an increase in de-
 10 mand or projected demand for a drug that the man-
 11 ufacturer likely will be unable to meet without mean-
 12 ingful shortfall or delay.”.

13 **SEC. 3. OUTSOURCING FACILITY COMPOUNDING.**

14 Section 503B of the Federal Food, Drug, and Cos-
 15 metic Act (21 U.S.C. 353b) is amended—

16 (1) by redesignating the 2 subsections (d) (re-
 17 lating to definitions and relating to obligation to pay
 18 fees) as subsections (e) and (f), respectively; and

19 (2) by inserting after subsection (c) the fol-
 20 lowing:

21 “(d) LIST OF IDENTIFIED BULK DRUG SUB-
 22 STANCES.—The Secretary shall make publicly available
 23 annual updates on the evaluation of bulk drug substances
 24 for purposes of the list maintained under subsection
 25 (a)(2)(A)(i).”.

1 **SEC. 4. HOSPITAL AND HEALTH SYSTEM COMPOUNDING.**

2 Not later than 1 year after the date of enactment
3 of this Act, the Secretary of Health and Human Services
4 shall finalize the draft guidance entitled “Hospital and
5 Health System Compounding Under Section 503A of the
6 Federal Food, Drug, and Cosmetic Act: Guidance for In-
7 dustry” issued in October 2021, and ensure that such
8 guidance is consistent with the most current research and
9 best clinical practices for pharmacy compounding relating
10 to implementing section 503A of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 353a).

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