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119TH CONGRESS
1ST SESSION

H. R. 5316

To amend the Federal Food, Drug, and Cosmetic Act to ensure patients have access to certain shortage and urgent-use compounded medications, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 11, 2025

Mrs. HARSHBARGER (for herself and Mr. CARTER of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure patients have access to certain shortage and urgent-use compounded medications, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Drug Shortage Compounding Patient Access Act of 2025''.

SEC. 2. PHARMACY COMPOUNDING.

(a) COMPOUNDING FOR URGENT ADMINISTRATION TO PATIENTS.—Section 503A(a) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 353a(a)) is amended—

(1) in paragraph (1), by striking ''or'' at the end;

(2) in paragraph (2)(B)(ii)(II), by striking the period at the end and inserting ''; or''; and

(3) by adding at the end the following:

''(3) notwithstanding the requirement in the matter preceding paragraph (1) that the drug product is compounded for an identified individual patient based on a valid prescription order or notation described in such matter, is by a licensed pharmacist or licensed physician and the compounded drug product is compounded for distribution in limited quantities to a licensed prescriber for urgent administration to a patient in a hospital or other clinical setting, provided that all of the following are met:

''(A) The drug product appeared on the drug shortage list in effect under section 506E at any time during the 60-day period ending on the date of the compounding, distribution, or dispensing of the drug product.

''(B) The licensed prescriber certifies by notation on the order to the compounding pharmacist or physician that the licensed prescriber

has made reasonable attempts to obtain, and has not been able to obtain, to address the urgent medical need a drug product that is compounded by an outsourcing facility in accordance with section 503B with the same active ingredient and the same route of administration.

''(C) The compounded drug product is labeled with a beyond-use-date in accordance with applicable United States Pharmacopeia standards.

''(D) The licensed pharmacist or licensed physician marks the packaging of the compounded drug product with text—

''(i) indicating that the drug product is provided to the hospital or other clinical setting only for urgent administration to a patient; and

''(ii) requesting that the hospital or other clinical setting provide to the compounding pharmacist or physician the records that identify the patient or patients to whom the drug products were administered within—

''(I) 7 days of each such patient receiving such medication; or

"(II) 7 days of each such patient being discharged.

"(E) Upon receipt of records requested pursuant to subparagraph (D)(ii), the licensed pharmacist or licensed physician ensures that the patient information in such records is linked with the respective order.

"(F) The licensed pharmacist or licensed physician reports adverse events associated with the compounded drug product as soon as possible but not later than 15 days after becoming aware of such events to the MedWatch Adverse Event Reporting program of the Food and Drug Administration (or any successor program).".

(b) DEFINITION.—Paragraph (2) of section 503A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a(b)(2)) is amended to read as follows:

"(2) DEFINITION.—For purposes of paragraph (1)(D), the term 'essentially a copy of a commercially available drug product' does not include—

"(A) a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the pre-

scribing practitioner, between the compounded drug and the comparable commercially available drug product; or

''(B) a drug product that meets each of the following conditions:

''(i) At any time during the 60-day period ending on the date of the compounding, distribution, or dispensing, the drug product appeared on the drug shortage list in effect under section 506E.

''(ii) If the drug product is not compounded for an identified individual patient based on a valid prescription order or notation, notwithstanding such requirement in the matter preceding paragraph (1) of subsection (a), the drug product—

''(I) is labeled in accordance subparagraphs (C) and (D) of subsection (a)(3); and

''(II) is documented by the compounding pharmacist or physician in accordance with subparagraphs (E) and (F) of subsection (a)(3).''.

SEC. 3. MITIGATING DRUG SHORTAGES THROUGH IMPROVED REPORTING.

Section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amended—

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

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

(A) by striking ''or an interruption of the manufacture of the drug'' and inserting '', an interruption of the manufacture of the drug, or a surge in demand for the drug'';

(B) by striking ''such discontinuance or interruption'' and inserting ''such discontinuance, interruption, or surge in demand'';

(C) by striking ''the discontinuation or interruption'' and inserting ''the discontinuation, interruption, or surge in demand'';

(D) by striking ''such discontinuation or interruption, the source'' and inserting ''such discontinuation, interruption, or surge in demand, the source''; and

(E) by striking ''such discontinuation or interruption; the expected duration of the interruption;'' and inserting ''such discontinuation,

interruption, or surge in demand; the expected duration of the interruption or surge in demand'';

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

''(1) in the case of a notice of a discontinuance or interruption in the manufacture of a drug—

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

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

''(2) in the case of a notice of a surge in demand for a drug, as soon as practicable.'';

(4) in subsection (c)—

(A) by striking ''discontinuance or interruption'' and inserting ''discontinuance, interruption, or surge in demand''; and

(B) by inserting ''and outsourcing facilities (as defined in section 503B(d))'' after ''patient organizations''; and

(5) in subsection (h)—

(A) in paragraph (1), by striking ''and that is subject to section 503(b)(1)'' and inserting ''or the active pharmaceutical ingredient of such a drug'';

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

''(2) the term 'drug shortage' or 'shortage', with respect to a drug, means a period of time with the demand or projected demand for the drug within the United States exceeds the supply of the drug, taking into consideration—

''(A) how the drug is prepared or dispensed, including the route of administration and dosage form; and

''(B) information reported by manufacturers, health care professionals, and patients;''.

(C) in paragraph (3)(B), by striking the period at the end and inserting ''; and''; and

(D) by adding at the end the following:

''(4) the term 'surge' means an increase in demand or projected demand for a drug that the manufacturer likely will be unable to meet without meaningful shortfall or delay.''.

SEC. 4. OUTSOURCING FACILITY COMPOUNDING.

Section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353b) is amended—

(1) in subsection (a)(2)(A)(ii)—

(A) by striking ''appears'' and inserting ''appeared''; and

(B) by striking ''at the time of'' and inserting ''at any time during the 180-day period ending on the date of'';

(2) in subsection (a)(10)(A)(iii)—

(A) in subclause (VIII), by striking the semicolon at the end and inserting ''; and'';

(B) by striking subclause (IX); and

(C) by redesignating subclause (X) as subclause (IX);

(3) by redesignating the 2 subsections (d) (relating to definitions and relating to obligation to pay fees) as subsections (e) and (f), respectively; and

(4) by inserting after subsection (c) the following:

''(d) LIST OF IDENTIFIED BULK DRUG SUBSTANCES.—The Secretary shall make publicly available annual updates on the evaluation of bulk drug substances for purposes of the list maintained under subsection (a)(2)(A)(i).'';

SEC. 5. CLARIFYING PROVISIONS; LABELING REQUIREMENT.

Section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) is amended—

(1) by striking subsection (b)(3)(B) and the matter following such subsection and inserting the following:

"(B) such drug product is labeled as follows: 'This medication has been compounded for dispensing to an individual patient and has not been approved by the Food and Drug Administration'."; and

(2) in subsection (b)(1)(A)(i)(I) by striking "National Formulary monograph" and inserting "National Formulary drug or dietary supplement monograph".

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