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117TH CONGRESS
1ST SESSION

H. R. 3662

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 1, 2021

Mr. GRIFFITH (for himself and Mr. CUELLAR) 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 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 "Patient Access to Urgent-Use Pharmacy Compounding Act of 2021".

SEC. 2. URGENT-USE COMPOUNDING FOR ADMINISTRATION IN HOSPITALS OR OTHER CLINICAL SETTINGS.

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 new paragraph:

''(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 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—

"(i) a drug product that is approved or authorized by the Food and Drug Administration with the same active ingredient and the same route of administration; or

"(ii) 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.

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

"(C) 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 com-

pounding 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.

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

"(E) The licensed pharmacist or licensed physician reports adverse events associated with the compounded drug product as soon as possible but no 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).".

SEC. 3. COMPOUNDING FOR SHORTAGES FOR ADMINISTRATION IN HOSPITALS OR OTHER CLINICAL SETTINGS.

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 prescribing 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 the time of compounding, distribution, or dispensing, the drug product appears on—

''(I) the drug shortage list in effect under section 506E; or

''(II) the drug shortage list maintained by the American Society of Hospital Pharmacists.

"(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), then the drug product—

"(I) is labeled in accordance subparagraphs (B) and (C) of subsection (a)(3); and

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

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