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115TH CONGRESS
1ST SESSION

H. R. 2871

To amend the Federal Food, Drug, and Cosmetic Act with respect to compounding pharmacies, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 12, 2017

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 with respect to compounding pharmacies, 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 ''Preserving Patient Access to Compounded Medications Act of 2017''.

SEC. 2. OFFICE-USE COMPOUNDING WHEN AUTHORIZED BY STATE LAW.

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

(1) in the matter preceding paragraph (1), by inserting ''or drug order for administration to a patient in an office or clinical setting'' after ''is necessary for the identified patient'';

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

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

(4) by adding at the end the following new paragraph:

''(3) is by a licensed pharmacist or licensed physician pursuant to a valid prescription order or drug order and the compounded drug is distributed or dispensed to a licensed prescriber in accordance with State law, for administration to a patient in an office or clinical setting.''.

SEC. 3. UNITED STATES PHARMACOPOEIA OR NATIONAL FORMULARY MONOGRAPH REQUIREMENT.

Section 503A(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353A(b)(1)(A)) is amended—

(1) in the matter preceding subclause (i), by inserting '', or dietary supplements'' after ''Regulations''; and

(2) in clause (i)—

(A) by amending subclause (I) to read as follows:

"(I) comply with the monograph standards in any section of the of the United States Pharmacopoeia or National Formulary, including drug substance or dietary supplement monograph, if a monograph exists."; and

(B) by amending subclause (III) to read as follows:

"(III) if such monograph does not exist and the drug substance or dietary supplement is not a component of a drug approved by the Secretary, but appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of this section;".

SEC. 4. DEFINITIONS.

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

"(e) DEFINITIONS.—In this section:

"(1) COMPOUNDING.—The term 'compounding' does not include mixing, reconstituting, or other

such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

''(2) DISTRIBUTE OR DISTRIBUTION.—The terms 'distribute' or 'distribution' do not include the act of dispensing of a compounded drug product in accordance with this section.

''(3) DISPENSE.—The term 'dispense' means for a drug product compounded in accordance with this section, the act of the drug product leaving the facility in which it was compounded for delivery to a patient, patient's agent, or health care facility (including a hospital, physician's office, or other health care setting) pursuant to a valid prescription order for an identified patient.''.

SEC. 5. APPLICABILITY OF RECORDS EXEMPTION FOR COMPOUNDING PHARMACIES.

(a) IN GENERAL.—Section 704(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(2)(A)) is amended to read as follows:

''(A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and, for compounding pharmacies, the

provisions of section 503A, and which are regularly engaged in dispensing or distributing prescription drugs or devices, upon prescriptions or drug orders of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business;''.

(b) REGISTRATION EXEMPTION.—Section 510(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(g)(1)) is amended to read as follows:

''(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and, for compounding pharmacies, the provisions of section 503A, and which are regularly engaged in dispensing or distributing prescription drugs or devices, upon prescriptions or drug orders of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or

process drugs or devices for sale other than in the regular course of their business;''.

SEC. 6. REGULATIONS.

(a) RULES IMPLEMENTING NEW REQUIREMENTS.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate rules on the record to carry out the amendments made by this Act, in accordance with chapter 5 of title 5, United States Code.

(b) OTHER RULES.—The Secretary of Health and Human Services shall promulgate rules on the record to carry out any of the provisions of section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) other than those amended by this Act, in accordance with chapter 5 of title 5, United States Code.

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