

116TH CONGRESS
1ST SESSION

H. R. 1959

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 28, 2019

Mr. GRIFFITH (for himself and Mr. CUELLAR) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with
respect to compounding pharmacies, 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 “Preserving Patient Ac-
5 cess to Compounded Medications Act of 2019”.

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

8 Section 503A(a) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 353a(a)) is amended—

1 (1) in the matter preceding paragraph (1), by
 2 inserting “or drug order for administration to a pa-
 3 tient in an office or clinical setting” after “is nec-
 4 essary for the identified patient”;

5 (2) in paragraph (1), by striking “or” at the
 6 end;

7 (3) in paragraph (2), by striking the period at
 8 the end and inserting “; or”; and

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

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

17 **SEC. 3. UNITED STATES PHARMACOPOEIA OR NATIONAL**
 18 **FORMULARY MONOGRAPH REQUIREMENT.**

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

22 (1) in the matter preceding subclause (i), by in-
 23 serting “, or dietary supplements” after “Regula-
 24 tions”; and

25 (2) in clause (i)—

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

3 “(I) comply with the monograph
 4 standards in any section of the United
 5 States Pharmacopoeia or National
 6 Formulary, including drug substance
 7 or dietary supplement monograph, if a
 8 monograph exists.”; and

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

11 “(III) if such monograph does
 12 not exist and the drug substance or
 13 dietary supplement is not a compo-
 14 nent of a drug approved by the Sec-
 15 retary, but appears on a list developed
 16 by the Secretary through regulations
 17 issued by the Secretary under sub-
 18 section (c) of this section;”.

19 **SEC. 4. DEFINITIONS.**

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

23 “(e) DEFINITIONS.—In this section:

24 “(1) COMPOUNDING.—The term ‘compounding’
 25 does not include mixing, reconstituting, or other

1 such acts that are performed in accordance with di-
 2 rections contained in approved labeling provided by
 3 the product’s manufacturer and other manufacturer
 4 directions consistent with that labeling.

5 “(2) DISTRIBUTE OR DISTRIBUTION.—The
 6 terms ‘distribute’ or ‘distribution’ do not include the
 7 act of dispensing of a compounded drug product in
 8 accordance with this section.

9 “(3) DISPENSE.—The term ‘dispense’ means
 10 for a drug product compounded in accordance with
 11 this section, the act of the drug product leaving the
 12 facility in which it was compounded for delivery to
 13 a patient, patient’s agent, or health care facility (in-
 14 cluding a hospital, physician’s office, or other health
 15 care setting) pursuant to a valid prescription order
 16 for an identified patient.”.

17 **SEC. 5. APPLICABILITY OF RECORDS EXEMPTION FOR**
 18 **COMPOUNDING PHARMACIES.**

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

22 “(A) pharmacies which maintain establish-
 23 ments in conformance with any applicable local
 24 laws regulating the practice of pharmacy and
 25 medicine and, for compounding pharmacies, the

1 provisions of section 503A, and which are regu-
2 larly engaged in dispensing or distributing pre-
3 scription drugs or devices, upon prescriptions or
4 drug orders of practitioners licensed to admin-
5 ister such drugs or devices to patients under
6 the care of such practitioners in the course of
7 their professional practice, and which do not, ei-
8 ther through a subsidiary or otherwise, manu-
9 facture, prepare, propagate, compound, or proc-
10 ess drugs or devices for sale other than in the
11 regular course of their business;”.

12 (b) REGISTRATION EXEMPTION.—Section 510(g)(1)
13 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 360(g)(1)) is amended to read as follows:

15 “(1) pharmacies which maintain establishments
16 in conformance with any applicable local laws regu-
17 lating the practice of pharmacy and medicine and,
18 for compounding pharmacies, the provisions of sec-
19 tion 503A, and which are regularly engaged in dis-
20 pensing or distributing prescription drugs or devices,
21 upon prescriptions or drug orders of practitioners li-
22 censed to administer such drugs or devices to pa-
23 tients under the care of such practitioners in the
24 course of their professional practice, and which do
25 not manufacture, prepare, propagate, compound, or

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

3 **SEC. 6. REGULATIONS.**

4 (a) RULES IMPLEMENTING NEW REQUIREMENTS.—

5 Not later than 90 days after the date of enactment of this
6 Act, the Secretary of Health and Human Services shall
7 promulgate rules on the record to carry out the amend-
8 ments made by this Act, in accordance with chapter 5 of
9 title 5, United States Code.

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

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