

118TH CONGRESS
1ST SESSION

H. R. 167

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

JANUARY 9, 2023

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 to ensure patients have access to certain urgent-use compounded medications, 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 “Patient Access to Ur-
5 gent-Use Pharmacy Compounding Act of 2023”.

1 **SEC. 2. URGENT-USE COMPOUNDING FOR ADMINISTRA-**
2 **TION IN HOSPITALS OR OTHER CLINICAL**
3 **SETTINGS.**

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

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

8 (2) in paragraph (2)(B)(ii)(II), by striking the
9 period at the end and inserting “; or”; and

10 (3) by adding at the end the following new
11 paragraph:

12 “(3) notwithstanding the requirement in the
13 matter preceding paragraph (1) that the drug prod-
14 uct is compounded for an identified individual pa-
15 tient based on a valid prescription order or notation
16 described in such matter, is by a licensed pharmacist
17 or licensed physician and the compounded drug
18 product is compounded for distribution in limited
19 quantities to a licensed prescriber for urgent admin-
20 istration to a patient in a hospital or other clinical
21 setting, provided that all of the following are met:

22 “(A) The licensed prescriber certifies by
23 notation on the order to the compounding phar-
24 macist or physician that the licensed prescriber
25 has made reasonable attempts to obtain, and

1 has not been able to obtain, to address the ur-
2 gent medical need—

3 “(i) a drug product that is approved
4 or authorized by the Food and Drug Ad-
5 ministration with the same active ingre-
6 dient and the same route of administra-
7 tion; or

8 “(ii) a drug product that is com-
9 pounded by an outsourcing facility in ac-
10 cordance with section 503B with the same
11 active ingredient and the same route of ad-
12 ministration.

13 “(B) The compounded drug product is la-
14 beled with a beyond-use-date in accordance with
15 applicable United States Pharmacopeia stand-
16 ards.

17 “(C) The licensed pharmacist or licensed
18 physician marks the packaging of the com-
19 pounded drug product with text—

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

24 “(ii) requesting that the hospital or
25 other clinical setting provide to the com-

1 pounding pharmacist or physician the
2 records that identify the patient or pa-
3 tients to whom the drug products were ad-
4 ministered within—

5 “(I) 7 days of each such patient
6 receiving such medication; or

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

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

14 “(E) The licensed pharmacist or licensed
15 physician reports adverse events associated with
16 the compounded drug product as soon as pos-
17 sible but no later than 15 days after becoming
18 aware of such events to the MedWatch Adverse
19 Event Reporting program of the Food and
20 Drug Administration (or any successor pro-
21 gram).”.

1 **SEC. 3. COMPOUNDING FOR SHORTAGES FOR ADMINISTRA-**
2 **TION IN HOSPITALS OR OTHER CLINICAL**
3 **SETTINGS.**

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

7 “(2) DEFINITION.—For purposes of paragraph
8 (1)(D), the term ‘essentially a copy of a commer-
9 cially available drug product’ does not include—

10 “(A) a drug product in which there is a
11 change, made for an identified individual pa-
12 tient, which produces for that patient a signifi-
13 cant difference, as determined by the pre-
14 scribing practitioner, between the compounded
15 drug and the comparable commercially available
16 drug product; or

17 “(B) a drug product that meets each of
18 the following conditions:

19 “(i) At the time of compounding, dis-
20 tribution, or dispensing, the drug product
21 appears on—

22 “(I) the drug shortage list in ef-
23 fect under section 506E; or

24 “(II) the drug shortage list main-
25 tained by the American Society of
26 Hospital Pharmacists.

1 “(ii) If the drug product is not com-
2 pounded for an identified individual patient
3 based on a valid prescription order or nota-
4 tion, notwithstanding such requirement in
5 the matter preceding paragraph (1) of sub-
6 section (a), then the drug product—

7 “(I) is labeled in accordance sub-
8 paragraphs (B) and (C) of subsection
9 (a)(3); and

10 “(II) is documented by the
11 compounding pharmacist or physician
12 in accordance with subparagraphs (D)
13 and (E) of subsection (a)(3).”.

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