

114TH CONGRESS
1ST SESSION

S. 1406

To amend the Federal Food, Drug, and Cosmetic Act with respect to pharmacy compounding.

IN THE SENATE OF THE UNITED STATES

MAY 20, 2015

Mr. VITTER introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to pharmacy compounding.

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 “Saving Access to Com-
5 pounded Medications for Special Needs Patients Act”.

6 **SEC. 2. PHARMACY COMPOUNDING.**

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

9 (1) by redesignating subsections (b) through (e)
10 as subsections (c) through (f), respectively;

1 (2) by inserting after subsection (a) the fol-
2 lowing:

3 “(b) DRUG PRODUCTS FOR DISTRIBUTION TO PRAC-
4 TITIONERS.—Sections 501(a)(2)(B), 502(f)(1), and 505
5 shall not apply to a drug product if the drug product is
6 compounded and distributed to a practitioner where, as
7 permitted under State law, the drug product is used in
8 the treatment of or administered to a patient of the practi-
9 tioner, and if the compounding is by—

10 “(1) a licensed pharmacist in a State licensed
11 pharmacy or a Federal facility; or

12 “(2) a licensed physician.”;

13 (3) in subsection (c), as so redesignated—

14 (A) in paragraph (1)—

15 (i) in the matter preceding subpara-
16 graph (A), by striking “subsection (a)”
17 and inserting “subsection (a) or (b)”;

18 (ii) in subparagraph (A)(i)(III), by
19 striking “subsection (c)” and inserting
20 “subsection (d)”;

21 (iii) in subparagraph (C), by striking
22 “; and” and inserting “;”;

23 (iv) in subparagraph (D), by striking
24 the period and inserting “; and”; and

25 (v) by adding at the end the following:

1 “(E) complies with standards contained
2 within the United States Pharmacopeial Con-
3 vention General Chapters pertaining to the
4 compounding of drug products.”;

5 (B) in paragraph (2), by striking “identi-
6 fied individual patient, which produces for that
7 patient” and inserting “identified individual pa-
8 tient for whom the drug product is compounded
9 under subsection (a) or patients of a practi-
10 tioner to whom the drug product is compounded
11 and dispensed under subsection (b), which pro-
12 duces for that patient or patients”;

13 (C) in paragraph (3)—

14 (i) in the matter preceding subpara-
15 graph (A), by striking “subsection (a)”
16 and inserting “subsection (a) or (b)”;

17 (ii) in subparagraph (B)—

18 (I) by amending clause (i) to
19 read as follows:

20 “(i) that has entered into a memo-
21 randum of understanding with the Sec-
22 retary that provides for appropriate inves-
23 tigation by a State agency of complaints
24 relating to compounded drug products dis-
25 tributed outside such State; or”; and

1 (II) by amending clause (ii) to
2 read as follows:

3 “(ii) that has not entered into a
4 memorandum of understanding described
5 in clause (i) and the licensed pharmacist,
6 licensed pharmacy, or licensed physician
7 distributes (or causes to be distributed)
8 compounded drug products out of the
9 State in which such products are com-
10 pounded in quantities that do not exceed 5
11 percent of the total prescription orders dis-
12 pensed or distributed by such pharmacy or
13 physician.”; and

14 (iii) in the flush text, by striking “Na-
15 tional Association of Boards of Pharmacy”
16 and inserting “States”; and

17 (D) by adding at the end the following:

18 “(4) LIMITATION ON MEMORANDUM OF UNDER-
19 STANDING.—A memorandum of understanding en-
20 tered into under paragraph (3)(B)(i) shall not create
21 an unfunded mandate on a State.”;

22 (4) in subsection (d), as so redesignated—

23 (A) in paragraph (1), by striking “sub-
24 sections (b)(1)(A)(i)(III), (b)(1)(C), or

1 (b)(3)(A)” and inserting “subsections
2 (c)(1)(A)(i)(III), (c)(1)(C), or (c)(3)(A)”;

3 (B) in paragraph (2), by striking “sub-
4 section (b)(1)(A)(i)(III)” and inserting “sub-
5 section (c)(1)(A)(i)(III)”;

6 (5) by amending subsection (f), as so redesign-
7 nated to read as follows:

8 “(f) DEFINITIONS.—

9 “(1) COMPOUNDING.—As used in this section,
10 the term ‘compounding’ does not include mixing, re-
11 constituting, or other such acts that are performed
12 in accordance with directions contained in approved
13 labeling provided by the product’s manufacturer and
14 other manufacturer directions consistent with that
15 labeling.

16 “(2) DISTRIBUTE.—For purposes of this sec-
17 tion, the term ‘distribute’ does not include the dis-
18 pensing of a compounded drug product for an identi-
19 fied individual patient.”.

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