114TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mr. VITTER introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

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

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 ''Saving Access to Compounded Medications for Special Needs Patients Act''.

SEC. 2. PHARMACY COMPOUNDING.

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

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

(2) by inserting after subsection (a) the following:

''(b) DRUG PRODUCTS FOR DISTRIBUTION TO PRACTITIONERS.—Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded and distributed to a practitioner where, as permitted under State law, the drug product is used in the treatment of or administered to a patient of the practitioner, and if the compounding is by—

''(1) a licensed pharmacist in a State licensed pharmacy or a Federal facility; or

''(2) a licensed physician.'';

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

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking ''subsection (a)'' and inserting ''subsection (a) or (b)'';

(ii) in subparagraph (A)(i)(III), by striking ''subsection (c)'' and inserting ''subsection (d)'';

(iii) in subparagraph (C), by striking ''; and'' and inserting '';'';

(iv) in subparagraph (D), by striking the period and inserting ''; and''; and

(v) by adding at the end the following:

''(E) complies with standards contained within the United States Pharmacopeial Convention General Chapters pertaining to the compounding of drug products.'';

(B) in paragraph (2), by striking ''identified individual patient, which produces for that patient'' and inserting ''identified individual patient for whom the drug product is compounded under subsection (a) or patients of a practitioner to whom the drug product is compounded and dispensed under subsection (b), which produces for that patient or patients'';

(C) in paragraph (3)—

(i) in the matter preceding subparagraph (A), by striking ''subsection (a)'' and inserting ''subsection (a) or (b)'';

(ii) in subparagraph (B)—

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

''(i) that has entered into a memorandum of understanding with the Secretary that provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or''; and

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

''(ii) that has not entered into a memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which such products are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.''; and

(iii) in the flush text, by striking ''National Association of Boards of Pharmacy'' and inserting ''States''; and

(D) by adding at the end the following:

''(4) LIMITATION ON MEMORANDUM OF UNDERSTANDING.—A memorandum of understanding entered into under paragraph (3)(B)(i) shall not create an unfunded mandate on a State.'';

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

(A) in paragraph (1), by striking ''subsections (b)(1)(A)(i)(III), (b)(1)(C), or

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

(B) in paragraph (2), by striking ''subsection (b)(1)(A)(i)(III)'' and inserting ''subsection (c)(1)(A)(i)(III)''; and

(5) by amending subsection (f), as so redesignated to read as follows:

''(f) DEFINITIONS.—

''(1) COMPOUNDING.—As used in this section, 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.—For purposes of this section, the term 'distribute' does not include the dispensing of a compounded drug product for an identified individual patient.''.