113TH CONGRESS
1ST SESSION

H. R. _____

To amend section 503A of the Federal Food, Drug, and Cosmetic Act with respect to pharmacy compounding.

IN THE HOUSE OF REPRESENTATIVES

Mr. GRIFFITH of Virginia introduced the following bill; which was referred to the Committee on _____

A BILL

To amend section 503A of 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 ''Compounding Clarity Act of 2013''.

SEC. 2. PHARMACY COMPOUNDING.

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

"SEC. 503A. PHARMACY COMPOUNDING.

"(a) IN GENERAL.—Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product for human use if each of the following conditions is met:

"(1) IDENTIFIED PATIENT AND RECEIPT OF PRESCRIPTION.—The drug product is compounded for an identified individual patient based on the receipt of a valid prescription order, approved by the prescribing practitioner, stating that a compounded product is necessary for the identified patient.

"(2) TIMING AND SPECIFICITY OF PRESCRIPTION OR PURCHASE ORDER.—The compounding of the drug product is performed—

"(A) by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or by a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to compound and prescribe drugs;

"(B) by a licensed pharmacist or licensed physician in limited quantities before (notwithstanding paragraph (1)) the receipt of a valid prescription order for such individual patient when—

"(i) the licensed pharmacist or licensed physician has historically received

valid prescription orders for the compounding of the drug product; and

''(ii) the orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and—

''(I) such individual patient; or

''(II) the physician or other licensed practitioner who will write such prescription order; or

''(C) by a licensed pharmacist or licensed physician pursuant to a non-patient-specific purchase order (notwithstanding paragraph (1)) submitted by a health care provider, which purchase order provides assurances that—

''(i) the drug product will be administered by a health care practitioner within a physician's office, a hospital, or another health care setting; and

''(ii) patient-specific valid prescription orders—

''(I) will be submitted, electronically or otherwise, to the pharmacist or physician not later than 7 days

after the drug product is administered; and

''(II) will, in the aggregate, account for the total volume of drug product compounded pursuant to the non-patient-specific purchase order.

The compounding of a drug product may not be performed under subparagraph (B) or (C) if compounding under subparagraph (B) or (C), respectively, is prohibited by the laws of the State in which such compounding occurs or is prohibited by the laws of any State in which the compounded preparation is dispensed, sold, distributed, or shipped.

''(3) UNITED STATES PHARMACOPOEIA CHAPTERS.—The drug product is compounded in compliance with all United States Pharmacopoeia chapters that are applicable to pharmaceutical compounding (including the chapter on sterile preparations).

''(4) BULK DRUG SUBSTANCES.—The drug product is compounded using bulk drug substances (as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations (or any successor regulations))—

''(A) that—

"(i) if an applicable monograph exists under the United States Pharmacopoeia, the National Formulary, or another compendium or pharmacopeia recognized under Federal or State law, each comply with the monograph;

"(ii) if such a monograph does not exist, each are drug substances that are components of drugs approved by the Secretary for human use; and

"(iii) if such a monograph does not exist and the drug substance is not a component of a drug so approved, each appear on a list published by the Secretary (through regulations issued under subsection (c));

"(B) that are each manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

"(C) that are each accompanied by a valid certificate of analysis.

"(5) INGREDIENTS (OTHER THAN BULK DRUG SUBSTANCES).—The drug product is compounded using ingredients (other than bulk drug substances)

that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph.

''(6) DRUG PRODUCTS WITHDRAWN OR REMOVED BECAUSE UNSAFE OR NOT EFFECTIVE.—The drug product does not appear on a list published by the Secretary (through regulations issued under subsection (c)) of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective.

''(7) ESSENTIALLY A COPY OF A COMMERCIALLY AVAILABLE DRUG PRODUCT.—The licensed pharmacists or licensed physician does not compound any drug product that is essentially a copy of a commercially available drug product.

''(8) DRUG PRODUCTS PRESENTING DEMONSTRABLE DIFFICULTIES FOR COMPOUNDING.—The drug product is not a drug product identified in a list published by the Secretary (through regulations issued under subsection (c)) as a drug product that presents demonstrable difficulties for compounding that demonstrate an adverse effect on the safety or effectiveness of that drug product when administered to or used by a patient.

''(9) VOLUME LIMITATION.—[*to be supplied*]

''(b) NOTIFICATION SYSTEM.—

''(1) DEVELOPMENT AND IMPLEMENTATION.—The Secretary shall develop and implement a system for receiving and reviewing submissions from State boards of pharmacy—

''(A) describing actions taken against compounding pharmacies; or

''(B) expressing concerns that a compounding pharmacy may be acting as a manufacturer of drug products in violation of law.

''(2) CONTENT OF SUBMISSIONS FROM STATE BOARDS OF PHARMACY.—An action referred to in paragraph (1)(A) is, with respect to a pharmacy that compounds drug products, any of the following:

''(A) The issuance of a warning letter, or the imposition of sanctions or penalties, by a State for violations of a State's pharmacy regulations pertaining to compounding.

''(B) The suspension or revocation of a State-issued pharmacy license or registration.

''(C) The recall of compounded drug products due to concerns relating to the quality or purity of such products.

''(3) CONSULTATION.—The Secretary shall develop the system under paragraph (1) in consultation with the National Association of Boards of Pharmacy.

''(4) REVIEW AND INSPECTION OF PHARMACIES.—

''(A) REVIEW AND DETERMINATION BY SECRETARY.—The Secretary shall—

''(i) review each submission received under paragraph (1) and such other information as the Secretary determines necessary (including information collected through an inspection or maintained in the Adverse Event Reporting System database); and

''(ii) make a determination as to whether the pharmacy involved is in violation of one or more requirements of this section.

''(B) REQUIRED INSPECTIONS.—

''(i) IN GENERAL.—Not later than 60 days after receiving a submission under paragraph (1) regarding a pharmacy, the Secretary shall—

''(I) assess whether there is evidence suggesting that the pharmacy is in violation of one of more requirements of this section; and

''(II) if the Secretary has reason to believe that the pharmacy is in violation of one or more requirements of this section, conduct an inspection of the pharmacy to the extent necessary for making a final determination under such subparagraph (A)(ii).

''(ii) COORDINATION.—As the Secretary deems appropriate, an inspection required by clause (i) may be conducted in coordination with the relevant State board or boards of pharmacy.

''(C) INSPECTION AUTHORITY.—The Secretary may inspect a pharmacy—

''(i) to the extent necessary to determine whether the pharmacy is in violation of one or more requirements of this section if the Secretary has reason to believe the pharmacy is in violation of such requirements; and

"(ii) to the extent necessary to determine whether the pharmacy has exceeded the scope of the exemption under section 704(a)(2)(A) if the Secretary has reason to believe that the pharmacy has exceeded such scope.

"(5) NOTIFYING STATE BOARDS OF PHARMACY.—The system under paragraph (1) shall be designed to immediately notify State boards of pharmacy when—

"(A) the Secretary receives a submission under paragraph (1); or

"(B) the Secretary makes a determination under paragraph (4)(A)(ii) that a pharmacy is in violation of one or more requirements of this section.

"(6) TIMING.—Not later than one year after the date of enactment of the Compounding Clarity Act of 2013, the Secretary shall begin implementation of the system under paragraph (1).

"(c) REGULATIONS.—

"(1) IN GENERAL.—The Secretary shall issue regulations to implement this section.

"(2) ADVISORY COMMITTEE ON COMPOUNDING.—Before issuing regulations to im-

plement subsections (a)(4)(A)(iii), (a)(6), and (a)(8), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

''(3) UPDATING LISTS.—The Secretary shall update the regulations containing the lists under subsection (a)(4)(A)(iii), (a)(6), and (a)(8) regularly, but not less than once each year.

''(d) DEFINITIONS.—In this section:

''(1) 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) The term 'essentially a copy of a commercially available drug product' does not include—

''(A) a drug product in which there is a change, made for an identified individual pa-

tient, which produces for that patient a difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product; or

''(B) a drug product that appears on the drug shortage list in effect under section 506E.

''(3) The term 'licensed pharmacist' includes any individual that compounds drug products under the supervision of a practitioner licensed to compound drug products under State law.''.

SEC. 3. PROHIBITION AGAINST INTENTIONAL FALSIFICATION OF PRESCRIPTION ORDER FOR COMPOUNDED DRUG PRODUCT.

Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after paragraph (bbb) the following:

''(ccc) The intentional falsification of a prescription order for a drug product to be compounded under section 503A.''.

SEC. 4. REVIEW OF ADVERSE EVENT REPORTING REGULATIONS.

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review the regulations of the Food and Drug Administration

on adverse event reporting and determine whether any revisions should be made with respect to adverse event reporting by pharmacies engaged in compounding drug products.

[SEC. 5. AMENDMENT TO SECTION 510.

Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended—]

[(1) in subsection (a)(1), by inserting ''compounding outside the scope of section 503A and'' after ''shall include'';]

[(2) in subsection (g)(1), strike ''compound'' and insert ''compound outside the scope of section 503A''; and]

(3) by adding at the end the following new subsection:

''(q) COMPOUNDING OUTSIDE THE SCOPE OF SECTION 503A.—

''(1) FACILITY INSPECTION FEE.—[*to be supplied*]

''(2) STANDARDS.—[*to be supplied*]

''(3) OTHER.—[*to be supplied*]''.