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113TH CONGRESS
1ST SESSION

# H. R. 3019

To amend chapter V of the Federal Food, Drug, and Cosmetic Act to enhance the requirements for pharmacies that compound drug products.

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IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 2013

Ms. DELAURO (for herself, Mrs. LOWEY, Mr. CONYERS, Mr. HONDA, and Mr. ELLISON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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# A BILL

To amend chapter V of the Federal Food, Drug, and Cosmetic Act to enhance the requirements for pharmacies that compound drug products.

*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 ''Supporting Access to Formulated and Effective Compounded Drugs Act of 2013'' or the ''S.A.F.E. Compounded Drugs Act of 2013''.

**SEC. 2. ENHANCED REQUIREMENTS FOR COMPOUNDED DRUGS.**

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

(1) in subsection (a)(1)(A), by inserting ''that is registered with the Secretary under subsection (b)(6) (or is subject to the exception under subsection (b)(6)(C))'' after ''State licensed pharmacy'';

(2) in subsection (b)—

(A) in paragraph (1)(A), by inserting ''(meaning not more than 5 percent of the total quantity of drugs products compounded by the pharmacist or physician in any 30 day period)'' after ''limited quantities'';

(B) in paragraph (1)(C), by striking ''and'' at the end;

(C) in paragraph (1)(D), by striking ''regularly or in inordinate amounts (as defined by the Secretary)'';

(D) by adding at the end of paragraph (1) the following:

''(E) does not compound a drug product that appears on the list promulgated by the Secretary under subsection (h); and

''(F) does not compound a drug product in violation of the minimum standards promulgated under subsection (i).''; and

(E) by adding at the end of the subsection the following:

''(4) NOTIFICATION.—

''(A) PRESCRIBER NOTIFICATION.—Before providing a prescription order for a drug to be compounded under subsection (a), the physician or other licensed practitioner who will write such order shall—

''(i) inform the individual patient for whom such order is being written that a compounded drug is being prescribed; and

''(ii) provide such patient with a written document containing information concerning the availability, safety, and production of compounded drugs.

''(B) CONFIRMATION BY PHARMACIST.—Except in the case of a compounded drug product used in a procedure described in subparagraph (C), a licensed pharmacist or licensed physician who dispenses a compounded drug under subsection (a) shall, at the time such drug is dispensed—

"(i) confirm that the patient (or the individual to whom the drug is delivered on behalf of the patient) understands that the drug is a compounded drug; and

"(ii) provide a written document containing the information described in subparagraph (A)(ii).

"(C) PROVIDER NOTIFICATION.—Prior to providing a health care service that will be conducted by a health care provider in a health care setting (such as a hospital or a physician's office) and during which service a drug compounded under subsection (a) will be administered to a patient for purposes of treating such patient, the health care provider shall—

"(i) inform the patient that a compounded drug will be used during the procedure; and

"(ii) provide such patient with a written document containing the information described in subparagraph (A)(ii).

"(5) LABELING.—

"(A) IN GENERAL.—A drug product compounded under subsection (a) shall be clearly

labeled as a 'non-FDA approved compounded drug product'.

''(B) DEVELOPMENT OF REQUIREMENTS.—In determining the requirements for the label under subparagraph (A), the Secretary—

''(i) shall establish, and consult with, a temporary advisory committee on compounded drug product labeling requirements; and

''(ii) may establish different labeling requirements for—

''(I) a compounded drug product intended for use by a health care provider in an office or treatment setting; and

''(II) a compounded drug product intended for any use not described in subclause (I).

''(6) REGISTRATION.—

''(A) ESTABLISHMENT OF PROCESS.—The Secretary, in consultation with experts and representatives of stakeholders including pharmacies, compounding pharmacies, State regulators, and health care providers, shall establish

a process for pharmacies described in subsection (a)(1)(A) to register as a compounding pharmacy. Such registration shall be conducted through an electronic method.

''(B) REGISTRATION REQUIREMENT.—Except as provided in subparagraph (C), in order to be registered with the Secretary for purposes of subsection (a)(1)(A), every person who owns or operates a pharmacy shall submit to the Secretary, in such time and manner as the Secretary may require—

''(i) contact information for the pharmacy;

''(ii) the State or States that the pharmacy is licensed in;

''(iii) the methods used by the facility in compounding; and

''(iv) any additional information required by the Secretary, which may include the quantity of product compounded at such pharmacy for the purpose of determining if a drug manufacturing facility is inappropriately registering as a compounding pharmacy.

''(C) PROHIBITION ON DUAL REGISTRATION.—An entity registered under this subsection shall not be required to submit a registration under section 510.

''(D) EXCEPTION.—A pharmacy shall be exempt from the requirement to register under subsection (a)(1)(A) if the pharmacy—

''(i) employs fewer than 20 full-time employees (or 20 full-time equivalents); and

''(ii) performs traditional compounding of drug products for use in a single State.''; and

(3) by adding at the end of section 503A the following:

''(g) DATABASE.—

''(1) IN GENERAL.—The Secretary shall establish and maintain a database of information on pharmacies compounding drug products under subsection (a) that are licensed in more than one State, including—

''(A) the minimum standards for a compounding pharmacy license in each State;

''(B) relevant information provided to the Secretary by State agencies that regulate pharmacies;

''(C) reliable, timely, and comprehensive data related to inspections of such pharmacies, including the classification of actions indicated as a result of such inspections; and

''(D) other information determined relevant by the Secretary.

''(2) DESIGN.—The database under paragraph (1)—

''(A) shall be accessible, as determined appropriate by the Secretary, to State agencies that regulate pharmacies that compound drug products;

''(B) shall enable States and the Secretary to share information to ensure appropriate oversight of pharmacies that compound drug products;

''(C) shall be used by the Secretary to inform the Federal inspection and oversight of pharmacies that compound drug products to ensure that issues and pharmacies identified in the database receive appropriate oversight; and

''(D) shall be accessible, as determined appropriate by the Secretary, to health care providers and consumers.

''(h) ACTIVE INGREDIENTS AND DOSAGE FORMS THAT SHOULD NOT BE COMPOUNDED.—The Secretary shall, after consultation with appropriate stakeholders (including pharmacists, patient and public health advocacy groups, manufacturers, and health care professionals), promulgate a list of active ingredients and dosage forms that should not be compounded, because the compounding of such active ingredient or dosage form is reasonably likely to present a risk to public health.

''(i) MINIMUM STANDARDS.—

''(1) IN GENERAL.—The Secretary shall promulgate minimum standards for the safe production of compounded drug products under this section.

''(2) CONTENTS.—The standards under paragraph (1) shall each specify—

''(A) the type of compounded drug products to which they apply; and

''(B) the intended route of administration.

''(j) TRAINING.—The Secretary shall conduct a series of regional training opportunities for State agencies that regulate pharmacies that compound drug products. These training opportunities shall include information on the

minimum standards under subsection (i), sample inspection protocol, and recordkeeping to facilitate the inclusion of State findings and inspections into the database under subsection (g).''.

(b) DEADLINES AND ADVISORY COMMITTEES.—

(1) DEADLINE FOR ISSUANCE OF REGULATIONS.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue regulations to implement—

(A) paragraphs (4) and (5) of section 503A(b) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a); and

(B) subsection (g) of section 503A of such Act.

(2) LABELING ADVISORY COMMITTEE.—

(A) ESTABLISHMENT.—The Secretary of Health and Human Services shall establish an advisory committee on labeling (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) of compounded drug products and shall consult such committee in the development of the regulations under paragraph (1)(A).

(B) MEMBERSHIP.—The advisory committee shall include representatives of patients or consumers, health care providers, compounding pharmacies, State agencies that regulate compounding pharmacies, and at least one member with expertise on clearly communicating information in such labeling of drugs.

(C) MEETINGS.—The advisory committee shall hold an initial meeting not later than 6 months after the date of enactment of this Act.

(D) RECOMMENDATIONS.—Not later than 12 months after the date of enactment of this Act, the advisory committee shall submit to the Secretary of Health and Human Services recommendations on the regulations under paragraph (1)(A), including recommendations on the type of information and language that should be included on the labels of drug products that are compounded pursuant to section 503A of the Federal Food, Drug, and Cosmetic Act.

(E) TERMINATION.—The advisory committee under this subparagraph shall terminate upon the submission of the recommendations under subparagraph (D).

(3) DATABASE ADVISORY COMMITTEE.—

(A) ESTABLISHMENT.—The Secretary of Health and Human Services shall establish an advisory committee on the database described in section 503A(g) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and shall consult such committee in the development of the regulations under paragraph (1)(B).

(B) MEMBERSHIP.—The advisory committee shall include representatives of patients or consumers, health care providers, compounding pharmacies, State agencies that regulate compounding pharmacies, and information technology experts.

(C) MEETINGS.—The advisory committee shall hold an initial meeting not later than 6 months after the date of enactment of this Act.

(D) RECOMMENDATIONS.—Not later than 12 months after the date of enactment of this Act, the advisory committee shall submit to the Secretary of Health and Human Services recommendations on the regulations under paragraph (1)(B).

(E) TERMINATION.—The advisory committee under this subparagraph shall terminate upon the submission of the recommendations under subparagraph (D).

(4) PERMANENT ADVISORY COMMITTEE ON PHARMACY COMPOUNDING.—The Secretary shall convene the Advisory Committee on Pharmacy Compounding as appropriate to consider issues related to the safety and availability of compounded drug products.

**SEC. 3. REPORTS AND STUDIES.**

(a) BIANNUAL REPORTS.—Not later than 6 months after the date of enactment of this Act, and at the end of each succeeding 6-month period that ends before the 25th month after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Congress a report on the status of the implementation of the requirements of this Act, and the amendments made by this Act.

(b) THIRD-PARTY ACCREDITATION.—Not later than 12 months after the date of enactment of this Act, the Secretary shall submit to the Congress a report that contains—

(1) a review of the standards used by organizations that provide accreditation to compounding pharmacies; and

(2) an evaluation of the effectiveness of such standards in ensuring the production of safe and effective compounded drug products.

(c) STRUCTURE OF STATE OVERSIGHT.—Not later than 18 months after the date of enactment of this Act, the Secretary shall submit to the Congress a report that contains—

(1) a review of the models used by States to structure their oversight of pharmacies that compound drug products, including the structure of the agency or office responsible for oversight and its relationship with the industry that it regulates; and

(2) consideration of how the structure and relationship of State regulators may impact the development and enforcement of regulations to ensure safe compounded drug products.

(d) GAO REPORT.—The Comptroller General of the United States shall review—

(1) the extent to which Federal health care programs (as such term is defined in section 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b)) ensure that compounded drug products which are

paid for by such programs are compounded in facilities that comply with the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

(2) whether the reimbursement rates for compounded drug products under such Federal health care programs are appropriate, taking into consideration the cost of production of such compounded drug products; and

(3) whether such Federal health care programs encourage the use of compounded drug products in place of otherwise available lawfully marketed drug products.

**SEC. 4. PROHIBITIONS AND PENALTIES.**

(a) PROHIBITION OF VIOLATIONS OF SECTION 503A.—Section 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(d)) is amended by inserting ''503A,'' before ''505,''.

(b) PENALTIES.—Section 303(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(b)) is amended by adding at the end the following:

''(8) Notwithstanding subsection (a), any person who violates section 301(d) with respect to any compounded drug product—

"(A) knowingly and intentionally to defraud or mislead; or

"(B) with conscious or reckless disregard of a risk of death or serious bodily injury,

shall be fined under title 18, United States Code, imprisoned for not more than 10 years, or both.".

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