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(Original Signature of Member)

112TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to provide for the compounding of drug products.

IN THE HOUSE OF REPRESENTATIVES

Mr. MARKEY introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the compounding of 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 "Verifying Authority and Legality In Drug Compounding Act of 2012".

SEC. 2. APPLICATION OF FEDERAL LAW TO PRACTICE OF PHARMACY COMPOUNDING.

(a) AMENDMENT.—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) and 505 shall not apply with respect to a drug product if each of the following applies:

"(1) The drug product is compounded for an identified individual patient based on the receipt of—

"(A) a valid prescription order; or

"(B) a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient.

"(2) The drug product is compounded by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or by a licensed physician, pursuant to such prescription order or notation.

"(3) The drug product is compounded exclusively from—

"(A) ingredients that comply with the standards of an applicable United States Phar-

macopoeia or National Formulary monograph; or

''(B) if such a monograph does not exist, ingredients that are ingredients in a drug—

''(i) for which an approval of an application filed under subsection (b) or (j) of section 505 is in effect; or

''(ii) that may be lawfully marketed in the United States without such an approval pursuant to the definition of a new drug in section 201.

''(4) Any bulk substance used for purposes of compounding the drug product—

''(A) is manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

''(B) is accompanied by valid certificates of analysis.

''(5) The pharmacist or physician compounding the drug product complies with the standards of any applicable United States Pharmacopoeia chapters on pharmacy compounding.

''(6) The drug product, including the dosage form and any ingredient thereof, is not included in the list under subsection (b).

''(7) The drug product is not a copy of a commercially available drug.

''(b) LIST OF DRUG PRODUCTS THAT SHOULD NOT BE COMPOUNDED.—

''(1) IN GENERAL.—For purposes of subsection (a)(6), the Secretary shall—

''(A) develop and maintain a list of drug products that should not be compounded, including any categories, dosage forms, or ingredients of such drug products; and

''(B) include on such list, at a minimum—

''(i) drug products (or categories, dosage forms, or ingredients thereof) whose compounding is reasonably likely to cause an adverse effect on safety or effectiveness of such drug product; and

''(ii) drug products (or categories, dosage forms, or ingredients thereof) that have been withdrawn or removed from the market because they have been found to be unsafe or not effective.

''(2) INITIAL PUBLICATION; UPDATES.—The Secretary shall—

''(A) not later than 1 year after the date of the enactment of the Verifying Authority and Legality In Drug Compounding Act of 2012, publish an initial list under paragraph (1); and

''(B) not less frequently than every year thereafter, review and, as appropriate, update the list under paragraph (1).

''(3) AVAILABILITY.—The Secretary shall make the list under paragraph (1) available on the public Web site of the Food and Drug Administration.

''(4) TRANSMISSION TO STATE REGULATORY AGENCIES.—Upon publication of the initial list under paragraph (1), and upon each update to the list, the Secretary shall transmit an up-to-date copy of the list to the agency in each State with primary responsibility for regulating the compounding of drugs.

''(c) WAIVER OF REQUIREMENT OF INDIVIDUALLY IDENTIFIED PATIENT FOR SPECIFIED DRUG PRODUCTS.—

''(1) WAIVER AUTHORITY.—The Secretary may, with respect to a drug product sold or dispensed by a pharmacy or pharmacist, waive the requirement of

subsection (a)(1) that the drug product be compounded for an individually identified patient if the Secretary determines that compounding the drug product is necessary—

''(A) to address a drug shortage; or

''(B) to protect public health or well-being.

''(2) DURATION.—The duration of a waiver under paragraph (1) shall not exceed 1 year, unless the Secretary determines that an extension is necessary to continue—

''(A) to address the drug shortage for which such waiver was originally approved; or

''(B) to protect public health or well-being.

''(3) WAIVERS BY STATES PROHIBITED.—The Secretary may not authorize any State to grant waivers under this subsection.

''(d) WAIVER OF REQUIREMENT OF INDIVIDUALLY IDENTIFIED PATIENT FOR SPECIFIED PHARMACIES AND PHARMACISTS.—

''(1) WAIVER AUTHORITY.—The Secretary may waive the requirement of subsection (a)(1) that the drug product be compounded for an individually identified patient if the pharmacy or pharmacist—

''(A) submits an application that meets the requirements of paragraph (5)(A) and is satis-

factory to the Secretary (or, subject to paragraph (3), the State); and

''(B) agrees to comply with any condition of operation and any limitations specified by the Secretary as a requirement for such waiver, including the conditions and limitations specified under paragraph (5).

''(2) INELIGIBLE PHARMACIES.—A pharmacy or pharmacist required to be registered under section 510 for purposes of compounding a drug product is not eligible for a waiver under this subsection for such purposes.

''(3) TYPES OF PHARMACIES ELIGIBLE FOR WAIVER.—Subject to paragraph (2), the Secretary shall specify types of pharmacies and pharmacists that are eligible for a waiver under this subsection, and shall include the following types:

''(A) Any pharmacy or pharmacist within a hospital system that is compounding drug products exclusively for dispensing to patients within that hospital system.

''(B) Any pharmacy or pharmacist that compounds sterile drug products.

''(C) Any pharmacy or pharmacist that compounds drug products in limited quantities

before the receipt of a valid prescription for an individual patient who is located in the same State as the pharmacy or pharmacist, based on a history of the pharmacy or pharmacist receiving such valid prescription.

''(4) WAIVERS BY STATES ALLOWED.—

''(A) MEMORANDUM OF UNDERSTANDING.—The Secretary may authorize a State to grant waivers under paragraph (1) to pharmacies and pharmacists in such State pursuant to a memorandum of understanding entered into between the Secretary and the State—

''(i) ensuring, to the Secretary's satisfaction, that the State's program for granting waivers will be implemented in accordance with the requirements of this section (including the application of different requirements for different types of pharmacies, as specified under paragraph (5)(B)); and

''(ii) including such other information and assurances as the Secretary may require.

''(B) DETERMINATION.—The Secretary shall establish criteria and a process for determining whether to authorize a State to grant waivers under paragraph (1).

''(C) SCOPE OF AUTHORIZATION.—In authorizing a State to grant waivers under subparagraph (A), the Secretary may limit such authority to apply only with respect to certain types of pharmacies and pharmacists specified under paragraph (3).

''(D) LIMITATION.—A waiver granted by a State to a pharmacy or pharmacist under subparagraph (A) shall only apply with respect to compounded drug products sold or dispensed within such State.

''(5) APPLICATIONS; REQUIREMENTS.—

''(A) IN GENERAL.—For each type of pharmacy or pharmacist specified under paragraph (3), the Secretary shall specify, in the regulations under subsection (j), the following:

''(i) The information that is required to be included in an application for a waiver under paragraph (1).

''(ii) The circumstances necessary to support the approval of such an applica-

tion by the Secretary, or by a State that is authorized to grant waivers under paragraph (4), including the criteria that shall be used to evaluate such an application.

''(iii) The conditions of operation, including good manufacturing practices and requirements for third-party testing, applicable to the compounding of drugs under such a waiver.

''(iv) Any limitations on the activities that a pharmacy or pharmacist may engage in under such a waiver.

''(v) The duration (and renewability) of such a waiver.

''(B) SPECIFICITY TO TYPES OF PHARMACIES AND PHARMACISTS.—In establishing requirements under subparagraph (A), the Secretary shall make the requirements specific to each type of pharmacy and pharmacist specified by the Secretary under paragraph (3).

''(e) WAIVER OF REQUIREMENT REGARDING COPIES OF COMMERCIALLY AVAILABLE DRUG.—

''(1) WAIVER AUTHORITY.—The Secretary may, with respect to a drug product sold or dispensed by a pharmacy or pharmacist, waive the requirement of

subsection (a)(7) if the Secretary determines that compounding the drug product is necessary to protect public health or well-being.

''(2) DURATION.—The duration of a waiver under paragraph (1) shall not exceed 1 year, unless the Secretary determines that an extension is necessary to protect public health or well-being.

''(3) WAIVERS BY STATES PROHIBITED.—The Secretary may not authorize any State to grant waivers under this subsection.

''(f) INSPECTIONS.—The facilities of any pharmacy or pharmacist compounding drug products pursuant to a waiver under subsection (c), (d), or (e) shall be subject to inspection under section 704 for purposes of determining compliance with the provisions of this Act applicable to such compounding.

''(g) CANCELLATION OF WAIVER.—

''(1) IN GENERAL.—The Secretary shall publish notice at least 30 days before cancelling a waiver under subsection (c), (d), or (e).

''(2) EXCEPTION FOR PUBLIC HEALTH AND SAFETY.—The Secretary may cancel a waiver without regard to paragraph (1) in order to prevent an adverse impact on public health or safety.

''(h) LABELING.—The labeling of any drug product compounded pursuant to subsection (a) shall include the following statement: 'This drug has not been tested for safety and effectiveness and is not approved by the FDA. Serious adverse reactions to this drug should be reported to the pharmacy where it was received and the FDA at _____.' The blank shall specify a phone number and a Web site, to be provided by the Secretary for purposes of this subsection.

''(i) REPORTING BY PHARMACISTS AND PHYSICIANS.—

''(1) ADVERSE EVENT.—If a pharmacist or physician compounding a drug product pursuant to this section becomes aware of any adverse event associated with the use of such product, not later than 10 calendar days after becoming so aware, the pharmacist or physician shall report such adverse event to the Secretary.

''(2) INFORMATION RELATED TO RISK OF INJURY OR DEATH.—If a pharmacist or physician compounding a drug product pursuant to this section becomes aware of information concerning any bacteriological, fungal, or other contamination; any significant chemical, physical, or other change; or any deterioration of a compounded drug product

that has already been distributed by the pharmacist or physician, that could cause serious injury or death, not later than 5 calendar days after becoming so aware, the pharmacist or physician shall report such information to the Secretary.

''(j) REGULATIONS.—The Secretary shall promulgate regulations for carrying out this section, which shall include the following:

''(1) The types of pharmacies and pharmacists specified pursuant to subsection (d)(3).

''(2) The criteria and process for determining whether a State may provide a waiver under subsection (d)(4).

''(3) The information specified under subsection (d)(5)(A).

''(4) The requirements applicable to different types of pharmacies and pharmacists under subsection (d)(5).

''(5) The requirements for inspections under subsection (f).

''(k) DEFINITIONS.—In this section:

''(1) The term 'copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a sig-

nificant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

''(2) 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.''.

(b) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(bb) If it is a drug product compounded pursuant to section 503A and its labeling does not include the statement required by section 503A(h).''.

(c) CONFORMING AMENDMENT.—Section 704(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(2)(A)) is amended by inserting ''subject to section 503A,'' before ''pharmacies which maintain establishments''.

(d) REGULATIONS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall promulgate final regulations for carrying out the amendments made by subsections (a), (b), and (c).

(e) EFFECTIVE DATE.—The amendments made by subsections (a), (b), and (c) shall take effect on the date that is 1 year after the date of the enactment of this Act.

SEC. 3. REGISTRATION AND INSPECTION OF MANUFACTURERS COMPOUNDING DRUG PRODUCTS.

(a) REGISTRATION.—Section 510(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(g)) is amended by adding at the end the following: ''With respect to compounding drugs, the exemption in paragraph (1) does not apply with respect to any pharmacy to the extent to which the pharmacy is, in effect, manufacturing such drugs, as determined by the Secretary, taking into consideration the extent to which such pharmacy sells the drugs across State lines, the quantity of the drugs sold, and any other factors determined appropriate by the Secretary.''.

(b) INSPECTION.—Section 704(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(2)) is amended by adding at the end the following flush text:

''With respect to compounding drugs, the exemption in subparagraph (A) does not apply with respect to any pharmacy to the extent to which the pharmacy is, in effect, manufacturing such drugs, as determined by the Secretary, taking into consideration the extent to which such pharmacy sells the drugs across State lines, the quantity of the drugs sold,

and any other factors determined appropriate by the Secretary.''.

(c) REGULATIONS.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations for carrying out the amendments made by subsections (a) and (b).

(d) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 1 year after the date of the enactment of this Act.