I

113TH CONGRESS
1ST SESSION

H. R. 2186

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

IN THE HOUSE OF REPRESENTATIVES

MAY 23, 2013

Mr. MARKEY (for himself, Ms. SLAUGHTER, Mr. CLAY, and Mr. RANGEL) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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 2013'' or the ''VALID Compounding Act''.

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), 502(f)(1), and 505 shall not apply with respect to a drug product if each of the following applies:

"(1) Except as provided in subsection (d), the drug product is compounded for an identified individual patient based on the receipt of a prescription order.

"(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) In the case of a drug product that is compounded using bulk substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulations)—

"(A) such bulk substances—

"(i) are components of one or more drugs for which an approval of an application filed under subsection (b) or (j) of section 505 is in effect;

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

''(iii) appear on the list in effect under subsection (b); and

''(B) such bulk substances comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph, if a monograph exists.

''(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 Pharmacopeia chapters on pharmacy compounding.

''(6) The drug product, including the dosage form and any ingredient thereof—

''(A) is not included in the list under subsection (c); and

''(B) is not withdrawn or removed from the market because such drug product or any ingredient thereof has been found to be unsafe or not effective.

''(7) Subject to subsection (e), the drug product is not a copy of a commercially available drug.

''(8) If the drug product is produced using high-risk sterile compounding, the drug product is compounded in accordance with the standards, processes, and procedures established under subsection (f).

''(b) LIST OF BULK SUBSTANCES FROM WHICH DRUG PRODUCTS MAY BE COMPOUNDED.—

''(1) IN GENERAL.—For purposes of subsection (a)(3)(A)(iii), the Secretary shall, by guidance—

''(A) develop and maintain a list of bulk substances from which drug products may be compounded; and

''(B) include in the list only bulk substances that are not described in clause (i) or (ii) of subsection (a)(3)(A) and may be compounded to meet a medical need that cannot be

filled by using a bulk substance that is described in such clause (i) or (ii);

''(C) specify for each bulk substance on the list under this subsection any limitation on compounding the bulk substance; and

''(D) specify for each bulk substance on the list under this subsection the particular medical need that is met by placing such substance on the list.

''(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 2013, 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 pharmacies.

''(5) PETITIONS.—

''(A) IN GENERAL.—In carrying out this subsection, the Secretary shall receive and consider petitions from any person identifying a substance that should be added to, or removed from, the list under this subsection.

''(B) REQUIREMENT FOR PETITIONS SEEKING TO ADD A BULK SUBSTANCE.—Any petition seeking to add a bulk substance to the list under this subsection shall specify the reasons—

''(i) why the bulk substance is needed for a procedure or population; and

''(ii) why such need is not met by bulk substances that are described in clause (i) or (ii) of subsection (a)(3)(A).

''(C) APPROVAL OR DENIAL.—The Secretary shall approve or deny any petition received under this paragraph, and update the list under paragraph (1) accordingly, not later than 90 days after receipt of the petition, unless an extension of time is mutually agreed upon by the Secretary and the petitioner.

''(D) FINAL AGENCY ACTION.—A decision of the Secretary to approve or deny a petition received under this paragraph shall constitute final agency action subject to judicial review.

''(E) PUBLIC POSTING.—The Secretary shall publically post—

''(i) all petitions received under this paragraph within 21 days of receipt; and

''(ii) each approval, denial, and extension under subparagraph (C) promptly.

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

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

''(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, including extended release products, metered dose inhalers,

transdermal patches, and liposomal products; 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) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of paragraphs (2), (3), and (4) of subsection (b) shall apply with respect to the list under this subsection to the same extent and in the same manner as such provisions apply with respect to the list under subsection (b).

''(3) PETITIONS.—In carrying out this subsection, the Secretary shall receive and consider petitions from any person identifying a drug product that should be added to, or removed from, the list under this subsection. Subparagraphs (C) through (E) of subsection (b)(2) shall apply with respect to petitions under this paragraph to the same extent and in the same manner as such subparagraphs apply with respect to petitions under subsection (b)(5).

''(d) EXCEPTION TO REQUIREMENT OF IDENTIFIED INDIVIDUAL PATIENT.—

''(1) IN GENERAL.—A pharmacy or pharmacist that is not required to be registered under section 510 may compound a drug product without regard to subsection (a)(1) if the pharmacy or pharmacist—

''(A) registers with the Secretary as specified pursuant to paragraph (2); and

''(B) agrees to comply with any condition of operation or limitation of activity specified by the Secretary, including the conditions and limitations specified pursuant to paragraph (2).

''(2) REGISTRATION AND REQUIREMENTS.—The Secretary shall specify by regulation for each type of pharmacy or pharmacist compounding drug products pursuant to the exception under this subsection—

''(A) the registration requirements for such pharmacy or pharmacist and the information that must be submitted with the registration, which information shall include—

''(i) the name and location of the pharmacy;

''(ii) the types of drugs that are compounded;

''(iii) the active ingredients in each such drug;

''(iv) the source and strength of the active ingredient in each drug;

''(v) the dosage form and route of administration of each drug;

''(vi) the number of individual units produced of each drug;

''(vii) the States to which drugs were shipped;

''(viii) the number of individual units of each drug that are shipped to each State; and

''(ix) affirmation that the pharmacy or pharmacist is in compliance with State pharmacy licensing regulations;

''(B) the frequency in which information described in subparagraph (A) must be submitted;

''(C) the conditions of operation, including good manufacturing practices and requirements for third-party testing, applicable to the compounding of drugs; and

''(D) any limitations on the activities of such pharmacy or pharmacist.

''(3) TYPES OF PHARMACIES ELIGIBLE.—The Secretary shall specify separate requirements for

each type of pharmacy and pharmacist authorized to compound drug products pursuant to the exception under this subsection. The Secretary shall include separate requirements for—

"(A) any pharmacy or pharmacist within a hospital system that is compounding drug products exclusively for dispensing to patients within that hospital system; and

"(B) any pharmacy or pharmacist that compounds sterile drug products.

"(4) MEMORANDUM OF UNDERSTANDING.—

"(A) IN GENERAL.—Subject to subparagraph (C), the Secretary may enter into appropriate memoranda of understanding with States to address State implementation of the exception under this subsection—

"(i) ensuring, to the Secretary's satisfaction, that the State will implement the exception under this subsection in accordance with the requirements of this section; and

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

''(B) PROCESS; CRITERIA.—The Secretary shall—

''(i) establish a process and criteria for entering into a memorandum of understanding under this paragraph, including the sharing of information between State and Federal authorities; and

''(ii) reevaluate each such memorandum of understanding not less than every 5 years to ensure, to the Secretary's satisfaction, that the State's implementation of the memorandum of understanding continues to conform to the requirements of this section.

''(C) EXCLUSIVE FEDERAL AUTHORITY.—The Secretary shall retain exclusive Federal authority to implement the exception under this subsection with respect to pharmacies and pharmacists that—

''(i) perform high-risk sterile compounding; or

''(ii) compound drug products for shipment across State lines.

''(5) MAINTENANCE OF LIST.—The Secretary shall maintain a publically available list—

''(A) identifying all pharmacies and pharmacists registered under this subsection; and

''(B) indicating, for each such pharmacy and pharmacist, whether the pharmacy or pharmacist is subject to regulation by a State pursuant to a memorandum of understanding in effect under paragraph (4).

''(e) EXCEPTIONS REGARDING COPIES OF COMMERCIALLY AVAILABLE DRUGS.—A drug that is a copy of a commercially available drug may be compounded pursuant to this section without regard to subsection (a)(7) if—

''(1)(A) the commercially available drug that is being compounded is at the time of distribution on the drug shortage list under section 506E, and the pharmacy has provided notice to the Secretary that such drug is being compounded not later than 5 days after distributing such drug; or

''(B) the Secretary determines that compounding the drug product is necessary to protect public health or wellbeing; and

''(2) in the case of a commercially available drug marketed pursuant to a risk evaluation and mitigation strategy approved under section 505–1 and including one or more elements to assure safe use, the pharmacy or pharmacist compounding the

drug that is a copy of such commercially available drug demonstrates to the Secretary that controls will be used that are comparable to such elements to assure safe use.

''(f) HIGH-RISK STERILE COMPOUNDING.—For purposes of subsection (a)(8), the Secretary shall establish standards, processes, and procedures for high-risk sterile compounding.

''(g) INSPECTIONS.—Notwithstanding section 704(a)(2)(A), the facilities of any pharmacy or pharmacist compounding drug products under this section—

''(1) shall be subject to inspection under section 704; and

''(2) shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to, and to copy and verify, records for purposes of determining compliance with the provisions of this Act applicable to such compounding.

''(h) SHARING OF INFORMATION.—If during an inspection of the facilities of a pharmacy or pharmacist under this section the Secretary discovers a violation of this Act, the Secretary shall give notice of the violation—

''(1) to the State in which the facilities are located; and

''(2) to any State to which the pharmacy or pharmacist has shipped a drug product during the preceding 30 days.

''(i) LABELING.—The labeling of any drug product compounded pursuant to this section shall include—

''(1) the name of each drug and ingredient included;

''(2) the name, address, and phone number of the licensed compounding pharmacy, pharmacist, or physician;

''(3) the date on which the drug was compounded;

''(4) instructions for storage and use;

''(5) the following statement: 'This drug has not been tested for safety and effectiveness and is not approved by the FDA. This drug was made specifically for you because your health care provider determined that no FDA-approved product would suit your needs. Serious adverse reactions to this drug should be reported to the FDA at _____, to the pharmacy where the drug was received, and to your health care provider.' (The blank shall specify a phone number and a Web site, to be provided by the Secretary for purposes of this subsection.); and

''(6) such other information as the Secretary may require.

''(j) 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 2 calendar days after becoming so aware, the pharmacist or physician shall report such information to the Secretary.

''(k) COMPOUNDING ESTABLISHMENT AND REINSPECTION FEES.—

''(1) DEFINITIONS.—In this subsection—

''(A) the term 'affiliate' has the meaning given such term in section 735(11);

''(B) the term 'covered compounding pharmacy' means a pharmacy that, pursuant to subsection (d) (the exception to the requirement of an identified individual patient)—

''(i) performs high-risk sterile compounding;

''(ii) compounds drug products for shipment across State lines; or

''(iii) otherwise performs compounding pursuant to subsection (d) that is not regulated by a State pursuant to a memorandum of understanding under subsection (d)(4);

''(C) the term 'gross annual sales' means the total worldwide gross annual sales, in United States dollars, for a covered compounding pharmacy, including the sales of all the affiliates of the covered compounding pharmacy; and

''(D) the term 'reinspection' means, with respect to a covered compounding pharmacy, one or more inspections conducted under sec-

tion 704 subsequent to an inspection conducted under such provision which identified noncompliance materially related to an applicable requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.

"(2) ESTABLISHMENT AND REINSPECTION FEES.—

"(A) IN GENERAL.—For fiscal year 2015 and each subsequent fiscal year, the Secretary shall, in accordance with this subsection, assess and collect—

"(i) an annual establishment fee from each covered compounding pharmacy; and

"(ii) a reinspection fee from each covered compounding pharmacy subject to a reinspection in such fiscal year.

"(B) MULTIPLE REINSPECTIONS.—A covered compounding pharmacy subject to multiple reinspections in a fiscal year shall be subject to a reinspection fee for each reinspection.

"(3) ESTABLISHMENT AND REINSPECTION FEE SETTING.—The Secretary shall establish the establishment and reinspection fee to be collected under this subsection for each fiscal year, based on the

methodology described in paragraph (4) and shall publish such fee in a Federal Register notice not later than 60 days before the start of each such year.

"(4) AMOUNT OF ESTABLISHMENT FEE AND REINSPECTION FEE.—

"(A) IN GENERAL.—For each covered compounding pharmacy in a fiscal year—

"(i) except as provided in subparagraph (D), the amount of the annual establishment fee under paragraph (2) shall be equal to the sum of—

"(I) $15,000, multiplied by the inflation adjustment factor described in subparagraph (B); plus

"(II) the small business adjustment factor described in subparagraph (C); and

"(ii) the amount of any reinspection fee (if applicable) under paragraph (2) shall be equal to $15,000, multiplied by the inflation adjustment factor described in subparagraph (B).

"(B) INFLATION ADJUSTMENT FACTOR.—

"(i) IN GENERAL.—For fiscal year 2015 and subsequent fiscal years, the fee amounts established in subparagraph (A) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

"(I) one;

"(II) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years; and

"(III) the average annual percent change that occurred in the Consumer Price Index for urban consumers

(U.S. City Average; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years.

''(ii) COMPOUNDED BASIS.—The adjustment made each fiscal year under clause (i) shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under clause (i).

''(C) SMALL BUSINESS ADJUSTMENT FACTOR.—The small business adjustment factor referred to subparagraph (A)(i)(II) shall be an amount established by the Secretary for each fiscal year based on the Secretary's estimate of—

''(i) the number of small businesses that will pay a reduced establishment fee for such fiscal year; and

''(ii) the adjustment to the establishment fee necessary to achieve total fees equaling the total fees that the Secretary would have collected if no entity qualified for the small business exception in subparagraph (D).

''(D) EXCEPTION FOR SMALL BUSINESSES.—

''(i) IN GENERAL.—In the case of a covered compounding pharmacy with gross annual sales of $1,000,000 or less in the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which the fees under this subsection are assessed, the amount of the establishment fee under paragraph (2) for a fiscal year shall be equal to ⅓ of the amount calculated under subparagraph (A)(i)(I) in such fiscal year.

''(ii) APPLICATION.—To qualify for the exception under this subparagraph, a small business shall submit to the Sec-

retary a written request for such exception, in a format specified by the Secretary in guidance, certifying its gross annual sales for the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which fees under this subsection are assessed. Any such application must be submitted to the Secretary not later than April 30 for the following fiscal year. Any statement or representation made to the Secretary shall be subject to section 1001 of title 18, United States Code.

''(E) CREDITING OF FEES.—In establishing the small business adjustment factor under subparagraph (C) for a fiscal year, the Secretary shall provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of the small business adjustment factor for such previous fiscal year, and consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

''(5) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to clauses (i) and (ii) of paragraph (2)(A) available solely to pay for

the costs of oversight of covered compounding pharmacies.

''(6) SUPPLEMENT NOT SUPPLANT.—Funds received by the Secretary pursuant to this subsection shall be used to supplement and not supplant any other Federal funds available to carry out the activities described in this section.

''(7) CREDITING AND AVAILABILITY OF FEES.—Fees authorized under this subsection shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the purpose of paying the costs of oversight of covered compounding pharmacies.

''(8) COLLECTION OF FEES.—

''(A) ESTABLISHMENT FEE.—A covered compounding pharmacy shall remit the establishment fee due under this subsection in a fis-

cal year when submitting a registration pursuant to subsection (d) for such fiscal year.

''(B) REINSPECTION FEE.—The Secretary shall specify in the Federal Register notice described in paragraph (3) the manner in which reinspection fees assessed under this subsection shall be collected and the timeline for payment of such fees. Such a fee shall be collected after the Secretary has conducted a reinspection of the covered compounding pharmacy involved.

''(C) EFFECT OF FAILURE TO PAY FEES.—

''(i) REGISTRATION.—A covered compounding pharmacy shall not be considered registered under subsection (d) in a fiscal year until the date that the covered compounding pharmacy remits the establishment fee under this subsection for such fiscal year.

''(ii) MISBRANDING.—All drugs manufactured, prepared, propagated, compounded, or processed by a covered compounding pharmacy for which any establishment fee or reinspection fee has not been paid as required by this subsection shall be deemed misbranded under section

502(cc) until the fees owed for such covered compounding pharmacy under this subsection have been paid.

"(D) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under this subsection within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

"(9) ANNUAL REPORT TO CONGRESS.—Not later than 120 days after each fiscal year in which fees are assessed and collected under this subsection, the Secretary shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, to include a description of fees assessed and collected for each year, a summary description of entities paying the fees, and the number of inspections and re-inspections of such entities performed each year.

"(10) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year 2015 and each subsequent fiscal year, there is authorized to be appropriated for fees under this subsection an amount equivalent to the

total amount of fees assessed for such fiscal year under this subsection.

''(l) DEFINITIONS.—In this section:

''(1) The terms 'compound' and 'compounding'—

''(A) do 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; and

''(B) in the case of a radioactive drug (as defined in section 310.3(n) of title 21, Code of Federal Regulations (or any successor regulations)), also do not include a minor deviation from such directions with regard to radioactivity, volume, or stability, that is made by or under the direct supervision of an 'authorized nuclear pharmacist' or a physician who is an 'authorized user' (as such terms are defined in section 35.2 of title 10, Code of Federal Regulations, (or any successor regulations)).

''(2) 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 indi-

vidual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product, provided that in the case of a radioactive drug (as defined in section 310.3(n) of title 21, Code of Federal Regulations (or any successor regulations)), the reasons for the determination by the prescribing practitioner have been documented and such documentation is maintained by the pharmacy.

''(3) The term 'high-risk sterile compounding' means compounding sterile drug products using nonsterile ingredients, nonsterile devices, or nonsterile components.''.

(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 information required by section 503A(i).

''(cc) If it is a drug, and it was manufactured, prepared, propagated, compounded, or processed by a compounding manufacturer for which fees have not been paid as required by section 503A(k).''.

(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 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) 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 amendment made by subsection (a).

(c) 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.

SEC. 4. NO PREEMPTION OF ADDITIONAL NON-FEDERAL REQUIREMENTS.

The requirements of this Act (including the requirements of the amendments made by this Act) do not preempt any non-Federal requirement that is in addition to, and compatible with, such requirements.

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