I

113TH CONGRESS
1ST SESSION

# H. R. 3089

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

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IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 12, 2013

Mr. GRIFFITH of Virginia (for himself, Ms. DEGETTE, and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

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# 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. TRADITIONAL 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. TRADITIONAL PHARMACY COMPOUNDING.**

"(a) IN GENERAL.—Sections 501(a)(2)(B), 502(f)(1), and 505 of this Act and section 351 of the Public Health Service Act 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 in accordance with one of the following:

"(A) IN GENERAL.—The drug product is compounded by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or by a licensed physician, for an identified individual patient based on the receipt of a valid prescription.

"(B) ANTICIPATORY COMPOUNDING.—The drug product is compounded by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or by a licensed physician, in limited quantities before the receipt of a valid prescription for an identified individual patient, based on—

"(i) historical demand for the drug product; and

"(ii) a history of prescriptions for the drug product generated solely within an established relationship between the licensed

pharmacist or licensed physician who is performing the compounding and—

"(I) the individual patient; or

"(II) the physician or other licensed practitioner who writes the prescription.

"(C) COMPOUNDING FOR OFFICE USE.—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 a non-patient-specific purchase order and—

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

"(ii) valid patient-specific prescriptions or, when a compounded drug product is administered within the same health system in which it was compounded, valid patient names—

"(I) are submitted, electronically or otherwise, to the pharmacist or physician who performs the compounding, not later than 7 business

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;

"(iii) during any 6-month period, of the total drug products dispensed from the facility at which the drug product was compounded, not more than 5 percent are compounded sterile drug products that are—

"(I) dispensed pursuant to this subparagraph; and

"(II) shipped interstate;

"(iv) records of the compounding will be kept for not less than 3 years; and

"(v) the statement 'Office Use Only' and the statement 'Not for resale' appear on the compounded drug product.

Compounding under this subparagraph shall not be considered to be in violation of clause (ii) because of the failure of a pharmacist or a physician to account for valid patient-specific prescriptions or valid patient names as required by

such clause, so long as the pharmacist or physician makes a good faith, reasonable effort to account for the prescriptions or names, as applicable, and does not continue to compound drug products under this subparagraph for a health care practitioner or facility with a history of failing to submit such prescriptions or patient names.

''(2) QUALITY STANDARDS.—Irrespective of whether a drug product is compounded under subparagraph (A), (B), or (C) of paragraph (1), the drug product is compounded, stored, and dated in compliance with the United States Pharmacopoeia chapters that are applicable to pharmaceutical compounding (including the chapter on sterile preparations).

''(3) BULK DRUG SUBSTANCES.—If 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) the bulk drug substances—

''(i) if an applicable monograph exists under the United States Pharmacopoeia, the National Formulary, or another com-

pendium or pharmacopeia recognized under Federal law, each comply with the monograph;

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

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

"(B) the bulk drug substances 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) the bulk drug substances are each accompanied by a valid certificate of analysis.

"(4) INGREDIENTS (OTHER THAN BULK DRUG SUBSTANCES).—If any ingredients (other than bulk drug substances) are used in compounding the drug product, such ingredients comply with the standards

of an applicable United States Pharmacopoeia or National Formulary monograph.

''(5) DRUG PRODUCTS WITHDRAWN OR REMOVED BECAUSE UNSAFE OR NOT EFFECTIVE.—The drug product does not appear on a list published by the Secretary 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.

''(6) ESSENTIALLY A COPY OF A MARKETED AND APPROVED DRUG PRODUCT.—The licensed pharmacist or licensed physician does not compound any drug product that is essentially a copy of a marketed and approved drug product.

''(7) DRUG PRODUCTS PRESENTING DEMONSTRABLE DIFFICULTIES FOR COMPOUNDING.—The drug product is not identified (directly or as part of a category of drug products) in a list published by the Secretary (through regulations issued under subsection (e)) as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product.

''(8) PROHIBITION ON WHOLESALING.—The drug product will not be sold by an entity other than

the pharmacy or physician that compounded such drug product.

''(b) STATE REGULATION.—Nothing in this section shall prevent a State from—

''(1) imposing restrictions on the type of compounding described in subparagraph (B) or (C) of subsection (a)(1) that are in addition to the restrictions applicable under this section; or

''(2) enforcing requirements or restrictions contained in the chapters or standards described in subsection (a)(2).

''(c) 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 in violation of one or more requirements of this section.

''(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 DETERMINATION BY SECRETARY.—The Secretary shall 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 make a determination as to whether the pharmacy involved may be in violation of one or more requirements of this section.

"(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 that a pharmacy may be 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).

''(d) INSPECTION AUTHORITY.—In accordance with section 704(a), the Secretary may inspect a pharmacy's records to determine whether the pharmacy is in violation of one or more requirements of this Act if—

''(1) the inspection is conducted in coordination with the relevant State board or boards of pharmacy; or

''(2) the Secretary has evidence that the pharmacy may be in violation of such a requirement.

''(e) 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)(3)(A)(iii) and (a)(7), the Secretary shall convene and consult an advisory committee on compounding. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacists having current experience and expertise in compounding, physicians having background and knowledge in compounding, and consumer organizations with an expertise in compounding.

''(3) INTERIM LISTS.—Before the date on which final regulations are issued to implement subsections (a)(3)(A)(iii) and (a)(7), if the Secretary determines it is necessary to protect the public health, the Secretary may designate drug products or substances as described in such subsections, by—

''(A) publishing a notice of such drug products or substances proposed for designation, including the rationale for such designation, in the Federal Register;

''(B) providing a period of not less than 60 calendar days for comment on the notice; and

''(C) publishing a notice in the Federal Register designating such drug products or substances.

''(4) UPDATING LISTS.—The Secretary shall update the regulations containing the lists of drug products and substances described in subsections (a)(3)(A)(iii) and (a)(7) regularly, but not less than once every three years.

''(5) SUNSET OF NOTICE.—Any notice published under paragraph (3) shall not be effective after the earlier of—

''(A) the date that is 3 years after the date of Compounding Clarity Act of 2013; and

''(B) the effective date of the final regulations issued to implement subsections (a)(3)(A)(iii) and (a)(7).

''(f) DEFINITIONS.—In this section:

''(1) The term 'compounding' includes—

''(A) the combining, admixing, mixing, diluting, reconstituting, or otherwise altering of a marketed drug product, except when performed in accordance with specific directions for such acts contained in approved labeling provided by the product's manufacturer or otherwise provided by that manufacturer consistent with that labeling;

''(B) the combining, admixing, mixing, diluting, reconstituting, or otherwise altering a

bulk drug substance to create a drug product; and

"(C) repackaging.

"(2) The term 'essentially a copy of a marketed and approved drug product' does not include—

"(A) a drug product in which there is a change, made for an identified individual patient, which produces for that patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug product and the comparable marketed and approved 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 who compounds drug products under the supervision of a practitioner licensed to compound drug products under State law.

"(4) The term 'marketed and approved drug product' means a drug product that—

"(A) is currently marketed; and

"(B) is approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act.

''(5)(A) The term 'repackaging' means taking a drug approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act from the container in which the drug is distributed by the original manufacturer and placing such drug in a different container of the same or smaller size without further manipulating the drug (such as by diluting it or mixing it with another, different drug or drugs).

''(B) Such term does not include removing the drug from its original container for immediate administration to an identified individual patient, such as withdrawing a drug into a syringe for immediate injection or removing the drug from its original container within a health care entity by a practitioner, or other licensed individual under the supervision or direction of such practitioner, for administration within the same day within such health care entity.''.

**SEC. 3. OUTSOURCING FACILITIES.**

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended—

(1) by redesignating section 503B as section 503C; and

(2) by inserting after section 503A (21 U.S.C. 353a) the following new section:

**"SEC. 503B. OUTSOURCING FACILITIES.**

"(a) IN GENERAL.—Sections 502(f)(1) and 505 of this Act and section 351 of the Public Health Service Act shall not apply to a drug product compounded for human use by a licensed pharmacist in an outsourcing facility if each of the following conditions is met:

"(1) REGISTRATION AND REPORTING.—The facility is in compliance with the registration and reporting requirements of subsection (b).

"(2) DRUG PRODUCT AND SUBSTANCE LIMITATIONS.—The facility does not compound drug products in violation of paragraphs (3) through (8) of section 503A(a).

"(3) FEES.—The facility has paid all fees owed by such facility pursuant to section 744K.

"(4) STANDARDIZED DRUG PRODUCTS FROM BULK.—The facility does not compound, from bulk drug substances, standardized dosages that are not otherwise commercially available of a marketed and approved drug product.

"(5) LABELING OF DRUG PRODUCTS.—

"(A) LABEL.—The label of a drug product compounded by an outsourcing facility shall include—

"(i) the statement 'This is a compounded drug.' or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug product;

"(ii) the name, address, and phone number of the applicable outsourcing facility; and

"(iii) with respect to the compounded drug product—

"(I) the lot or batch number;

"(II) the established name of the drug product;

"(III) the dosage form and strength;

"(IV) the statement of quantity or volume, as appropriate;

"(V) the date that the drug product was compounded;

"(VI) the expiration date;

"(VII) storage and handling instructions;

"(VIII) the National Drug Code number, if available;

"(IX) the 'Not for resale' statement required under section 503A(a)(1)(C)(v); and

"(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

"(B) CONTAINER.—The container from which the individual units of a drug product compounded by an outsourcing facility are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include—

"(i) the information described under subparagraph (A)(iii)(X), if there is not space on the label for such information;

"(ii) the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088; and

"(iii) directions for use, including, as appropriate, dosage and administration.

"(C) ADDITIONAL INFORMATION.—The label and labeling of a drug product compounded by an outsourcing facility shall include any other information as determined necessary and specified in regulations promulgated by the Secretary

"(b) REGISTRATION OF OUTSOURCING FACILITIES AND REPORTING OF DRUG PRODUCTS.—

"(1) REGISTRATION OF OUTSOURCING FACILITIES.—

"(A) ANNUAL REGISTRATION.—During the period beginning on October 1 and ending on December 31 each year, each outsourcing facility—

"(i) shall register with the Secretary its name, place of business, and unique facility identifier (which shall conform to the requirements for the unique facility identifier established under section 510), and a point of contact e-mail address; and

"(ii) shall indicate whether the outsourcing facility intends to compound a drug product that appears on the list in effect under section 506E during the subsequent calendar year.

"(B) NEW OUTSOURCING FACILITIES.—Each outsourcing facility, upon first engaging in compounding pursuant to this section, shall immediately register with the Secretary and provide the information described in paragraph (1)(A). The Secretary shall establish a timeline for registration for the first calendar year following the effective date of the Compounding Clarity Act of 2013. In no case may registration be required until at least 60 calendar days following publication of the timeline in the Federal Register.

"(C) AVAILABILITY OF REGISTRATION FOR INSPECTION; LIST.—

"(i) REGISTRATIONS.—The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this paragraph.

"(ii) LIST.—The Secretary shall make available on the public Internet Web site of the Food and Drug Administration a list of the name of each facility registered under this subsection as an outsourcing facility, the State in which each such facility is located, whether the facility compounds

from bulk drug substances, and whether any such compounding from bulk drug substances is for sterile or non-sterile drug products.

''(2) DRUG PRODUCT REPORTING BY OUTSOURCING FACILITIES.—

''(A) IN GENERAL.—Upon initially registering as an outsourcing facility, once during the month of June of each year, and once during the month of December of each year, each outsourcing facility that registers with the Secretary under paragraph (1) shall submit to the Secretary a report—

''(i) identifying the drug products compounded by such outsourcing facility during the previous 6-month period; and

''(ii) with respect to each drug product identified under clause (i), providing the active ingredient; the source of such active ingredient; the National Drug Code number, if available, of the source drug product or bulk active ingredient; the strength of the active ingredient per unit; the dosage form and route of administration; the package description; the number

of individual units produced; and the National Drug Code number of the final product, if assigned.

"(B) FORM.—Each report under subparagraph (A) shall be prepared in such form and manner as the Secretary may prescribe by regulation or guidance.

"(C) CONFIDENTIALITY.—Reports submitted under this paragraph shall be exempt from inspection under paragraph (1)(C), unless the Secretary finds that such an exemption would be inconsistent with the protection of the public health.

"(3) ELECTRONIC REGISTRATION AND REPORTING.—Registrations and drug product reporting under this subsection (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting waiver.

"(4) RISK-BASED INSPECTION FREQUENCY.—

"(A) IN GENERAL.—Outsourcing facilities—

''(i) shall be subject to inspection pursuant to section 704; and

''(ii) shall not be eligible for the exemption under section 704(a)(2)(A).

''(B) RISK-BASED SCHEDULE.—The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect outsourcing facilities in accordance with a risk-based schedule established by the Secretary.

''(C) RISK FACTORS.—In establishing the risk-based schedule, the Secretary shall inspect outsourcing facilities according to the known safety risks of such outsourcing facilities, which shall be based on the following factors:

''(i) The compliance history of the outsourcing facility.

''(ii) The record, history, and nature of recalls linked to the outsourcing facility.

''(iii) The inherent risk of the drug products compounded at the outsourcing facility.

''(iv) The inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has

been inspected pursuant to section 704 within the last 4 years.

''(v) Whether the outsourcing facility has registered under this paragraph as an entity that intends to compound a drug product that appears on the list in effect under section 506E.

''(vi) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

''(5) ADVERSE EVENT REPORTING.—Outsourcing facilities shall be required to submit adverse event reports to the Secretary in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations) or section 600.80 of title 21, Code of Federal Regulations (or any successor regulations).

''(c) DEFINITIONS.—In this section:

''(1) OUTSOURCING FACILITY.—The term 'outsourcing facility' means a facility at one geographic location or address that compounds sterile drug

products for office use in excess of the limitation set forth in section 503A(a)(1)(C)(iii).

''(2) OTHER DEFINITIONS.—The terms 'compounding', 'essentially a copy of a marketed and approved drug product', 'licensed pharmacist', and 'marketed and approved drug product' have the meanings given such terms in section 503A(f).''.

(b) FEES.—Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

**''PART 9—FEES RELATING TO OUTSOURCING FACILITIES**

**''SEC. 744J. DEFINITIONS.**

''In this part:

''(1) The term 'affiliate' has the meaning given such term in section 735(11).

''(2) The term 'gross annual sales' means the total worldwide gross annual sales, in United States dollars, for an outsourcing facility, including the sales of all the affiliates of the outsourcing facility.

''(3) The term 'outsourcing facility' has the meaning given to such term in section 503B(c).

''(4) The term 'reinspection' means, with respect to an outsourcing facility, one or more inspections conducted under section 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.

**"SEC. 744K. AUTHORITY TO ASSESS AND USE OUTSOURCING FACILITY FEES.**

"(a) ESTABLISHMENT AND REINSPECTION FEES.——

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

"(A) an annual establishment fee from each outsourcing facility; and

"(B) a reinspection fee from each outsourcing facility subject to a reinspection in such fiscal year.

"(2) MULTIPLE REINSPECTIONS.—An outsourcing facility subject to multiple reinspections in a fiscal year shall be subject to a reinspection fee for each reinspection.

"(b) ESTABLISHMENT AND REINSPECTION FEE SETTING.—The Secretary shall—

"(1) establish the amount of the establishment and reinspection fee to be collected under this sec-

tion for each fiscal year based on the methodology described in subsection (c); and

''(2) publish such fee amounts in a Federal Register notice not later than 60 calendar days before the start of each such year.

''(c) AMOUNT OF ESTABLISHMENT FEE AND REINSPECTION FEE.—

''(1) IN GENERAL.—For each outsourcing facility in a fiscal year—

''(A) except as provided in paragraph (4), the amount of the annual establishment fee under subsection (b) shall be equal to the sum of—

''(i) $15,000, multiplied by the inflation adjustment factor described in paragraph (2); plus

''(ii) the small business adjustment factor described in paragraph (3); and

''(B) the amount of any reinspection fee (if applicable) under subsection (b) shall be equal to $15,000, multiplied by the inflation adjustment factor described in paragraph (3).

''(2) INFLATION ADJUSTMENT FACTOR.—

''(A) IN GENERAL.—For fiscal year 2015 and subsequent fiscal years, the fee amounts es-

tablished in paragraph (1) 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.

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

''(3) SMALL BUSINESS ADJUSTMENT FACTOR.—The small business adjustment factor referred to in paragraph (1)(A)(ii) shall be an amount established by the Secretary for each fiscal year based on the Secretary's estimate of—

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

''(B) 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 paragraph (4).

''(4) EXCEPTION FOR SMALL BUSINESSES.—

"(A) IN GENERAL.—In the case of an outsourcing facility 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 section are assessed, the amount of the establishment fee under subsection (b) for a fiscal year shall be equal to ⅓ of the amount calculated under paragraph (1)(A)(i) for such fiscal year.

"(B) APPLICATION.—To qualify for the exception under this paragraph, a small business shall submit to the Secretary 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 shall be submitted to the Secretary not later than April 30 of such immediately preceding fiscal year.

"(5) CREDITING OF FEES.—In establishing the small business adjustment factor under paragraph (3) for a fiscal year, the Secretary shall—

"(A) provide for the crediting of fees from the previous year to the next year if the Sec-

retary overestimated the amount of the small business adjustment factor for such previous fiscal year; and

''(B) consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

''(d) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to subparagraphs (A) and (B) of subsection (a)(1) available solely to pay for the costs of oversight of outsourcing facilities.

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

''(f) CREDITING AND AVAILABILITY OF FEES.—Fees authorized under this section 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 outsourcing facilities.

''(g) COLLECTION OF FEES.—

''(1) ESTABLISHMENT FEE.—An outsourcing facility shall remit the establishment fee due under this section in a fiscal year when submitting a registration pursuant to section 503B(b) for such fiscal year.

''(2) REINSPECTION FEE.—The Secretary shall specify in the Federal Register notice described in subsection (b)(2) the manner in which reinspection fees assessed under this section 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 outsourcing facility involved.

''(3) EFFECT OF FAILURE TO PAY FEES.—

''(A) REGISTRATION.—An outsourcing facility shall not be considered registered under section 503B(b) in a fiscal year until the date that the outsourcing facility remits the establishment fee under this subsection for such fiscal year.

''(B) MISBRANDING.—All drug products manufactured, prepared, propagated, com-

pounded, or processed by an outsourcing facility for which any establishment fee or reinspection fee has not been paid, as required by this section, shall be deemed misbranded under section 502 until the fees owed for such outsourcing facility under this section have been paid.

''(4) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under this section within 30 calendar 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.

''(h) ANNUAL REPORT TO CONGRESS.—Not later than 120 calendar days after each fiscal year in which fees are assessed and collected under this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to include a description of fees assessed and collected for such year, a summary description of entities paying the fees, a description of the hiring and placement of new staff, a description of the use of fee resources to support inspecting outsourcing facilities, and the num-

ber of inspections and reinspections of such facilities performed each year.

''(i) 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 section.''.

**SEC. 4. PROHIBITED ACTS.**

(a) 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) With respect to a drug product to be compounded under section 503A or 503B, the intentional falsification of a prescription, a purchase order, or patient name required under section 503A or 503B.''.

(b) INTENTIONAL FAILURE OF OUTSOURCING FACILITY TO REGISTER.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by subsection (a), is further amended by inserting after paragraph (ccc) (as added by such subsection), the following:

''(ddd) With respect to any year in which an outsourcing facility is required to register with the Secretary

under section 503B(b), the intentional failure of the outsourcing facility to so register.''.

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