

113TH CONGRESS
1ST SESSION

H. R. 3089

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

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Compounding Clarity
5 Act of 2013”.

6 **SEC. 2. TRADITIONAL PHARMACY COMPOUNDING.**

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

1 **“SEC. 503A. TRADITIONAL PHARMACY COMPOUNDING.**

2 “(a) IN GENERAL.—Sections 501(a)(2)(B),
3 502(f)(1), and 505 of this Act and section 351 of the Pub-
4 lic Health Service Act shall not apply to a drug product
5 for human use if each of the following conditions is met:

6 “(1) IDENTIFIED PATIENT AND RECEIPT OF
7 PRESCRIPTION.—The drug product is compounded
8 in accordance with one of the following:

9 “(A) IN GENERAL.—The drug product is
10 compounded by a licensed pharmacist in a
11 State-licensed pharmacy or a Federal facility,
12 or by a licensed physician, for an identified in-
13 dividual patient based on the receipt of a valid
14 prescription.

15 “(B) ANTICIPATORY COMPOUNDING.—The
16 drug product is compounded by a licensed phar-
17 macist in a State-licensed pharmacy or a Fed-
18 eral facility, or by a licensed physician, in lim-
19 ited quantities before the receipt of a valid pre-
20 scription for an identified individual patient,
21 based on—

22 “(i) historical demand for the drug
23 product; and

24 “(ii) a history of prescriptions for the
25 drug product generated solely within an es-
26 tablished relationship between the licensed

1 pharmacist or licensed physician who is
2 performing the compounding and—

3 “(I) the individual patient; or

4 “(II) the physician or other li-
5 censed practitioner who writes the
6 prescription.

7 “(C) COMPOUNDING FOR OFFICE USE.—

8 The drug product is compounded by a licensed
9 pharmacist in a State-licensed pharmacy or a
10 Federal facility, or by a licensed physician, pur-
11 suant to a non-patient-specific purchase order
12 and—

13 “(i) the drug product will be adminis-
14 tered by a health care practitioner within
15 a physician’s office, a hospital, or another
16 health care setting;

17 “(ii) valid patient-specific prescrip-
18 tions or, when a compounded drug product
19 is administered within the same health sys-
20 tem in which it was compounded, valid pa-
21 tient names—

22 “(I) are submitted, electronically
23 or otherwise, to the pharmacist or
24 physician who performs the com-
25 pounding, not later than 7 business

1 days after the drug product is admin-
2 istered; and

3 “(II) will, in the aggregate, ac-
4 count for the total volume of drug
5 product compounded pursuant to the
6 non-patient-specific purchase order;

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

13 “(I) dispensed pursuant to this
14 subparagraph; and

15 “(II) shipped interstate;

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

18 “(v) the statement ‘Office Use Only’
19 and the statement ‘Not for resale’ appear
20 on the compounded drug product.

21 Compounding under this subparagraph shall
22 not be considered to be in violation of clause (ii)
23 because of the failure of a pharmacist or a phy-
24 sician to account for valid patient-specific pre-
25 scriptions or valid patient names as required by

1 such clause, so long as the pharmacist or physi-
2 cian makes a good faith, reasonable effort to
3 account for the prescriptions or names, as ap-
4 plicable, and does not continue to compound
5 drug products under this subparagraph for a
6 health care practitioner or facility with a his-
7 tory of failing to submit such prescriptions or
8 patient names.

9 “(2) QUALITY STANDARDS.—Irrespective of
10 whether a drug product is compounded under sub-
11 paragraph (A), (B), or (C) of paragraph (1), the
12 drug product is compounded, stored, and dated in
13 compliance with the United States Pharmacopoeia
14 chapters that are applicable to pharmaceutical
15 compounding (including the chapter on sterile prep-
16 arations).

17 “(3) BULK DRUG SUBSTANCES.—If the drug
18 product is compounded using bulk drug substances
19 (as defined in regulations of the Secretary published
20 at section 207.3(a)(4) of title 21 of the Code of Fed-
21 eral Regulations (or any successor regulations))—

22 “(A) the bulk drug substances—

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

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

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

9 “(iii) if such a monograph does not
10 exist and the drug substance is not a com-
11 ponent of a drug product so approved or li-
12 censed, each appear on a list published by
13 the Secretary (through regulations issued
14 under subsection (e));

15 “(B) the bulk drug substances are each
16 manufactured by an establishment that is reg-
17 istered under section 510 (including a foreign
18 establishment that is registered under section
19 510(i)); and

20 “(C) the bulk drug substances are each ac-
21 companied by a valid certificate of analysis.

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

1 of an applicable United States Pharmacopoeia or
2 National Formulary monograph.

3 “(5) DRUG PRODUCTS WITHDRAWN OR RE-
4 MOVED BECAUSE UNSAFE OR NOT EFFECTIVE.—The
5 drug product does not appear on a list published by
6 the Secretary of drug products that have been with-
7 drawn or removed from the market because such
8 drug products or components of such drug products
9 have been found to be unsafe or not effective.

10 “(6) ESSENTIALLY A COPY OF A MARKETED
11 AND APPROVED DRUG PRODUCT.—The licensed
12 pharmacist or licensed physician does not compound
13 any drug product that is essentially a copy of a mar-
14 keted and approved drug product.

15 “(7) DRUG PRODUCTS PRESENTING DEMON-
16 STRABLE DIFFICULTIES FOR COMPOUNDING.—The
17 drug product is not identified (directly or as part of
18 a category of drug products) in a list published by
19 the Secretary (through regulations issued under sub-
20 section (e)) as a drug product that presents demon-
21 strable difficulties for compounding that reasonably
22 demonstrate an adverse effect on the safety or effec-
23 tiveness of that drug product.

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

1 the pharmacy or physician that compounded such
2 drug product.

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

5 “(1) imposing restrictions on the type of
6 compounding described in subparagraph (B) or (C)
7 of subsection (a)(1) that are in addition to the re-
8 strictions applicable under this section; or

9 “(2) enforcing requirements or restrictions con-
10 tained in the chapters or standards described in sub-
11 section (a)(2).

12 “(c) NOTIFICATION SYSTEM.—

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

17 “(A) describing actions taken against
18 compounding pharmacies; or

19 “(B) expressing concerns that a com-
20 pounding pharmacy may be acting in violation
21 of one or more requirements of this section.

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

1 “(A) The issuance of a warning letter, or
2 the imposition of sanctions or penalties, by a
3 State for violations of a State’s pharmacy regu-
4 lations pertaining to compounding.

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

7 “(C) The recall of compounded drug prod-
8 ucts due to concerns relating to the quality or
9 purity of such products.

10 “(3) CONSULTATION.—The Secretary shall de-
11 velop the system under paragraph (1) in consulta-
12 tion with the National Association of Boards of
13 Pharmacy.

14 “(4) REVIEW AND DETERMINATION BY SEC-
15 RETARY.—The Secretary shall review each submis-
16 sion received under paragraph (1) and such other in-
17 formation as the Secretary determines necessary (in-
18 cluding information collected through an inspection
19 or maintained in the Adverse Event Reporting Sys-
20 tem database) and make a determination as to
21 whether the pharmacy involved may be in violation
22 of one or more requirements of this section.

23 “(5) NOTIFYING STATE BOARDS OF PHAR-
24 MACY.—The system under paragraph (1) shall be

1 designed to immediately notify State boards of phar-
2 macy when—

3 “(A) the Secretary receives a submission
4 under paragraph (1); or

5 “(B) the Secretary makes a determination
6 that a pharmacy may be in violation of one or
7 more requirements of this section.

8 “(6) TIMING.—Not later than one year after
9 the date of enactment of the Compounding Clarity
10 Act of 2013, the Secretary shall begin implementa-
11 tion of the system under paragraph (1).

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

16 “(1) the inspection is conducted in coordination
17 with the relevant State board or boards of phar-
18 macy; or

19 “(2) the Secretary has evidence that the phar-
20 macy may be in violation of such a requirement.

21 “(e) REGULATIONS.—

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

24 “(2) ADVISORY COMMITTEE ON
25 COMPOUNDING.—Before issuing regulations to im-

1 plement subsections (a)(3)(A)(iii) and (a)(7), the
2 Secretary shall convene and consult an advisory
3 committee on compounding. The advisory committee
4 shall include representatives from the National Asso-
5 ciation of Boards of Pharmacy, the United States
6 Pharmacopoeia, pharmacists having current experi-
7 ence and expertise in compounding, physicians hav-
8 ing background and knowledge in compounding, and
9 consumer organizations with an expertise in
10 compounding.

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

17 “(A) publishing a notice of such drug
18 products or substances proposed for designa-
19 tion, including the rationale for such designa-
20 tion, in the Federal Register;

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

23 “(C) publishing a notice in the Federal
24 Register designating such drug products or sub-
25 stances.

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

6 “(5) SUNSET OF NOTICE.—Any notice pub-
7 lished under paragraph (3) shall not be effective
8 after the earlier of—

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

11 “(B) the effective date of the final regula-
12 tions issued to implement subsections
13 (a)(3)(A)(iii) and (a)(7).

14 “(f) DEFINITIONS.—In this section:

15 “(1) The term ‘compounding’ includes—

16 “(A) the combining, admixing, mixing, di-
17 luting, reconstituting, or otherwise altering of a
18 marketed drug product, except when performed
19 in accordance with specific directions for such
20 acts contained in approved labeling provided by
21 the product’s manufacturer or otherwise pro-
22 vided by that manufacturer consistent with that
23 labeling;

24 “(B) the combining, admixing, mixing, di-
25 luting, reconstituting, or otherwise altering a

1 bulk drug substance to create a drug product;
2 and

3 “(C) repackaging.

4 “(2) The term ‘essentially a copy of a marketed
5 and approved drug product’ does not include—

6 “(A) a drug product in which there is a
7 change, made for an identified individual pa-
8 tient, which produces for that patient a clinical
9 difference, as determined by the prescribing
10 practitioner, between the compounded drug
11 product and the comparable marketed and ap-
12 proved drug product; or

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

15 “(3) The term ‘licensed pharmacist’ includes
16 any individual who compounds drug products under
17 the supervision of a practitioner licensed to com-
18 pound drug products under State law.

19 “(4) The term ‘marketed and approved drug
20 product’ means a drug product that—

21 “(A) is currently marketed; and

22 “(B) is approved under section 505 of this
23 Act or licensed under section 351 of the Public
24 Health Service Act.

1 “(5)(A) The term ‘repackaging’ means taking a
2 drug approved under section 505 of this Act or li-
3 censed under section 351 of the Public Health Serv-
4 ice Act from the container in which the drug is dis-
5 tributed by the original manufacturer and placing
6 such drug in a different container of the same or
7 smaller size without further manipulating the drug
8 (such as by diluting it or mixing it with another, dif-
9 ferent drug or drugs).

10 “(B) Such term does not include removing the
11 drug from its original container for immediate ad-
12 ministration to an identified individual patient, such
13 as withdrawing a drug into a syringe for immediate
14 injection or removing the drug from its original con-
15 tainer within a health care entity by a practitioner,
16 or other licensed individual under the supervision or
17 direction of such practitioner, for administration
18 within the same day within such health care entity.”.

19 **SEC. 3. OUTSOURCING FACILITIES.**

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

23 (1) by redesignating section 503B as section
24 503C; and

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

3 **“SEC. 503B. OUTSOURCING FACILITIES.**

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

9 “(1) REGISTRATION AND REPORTING.—The fa-
10 cility is in compliance with the registration and re-
11 porting requirements of subsection (b).

12 “(2) DRUG PRODUCT AND SUBSTANCE LIMITA-
13 TIONS.—The facility does not compound drug prod-
14 ucts in violation of paragraphs (3) through (8) of
15 section 503A(a).

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

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

23 “(5) LABELING OF DRUG PRODUCTS.—

1 “(A) LABEL.—The label of a drug product
2 compounded by an outsourcing facility shall in-
3 clude—

4 “(i) the statement ‘This is a com-
5 pounded drug.’ or a reasonable comparable
6 alternative statement (as specified by the
7 Secretary) that prominently identifies the
8 drug as a compounded drug product;

9 “(ii) the name, address, and phone
10 number of the applicable outsourcing facil-
11 ity; and

12 “(iii) with respect to the compounded
13 drug product—

14 “(I) the lot or batch number;

15 “(II) the established name of the
16 drug product;

17 “(III) the dosage form and
18 strength;

19 “(IV) the statement of quantity
20 or volume, as appropriate;

21 “(V) the date that the drug prod-
22 uct was compounded;

23 “(VI) the expiration date;

24 “(VII) storage and handling in-
25 structions;

1 “(VIII) the National Drug Code
2 number, if available;

3 “(IX) the ‘Not for resale’ state-
4 ment required under section
5 503A(a)(1)(C)(v); and

6 “(X) subject to subparagraph
7 (B)(i), a list of active and inactive in-
8 gredients, identified by established
9 name and the quantity or proportion
10 of each ingredient.

11 “(B) CONTAINER.—The container from
12 which the individual units of a drug product
13 compounded by an outsourcing facility are re-
14 moved for dispensing or for administration
15 (such as a plastic bag containing individual
16 product syringes) shall include—

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

20 “(ii) the following information to fa-
21 cilitate adverse event reporting:
22 www.fda.gov/medwatch and 1-800-FDA-
23 1088; and

24 “(iii) directions for use, including, as
25 appropriate, dosage and administration.

1 “(C) ADDITIONAL INFORMATION.—The
2 label and labeling of a drug product com-
3 pounded by an outsourcing facility shall include
4 any other information as determined necessary
5 and specified in regulations promulgated by the
6 Secretary

7 “(b) REGISTRATION OF OUTSOURCING FACILITIES
8 AND REPORTING OF DRUG PRODUCTS.—

9 “(1) REGISTRATION OF OUTSOURCING FACILI-
10 TIES.—

11 “(A) ANNUAL REGISTRATION.—During the
12 period beginning on October 1 and ending on
13 December 31 each year, each outsourcing facil-
14 ity—

15 “(i) shall register with the Secretary
16 its name, place of business, and unique fa-
17 cility identifier (which shall conform to the
18 requirements for the unique facility identi-
19 fier established under section 510), and a
20 point of contact e-mail address; and

21 “(ii) shall indicate whether the out-
22 sourcing facility intends to compound a
23 drug product that appears on the list in ef-
24 fect under section 506E during the subse-
25 quent calendar year.

1 “(B) NEW OUTSOURCING FACILITIES.—
2 Each outsourcing facility, upon first engaging
3 in compounding pursuant to this section, shall
4 immediately register with the Secretary and
5 provide the information described in paragraph
6 (1)(A). The Secretary shall establish a timeline
7 for registration for the first calendar year fol-
8 lowing the effective date of the Compounding
9 Clarity Act of 2013. In no case may registra-
10 tion be required until at least 60 calendar days
11 following publication of the timeline in the Fed-
12 eral Register.

13 “(C) AVAILABILITY OF REGISTRATION FOR
14 INSPECTION; LIST.—

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

19 “(ii) LIST.—The Secretary shall make
20 available on the public Internet Web site of
21 the Food and Drug Administration a list
22 of the name of each facility registered
23 under this subsection as an outsourcing fa-
24 cility, the State in which each such facility
25 is located, whether the facility compounds

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

5 “(2) DRUG PRODUCT REPORTING BY OUT-
6 SOURCING FACILITIES.—

7 “(A) IN GENERAL.—Upon initially reg-
8 istering as an outsourcing facility, once during
9 the month of June of each year, and once dur-
10 ing the month of December of each year, each
11 outsourcing facility that registers with the Sec-
12 retary under paragraph (1) shall submit to the
13 Secretary a report—

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

17 “(ii) with respect to each drug prod-
18 uct identified under clause (i), providing
19 the active ingredient; the source of such
20 active ingredient; the National Drug Code
21 number, if available, of the source drug
22 product or bulk active ingredient; the
23 strength of the active ingredient per unit;
24 the dosage form and route of administra-
25 tion; the package description; the number

1 of individual units produced; and the Na-
2 tional Drug Code number of the final prod-
3 uct, if assigned.

4 “(B) FORM.—Each report under subpara-
5 graph (A) shall be prepared in such form and
6 manner as the Secretary may prescribe by regu-
7 lation or guidance.

8 “(C) CONFIDENTIALITY.—Reports sub-
9 mitted under this paragraph shall be exempt
10 from inspection under paragraph (1)(C), unless
11 the Secretary finds that such an exemption
12 would be inconsistent with the protection of the
13 public health.

14 “(3) ELECTRONIC REGISTRATION AND REPORT-
15 ING.—Registrations and drug product reporting
16 under this subsection (including the submission of
17 updated information) shall be submitted to the Sec-
18 retary by electronic means unless the Secretary
19 grants a request for waiver of such requirement be-
20 cause use of electronic means is not reasonable for
21 the person requesting waiver.

22 “(4) RISK-BASED INSPECTION FREQUENCY.—

23 “(A) IN GENERAL.—Outsourcing facili-
24 ties—

1 “(i) shall be subject to inspection pur-
2 suant to section 704; and

3 “(ii) shall not be eligible for the ex-
4 emption under section 704(a)(2)(A).

5 “(B) RISK-BASED SCHEDULE.—The Sec-
6 retary, acting through one or more officers or
7 employees duly designated by the Secretary,
8 shall inspect outsourcing facilities in accordance
9 with a risk-based schedule established by the
10 Secretary.

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

16 “(i) The compliance history of the
17 outsourcing facility.

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

20 “(iii) The inherent risk of the drug
21 products compounded at the outsourcing
22 facility.

23 “(iv) The inspection frequency and
24 history of the outsourcing facility, includ-
25 ing whether the outsourcing facility has

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

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

8 “(vi) Any other criteria deemed nec-
9 essary and appropriate by the Secretary
10 for purposes of allocating inspection re-
11 sources.

12 “(5) ADVERSE EVENT REPORTING.—Outsourc-
13 ing facilities shall be required to submit adverse
14 event reports to the Secretary in accordance with the
15 content and format requirements established
16 through guidance or regulation under section
17 310.305 of title 21, Code of Federal Regulations (or
18 any successor regulations) or section 600.80 of title
19 21, Code of Federal Regulations (or any successor
20 regulations).

21 “(c) DEFINITIONS.—In this section:

22 “(1) OUTSOURCING FACILITY.—The term ‘out-
23 sourcing facility’ means a facility at one geographic
24 location or address that compounds sterile drug

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

3 “(2) OTHER DEFINITIONS.—The terms
4 ‘compounding’, ‘essentially a copy of a marketed and
5 approved drug product’, ‘licensed pharmacist’, and
6 ‘marketed and approved drug product’ have the
7 meanings given such terms in section 503A(f).”.

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

11 **“PART 9—FEES RELATING TO OUTSOURCING**

12 **FACILITIES**

13 **“SEC. 744J. DEFINITIONS.**

14 “In this part:

15 “(1) The term ‘affiliate’ has the meaning given
16 such term in section 735(11).

17 “(2) The term ‘gross annual sales’ means the
18 total worldwide gross annual sales, in United States
19 dollars, for an outsourcing facility, including the
20 sales of all the affiliates of the outsourcing facility.

21 “(3) The term ‘outsourcing facility’ has the
22 meaning given to such term in section 503B(e).

23 “(4) The term ‘reinspection’ means, with re-
24 spect to an outsourcing facility, one or more inspec-
25 tions conducted under section 704 subsequent to an

1 inspection conducted under such provision which
2 identified noncompliance materially related to an ap-
3 plicable requirement of this Act, specifically to deter-
4 mine whether compliance has been achieved to the
5 Secretary's satisfaction.

6 **“SEC. 744K. AUTHORITY TO ASSESS AND USE OUTSOURC-**
7 **ING FACILITY FEES.**

8 “(a) ESTABLISHMENT AND REINSPECTION
9 FEES.—

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

13 “(A) an annual establishment fee from
14 each outsourcing facility; and

15 “(B) a reinspection fee from each out-
16 sourcing facility subject to a reinspection in
17 such fiscal year.

18 “(2) MULTIPLE REINSPECTIONS.—An outsourc-
19 ing facility subject to multiple reinspections in a fis-
20 cal year shall be subject to a reinspection fee for
21 each reinspection.

22 “(b) ESTABLISHMENT AND REINSPECTION FEE SET-
23 TING.—The Secretary shall—

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

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

3 “(2) publish such fee amounts in a Federal
4 Register notice not later than 60 calendar days be-
5 fore the start of each such year.

6 “(c) AMOUNT OF ESTABLISHMENT FEE AND REIN-
7 SPECTION FEE.—

8 “(1) IN GENERAL.—For each outsourcing facil-
9 ity in a fiscal year—

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

14 “(i) \$15,000, multiplied by the infla-
15 tion adjustment factor described in para-
16 graph (2); plus

17 “(ii) the small business adjustment
18 factor described in paragraph (3); and

19 “(B) the amount of any reinspection fee (if
20 applicable) under subsection (b) shall be equal
21 to \$15,000, multiplied by the inflation adjust-
22 ment factor described in paragraph (3).

23 “(2) INFLATION ADJUSTMENT FACTOR.—

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

1 tablished in paragraph (1) shall be adjusted by
2 the Secretary by notice, published in the Fed-
3 eral Register, for a fiscal year by the amount
4 equal to the sum of—

5 “(i) one;

6 “(ii) the average annual percent
7 change in the cost, per full-time equivalent
8 position of the Food and Drug Administra-
9 tion, of all personnel compensation and
10 benefits paid with respect to such positions
11 for the first 3 years of the preceding 4 fis-
12 cal years, multiplied by the proportion of
13 personnel compensation and benefits costs
14 to total costs of an average full-time equiv-
15 alent position of the Food and Drug Ad-
16 ministration for the first 3 years of the
17 preceding 4 fiscal years; and

18 “(iii) the average annual percent
19 change that occurred in the Consumer
20 Price Index for urban consumers (U.S.
21 City Average; Not Seasonally Adjusted; All
22 items; Annual Index) for the first 3 years
23 of the preceding 4 years of available data
24 multiplied by the proportion of all costs
25 other than personnel compensation and

1 benefits costs to total costs of an average
2 full-time equivalent position of the Food
3 and Drug Administration for the first 3
4 years of the preceding 4 fiscal years.

5 “(B) COMPOUNDED BASIS.—The adjust-
6 ment made each fiscal year under subparagraph
7 (A) shall be added on a compounded basis to
8 the sum of all adjustments made each fiscal
9 year after fiscal year 2014 under subparagraph
10 (A).

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

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

19 “(B) the adjustment to the establishment
20 fee necessary to achieve total fees equaling the
21 total fees that the Secretary would have col-
22 lected if no entity qualified for the small busi-
23 ness exception in paragraph (4).

24 “(4) EXCEPTION FOR SMALL BUSINESSES.—

1 “(A) IN GENERAL.—In the case of an out-
2 sourcing facility with gross annual sales of
3 \$1,000,000 or less in the 12 months ending
4 April 1 of the fiscal year immediately preceding
5 the fiscal year in which the fees under this sec-
6 tion are assessed, the amount of the establish-
7 ment fee under subsection (b) for a fiscal year
8 shall be equal to $\frac{1}{3}$ of the amount calculated
9 under paragraph (1)(A)(i) for such fiscal year.

10 “(B) APPLICATION.—To qualify for the ex-
11 ception under this paragraph, a small business
12 shall submit to the Secretary a written request
13 for such exception, in a format specified by the
14 Secretary in guidance, certifying its gross an-
15 nual sales for the 12 months ending April 1 of
16 the fiscal year immediately preceding the fiscal
17 year in which fees under this subsection are as-
18 sessed. Any such application shall be submitted
19 to the Secretary not later than April 30 of such
20 immediately preceding fiscal year.

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

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

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

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

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

11 “(e) SUPPLEMENT NOT SUPPLANT.—Funds received
12 by the Secretary pursuant to this section shall be used
13 to supplement and not supplant any other Federal funds
14 available to carry out the activities described in this sec-
15 tion.

16 “(f) CREDITING AND AVAILABILITY OF FEES.—Fees
17 authorized under this section shall be collected and avail-
18 able for obligation only to the extent and in the amount
19 provided in advance in appropriations Acts. Such fees are
20 authorized to remain available until expended. Such sums
21 as may be necessary may be transferred from the Food
22 and Drug Administration salaries and expenses appropria-
23 tion account without fiscal year limitation to such appro-
24 priation account for salaries and expenses with such fiscal
25 year limitation. The sums transferred shall be available

1 solely for the purpose of paying the costs of oversight of
2 outsourcing facilities.

3 “(g) COLLECTION OF FEES.—

4 “(1) ESTABLISHMENT FEE.—An outsourcing
5 facility shall remit the establishment fee due under
6 this section in a fiscal year when submitting a reg-
7 istration pursuant to section 503B(b) for such fiscal
8 year.

9 “(2) REINSPECTION FEE.—The Secretary shall
10 specify in the Federal Register notice described in
11 subsection (b)(2) the manner in which reinspection
12 fees assessed under this section shall be collected
13 and the timeline for payment of such fees. Such a
14 fee shall be collected after the Secretary has con-
15 ducted a reinspection of the outsourcing facility in-
16 volved.

17 “(3) EFFECT OF FAILURE TO PAY FEES.—

18 “(A) REGISTRATION.—An outsourcing fa-
19 cility shall not be considered registered under
20 section 503B(b) in a fiscal year until the date
21 that the outsourcing facility remits the estab-
22 lishment fee under this subsection for such fis-
23 cal year.

24 “(B) MISBRANDING.—All drug products
25 manufactured, prepared, propagated, com-

1 pounded, or processed by an outsourcing facility
2 for which any establishment fee or reinspection
3 fee has not been paid, as required by this sec-
4 tion, shall be deemed misbranded under section
5 502 until the fees owed for such outsourcing fa-
6 cility under this section have been paid.

7 “(4) COLLECTION OF UNPAID FEES.—In any
8 case where the Secretary does not receive payment
9 of a fee assessed under this section within 30 cal-
10 endar days after it is due, such fee shall be treated
11 as a claim of the United States Government subject
12 to provisions of subchapter II of chapter 37 of title
13 31, United States Code.

14 “(h) ANNUAL REPORT TO CONGRESS.—Not later
15 than 120 calendar days after each fiscal year in which fees
16 are assessed and collected under this section, the Sec-
17 retary shall submit a report to the Committee on Health,
18 Education, Labor, and Pensions of the Senate and the
19 Committee on Energy and Commerce of the House of
20 Representatives, to include a description of fees assessed
21 and collected for such year, a summary description of enti-
22 ties paying the fees, a description of the hiring and place-
23 ment of new staff, a description of the use of fee resources
24 to support inspecting outsourcing facilities, and the num-

1 ber of inspections and reinspections of such facilities per-
2 formed each year.

3 “(i) AUTHORIZATION OF APPROPRIATIONS.—For fis-
4 cal year 2015 and each subsequent fiscal year, there is
5 authorized to be appropriated for fees under this sub-
6 section an amount equivalent to the total amount of fees
7 assessed for such fiscal year under this section.”.

8 **SEC. 4. PROHIBITED ACTS.**

9 (a) INTENTIONAL FALSIFICATION OF PRESCRIPTION
10 ORDER FOR COMPOUNDED DRUG PRODUCT.—Section
11 301 of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 331) is amended by inserting after paragraph
13 (bbb) the following:

14 “(ccc) With respect to a drug product to be com-
15 pounded under section 503A or 503B, the intentional fal-
16 sification of a prescription, a purchase order, or patient
17 name required under section 503A or 503B.”.

18 (b) INTENTIONAL FAILURE OF OUTSOURCING FACIL-
19 ITY TO REGISTER.—Section 301 of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 331), as amended by
21 subsection (a), is further amended by inserting after para-
22 graph (ccc) (as added by such subsection), the following:

23 “(ddd) With respect to any year in which an out-
24 sourcing facility is required to register with the Secretary

1 under section 503B(b), the intentional failure of the out-
2 sourcing facility to so register.”.

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