

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) in-
troduced the following bill; which was referred to the Committee on En-
ergy and Commerce

A BILL

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

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 “Verifying Authority
5 and Legality In Drug Compounding Act of 2013” or the
6 “VALID Compounding Act”.

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

3 (a) AMENDMENT.—Section 503A of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 353a) is
5 amended to read as follows:

6 **“SEC. 503A. PHARMACY COMPOUNDING.**

7 “(a) IN GENERAL.—Sections 501(a)(2)(B),
8 502(f)(1), and 505 shall not apply with respect to a drug
9 product if each of the following applies:

10 “(1) Except as provided in subsection (d), the
11 drug product is compounded for an identified indi-
12 vidual patient based on the receipt of a prescription
13 order.

14 “(2) The drug product is compounded by a li-
15 censed pharmacist in a State-licensed pharmacy or a
16 Federal facility, or by a licensed physician, pursuant
17 to such prescription order or notation.

18 “(3) In the case of a drug product that is com-
19 pounded using bulk substances (as defined in section
20 207.3(a)(4) of title 21, Code of Federal Regulations
21 (or any successor regulations)—

22 “(A) such bulk substances—

23 “(i) are components of one or more
24 drugs for which an approval of an applica-
25 tion filed under subsection (b) or (j) of sec-
26 tion 505 is in effect;

1 “(ii) are components of drugs that
2 may be lawfully marketed in the United
3 States without such an approval pursuant
4 to the definition of a new drug in section
5 201; or

6 “(iii) appear on the list in effect
7 under subsection (b); and

8 “(B) such bulk substances comply with the
9 standards of an applicable United States Phar-
10 macopeia or National Formulary monograph, if
11 a monograph exists.

12 “(4) Any bulk substance used for purposes of
13 compounding the drug product—

14 “(A) is manufactured by an establishment
15 that is registered under section 510 (including
16 a foreign establishment that is registered under
17 section 510(i)); and

18 “(B) is accompanied by valid certificates of
19 analysis.

20 “(5) The pharmacist or physician compounding
21 the drug product complies with the standards of any
22 applicable United States Pharmacopeia chapters on
23 pharmacy compounding.

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

1 “(A) is not included in the list under sub-
2 section (c); and

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

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

9 “(8) If the drug product is produced using
10 high-risk sterile compounding, the drug product is
11 compounded in accordance with the standards, proc-
12 esses, and procedures established under subsection
13 (f).

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

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

18 “(A) develop and maintain a list of bulk
19 substances from which drug products may be
20 compounded; and

21 “(B) include in the list only bulk sub-
22 stances that are not described in clause (i) or
23 (ii) of subsection (a)(3)(A) and may be com-
24 pounded to meet a medical need that cannot be

1 filled by using a bulk substance that is de-
2 scribed in such clause (i) or (ii);

3 “(C) specify for each bulk substance on the
4 list under this subsection any limitation on
5 compounding the bulk substance; and

6 “(D) specify for each bulk substance on
7 the list under this subsection the particular
8 medical need that is met by placing such sub-
9 stance on the list.

10 “(2) INITIAL PUBLICATION; UPDATES.—The
11 Secretary shall—

12 “(A) not later than 1 year after the date
13 of the enactment of the Verifying Authority and
14 Legality In Drug Compounding Act of 2013,
15 publish an initial list under paragraph (1); and

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

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

22 “(4) TRANSMISSION TO STATE REGULATORY
23 AGENCIES.—Upon publication of the initial list
24 under paragraph (1), and upon each update to the
25 list, the Secretary shall transmit an up-to-date copy

1 of the list to the agency in each State with primary
2 responsibility for regulating pharmacies.

3 “(5) PETITIONS.—

4 “(A) IN GENERAL.—In carrying out this
5 subsection, the Secretary shall receive and con-
6 sider petitions from any person identifying a
7 substance that should be added to, or removed
8 from, the list under this subsection.

9 “(B) REQUIREMENT FOR PETITIONS SEEK-
10 ING TO ADD A BULK SUBSTANCE.—Any petition
11 seeking to add a bulk substance to the list
12 under this subsection shall specify the rea-
13 sons—

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

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

19 “(C) APPROVAL OR DENIAL.—The Sec-
20 retary shall approve or deny any petition re-
21 ceived under this paragraph, and update the list
22 under paragraph (1) accordingly, not later than
23 90 days after receipt of the petition, unless an
24 extension of time is mutually agreed upon by
25 the Secretary and the petitioner.

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

5 “(E) PUBLIC POSTING.—The Secretary
6 shall publically post—

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

9 “(ii) each approval, denial, and exten-
10 sion under subparagraph (C) promptly.

11 “(c) LIST OF DRUG PRODUCTS THAT SHOULD NOT
12 BE COMPOUNDED.—

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

15 “(A) develop and maintain a list of drug
16 products that should not be compounded, in-
17 cluding any categories, dosage forms, or ingre-
18 dients of such drug products; and

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

20 “(i) drug products (or categories, dos-
21 age forms, or ingredients thereof) whose
22 compounding is reasonably likely to cause
23 an adverse effect on safety or effectiveness
24 of such drug product, including extended
25 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 “(1) IN GENERAL.—A pharmacy or pharmacist
2 that is not required to be registered under section
3 510 may compound a drug product without regard
4 to subsection (a)(1) if the pharmacy or phar-
5 macist—

6 “(A) registers with the Secretary as speci-
7 fied pursuant to paragraph (2); and

8 “(B) agrees to comply with any condition
9 of operation or limitation of activity specified by
10 the Secretary, including the conditions and limi-
11 tations specified pursuant to paragraph (2).

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

16 “(A) the registration requirements for such
17 pharmacy or pharmacist and the information
18 that must be submitted with the registration,
19 which information shall include—

20 “(i) the name and location of the
21 pharmacy;

22 “(ii) the types of drugs that are com-
23 pounded;

24 “(iii) the active ingredients in each
25 such drug;

1 “(iv) the source and strength of the
2 active ingredient in each drug;

3 “(v) the dosage form and route of ad-
4 ministration of each drug;

5 “(vi) the number of individual units
6 produced of each drug;

7 “(vii) the States to which drugs were
8 shipped;

9 “(viii) the number of individual units
10 of each drug that are shipped to each
11 State; and

12 “(ix) affirmation that the pharmacy
13 or pharmacist is in compliance with State
14 pharmacy licensing regulations;

15 “(B) the frequency in which information
16 described in subparagraph (A) must be sub-
17 mitted;

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

22 “(D) any limitations on the activities of
23 such pharmacy or pharmacist.

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

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

5 “(A) any pharmacy or pharmacist within a
6 hospital system that is compounding drug prod-
7 ucts exclusively for dispensing to patients with-
8 in that hospital system; and

9 “(B) any pharmacy or pharmacist that
10 compounds sterile drug products.

11 “(4) MEMORANDUM OF UNDERSTANDING.—

12 “(A) IN GENERAL.—Subject to subpara-
13 graph (C), the Secretary may enter into appro-
14 priate memoranda of understanding with States
15 to address State implementation of the excep-
16 tion under this subsection—

17 “(i) ensuring, to the Secretary’s satis-
18 faction, that the State will implement the
19 exception under this subsection in accord-
20 ance with the requirements of this section;
21 and

22 “(ii) including such other information
23 and assurances as the Secretary may re-
24 quire.

1 “(B) PROCESS; CRITERIA.—The Secretary
2 shall—

3 “(i) establish a process and criteria
4 for entering into a memorandum of under-
5 standing under this paragraph, including
6 the sharing of information between State
7 and Federal authorities; and

8 “(ii) reevaluate each such memo-
9 randum of understanding not less than
10 every 5 years to ensure, to the Secretary’s
11 satisfaction, that the State’s implementa-
12 tion of the memorandum of understanding
13 continues to conform to the requirements
14 of this section.

15 “(C) EXCLUSIVE FEDERAL AUTHORITY.—
16 The Secretary shall retain exclusive Federal au-
17 thority to implement the exception under this
18 subsection with respect to pharmacies and
19 pharmacists that—

20 “(i) perform high-risk sterile
21 compounding; or

22 “(ii) compound drug products for
23 shipment across State lines.

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

1 “(A) identifying all pharmacies and phar-
2 macists registered under this subsection; and

3 “(B) indicating, for each such pharmacy
4 and pharmacist, whether the pharmacy or phar-
5 macist is subject to regulation by a State pur-
6 suant to a memorandum of understanding in ef-
7 fect under paragraph (4).

8 “(e) EXCEPTIONS REGARDING COPIES OF COMMER-
9 cially AVAILABLE DRUGS.—A drug that is a copy of a
10 commercially available drug may be compounded pursuant
11 to this section without regard to subsection (a)(7) if—

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

18 “(B) the Secretary determines that compound-
19 ing the drug product is necessary to protect public
20 health or wellbeing; and

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

1 drug that is a copy of such commercially available
2 drug demonstrates to the Secretary that controls will
3 be used that are comparable to such elements to as-
4 sure safe use.

5 “(f) HIGH-RISK STERILE COMPOUNDING.—For pur-
6 poses of subsection (a)(8), the Secretary shall establish
7 standards, processes, and procedures for high-risk sterile
8 compounding.

9 “(g) INSPECTIONS.—Notwithstanding section
10 704(a)(2)(A), the facilities of any pharmacy or pharmacist
11 compounding drug products under this section—

12 “(1) shall be subject to inspection under section
13 704; and

14 “(2) shall, upon request of an officer or em-
15 ployee designated by the Secretary, permit such offi-
16 cer or employee at all reasonable times to have ac-
17 cess to, and to copy and verify, records for purposes
18 of determining compliance with the provisions of this
19 Act applicable to such compounding.

20 “(h) SHARING OF INFORMATION.—If during an in-
21 spection of the facilities of a pharmacy or pharmacist
22 under this section the Secretary discovers a violation of
23 this Act, the Secretary shall give notice of the violation—

24 “(1) to the State in which the facilities are lo-
25 cated; and

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

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

6 “(1) the name of each drug and ingredient in-
7 cluded;

8 “(2) the name, address, and phone number of
9 the licensed compounding pharmacy, pharmacist, or
10 physician;

11 “(3) the date on which the drug was com-
12 pounded;

13 “(4) instructions for storage and use;

14 “(5) the following statement: ‘This drug has
15 not been tested for safety and effectiveness and is
16 not approved by the FDA. This drug was made spe-
17 cifically for you because your health care provider
18 determined that no FDA-approved product would
19 suit your needs. Serious adverse reactions to this
20 drug should be reported to the FDA at
21 _____, to the phar-
22 macy where the drug was received, and to your
23 health care provider.’ (The blank shall specify a
24 phone number and a Web site, to be provided by the
25 Secretary for purposes of this subsection.); and

1 “(6) such other information as the Secretary
2 may require.

3 “(j) REPORTING BY PHARMACISTS AND PHYSI-
4 CIANS.—

5 “(1) ADVERSE EVENT.—If a pharmacist or
6 physician compounding a drug product pursuant to
7 this section becomes aware of any adverse event as-
8 sociated with the use of such product, not later than
9 10 calendar days after becoming so aware, the phar-
10 macist or physician shall report such adverse event
11 to the Secretary.

12 “(2) INFORMATION RELATED TO RISK OF IN-
13 JURY OR DEATH.—If a pharmacist or physician
14 compounding a drug product pursuant to this sec-
15 tion becomes aware of information concerning any
16 bacteriological, fungal, or other contamination; any
17 significant chemical, physical, or other change; or
18 any deterioration of a compounded drug product
19 that has already been distributed by the pharmacist
20 or physician, that could cause serious injury or
21 death, not later than 2 calendar days after becoming
22 so aware, the pharmacist or physician shall report
23 such information to the Secretary.

24 “(k) COMPOUNDING ESTABLISHMENT AND REIN-
25 SPECTION FEES.—

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

2 “(A) the term ‘affiliate’ has the meaning
3 given such term in section 735(11);

4 “(B) the term ‘covered compounding phar-
5 macy’ means a pharmacy that, pursuant to sub-
6 section (d) (the exception to the requirement of
7 an identified individual patient)—

8 “(i) performs high-risk sterile
9 compounding;

10 “(ii) compounds drug products for
11 shipment across State lines; or

12 “(iii) otherwise performs compounding
13 pursuant to subsection (d) that is not reg-
14 ulated by a State pursuant to a memo-
15 randum of understanding under subsection
16 (d)(4);

17 “(C) the term ‘gross annual sales’ means
18 the total worldwide gross annual sales, in
19 United States dollars, for a covered compound-
20 ing pharmacy, including the sales of all the af-
21 filiates of the covered compounding pharmacy;
22 and

23 “(D) the term ‘reinspection’ means, with
24 respect to a covered compounding pharmacy,
25 one or more inspections conducted under sec-

tion 704 subsequent to an inspection conducted under such provision which identified non-compliance 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

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

5 “(4) AMOUNT OF ESTABLISHMENT FEE AND
6 REINSPECTION FEE.—

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

9 “(i) except as provided in subpara-
10 graph (D), the amount of the annual es-
11 tablishment fee under paragraph (2) shall
12 be equal to the sum of—

13 “(I) \$15,000, multiplied by the
14 inflation adjustment factor described
15 in subparagraph (B); plus

16 “(II) the small business adjust-
17 ment factor described in subpara-
18 graph (C); and

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

24 “(B) INFLATION ADJUSTMENT FACTOR.—

1 “(i) IN GENERAL.—For fiscal year
2 2015 and subsequent fiscal years, the fee
3 amounts established in subparagraph (A)
4 shall be adjusted by the Secretary by no-
5 tice, published in the Federal Register, for
6 a fiscal year by the amount equal to the
7 sum of—

8 “(I) one;

9 “(II) the average annual percent
10 change in the cost, per full-time equiv-
11 alent position of the Food and Drug
12 Administration, of all personnel com-
13 pensation and benefits paid with re-
14 spect to such positions for the first 3
15 years of the preceding 4 fiscal years,
16 multiplied by the proportion of per-
17 sonnel compensation and benefits
18 costs to total costs of an average full-
19 time equivalent position of the Food
20 and Drug Administration for the first
21 3 years of the preceding 4 fiscal
22 years; and

23 “(III) the average annual percent
24 change that occurred in the Consumer
25 Price Index for urban consumers

1 (U.S. City Average; Not Seasonally
2 Adjusted; All items; Annual Index) for
3 the first 3 years of the preceding 4
4 years of available data multiplied by
5 the proportion of all costs other than
6 personnel compensation and benefits
7 costs to total costs of an average full-
8 time equivalent position of the Food
9 and Drug Administration for the first
10 3 years of the preceding 4 fiscal
11 years.

12 “(ii) COMPOUNDED BASIS.—The ad-
13 justment made each fiscal year under
14 clause (i) shall be added on a compounded
15 basis to the sum of all adjustments made
16 each fiscal year after fiscal year 2014
17 under clause (i).

18 “(C) SMALL BUSINESS ADJUSTMENT FAC-
19 TOR.—The small business adjustment factor re-
20 ferred to subparagraph (A)(i)(II) shall be an
21 amount established by the Secretary for each
22 fiscal year based on the Secretary’s estimate
23 of—

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

4 “(ii) the adjustment to the establish-
5 ment fee necessary to achieve total fees
6 equaling the total fees that the Secretary
7 would have collected if no entity qualified
8 for the small business exception in sub-
9 paragraph (D).

10 “(D) EXCEPTION FOR SMALL BUSI-
11 NESSES.—

12 “(i) IN GENERAL.—In the case of a
13 covered compounding pharmacy with gross
14 annual sales of \$1,000,000 or less in the
15 12 months ending April 1 of the fiscal year
16 immediately preceding the fiscal year in
17 which the fees under this subsection are
18 assessed, the amount of the establishment
19 fee under paragraph (2) for a fiscal year
20 shall be equal to $\frac{1}{3}$ of the amount cal-
21 culated under subparagraph (A)(i)(I) in
22 such fiscal year.

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

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

13 “(E) CREDITING OF FEES.—In estab-
14 lishing the small business adjustment factor
15 under subparagraph (C) for a fiscal year, the
16 Secretary shall provide for the crediting of fees
17 from the previous year to the next year if the
18 Secretary overestimated the amount of the
19 small business adjustment factor for such pre-
20 vious fiscal year, and consider the need to ac-
21 count for any adjustment of fees and such other
22 factors as the Secretary determines appropriate.

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

1 the costs of oversight of covered compounding phar-
2 macies.

3 “(6) SUPPLEMENT NOT SUPPLANT.—Funds re-
4 ceived by the Secretary pursuant to this subsection
5 shall be used to supplement and not supplant any
6 other Federal funds available to carry out the activi-
7 ties described in this section.

8 “(7) CREDITING AND AVAILABILITY OF FEES.—
9 Fees authorized under this subsection shall be col-
10 lected and available for obligation only to the extent
11 and in the amount provided in advance in appropria-
12 tions Acts. Such fees are authorized to remain avail-
13 able until expended. Such sums as may be necessary
14 may be transferred from the Food and Drug Admin-
15 istration salaries and expenses appropriation account
16 without fiscal year limitation to such appropriation
17 account for salaries and expenses with such fiscal
18 year limitation. The sums transferred shall be avail-
19 able solely for the purpose of paying the costs of
20 oversight of covered compounding pharmacies.

21 “(8) COLLECTION OF FEES.—

22 “(A) ESTABLISHMENT FEE.—A covered
23 compounding pharmacy shall remit the estab-
24 lishment fee due under this subsection in a fis-

1 cal year when submitting a registration pursu-
2 ant to subsection (d) for such fiscal year.

3 “(B) REINSPECTION FEE.—The Secretary
4 shall specify in the Federal Register notice de-
5 scribed in paragraph (3) the manner in which
6 reinspection fees assessed under this subsection
7 shall be collected and the timeline for payment
8 of such fees. Such a fee shall be collected after
9 the Secretary has conducted a reinspection of
10 the covered compounding pharmacy involved.

11 “(C) EFFECT OF FAILURE TO PAY FEES.—

12 “(i) REGISTRATION.—A covered
13 compounding pharmacy shall not be con-
14 sidered registered under subsection (d) in
15 a fiscal year until the date that the covered
16 compounding pharmacy remits the estab-
17 lishment fee under this subsection for such
18 fiscal year.

19 “(ii) MISBRANDING.—All drugs manu-
20 factured, prepared, propagated, com-
21 pounded, or processed by a covered
22 compounding pharmacy for which any es-
23 tablishment fee or reinspection fee has not
24 been paid as required by this subsection
25 shall be deemed misbranded under section

1 502(cc) until the fees owed for such cov-
2 ered compounding pharmacy under this
3 subsection have been paid.

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

11 “(9) ANNUAL REPORT TO CONGRESS.—Not
12 later than 120 days after each fiscal year in which
13 fees are assessed and collected under this subsection,
14 the Secretary shall submit a report to the Com-
15 mittee on Energy and Commerce of the House of
16 Representatives and the Committee on Health, Edu-
17 cation, Labor, and Pensions of the Senate, to in-
18 clude a description of fees assessed and collected for
19 each year, a summary description of entities paying
20 the fees, and the number of inspections and re-
21 inspections of such entities performed each year.

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

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

3 “(l) DEFINITIONS.—In this section:

4 “(1) The terms ‘compound’ and ‘compound-
5 ing’—

6 “(A) do not include mixing, reconstituting,
7 or other such acts that are performed in ac-
8 cordance with directions contained in approved
9 labeling provided by the product’s manufacturer
10 and other manufacturer directions consistent
11 with that labeling; and

12 “(B) in the case of a radioactive drug (as
13 defined in section 310.3(n) of title 21, Code of
14 Federal Regulations (or any successor regula-
15 tions)), also do not include a minor deviation
16 from such directions with regard to radioac-
17 tivity, volume, or stability, that is made by or
18 under the direct supervision of an ‘authorized
19 nuclear pharmacist’ or a physician who is an
20 ‘authorized user’ (as such terms are defined in
21 section 35.2 of title 10, Code of Federal Regu-
22 lations, (or any successor regulations)).

23 “(2) The term ‘copy of a commercially available
24 drug product’ does not include a drug product in
25 which there is a change, made for an identified indi-

1 vidual patient, which produces for that patient a sig-
2 nificant difference, as determined by the prescribing
3 practitioner, between the compounded drug and the
4 comparable commercially available drug product,
5 provided that in the case of a radioactive drug (as
6 defined in section 310.3(n) of title 21, Code of Fed-
7 eral Regulations (or any successor regulations)), the
8 reasons for the determination by the prescribing
9 practitioner have been documented and such docu-
10 mentation is maintained by the pharmacy.

11 “(3) The term ‘high-risk sterile compounding’
12 means compounding sterile drug products using non-
13 sterile ingredients, nonsterile devices, or nonsterile
14 components.”.

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

18 “(bb) If it is a drug product compounded pursuant
19 to section 503A and its labeling does not include the infor-
20 mation required by section 503A(i).

21 “(cc) If it is a drug, and it was manufactured, pre-
22 pared, propagated, compounded, or processed by a
23 compounding manufacturer for which fees have not been
24 paid as required by section 503A(k).”.

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

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

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

13 **SEC. 3. REGISTRATION OF MANUFACTURERS COMPOUND-**
14 **ING DRUG PRODUCTS.**

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

1 (b) REGULATIONS.—Not later than 1 year after the
2 date of the enactment of this Act, the Secretary of Health
3 and Human Services shall promulgate regulations for car-
4 rying out the amendment made by subsection (a).

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

8 **SEC. 4. NO PREEMPTION OF ADDITIONAL NON-FEDERAL**
9 **REQUIREMENTS.**

10 The requirements of this Act (including the require-
11 ments of the amendments made by this Act) do not pre-
12 empt any non-Federal requirement that is in addition to,
13 and compatible with, such requirements.

○