

Calendar No. 89

113TH CONGRESS
1ST SESSION**S. 959**

To amend the Federal Food, Drug, and Cosmetic Act with respect to
compounding drugs.

IN THE SENATE OF THE UNITED STATES

MAY 15, 2013

Mr. HARKIN (for himself, Mr. ALEXANDER, Mr. ROBERTS, Mr. FRANKEN, Ms. MIKULSKI, and Ms. WARREN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JUNE 19, 2013

Reported by Mr. HARKIN, with an amendment and an amendment to the title
[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with
respect to compounding drugs.

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; REFERENCES IN ACT.**

4 ~~(a) SHORT TITLE.—This Act may be cited as the~~
5 ~~“Pharmaceutical Compounding Quality and Account-~~
6 ~~ability Act”.~~

1 (b) REFERENCES IN ACT.—Except as otherwise spec-
 2 ified, amendments made by this Act to a section or other
 3 provision of law are amendments to such section or other
 4 provision of the Federal Food, Drug, and Cosmetic Act
 5 (21 U.S.C. 301 et seq.).

6 **SEC. 2. REGULATION OF HUMAN AND ANIMAL DRUG**
 7 **COMPOUNDING.**

8 (a) CLARIFICATION OF NEW DRUG AND NEW ANI-
 9 MAL DRUG STATUS.—For purposes of the Federal Food,
 10 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the
 11 terms “new drug” (as defined in section 201(p) of such
 12 Act) and “new animal drug” (as defined in section 201(v)
 13 of such Act) shall include a compounded human drug and
 14 a compounded animal drug, respectively.

15 (b) REGULATION OF HUMAN AND ANIMAL DRUG
 16 COMPOUNDING.—Section 503A (21 U.S.C. 353a) is
 17 amended to read as follows:

18 **“SEC. 503A. HUMAN AND ANIMAL DRUG COMPOUNDING.**

19 “(a) SCOPE.—

20 “(1) COMPOUNDING.—In this section, the terms
 21 ‘compounding’ and ‘compound’—

22 “(A) include—

23 “(i) the combining, admixing, mixing,
 24 diluting, reconstituting, or otherwise alter-
 25 ing of a marketed drug;

1 “(ii) compounding a drug from a bulk
2 drug substance; and

3 “(iii) repackaging, as defined in sub-
4 section (b)(5); and

5 “(B) exclude mixing, reconstituting, or
6 other such acts with respect to a marketed drug
7 that are limited to and performed solely in ac-
8 cordance with specific directions for such acts
9 contained in approved labeling provided by a
10 drug’s manufacturer, when performed upon re-
11 ceipt of a prescription order for an identified in-
12 dividual patient.

13 “(2) DISPENSING NOT A SALE.—In this section,
14 the terms ‘sell’ or ‘resale’ do not include dispensing
15 to patients, or, in the case of animal drugs, to the
16 individual responsible for providing care for the ani-
17 mal for which the drug is intended, in accordance
18 with State law, including any fee associated with
19 such dispensing.

20 “(3) EXEMPTIONS.—This section shall not
21 apply to—

22 “(A) medical gases;

23 “(B) animal drugs that are subject to reg-
24 ulation as biological products by the Secretary

of Agriculture under the Act commonly known
as the Virus-Serum-Toxin Act; or

~~“(C) human blood and blood components
for transfusion.~~

~~“(b) DEFINITIONS.—In this section:~~

~~“(1) COMPOUNDING MANUFACTURER.—~~

~~“(A) IN GENERAL.—The term
‘compounding manufacturer’ means a facility at
one geographic location or address—~~

~~“(i) that compounds any sterile drug
product without receiving a prescription
order for such sterile drug product prior to
beginning compounding, and distributes or
offers to sell such compounded sterile drug
product in interstate commerce; or~~

~~“(ii) that repackages any preservative-
free sterile drug product or pools any ster-
ile drug products, except as provided in
paragraph (7)(B).~~

~~“(B) EXCLUDED ACTIVITIES.—Notwith-
standing subparagraph (A)(ii), a facility shall
not be considered a compounding manufacturer
if such facility—~~

1 “(i) repackages drugs in accordance
2 with section 506F or the final guidance de-
3 scribed in section 506F(d); and

4 “(ii) does not otherwise meet the defi-
5 nition of compounding manufacturer under
6 subparagraph (A).

7 “(2) POOLING; POOLS.—The terms ‘pooling’
8 and ‘pool’—

9 “(A) mean taking a single drug approved
10 under section 505 or 512, conditionally ap-
11 proved under section 571, included on the index
12 established under section 572(a)(1), or licensed
13 under section 351 of the Public Health Service
14 Act from the container in which it is distributed
15 by the original manufacturer and combining it
16 with the same drug from one or more other
17 containers without or before further manipu-
18 lating the product (such as by diluting it or
19 mixing it with another, different drug or
20 drugs);

21 “(B) do not include combining the drug
22 from two or more separate containers of the
23 same drug when a single container of the drug
24 is not sufficient to prepare a single dose for ad-
25 ministration to an individual patient; and

1 ~~“(C) do not include combining the drug~~
 2 ~~from two or more separate containers of compo-~~
 3 ~~nent products of a total parenteral nutrition~~
 4 ~~product, if such pooling, and labeling and use~~
 5 ~~of the finished total parenteral nutrition prod-~~
 6 ~~uct, comply with State pharmacy law.~~

7 ~~“(3) PRACTITIONER.—The term ‘practitioner’~~
 8 ~~includes a physician, veterinarian, or any other per-~~
 9 ~~son that is authorized to prescribe medication under~~
 10 ~~State law.~~

11 ~~“(4) PRESCRIPTION; PRESCRIPTION ORDER.—~~
 12 ~~The term ‘prescription’ or ‘prescription order’ means~~
 13 ~~a prescription or prescription order, as defined~~
 14 ~~under applicable State law, that complies with re-~~
 15 ~~quirements applicable under such State law.~~

16 ~~“(5) REPACKAGE OR REPACKAGING.—The term~~
 17 ~~‘repackage’ or ‘repackaging’ means taking a drug~~
 18 ~~approved under section 505 or 512, conditionally ap-~~
 19 ~~proved under section 571, included on the index es-~~
 20 ~~tablished under section 572(a)(1), or licensed under~~
 21 ~~section 351 of the Public Health Service Act from~~
 22 ~~the container in which it is distributed by the origi-~~
 23 ~~nal manufacturer and placing it in a different con-~~
 24 ~~tainer of the same or smaller size without further~~
 25 ~~manipulating the drug (such as by diluting it or~~

1 mixing it with another, different drug or drugs); un-
 2 less such repackaging is done pursuant to a pre-
 3 scription for an identified individual patient.

4 “(6) STERILE DRUG PRODUCT.—The term
 5 ‘sterile drug product’ means a drug that is—

6 “(A) intended for parenteral administra-
 7 tion;

8 “(B) an ophthalmic or inhalation drug; or

9 “(C) required to be sterile under Federal
 10 or State law.

11 “(7) TRADITIONAL COMPOUNDER.—

12 “(A) IN GENERAL.—The term ‘traditional
 13 compounder’ means an entity—

14 “(i) wherein a drug is compounded
 15 by—

16 “(I) a licensed pharmacist, or
 17 other pharmacy personnel (to the ex-
 18 tent permitted under State law); in a
 19 State-licensed pharmacy or a Federal
 20 facility; or

21 “(II) a licensed physician or li-
 22 censed veterinarian; to the extent per-
 23 mitted under State law;

24 “(ii) that—

1 “(I) compounds a drug upon re-
2 ceipt of a prescription order for an
3 identified individual patient; or

4 “(II) compounds a drug in lim-
5 ited quantities before receipt of a pre-
6 scription order for an identified indi-
7 vidual patient, to the extent permitted
8 under State law, if such compounding
9 is based on a history of the licensed
10 pharmacist, licensed physician, or li-
11 censed veterinarian receiving prescrip-
12 tion orders for the compounding of
13 the drug, which orders have been gen-
14 erated solely within an established re-
15 lationship between the licensed phar-
16 macist, licensed physician, or licensed
17 veterinarian and—

18 “(aa) such individual patient
19 for whom the prescription order
20 will be provided; or, in the case
21 of an animal drug, such indi-
22 vidual responsible for providing
23 care for the animal for which the
24 drug is ordered; or

1 “(bb) the licensed physician;
 2 licensed veterinarian, or other li-
 3 censed practitioner who will write
 4 such prescription order; and

5 “(iii) that does not meet the definition
 6 of a compounding manufacturer under
 7 paragraph (1).

8 “(B) EXCEPTIONS.—

9 “(i) HOSPITALS AND HEALTH SYS-
 10 TEMS.—

11 “(I) IN GENERAL.—A pharmacy
 12 within a hospital, veterinary hospital,
 13 or health system that compounds a
 14 drug and dispenses such drug (which
 15 may include interstate shipment)
 16 within such hospital or health system
 17 or ships such drug for dispensing to
 18 patients with an established relation-
 19 ship with the hospital or health sys-
 20 tem (which may include interstate
 21 shipment); or that repackages preserv-
 22 ative-free sterile drug product or pools
 23 sterile drug products, shall be consid-
 24 ered a traditional compounder if such

1 pharmacy otherwise meets the defini-
 2 tion under subparagraph (A).

3 ~~“(H) HEALTH SYSTEM DE-~~
 4 ~~FINED.—~~For purposes of this sub-
 5 paragraph, the term ‘health system’
 6 means two or more hospitals or veteri-
 7 nary hospitals that are owned and op-
 8 erated by the same entity and that
 9 share access to databases with drug
 10 order information for patients or ani-
 11 mals, as applicable. A health system
 12 includes both the inpatient and out-
 13 patient facilities of hospitals within
 14 the health system.

15 ~~“(ii) PET AND RADIOPHARMA-~~
 16 ~~CEUTICALS.—~~A pharmacy that compounds
 17 positron emission tomography drugs or
 18 radiopharmaceuticals shall be considered a
 19 traditional compounder if it does not com-
 20 pound other drugs that would cause it to
 21 be a compounding manufacturer described
 22 in paragraph (1)(A).

23 ~~“(e) EXEMPTIONS FROM CERTAIN REQUIRE-~~
 24 ~~MENTS.—~~

1 “(1) DRUGS COMPOUNDED BY TRADITIONAL
 2 COMPOUNDERS.—Sections 501(a)(2)(B), 502(f)(1),
 3 505 (in the case of a human drug), section 512 (in
 4 the case of an animal drug), and section 351 of the
 5 Public Health Service Act (in the case of a biological
 6 product) shall not apply to a compounded drug if
 7 such drug—

8 “(A) is compounded by a traditional
 9 compounder that is in compliance with this sec-
 10 tion; and

11 “(B) meets the requirements of this sec-
 12 tion applicable to drugs compounded by tradi-
 13 tional compounders.

14 “(2) DRUGS COMPOUNDED BY COMPOUNDING
 15 MANUFACTURERS.—Sections 502(f)(1), 505 (in the
 16 case of a human drug), section 512 (in the case of
 17 an animal drug), and section 351 of the Public
 18 Health Service Act (in the case of a biological prod-
 19 uct) shall not apply to a compounded prescription
 20 drug if such drug—

21 “(A) is compounded by a compounding
 22 manufacturer—

23 “(i) that is not licensed as a phar-
 24 macy in any State; and

1 “(ii) that is in compliance with this
2 section; and

3 “(B) meets the requirements of this sec-
4 tion applicable to drugs compounded by
5 compounding manufacturers.

6 ~~“(d) DRUGS THAT MAY NOT BE COMPOUNDED.—~~

7 ~~“(1) IN GENERAL.—~~The following drugs may
8 not be compounded, except under conditions speci-
9 fied by the Secretary:

10 ~~“(A) DRUGS THAT ARE DEMONSTRABLY~~
11 ~~DIFFICULT TO COMPOUND.—~~A drug or category
12 of drugs that presents demonstrable difficulties
13 for compounding, which may include a complex
14 dosage form or biological product, as designated
15 by the Secretary pursuant to paragraph (2).

16 ~~“(B) MARKETED DRUGS.—~~A drug, other
17 than a biological product, that is a copy of a
18 marketed drug approved under 505 or 512,
19 conditionally approved under section 571, or in-
20 cluded on the index established under section
21 572(a)(1), except as provided in paragraph (3).

22 ~~“(C) BIOLOGICAL PRODUCTS.—~~A drug
23 that is a biological product, except as provided
24 in paragraph (4).

1 “(D) DRUGS REMOVED FOR SAFETY AND
 2 EFFICACY.—A drug that appears on a list pub-
 3 lished by the Secretary in the Federal Register
 4 of drugs that have been withdrawn or removed
 5 from the market because such drug or compo-
 6 nents of such drug have been found to be un-
 7 safe or not effective, subject to paragraph (5).
 8 “(2) DRUGS THAT ARE DEMONSTRABLY DIFF-
 9 FICULT TO COMPOUND.—

10 “(A) IN GENERAL.—The Secretary may
 11 promulgate a regulation that designates drugs
 12 or categories of drugs that are demonstrably
 13 difficult to compound that may not be com-
 14 pounded, or that may be compounded only
 15 under conditions specified by the Secretary.
 16 Such regulation—

17 “(i) may include the designation of
 18 drugs or categories of drugs that are com-
 19 plex dosage forms or biological products;
 20 such as extended release products, metered
 21 dose inhalers, transdermal patches, and
 22 sterile liposomal products; and

23 “(ii) shall specify, for each drug in-
 24 cluded on the list, whether the prohibition

1 or condition applies to the use of the drug
2 in humans, animals, or both.

3 ~~“(B) INTERIM LIST.—~~

4 ~~“(i) IN GENERAL.—Before the effec-~~
5 ~~tive date of the regulation promulgated~~
6 ~~under subparagraph (A), the Secretary~~
7 ~~may designate drugs that are complex dos-~~
8 ~~age forms or biological products that can-~~
9 ~~not be compounded by—~~

10 ~~“(I) publishing a notice of such~~
11 ~~drugs proposed for designation, in-~~
12 ~~cluding the rationale for such designa-~~
13 ~~tion, in the Federal Register;~~

14 ~~“(II) providing a period of not~~
15 ~~less than 60 days for comment on the~~
16 ~~notice; and~~

17 ~~“(III) publishing a notice in the~~
18 ~~Federal Register designating the~~
19 ~~drugs that are complex dosage forms~~
20 ~~and biological products that cannot be~~
21 ~~compounded.~~

22 ~~“(ii) SUNSET.—Any notice provided~~
23 ~~under clause (i) shall cease to have force or~~
24 ~~effect on the date that is 5 years after the~~
25 ~~date of enactment of the Pharmaceutical~~

1 Compounding Quality and Accountability
 2 Act or on the effective date of the final
 3 regulation under subparagraph (A), which-
 4 ever is earlier.

5 “(3) EXCEPTIONS REGARDING MARKETED
 6 DRUGS.—

7 “(A) IN GENERAL.—A drug (other than a
 8 biological product) that is a copy of a marketed
 9 drug approved under 505 or 512, conditionally
 10 approved under section 571, or included on the
 11 index established under section 572(a)(1), in-
 12 cluding variations of such drug compounded
 13 from bulk substances, may be compounded only
 14 if—

15 “(i)(I) the compounded variation pro-
 16 duces for the patient a clinical difference
 17 between the compounded drug and such
 18 marketed drug, as determined by the pre-
 19 scribing practitioner, and, prior to begin-
 20 ning compounding a variation of such
 21 drug, the facility compounding the vari-
 22 ation receives a prescription order speci-
 23 fying that the variation may be com-
 24 pounded; or

1 “(H)(aa) such marketed drug, at the
2 time of compounding a copy of such drug
3 and at the time of distribution of the com-
4 pounded drug, is on the drug shortage list
5 under section 506E (in the case of a
6 human drug), on the Current Drug Short-
7 ages list for veterinary products main-
8 tained on the Internet Web site of the
9 Food and Drug Administration (in the
10 case of an animal drug), or in the Sec-
11 retary’s sole discretion, has otherwise been
12 identified by the Secretary as in shortage
13 such as in a specific region or on a drug
14 shortage list maintained by a private
15 party; and

16 “(bb) the traditional compounder or
17 the compounding manufacturer notifies the
18 Secretary not later than 3 calendar days
19 after beginning the compounding, unless
20 the Secretary waives the notice require-
21 ment; and

22 “(ii) in the case of a marketed drug
23 approved under section 505 that is subject
24 to a risk evaluation and mitigation strat-
25 egy approved with elements to assure safe

1 use pursuant to section 505–1, the entity
2 compounding the drug demonstrates to the
3 Secretary that the entity will utilize con-
4 trols that are comparable to the controls
5 applicable under the relevant risk evalua-
6 tion and mitigation strategy.

7 “(B) EXCLUSION.—For purposes of this
8 paragraph, repackaging a marketed drug ap-
9 proved under section 505, 512, conditionally ap-
10 proved under section 571, or included on the
11 index established under section 572(a)(1), does
12 not make the repackaged drug a copy of such
13 marketed drug.

14 “(4) EXCEPTIONS REGARDING BIOLOGICAL
15 PRODUCTS.—A drug that is a biological product may
16 be compounded only if—

17 “(A) such drug is compounded from a li-
18 censed biological product and the compounding
19 does not involve combining or mixing the li-
20 censed biological product with—

21 “(i) a bulk drug substance; or

22 “(ii) another, different drug or drugs
23 approved under 505 or 512, conditionally
24 approved under section 571, included on
25 the index established under section

1 ~~572(a)(1), or licensed under section 351 of~~
2 ~~the Public Health Service Act, unless the~~
3 ~~compounding is limited to the combining,~~
4 ~~mixing, or diluting of licensed allergenic~~
5 ~~products; and~~

6 “(B)(i) with respect to a traditional
7 compounder, the compounded biological product
8 produces for the patient a clinical difference be-
9 tween the compounded drug and the licensed bi-
10 ological product, as determined by the pre-
11 scribing practitioner, and, prior to beginning
12 compounding such drug, the facility
13 compounding the variation receives a prescrip-
14 tion order specifying that the biological product
15 may be compounded;

16 “(ii) with respect to a compounding manu-
17 facturer, the compounded variation biological
18 product produces for the patient a clinical dif-
19 ference between the compounded drug and the
20 licensed biological product, as determined by a
21 licensed practitioner responsible for the pa-
22 tient’s care in a health care entity that provides
23 medical services through licensed prescribers di-
24 rectly to patients, and, prior to beginning
25 compounding such drug, the compounding man-

1 manufacturer receives a duly authorized medical
 2 order from a hospital or health system speci-
 3 fying that the biological product may be com-
 4 pounded; or

5 “(iii) the compounded biological product is
 6 an allergenic product.

7 “(5) REQUIREMENT REGARDING DRUGS RE-
 8 MOVED FOR SAFETY OR EFFICACY.—The list pub-
 9 lished by the Secretary in the Federal Register of
 10 drugs that have been withdrawn or removed from
 11 the market, as described in paragraph (1)(D), shall
 12 specify whether a human drug on such list may, not-
 13 withstanding the inclusion on such list, be com-
 14 pounded for use in animals. The Secretary shall up-
 15 date the lists described in subparagraphs (D) and
 16 (E) of subsection (c)(2), as appropriate, to conform
 17 with the list described in paragraph (1)(D).

18 “(e) QUALITY OF DRUG INGREDIENTS.—

19 “(1) HUMAN DRUGS.—A traditional
 20 compounder or a compounding manufacturer shall—

21 “(A) compound a human drug using only
 22 bulk drug substances (as defined in regulations
 23 of the Secretary published at section
 24 207.3(a)(4) of title 21, Code of Federal Regula-
 25 tions (or any successor regulations))—

1 “(i) that—

2 “(I) comply with the standards of
3 an applicable United States Pharma-
4 copoeia or National Formulary mono-
5 graph, if a monograph exists and has
6 not been identified under paragraph
7 (6), and the United States Pharma-
8 copoeia chapters on pharmacy
9 compounding;

10 “(II) if such a monograph does
11 not exist, are drug substances that
12 are components of drugs approved by
13 the Secretary; or

14 “(III) if such a monograph does
15 not exist and the drug substance is
16 not a component of a drug approved
17 by the Secretary, that appear on a list
18 developed by the Secretary through
19 regulations issued by the Secretary;

20 “(ii) that are manufactured by an es-
21 tablishment that is registered under sec-
22 tion 510 (including a foreign establishment
23 that is registered under section 510(i));
24 and

1 “(iii) that are accompanied by valid
2 certificates of analysis for each specific lot
3 of bulk drug substance; and

4 “(B) use ingredients (other than bulk drug
5 substances) that comply with the standards of
6 an applicable United States Pharmacopoeia or
7 National Formulary monograph, if a mono-
8 graph exists and has not been identified under
9 paragraph (6); and with the United States
10 Pharmacopoeia chapter on pharmacy
11 compounding.

12 “(2) ANIMAL DRUGS.—A traditional
13 compounder or a compounding manufacturer shall—

14 “(A) compound an animal drug using only
15 bulk drug substances (as defined in regulations
16 of the Secretary published at section
17 207.3(a)(4) of title 21, Code of Federal Regula-
18 tions (or any successor regulations)) that—

19 “(i) are manufactured by an establish-
20 ment that is registered under section 510
21 (including a foreign establishment that is
22 registered under section 510(i)); and

23 “(ii) are accompanied by valid certifi-
24 cates of analysis for each specific lot of
25 bulk drug substance;

“(B) use ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists and has not been identified under paragraph (6); and with the United States Pharmacopoeia chapters on pharmacy compounding;

“(C) in the case of a compounded animal drug for use in non-food-producing minor species, use bulk substances that—

“(i) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists and has not been identified under paragraph (6); and with the United States Pharmacopoeia chapters on pharmacy compounding;

“(ii) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

“(iii) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Sec-

retary, that appear on a list developed by
the Secretary through regulations issued
by the Secretary;

“(D) in the case of a compounded animal
drug for use in non-food-producing major spe-
cies, beginning on the date of publication of the
list established in accordance with paragraph
(3)(A), shall use bulk substances that are in-
cluded on such list, subject to paragraph
(3)(C); and

“(E) in the case of a compounded animal
drug for use in food-producing major and minor
species, shall use bulk substances that are in-
cluded on a list established by the Secretary of
bulk substances acceptable for use in
compounding a drug for one or more such spe-
cies, in accordance with paragraph (4).

“(3) ~~NON-FOOD-PRODUCING MAJOR SPECIES~~

~~LISTING PROCEDURE.—~~

“(A) ~~IN GENERAL.—~~Not later than 30
days after the effective date of the Pharma-
ceutical Compounding Quality and Account-
ability Act, the Secretary shall establish a list
of bulk substances acceptable for compounding
a drug for use in non-food-producing major spe-

1 cies, and any conditions applicable to such use;
2 and may also identify bulk substances that the
3 Secretary has determined not acceptable for
4 compounding with respect to a drug for use in
5 such species.

6 “(B) PROCEDURE.—In developing and up-
7 dating the list under subparagraph (A), the
8 Secretary shall—

9 “(i) publish a notice in the Federal
10 Register identifying bulk substances pro-
11 posed as acceptable and any bulk sub-
12 stance determine to be unacceptable, and
13 the rationale for such proposed designa-
14 tions;

15 “(ii) provide a period of not less than
16 30 days for comment on the notice; and

17 “(iii) publish a notice in the Federal
18 Register designating the bulk substances
19 acceptable, and any bulk substances deter-
20 mined to be unacceptable, and the ration-
21 ale for such designations and determina-
22 tions.

23 “(C) NOTIFICATION.—Upon initial publica-
24 tion of the list under subparagraph (B)(iii), any
25 traditional compounder or compounding manu-

1 manufacturer that has received and filled a prescrip-
2 tion in the 60 days prior to such publication for
3 a compounded drug for a non-food-producing
4 major species from a bulk substance not ad-
5 dressed in the notice (either as acceptable or
6 unacceptable); and that reasonably expect to re-
7 ceive and fill another prescription for such a
8 drug for such species within 60 days after such
9 publication, may notify the Secretary of such
10 bulk substance within 30 days of such publica-
11 tion, in a manner to be determined by the Sec-
12 retary and published in the Federal Register on
13 or before publication of the list under subpara-
14 graph (B)(iii). A traditional compounder or
15 compounding manufacturer that provides such
16 notice shall not be subject to the restriction in
17 paragraph (2)(D) until such time as the Sec-
18 retary designates such bulk substance as ac-
19 ceptable or determines it to be unacceptable
20 pursuant to the process described in subpara-
21 graph (B)(iii).

22 “(D) MODIFICATION OF LIST.—The Sec-
23 retary may amend the list at any time, in ac-
24 cordance with process described in subpara-
25 graph (B).

1 “(E) CRITERIA.—In evaluating bulk sub-
2 stances for purposes of subparagraph (B), the
3 Secretary shall consider, among other factors—

4 “(i) the safety of the bulk substance;

5 “(ii) historical use of the substance in
6 pharmacy compounding;

7 “(iii) evidence of the effectiveness of
8 the bulk substance or lack of effectiveness;

9 “(iv) whether any drug approved
10 under section 505 or 512, conditionally ap-
11 proved under section 571, or included on
12 the index established under section
13 572(a)(1), can be used on label, or any
14 drug approved under section 505 or 512
15 can be used in an extralabel manner in ac-
16 cordance with section paragraphs (4) and
17 (5) of section 512(a), to treat the applica-
18 ble condition in the identified species; and

19 “(v) whether a compounded drug ap-
20 propriate to treat the applicable condition
21 in the identified species could be obtained
22 by manipulating a drug approved under
23 505 or 512, conditionally approved under
24 section 571, or included on the index es-
25 tablished under section 572(a)(1).

1 “(4) ~~FOOD-PRODUCING ANIMALS LISTING PRO-~~
 2 ~~CEDURE.~~—In establishing a list of designated bulk
 3 substances acceptable for use in compounding a
 4 drug for use in food-producing major and minor spe-
 5 cies under paragraph (2), and any conditions appli-
 6 cable to such use, the Secretary shall—

7 “(A) publish a notice in the Federal Reg-
 8 ister identifying bulk substances proposed as
 9 acceptable and any bulk substance determine to
 10 be unacceptable, and the rationale for such des-
 11 ignations;

12 “(B) provide a period of not less than 30
 13 days for comment on the notice; and

14 “(C) publish a notice in the Federal Reg-
 15 ister designating the bulk substances acceptable
 16 for use in compounding a drug for use in food-
 17 producing major and minor species, and the ra-
 18 tionale for such designations.

19 “(5) ~~WITHDRAWAL PERIODS.~~—The require-
 20 ments for establishing substantially extended with-
 21 drawal periods in accordance with section 530.20 of
 22 title 21, Code of Federal Regulations (or any suc-
 23 cessor regulations) shall apply to compounded ani-
 24 mal drugs for use in food-producing animals that
 25 are compounded using bulk substances.

1 “(6) IDENTIFICATION BY SECRETARY.—

2 “(A) IN GENERAL.—Notwithstanding the
3 existence of an applicable monograph under
4 subparagraph (A)(i)(I) or (B) of paragraph (1)
5 or subparagraph (B) or (C)(i) of paragraph (2),
6 the Secretary may identify bulk substances that
7 the Secretary determines, based on public
8 health concerns, may not be used in
9 compounding a drug.

10 “(B) PROCEDURE.—In identifying the bulk
11 substances that may not be used in
12 compounding, the Secretary shall—

13 “(i) publish a notice of such bulk sub-
14 stances proposed for identification in the
15 Federal Register;

16 “(ii) provide a period of not less than
17 60 days for comment on the notice;

18 “(iii) publish a notice in the Federal
19 Register identifying the bulk substances
20 that may not be used in compounding a
21 drug; and

22 “(iv) state whether the bulk is not
23 suitable for compounding of human drugs,
24 animal drugs, or both.

1 “(f) REQUIREMENTS REGARDING WHOLESALING
 2 AND LABELING APPLICABLE TO TRADITIONAL
 3 COMPOUNDERS AND COMPOUNDING MANUFACTURERS.—

4 “(1) IN GENERAL.—A compounded drug—

5 “(A) may not be sold by an entity other
 6 than the compounding manufacturer or tradi-
 7 tional compounder that compounded the drug;

8 “(B) compounded by a compounding man-
 9 ufacturer may not be sold to an entity other
 10 than a health care entity that provides medical
 11 services through licensed prescribers directly to
 12 patients or animals; or a network of such pro-
 13 viders; except that a compounding manufac-
 14 turer may transfer without profit a compounded
 15 sterile drug to a licensed pharmacy if—

16 “(i) the licensed pharmacy falls under
 17 the same corporate ownership as the
 18 compounding manufacturer;

19 “(ii) the transfer of such compounded
 20 sterile drug is solely for the purpose of dis-
 21 pensing the compounded sterile drug to the
 22 end user, who has been instructed by the
 23 prescribing physician to self-administer
 24 such compounded sterile drug;

1 “(iii) as of the date of enactment of
2 the Pharmaceutical Compounding Quality
3 and Accountability Act, the compounding
4 manufacturer is an entity that provides
5 pharmacy benefits management services on
6 behalf of a health benefits plan;

7 “(iv) the compounding manufacturer
8 identifies itself to the Secretary upon reg-
9 istering under subsection (g)(2) as an enti-
10 ty that qualifies for the exemption under
11 this subparagraph, and provides docu-
12 mentation of the compounding of such
13 drugs as of the date of enactment of the
14 Pharmaceutical Compounding Quality and
15 Accountability Act, in a manner described
16 by the Secretary; and

17 “(v) the compounding manufacturer
18 receives confirmation from the Secretary
19 that the compounding manufacturer quali-
20 fies for the exemption under this subpara-
21 graph and the sterile drug or drugs for
22 which the exemption applies; and

23 “(C) in the case of a compounded drug
24 sold to a health care entity described in sub-
25 paragraph (B), shall be labeled ‘not for resale’.

1 ~~“(2) ADVERTISING AND PROMOTION.—The ad-~~
 2 ~~vertising and promotion of compounded drugs shall~~
 3 ~~not be false or misleading in any particular.~~

4 ~~“(g) OTHER REQUIREMENTS APPLICABLE TO~~
 5 ~~COMPOUNDING MANUFACTURERS.—~~

6 ~~“(1) LICENSED PHARMACIST OVERSIGHT.—A~~
 7 ~~compounding manufacturer shall ensure that a phar-~~
 8 ~~macist licensed in the State where the compounding~~
 9 ~~manufacturer is located exercises direct supervision~~
 10 ~~over the operations of the compounding manufac-~~
 11 ~~turer.~~

12 ~~“(2) REGISTRATION OF COMPOUNDING MANU-~~
 13 ~~FACTURERS AND REPORTING OF DRUGS.—~~

14 ~~“(A) REGISTRATION OF COMPOUNDING~~
 15 ~~MANUFACTURERS.—~~

16 ~~“(i) ANNUAL REGISTRATION.—During~~
 17 ~~the period beginning on October 1 and~~
 18 ~~ending on December 31 each year, each~~
 19 ~~compounding manufacturer shall register~~
 20 ~~with the Secretary its name, place of busi-~~
 21 ~~ness, and unique facility identifier (which~~
 22 ~~shall conform to the requirements for the~~
 23 ~~unique facility identifier established under~~
 24 ~~section 510), and a point of contact e-mail~~
 25 ~~address.~~

1 “(ii) NEW COMPOUNDING MANUFAC-
2 TURERS.—Each compounding manufac-
3 turer, upon first engaging in the oper-
4 ations described in subsection (b)(1), shall
5 immediately register with the Secretary
6 and provide the information described
7 under clause (i). The Secretary shall estab-
8 lish a timeline for registration for the first
9 year following the effective date of the
10 Pharmaceutical Compounding Quality and
11 Accountability Act. In no case may reg-
12 istration be required until at least 60 days
13 following publication of the timeline in the
14 Federal Register.

15 “(iii) ADDITIONAL FACILITIES.—Each
16 compounding manufacturer duly registered
17 in accordance with clauses (i) and (ii) shall
18 immediately identify to the Secretary any
19 additional facility that engages in the ac-
20 tivities described in subsection (b)(1) and
21 that is owned or operated in any State by
22 the person that owns or operates the
23 compounding manufacturer.

24 “(iv) AVAILABILITY OF REGISTRATION
25 FOR INSPECTION.—The Secretary shall

1 make available for inspection, to any per-
 2 son so requesting, any registration filed
 3 pursuant to this subparagraph, except that
 4 any drug reporting information submitted
 5 pursuant to this subparagraph and the in-
 6 formation accompanying such reporting
 7 shall be exempt from such inspection, un-
 8 less the Secretary finds that such an ex-
 9 emption would be inconsistent with the
 10 protection of the public health.

11 “(B) DRUG REPORTING BY COMPOUNDING
 12 MANUFACTURERS.—

13 “(i) IN GENERAL.—Each compound-
 14 ing manufacturer who registers with the
 15 Secretary under subparagraph (A) shall
 16 submit to the Secretary, once during the
 17 month of June of each year and once dur-
 18 ing the month of December of each year,
 19 a report—

20 “(I) identifying the drugs com-
 21 pounded by such compounding manu-
 22 facturer during the previous 6-month
 23 period; and

24 “(II) with respect to each drug
 25 identified under subclause (I), pro-

1 viding the active ingredient, the
 2 source of such active ingredient, the
 3 National Drug Code number of the
 4 source drug or bulk active ingredient,
 5 the strength of the active ingredient
 6 per unit, the dosage form and route of
 7 administration, the package descrip-
 8 tion, the number of individual units
 9 produced, the National Drug Code
 10 number of the final product, and
 11 which conforms to other applicable re-
 12 quirements identified by the Secretary
 13 in accordance with clause (ii).

14 “(ii) FORM.—Each report under
 15 clause (i) shall be prepared in such form
 16 and manner as the Secretary may pre-
 17 scribe by regulation or guidance.

18 “(C) ELECTRONIC REGISTRATION AND RE-
 19 PORTING.—Registrations and drug reporting
 20 under this paragraph (including the submission
 21 of updated information) shall be submitted to
 22 the Secretary by electronic means unless the
 23 Secretary grants a request for waiver of such
 24 requirement because use of electronic means is
 25 not reasonable for the person requesting waiver.

1 “(D) ~~RISK-BASED INSPECTION FRE-~~
2 ~~QUENCY.—~~

3 “(i) ~~IN GENERAL.—~~Compounding
4 manufacturers shall be subject to inspec-
5 tion pursuant to section 704.

6 “(ii) ~~RISK-BASED SCHEDULE.—~~The
7 Secretary, acting through one or more offi-
8 cers or employees duly designated by the
9 Secretary, shall inspect compounding man-
10 ufacturers described in clause (i) in accord-
11 ance with a risk-based schedule established
12 by the Secretary.

13 “(iii) ~~RISK FACTORS.—~~In establishing
14 the risk-based schedule under clause (ii),
15 the Secretary shall inspect compounding
16 manufacturers according to the known
17 safety risks of such compounding manufac-
18 turers, which shall be based on the fol-
19 lowing factors:

20 “(I) The compliance history of
21 the compounding manufacturer.

22 “(H) The record, history, and na-
23 ture of recalls linked to the
24 compounding manufacturer.

1 “(III) The inherent risk of the
2 drug compounded at the compounding
3 manufacturer.

4 “(IV) The inspection frequency
5 and history of the compounding man-
6 ufacturer, including whether the
7 compounding manufacturer has been
8 inspected pursuant to section 704
9 within the last 4 years.

10 “(V) Any other criteria deemed
11 necessary and appropriate by the Sec-
12 retary for purposes of allocating in-
13 spection resources.

14 “(3) ADVERSE EVENT REPORTING.—

15 “(A) DEFINITIONS.—In this paragraph:

16 “(i) ADVERSE EVENT.—The term ‘ad-
17 verse event’ means any health-related event
18 associated with the use of a compounded
19 drug that is adverse, including—

20 “(I) an event occurring in the
21 course of the use of the drug in pro-
22 fessional practice;

23 “(II) an event occurring from an
24 overdose of the drug, whether acci-
25 dental or intentional;

1 “(III) an event occurring from
2 abuse of the drug;

3 “(IV) an event occurring from
4 withdrawal of the drug; and

5 “(V) any failure of expected
6 pharmacological action of the drug.

7 “(ii) **SERIOUS ADVERSE EVENT.**—The
8 term ‘serious adverse event’ means an ad-
9 verse event that—

10 “(I) results in—

11 “(aa) death;

12 “(bb) an adverse drug event
13 that places the patient at imme-
14 diate risk of death from the ad-
15 verse drug event as it occurred
16 (not including an adverse drug
17 event that might have caused
18 death had it occurred in a more
19 severe form);

20 “(cc) inpatient hospitaliza-
21 tion or prolongation of existing
22 hospitalization;

23 “(dd) a persistent or signifi-
24 cant incapacity or substantial

1 disruption of the ability to con-
 2 duct normal life functions; or

3 ~~“(cc) a congenital anomaly~~
 4 ~~or birth defect; or~~

5 ~~“(II) based on appropriate med-~~
 6 ~~ical judgment, may jeopardize the pa-~~
 7 ~~tient and may require a medical or~~
 8 ~~surgical intervention to prevent an~~
 9 ~~outcome described in subclause (I).~~

10 ~~“(B) REPORTS.—~~

11 ~~“(i) ADVERSE EVENT REPORTING RE-~~
 12 ~~QUIREMENT.—~~

13 ~~“(I) 15-DAY REPORT.—If a~~
 14 ~~compounding manufacturer becomes~~
 15 ~~aware of any serious adverse event,~~
 16 ~~such manufacturer shall submit re-~~
 17 ~~ports of each instance to the Sec-~~
 18 ~~retary as soon as practicable, but in~~
 19 ~~no case later than 15 calendar days~~
 20 ~~after the initial receipt of the applica-~~
 21 ~~ble information. Such manufacturer~~
 22 ~~shall investigate and submit to the~~
 23 ~~Secretary followup reports for each~~
 24 ~~such instance not later than 15 cal-~~
 25 ~~endar days after receipt of new infor-~~

1 mation or as requested by the Sec-
2 retary. Unless and until the Secretary
3 establishes the content and format of
4 adverse event reports by guidance or
5 regulation, reports shall be submitted
6 in accordance with the content and
7 format requirements under section
8 310.305 of title 21, Code of Federal
9 Regulations (or any successor regula-
10 tions) (in the case of human drugs);
11 section 600.80 of title 21, Code of
12 Federal Regulations (or any successor
13 regulations) (in the case of biological
14 products); or section 514.80 of title
15 21, Code of Federal Regulations (or
16 any successor regulations) (in the case
17 of animal drugs).

18 “(H) ANNUAL REPORT.—

19 Compounding manufacturers that re-
20 port serious adverse events shall sub-
21 mit in December of each year a nar-
22 rative summary of any analysis of
23 each report submitted under subclause
24 (I), including a history of actions
25 taken during the year because of each

1 report, using the content, format, and
2 manner established by the Secretary
3 by guidance or regulation. Until such
4 time as the Secretary publishes such
5 guidance or regulation, each
6 compounding manufacturer shall re-
7 tain such summaries as part of the
8 records to be maintained in accord-
9 ance with subparagraph (C).

10 “(ii) PRODUCT QUALITY REPORTING
11 REQUIREMENT.—Not later than 3 calendar
12 days after the compounding manufacturer
13 becomes aware of information pertaining
14 to sterility, stability, or other product qual-
15 ity concerns that could result in serious
16 adverse events, the compounding manufac-
17 turer shall submit to the Secretary a prod-
18 uct quality report, in a form and manner
19 established by the Secretary by guidance or
20 regulation.

21 “(C) MAINTENANCE OF RECORDS.—A
22 compounding manufacturer shall maintain for a
23 period of 10 years records of all serious adverse
24 drug events known to the compound manufac-
25 turer in accordance with section 314.80(i) of

1 title 21, Code of Federal Regulations (or any
2 successor regulation), or as otherwise directed
3 by the Secretary in regulations.

4 “(4) LABELING OF DRUGS.—

5 “(A) LABEL.—The label of a drug com-
6 pounded by a compounding manufacturer shall
7 include—

8 “(i) the statement ‘This is a com-
9 pounded drug.’ or a reasonable comparable
10 alternative statement (as specified by the
11 Secretary) that identifies the drug as a
12 compounded drug;

13 “(ii) the name, address, and phone
14 number of the applicable compounding
15 manufacturer; and

16 “(iii) with respect to the compounded
17 drug—

18 “(I) the lot or batch number;

19 “(II) the established name of the
20 medication;

21 “(III) the dosage form and
22 strength;

23 “(IV) the statement of quantity
24 or volume, as appropriate;

1 “(V) in the case of a drug in-
 2 tended for use in a food-producing
 3 animal, the withdrawal period estab-
 4 lished pursuant to subsection (c)(5) to
 5 ensure that no residues from the com-
 6 pounded drug can be detected in edi-
 7 ble tissues of the treated animal;

8 “(VI) the date that the drug was
 9 compounded;

10 “(VII) the expiration date;

11 “(VIII) storage and handling in-
 12 structions;

13 “(IX) the National Drug Code
 14 number, if available;

15 “(X) the ‘not for resale’ state-
 16 ment required as required by sub-
 17 section (f)(1)(C); and

18 “(XI) subject to subparagraph
 19 (B)(i), a list of active and inactive in-
 20 gredients, identified by established
 21 name and the quantity or proportion
 22 of each ingredient.

23 “(B) CONTAINER.—The container from
 24 which the individual units of a drug com-
 25 pounded by a compounding manufacturer 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)(XI), if there is not
space on the label for such information;

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

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

“(C) ~~ADDITIONAL INFORMATION.—~~The
label and labeling of a drug compounded by a
compounding manufacturer shall include any
other information as determined necessary and
specified in regulations promulgated by the Sec-
retary.

“(h) ~~COMPOUNDING MANUFACTURER ESTABLISH-~~
~~MENT AND REINSPECTION FEES.—~~

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

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

“(B) the term ‘gross annual sales’ means
the total worldwide gross annual sales, in

United States dollars, for a compounding manufacturer, including the sales of all the affiliates of the compounding manufacturer; and

“(C) the term ‘reinspection’ means, with respect to a compounding manufacturer, 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.

“(2) ESTABLISHMENT AND REINSPECTION FEES.—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 compounding manufacturer to cover inspection-related costs relating to inspections of drug compounders for such year; and

“(B) a reinspection fee from each compounding manufacturer subject to a reinspection in such fiscal year.

“(3) ESTABLISHMENT AND REINSPECTION FEE SETTING.—The Secretary shall establish the estab-

lishment and reinspection fee to be collected under this subsection for each fiscal year, based on the methodology described in paragraph (4) and shall publish such fee in a Federal Register notice not later than 60 days before the start of each such year.

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

~~“(A) IN GENERAL.—~~Except as provided in subparagraph (D), the amount of the annual establishment fee and the reinspection fee (if applicable) under paragraph (2) for each compounding manufacturer in a fiscal year shall be equal to the sum of—

~~“(i)(I) \$15,000 per compounding manufacturer, multiplied by~~

~~“(II) the inflation adjustment factor described in subparagraph (B); plus~~

~~“(ii) the small business adjustment factor described in subparagraph (C).—~~

~~“(B) INFLATION ADJUSTMENT FACTOR.—~~

~~“(i) IN GENERAL.—~~For fiscal year 2015 and subsequent fiscal years, the revenues established in subparagraph (A) shall be adjusted by the Secretary by notice,

published in the Federal Register, for a
fiscal year by the amount equal to the sum
of—

“(I) one;

“(II) the average annual percent
change in the cost, per full-time equiv-
alent position of the Food and Drug
Administration, of all personnel com-
pensation and benefits paid with re-
spect to such positions for the first 3
years of the preceding 4 fiscal years;
multiplied by the proportion of per-
sonnel 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

1 the proportion of all costs other than
 2 personnel compensation and benefits
 3 costs to total costs of an average full-
 4 time equivalent position of the Food
 5 and Drug Administration for the first
 6 3 years of the preceding 4 fiscal
 7 years.

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

14 “(C) SMALL BUSINESS ADJUSTMENT FAC-
 15 TOR.—The small business adjustment factor de-
 16 scribed in subparagraph (A)(ii) shall be an
 17 amount established by the Secretary for each
 18 fiscal year based on the Secretary’s estimate
 19 of—

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

23 “(ii) the adjustment to the establish-
 24 ment fee necessary to achieve total fees
 25 equaling the total fees that the Secretary

would have collected if no entity qualified for the small business exception in subparagraph (D).

“(D) EXCEPTION FOR SMALL BUSINESSES.—

“(i) IN GENERAL.—In the case of a compounding manufacturer with gross annual sales of \$1,000,000 or less in the 12 months ending June 1 of the fiscal year immediately preceding the fiscal year in which the fees under this subsection are assessed, the amount of the establishment fee and reinspection fee under paragraph (2) for a fiscal year shall be equal to $\frac{1}{3}$ of the amount calculated under subparagraph (A)(i) in such fiscal year.

“(ii) APPLICATION.—The Secretary may require a small business to apply for the exception under this subparagraph by certifying its gross annual sales for the 12 months ending June 1 of the fiscal year immediately preceding the fiscal year in which fees under this subsection are assessed. Any such application must be submitted to the Secretary prior to August 1

1 for the following fiscal year. Any statement
2 or representation made to the Secretary
3 shall be subject to section 1001 of title 18,
4 United States Code.

5 “(E) CREDITING OF FEES.—In estab-
6 lishing the small business adjustment factor
7 under subparagraph (C) for a fiscal year, the
8 Secretary shall provide for the crediting of fees
9 from the previous year to the next year if the
10 Secretary overestimated the amount of the
11 small business adjustment factor for such pre-
12 vious fiscal year, and consider the need to ac-
13 count for any adjustment of fees and such other
14 factors as the Secretary determines appropriate.

15 “(5) USE OF FEES.—The Secretary shall make
16 all of the fees collected pursuant to subparagraph
17 (A) and (B) of paragraph (2) available solely to pay
18 for the inspection-related costs (including re-inspec-
19 tion) for the oversight of drug compounding.

20 “(6) SUPPLEMENT NOT SUPPLANT.—Funds re-
21 ceived by the Secretary pursuant to this subsection
22 shall be used to supplement and not supplant any
23 other Federal funds available to carry out the activi-
24 ties described in this subsection.

1 ~~“(7) CREDITING AND AVAILABILITY OF FEES.—~~

2 Fees authorized under this subsection shall be col-
 3 lected and available for obligation only to the extent
 4 and in the amount provided in advance in appropria-
 5 tions Acts. Such fees are authorized to remain avail-
 6 able until expended. Such sums as may be necessary
 7 may be transferred from the Food and Drug Admin-
 8 istration salaries and expenses appropriation account
 9 without fiscal year limitation to such appropriation
 10 account for salaries and expenses with such fiscal
 11 year limitation. The sums transferred shall be avail-
 12 able solely for the purpose of paying the inspection-
 13 related costs (including reinspection) for the over-
 14 sight of drug compounding.

15 ~~“(8) COLLECTION OF FEES.—~~

16 ~~“(A) ESTABLISHMENT FEE.—A~~

17 compounding manufacturer shall remit the es-
 18 tablishment fee due under this subsection in a
 19 fiscal year when submitting a registration pur-
 20 suant to subsection (g) for such fiscal year.

21 ~~“(B) REINSPECTION FEE.—The Secretary~~

22 shall specify in the Federal Register notice de-
 23 scribed in paragraph (3) the manner in which
 24 reinspection fees assessed under this subsection
 25 shall be collected and the timeline for payment

1 of such fees. Such a fee shall be collected after
 2 the Secretary has conducted a reinspection of
 3 the compounding manufacturer involved.

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

5 ~~“(i) REGISTRATION.—A compounding~~
 6 ~~manufacturer shall not be considered reg-~~
 7 ~~istered under subsection (g) in a fiscal year~~
 8 ~~until the date that the compounding manu-~~
 9 ~~facturer remits the establishment fee under~~
 10 ~~this subsection for such fiscal year.~~

11 ~~“(ii) MISBRANDING.—All drugs com-~~
 12 ~~pounded by a compounding manufacturer~~
 13 ~~for which any establishment fee or rein-~~
 14 ~~spection fee has not been paid as required~~
 15 ~~by this subsection shall be deemed mis-~~
 16 ~~branded under section 502(cc) until the~~
 17 ~~fees owed for such compounding manufac-~~
 18 ~~turer under this subsection have been paid.~~

19 ~~“(D) COLLECTION OF UNPAID FEES.—In~~
 20 ~~any case where the Secretary does not receive~~
 21 ~~payment of a fee assessed under this subsection~~
 22 ~~within 30 days after it is due, such fee shall be~~
 23 ~~treated as a claim of the United States Govern-~~
 24 ~~ment subject to provisions of subchapter H of~~
 25 ~~chapter 37 of title 31, United States Code.~~

1 “(9) ANNUAL REPORT TO CONGRESS.—Not
 2 later than 120 days after each fiscal year in which
 3 fees are assessed and collected under this subsection,
 4 the Secretary shall submit a report to the Com-
 5 mittee on Health, Education, Labor, and Pensions
 6 of the Senate and the Committee on Energy and
 7 Commerce of the House of Representatives, to in-
 8 clude a description of fees assessed and collected for
 9 each year, a summary description of entities paying
 10 the fees, and the number of inspections and re-
 11 inspections of such entities performed each year.

12 “(10) AUTHORIZATION OF APPROPRIATIONS.—
 13 For fiscal year 2015 and each subsequent fiscal
 14 year, there is authorized to be appropriated for fees
 15 under this subsection an amount equivalent to the
 16 total amount of fees assessed for such fiscal year
 17 under this subsection.

18 “(i) ACTION BY SECRETARY REGARDING COM-
 19 PLAINTS FROM STATE BOARDS OF PHARMACY.—

20 “(1) DESIGNATION.—The Secretary shall des-
 21 ignate a point of contact and establish a format and
 22 procedure for a State Board of Pharmacy to notify
 23 the Secretary if it appears to a State Board of Phar-
 24 macy that an entity licensed by a State as a phar-

1 macy is required to be registered with the Secretary
2 as a compounding manufacturer.

3 ~~“(2) DETERMINATION.—If the Secretary deter-~~
4 mines that such an entity described in paragraph (1)
5 is required to be registered with the Secretary as a
6 compounding manufacturer, the Secretary shall
7 transmit such determination to the State Board of
8 Pharmacy in the State in which the entity is located,
9 and to the State Board of Pharmacy in the notifying
10 State, if different, within 15 days of such determina-
11 tion.

12 ~~“(3) EFFECT.—The Secretary shall encourage~~
13 direct communications between States regarding tra-
14 ditional compounders. Nothing in this subsection
15 shall expand the Secretary’s authority over or re-
16 sponsibility for traditional compounding.

17 ~~“(j) PRESCRIPTION ORDER REFERENCE.—For pur-~~
18 poses of this section, reference to a prescription order for
19 an identified individual patient includes, in the case of ani-
20 mal drugs, a prescription order for a specific herd or flock
21 (or other identified group) of animals.”.

22 ~~(c) PROHIBITED ACT.—Section 301 (21 U.S.C. 331)~~
23 is amended—

24 (1) in subsection (c), by striking “417, 416,
25 504” and inserting “417, 416, 503A(g), 504”; and

1 (2) by adding at the end the following:

2 “~~(eee)~~ The resale of a compounded drug that is la-
3 beled ‘not for resale’ as required by section 503A.”.

4 ~~(d) REPORT BY GAO.—~~Not later than November 1,
5 2016, the Comptroller General of the United States shall
6 conduct study and submit to Congress a report regarding
7 the impact of this Act ~~(and the amendments made by this~~
8 Act) on the safety of animal drug compounding and the
9 availability of safe and effective drugs for animals.

10 **SEC. 3. OTHER REQUIREMENTS RELATING TO**
11 **COMPOUNDING MANUFACTURERS.**

12 ~~(a) LABELING.—~~Section 502 ~~(21 U.S.C. 352)~~ is
13 amended by adding at the end the following:

14 “~~(bb)~~ If it is a compounded drug and the labeling
15 does not include the information as required by sub-
16 sections ~~(f)(1)(C)~~ and ~~(g)(4)~~ of section 503A, as applica-
17 ble:

18 “~~(ee)~~ If it is a drug, and it was compounded by a
19 compounding manufacturer for which fees have not been
20 paid as required by section 503A(g).”.

21 ~~(b) APPLICATION OF INSPECTION REQUIREMENTS TO~~
22 COMPOUNDING MANUFACTURERS.—Section 704(a)(2)
23 ~~(21 U.S.C. 374(a)(2))~~ is amended by adding at the end
24 the following flush text:

1 “The exemption in subparagraph (A) does not apply with
 2 respect to compounding manufacturers (as such term is
 3 defined in section 503A).”.

4 (c) ADULTERATION OF COMPOUNDED ANIMAL
 5 DRUGS CONTAINING DRUG RESIDUES.—Section
 6 402(a)(2)(C) is amended by striking “512;” and inserting
 7 “512; or (iii) any residue from a compounded animal
 8 drug;”.

9 **SEC. 4. IMPLEMENTATION.**

10 In promulgating any regulations to implement this
 11 Act (and the amendments made by this Act), the Sec-
 12 retary of Health and Human Services shall—

13 (1) issue a notice of proposed rulemaking that
 14 includes the proposed regulation;

15 (2) provide a period of not less than 60 days
 16 for comments on the proposed regulation; and

17 (3) publish the final regulation not more than
 18 18 months following publication of the proposed rule
 19 and not less than 30 days before the effective date
 20 of such final regulation.

21 **SEC. 5. EFFECTIVE DATE.**

22 This Act (and the amendments made by this Act)
 23 shall take effect on the date that is 1 year after the date
 24 of enactment of this Act.

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Pharmaceutical Quality,*
 3 *Security, and Accountability Act”.*

4 **SEC. 2. REFERENCES IN ACT; TABLE OF CONTENTS.**

5 (a) *REFERENCES IN ACT.*—*Except as otherwise speci-*
 6 *fied, amendments made by this Act to a section or other*
 7 *provision of law are amendments to such section or other*
 8 *provision of the Federal Food, Drug, and Cosmetic Act (21*
 9 *U.S.C. 301 et seq.).*

10 (b) *TABLE OF CONTENTS.*—*The table of contents of this*
 11 *Act is as follows:*

Sec. 1. Short title.

Sec. 2. References in Act; table of contents.

TITLE I—HUMAN DRUG COMPOUNDING

Sec. 101. Short title.

Sec. 102. Regulation of human drug compounding.

Sec. 103. Other requirements.

Sec. 104. Implementation.

Sec. 105. Effective date.

TITLE II—DRUG SUPPLY CHAIN SECURITY

Sec. 201. Short title.

Sec. 202. Pharmaceutical distribution supply chain.

Sec. 203. Enhanced drug distribution security.

Sec. 204. National licensure standards for prescription drug wholesale distribu-
tors.

Sec. 205. National licensure standards for third-party logistics providers; uniform
national policy.

Sec. 206. Penalties.

Sec. 207. Conforming amendment.

Sec. 208. Savings clause.

TITLE I—HUMAN DRUG COMPOUNDING

SEC. 101. SHORT TITLE.

This title may be cited as the “Pharmaceutical Compounding Quality and Accountability Act”.

SEC. 102. REGULATION OF HUMAN DRUG COMPOUNDING.

(a) CLARIFICATION OF NEW DRUG STATUS.—For purposes of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), the term “new drug” (as defined in section 201(p) of such Act) shall include a compounded human drug.

(b) REGULATION OF HUMAN DRUG COMPOUNDING.—Section 503A (21 U.S.C. 353a) is amended to read as follows:

“SEC. 503A. HUMAN DRUG COMPOUNDING.

“(a) SCOPE.—

“(1) COMPOUNDING.—In this section, the terms ‘compounding’ and ‘compound’—

“(A) include—

“(i) the combining, admixing, mixing, diluting, reconstituting, or otherwise altering of a marketed drug;

“(ii) compounding a drug from a bulk drug substance; and

“(iii) repackaging; and

1 “(B) *exclude mixing, reconstituting, or*
 2 *other such acts with respect to a marketed drug*
 3 *that are limited to and performed in accordance*
 4 *with specific directions for such acts contained*
 5 *in approved labeling provided by a drug’s manu-*
 6 *facturer, when performed based upon a prescrip-*
 7 *tion order for an identified individual patient.*

8 “(2) *ADMINISTRATION AND DISPENSING NOT A*
 9 *SALE.—In this section, the terms ‘sell’ or ‘resale’ do*
 10 *not include—*

11 “(A) *circumstances in which drug is ad-*
 12 *ministered to a patient or provided to a patient*
 13 *who has been instructed to self-administer the*
 14 *drug;*

15 “(B) *the dispensing of a drug pursuant to*
 16 *a prescription executed in accordance with sec-*
 17 *tion 503(b)(1); or*

18 “(C) *any fee associated with such adminis-*
 19 *tration, provision, or dispensing of the drug.*

20 “(3) *INAPPLICABILITY TO CERTAIN DRUGS.—*

21 “(A) *IN GENERAL.—For purposes of this*
 22 *section, the activities described in paragraph (1)*
 23 *shall not be considered ‘compounding’ if such ac-*
 24 *tivities are conducted in whole or in part with*
 25 *respect to a drug described in subparagraph (B).*

1 “(B) *EXCLUDED DRUGS.*—*The drugs de-*
 2 *scribed in this subparagraph are the following:*

3 “(i) *Blood and blood components for*
 4 *transfusion.*

5 “(ii) *Medical gases, as defined in sec-*
 6 *tion 575.*

7 “(4) *ANIMAL DRUGS FOR HUMAN USE.*—*Nothing*
 8 *in this section shall be construed to permit the use of*
 9 *animal drugs in compounding a drug for human use.*

10 “(b) *DEFINITIONS.*—*In this section:*

11 “(1) *COMPOUNDING MANUFACTURER.*—

12 “(A) *IN GENERAL.*—*The term ‘compounding*
 13 *manufacturer’ means a facility at one geo-*
 14 *graphic location or address—*

15 “(i) *that compounds any sterile drug*
 16 *without receiving a prescription order for*
 17 *an identified individual patient for such*
 18 *sterile drug prior to beginning*
 19 *compounding, and distributes or offers to*
 20 *sell such compounded sterile drug in inter-*
 21 *state commerce; or*

22 “(ii) *that repackages any preservative-*
 23 *free sterile drug or engages in sterile pool-*
 24 *ing.*

25 “(B) *EXCLUSIONS.*—

1 “(i) *EXCLUDED ACTIVITIES.*—*Notwith-*
 2 *standing subparagraph (A)(ii), a facility*
 3 *shall not be considered a compounding*
 4 *manufacturer if such facility—*

5 “(I) *repackages drugs in accord-*
 6 *ance with section 506F or the final*
 7 *guidance described in section 506F(d)*
 8 *once the final guidance is published;*
 9 *and*

10 “(II) *does not otherwise meet the*
 11 *definition of compounding manufac-*
 12 *turer under subparagraph (A).*

13 “(ii) *COMPOUNDING NUCLEAR PHAR-*
 14 *MACY.*—*The term ‘compounding manufac-*
 15 *turer’ shall not include a compounding nu-*
 16 *clear pharmacy.*

17 “(2) *COMPOUNDING NUCLEAR PHARMACY.*—*The*
 18 *term ‘compounding nuclear pharmacy’ means an en-*
 19 *tity that—*

20 “(A) *is a State-licensed pharmacy or a Fed-*
 21 *eral facility;*

22 “(B) *holds a license currently in effect from*
 23 *the Nuclear Regulatory Commission or from a*
 24 *State pursuant to an agreement with such com-*

1 *mission under section 274 of the Atomic Energy*
2 *Act of 1954; and*

3 “(C) *does not compound non-radioactive*
4 *drugs that would cause the entity to be a*
5 *compounding manufacturer described in para-*
6 *graph (1)(A).*

7 “(3) *COPY.—The term ‘copy’ means an identical*
8 *or nearly identical version of a drug.*

9 “(4) *PRACTITIONER.—The term ‘practitioner’ in-*
10 *cludes a physician or any other person that is author-*
11 *ized to prescribe medication under State law.*

12 “(5) *RADIOACTIVE DRUG.—The term ‘radioactive*
13 *drug’—*

14 “(A) *means any substance defined as a drug*
15 *in section 201(g)(1) that exhibits spontaneous*
16 *disintegration of unstable nuclei with the emis-*
17 *sion of nuclear particles or photons and includes*
18 *any nonradioactive reagent kit or nuclide regen-*
19 *erator which is intended to be used in the prepa-*
20 *ration of any such substance but does not include*
21 *drugs such as carbon-containing compounds or*
22 *potassium-containing salts which contain trace*
23 *quantities of naturally occurring radionuclides;*
24 *and*

1 “(B) includes a ‘radioactive biological prod-
 2 uct,’ which means a biological product which is
 3 labeled with a radionuclide or intended solely to
 4 be labeled with a radionuclide.

5 “(6) *REPACKAGE OR REPACKAGING*.—The term
 6 ‘repackage’ or ‘repackaging’—

7 “(A) means taking a drug approved under
 8 section 505 or licensed under section 351 of the
 9 Public Health Service Act from the container in
 10 which it is distributed by the original manufac-
 11 turer and placing it in a different container of
 12 the same or smaller size without further manipu-
 13 lating the drug (such as by diluting it or mixing
 14 it with another, different drug or drugs); and

15 “(B) does not include removing the drug
 16 from its original container for immediate ad-
 17 ministration to an identified individual patient,
 18 such as withdrawing a drug into a syringe for
 19 immediate injection or filling a cassette for im-
 20 mediate use within a drug delivery device.

21 “(7) *STERILE DRUG*.—The term ‘sterile drug’
 22 means a drug that is—

23 “(A) intended for parenteral administra-
 24 tion;

1 “(B) *an ophthalmic or oral inhalation drug*
 2 *in aqueous format; or*

3 “(C) *required to be sterile under Federal or*
 4 *State law.*

5 “(8) *STERILE POOLING.—The term ‘sterile pool-*
 6 *ing’—*

7 “(A) *means taking a single sterile drug ap-*
 8 *proved under section 505 from the container in*
 9 *which it is distributed by the original manufac-*
 10 *turer and combining it with the same sterile*
 11 *drug from one or more other containers without*
 12 *or before further manipulating the product (such*
 13 *as by diluting it or mixing it with another, dif-*
 14 *ferent drug or drugs);*

15 “(B) *does not include combining the drug*
 16 *from two or more separate containers of the same*
 17 *drug when a single container of the drug is not*
 18 *sufficient to prepare a single dose for adminis-*
 19 *tration to an individual patient; and*

20 “(C) *does not include combining a single*
 21 *drug from two or more separate containers of*
 22 *component products of a parenteral nutrition*
 23 *product, if such pooling, labeling, and use of the*
 24 *finished parenteral nutrition product, comply*
 25 *with State pharmacy law.*

1 “(9) *TRADITIONAL COMPOUNDER.*—

2 “(A) *IN GENERAL.*—*The term ‘traditional*
 3 *compounder’ means a facility operating pursu-*
 4 *ant to State law—*

5 “(i) *wherein a drug is compounded*
 6 *by—*

7 “(I) *a licensed pharmacist in a*
 8 *State-licensed pharmacy or a licensed*
 9 *Federal facility; or*

10 “(II) *a licensed physician;*

11 “(ii) *that—*

12 “(I) *compounds a drug upon re-*
 13 *ceipt of a prescription order for an*
 14 *identified individual patient; or*

15 “(II) *compounds a drug in lim-*
 16 *ited quantities before receipt of a pre-*
 17 *scription order for an identified indi-*
 18 *vidual patient, if such compounding is*
 19 *based on a history of the licensed phar-*
 20 *macist or licensed physician receiving*
 21 *prescription orders for the*
 22 *compounding of the drug, which orders*
 23 *have been generated solely within an*
 24 *established relationship between the li-*

1 *censed pharmacist or licensed physi-*
 2 *cian and—*

3 *“(aa) such individual pa-*
 4 *tient for whom the prescription*
 5 *order will be provided; or*

6 *“(bb) the licensed physician*
 7 *or other licensed practitioner who*
 8 *will write such prescription order;*
 9 *and*

10 *“(iii) that does not meet the definition*
 11 *of a compounding manufacturer under*
 12 *paragraph (1).*

13 *“(B) EXCEPTIONS.—*

14 *“(i) HOSPITALS AND HEALTH SYS-*
 15 *TEMS.—A pharmacy within a hospital or*
 16 *health system shall be considered a tradi-*
 17 *tional compounder if such pharmacy other-*
 18 *wise meets the definition under subpara-*
 19 *graph (A) and if, with respect to a drug*
 20 *compounded by such pharmacy, the only ac-*
 21 *tivity conducted by the pharmacy is to dis-*
 22 *perse or administer such drug (which may*
 23 *include interstate shipment) solely to a pa-*
 24 *tient of such hospital or health system.*

1 “(ii) *HEALTH SYSTEM DEFINED.*—The
2 term ‘health system’—

3 “(I) *means an entity that owns*
4 *and operates—*

5 “(aa) *one hospital; or*

6 “(bb) *two or more hospitals*
7 *that have common access to data-*
8 *bases with drug order information*
9 *for patients; and*

10 “(II) *includes only the inpatient,*
11 *outpatient, and ambulatory facilities*
12 *wholly owned and operated by such en-*
13 *tity, and accredited by a national ac-*
14 *creditation body recognized by the Sec-*
15 *retary.*

16 “(c) *EXEMPTIONS FROM CERTAIN REQUIREMENTS.*—

17 “(1) *IN GENERAL.*—*Except as otherwise provided*
18 *in paragraphs (2), (3), and (4), a compounded drug*
19 *shall be subject to all the requirements of this Act ap-*
20 *plicable to new drugs.*

21 “(2) *DRUGS COMPOUNDED BY TRADITIONAL*
22 *COMPOUNDERS.*—*Sections 501(a)(2)(B), 502(f)(1),*
23 *and 505 of this Act and section 351 of the Public*
24 *Health Service Act shall not apply to a compounded*
25 *drug if such drug—*

1 “(A) is compounded by a traditional
2 compounder that is in compliance with this sec-
3 tion; and

4 “(B) meets the requirements of this section
5 applicable to drugs compounded by traditional
6 compounders.

7 “(3) *DRUGS COMPOUNDED BY COMPOUNDING*
8 *MANUFACTURERS.*—Sections 502(f)(1) and 505 of this
9 Act and section 351 of the Public Health Service Act
10 shall not apply to a compounded prescription drug,
11 if such prescription drug—

12 “(A) is compounded by a compounding
13 manufacturer—

14 “(i) that is not licensed as a pharmacy
15 in any State; and

16 “(ii) that is in compliance with this
17 section; and

18 “(B) meets the requirements of this section
19 applicable to drugs compounded by compounding
20 manufacturers.

21 “(4) *DRUGS COMPOUNDED BY COMPOUNDING NU-*
22 *CLEAR PHARMACIES.*—Sections 501(a)(2)(B),
23 502(f)(1), and 505 of this Act and section 351 of the
24 Public Health Service Act shall not apply to a com-

1 *pounded radioactive drug if such drug is com-*
 2 *pounded—*

3 *“(A) by a licensed pharmacist in a*
 4 *compounding nuclear pharmacy;*

5 *“(B) solely using a radioactive drug ap-*
 6 *proved under section 505 or licensed under sec-*
 7 *tion 351 of the Public Health Service Act, and*
 8 *one or more ingredients in compliance with sub-*
 9 *section (e)(1)(B); and*

10 *“(C) in compliance with the United States*
 11 *Pharmacopoeia chapters on pharmacy*
 12 *compounding.*

13 *“(d) DRUGS THAT MAY NOT BE COMPOUNDED.—*

14 *“(1) IN GENERAL.—The following drugs may not*
 15 *be compounded:*

16 *“(A) DRUGS THAT ARE DEMONSTRABLY*
 17 *DIFFICULT TO COMPOUND.—A drug or category*
 18 *of drugs that presents demonstrable difficulties*
 19 *for compounding, which may include a complex*
 20 *dosage form or biological product, as designated*
 21 *by the Secretary pursuant to paragraph (2).*

22 *“(B) MARKETING DRUGS.—A drug (other*
 23 *than a biological product) that is a copy of a*
 24 *marketed drug approved under 505 or a vari-*

1 *ation of such drug compounded from bulk drug*
 2 *substances, except as provided in paragraph (3).*

3 “(C) *BIOLOGICAL PRODUCTS.*—*A drug that*
 4 *is a biological product, except as provided in*
 5 *paragraph (4).*

6 “(D) *DRUGS SUBJECT TO RISK EVALUATION*
 7 *AND MITIGATION STRATEGY.*—*A copy or vari-*
 8 *ation of a drug approved under section 505 or*
 9 *licensed under section 351 of the Public Health*
 10 *Service Act that is the subject of a risk evalua-*
 11 *tion and mitigation strategy approved with ele-*
 12 *ments to assure safe use pursuant to section*
 13 *505–1, except provided in paragraph (5).*

14 “(E) *DRUGS REMOVED FOR SAFETY AND*
 15 *EFFICACY.*—*A drug that appears on a list pub-*
 16 *lished by the Secretary in the Federal Register of*
 17 *drugs that have been withdrawn or removed from*
 18 *the market because such drug or components of*
 19 *such drug have been found to be unsafe or not ef-*
 20 *fective.*

21 “(2) *DRUGS THAT ARE DEMONSTRABLY DIF-*
 22 *FICULT TO COMPOUND.*—

23 “(A) *IN GENERAL.*—*The Secretary may*
 24 *promulgate a regulation that designates drugs or*
 25 *categories of drugs that are demonstrably dif-*

1 *ficult to compound that may not be compounded,*
2 *or that may be compounded only under condi-*
3 *tions specified by the Secretary. Such regulation*
4 *may include the designation of drugs or cat-*
5 *egories of drugs that are complex dosage forms or*
6 *biological products, such as extended release*
7 *products, metered dose inhalers, transdermal*
8 *patches, and sterile liposomal products.*

9 *“(B) INTERIM LIST.—*

10 *“(i) IN GENERAL.—Before the effective*
11 *date of the regulation promulgated under*
12 *subparagraph (A), the Secretary may des-*
13 *ignate drugs or categories of drugs that*
14 *present demonstrable difficulties for*
15 *compounding, which may include complex*
16 *dosage forms or biological products that*
17 *cannot be compounded, except under condi-*
18 *tions specified by the Secretary, by—*

19 *“(I) publishing a notice of such*
20 *drugs or categories of drugs proposed*
21 *for designation, including the rationale*
22 *for such designation, in the Federal*
23 *Register;*

1 “(II) providing a period of not
2 less than 60 calendar days for com-
3 ment on the notice; and

4 “(III) publishing a notice in the
5 *Federal Register* designating such
6 drugs or categories of drugs that can-
7 not be compounded, including the ra-
8 tionale for such designation.

9 “(ii) *SUNSET*.—Any notice provided
10 under clause (i) shall cease to have force or
11 effect on the date that is 5 years after the
12 date of enactment of the *Pharmaceutical*
13 *Compounding Quality and Accountability*
14 *Act* or on the effective date of the final regu-
15 lation under subparagraph (A), whichever
16 is earlier.

17 “(C) *CONSULTATION WITH STAKE-*
18 *HOLDERS*.—Prior to establishing the lists de-
19 scribed in this paragraph, the Secretary shall
20 consult with relevant stakeholders including
21 pharmacists, professional associations, patient
22 and public health advocacy groups, manufactur-
23 ers and physicians about the need for the com-
24 pounded drugs to be included or excluded from
25 the lists.

“(D) *UPDATES TO DIFFICULT TO COM-
POUND LIST.*—Five years after the effective date
of the regulation described in subparagraph (A),
and every 5 years thereafter, the Secretary shall
publish a Federal Register notice seeking public
input about the need for the compounded drugs
to be included or excluded from the list described
in subparagraph (A). Nothing in the previous
sentence prohibits notifications or submissions
before or during any 5-year period described
under such sentence regarding the need for the
compounded drugs to be included or excluded
from the list.

“(3) *EXCEPTIONS REGARDING MARKETED
DRUGS.*—

“(A) *IN GENERAL.*—A drug (other than a
biological product) that is a copy of a marketed
drug approved under 505, including variations
of such drug compounded from bulk drug sub-
stances, may be compounded only if—

“(i) the compounded variation pro-
duces for the individually identified patient
a clinical difference between the com-
pounded drug and such marketed drug, as
determined by the prescribing practitioner,

1 *and, prior to beginning compounding such*
2 *variation, the traditional compounder*
3 *compounding the variation receives a pre-*
4 *scription order for an identified individual*
5 *patient specifying that the variation may be*
6 *compounded; or*

7 “(ii)(I) *such marketed drug, at the*
8 *time of compounding a copy of such drug*
9 *and at the time of distribution of the com-*
10 *pounded drug, is on the drug shortage list*
11 *under section 506E, or has otherwise been*
12 *identified by the Secretary, in the Sec-*
13 *retary’s sole discretion, as in shortage, such*
14 *as in a specific region or on a drug shortage*
15 *list maintained by a private party;*

16 “(II) *the facility compounding the*
17 *drug notifies the Secretary not later than 3*
18 *calendar days after beginning the*
19 *compounding; and*

20 “(III) *in the case of a compounding*
21 *manufacturer, the compounding manufac-*
22 *turer has registered under subsection (g)(2)*
23 *as an entity that intends to compound pur-*
24 *suant to this paragraph and notifies the*

1 *Secretary at least 14 calendar days prior to*
2 *beginning the compounding.*

3 “(B) *NOTICE WAIVER.*—*The Secretary may*
4 *waive a notice required under subparagraph*
5 *(A)(ii).*

6 “(C) *EXCLUSION.*—*For purposes of this*
7 *paragraph, repackaging a marketed drug ap-*
8 *proved under section 505 does not make the re-*
9 *packaged drug a copy of such marketed drug,*
10 *unless the repackaged drug is also a marketed*
11 *drug approved under section 505.*

12 “(4) *EXCEPTIONS REGARDING BIOLOGICAL PROD-*
13 *UCTS.*—

14 “(A) *IN GENERAL.*—*A drug that is a vari-*
15 *ation of a licensed biological product may be*
16 *compounded only if—*

17 “(i)(I) *such compounded variation is*
18 *compounded solely using a licensed biologi-*
19 *cal product, or solely using a licensed bio-*
20 *logical product and one or more ingredients*
21 *in compliance with subsection (e)(1)(B); or*

22 “(II) *in the case of a licensed aller-*
23 *genic product, such variation is com-*
24 *pounded solely using one or more licensed*
25 *allergenic products, or solely using one or*

1 *more licensed allergenic products and one or*
2 *more ingredients in compliance with sub-*
3 *section (e)(1)(B);*

4 “(ii) *such compounded variation pro-*
5 *duces for the patient a clinical difference be-*
6 *tween such compounded variation and the*
7 *licensed biological product, as determined*
8 *by—*

9 “(I) *the prescribing practitioner*
10 *(in the case of a variation compounded*
11 *by a traditional compounder); or*

12 “(II) *a licensed practitioner re-*
13 *sponsible for the patient’s care in a*
14 *health care entity that provides med-*
15 *ical services through licensed practi-*
16 *tioners directly to patients (in the case*
17 *of a variation compounded by a*
18 *compounding manufacturer);*

19 “(iii) *prior to beginning*
20 *compounding—*

21 “(I) *except as provided in sub-*
22 *paragraph (B), the traditional*
23 *compounder receives a prescription*
24 *order for an identified individual pa-*
25 *tient specifying that the biological*

1 *product may be compounded for an*
 2 *identified individual patient; or*

3 “(II) *the compounding manufac-*
 4 *turer receives a duly authorized med-*
 5 *ical order from a health care entity*
 6 *that provides medical services through*
 7 *licensed practitioners directly to pa-*
 8 *tients, specifying that the biological*
 9 *product may be compounded based on*
 10 *such order for an identified patient or*
 11 *patients; and*

12 “(iv) *in the case of a radioactive bio-*
 13 *logical product, the compounded variation*
 14 *is compounded by a compounding nuclear*
 15 *pharmacy in accordance with subsection*
 16 *(b)(2).*

17 “(B) *SPECIAL RULE FOR PEDIATRIC*
 18 *USES.—A traditional compounder that is a hos-*
 19 *pital or health system may begin compounding*
 20 *a drug that is a variation of a licensed biological*
 21 *product prior to receiving a prescription order*
 22 *as required under subparagraph (A)(iii) if—*

23 “(i) *such compounded variation is a*
 24 *diluted or repackaged variation of the li-*

1 *censed biological product for emergent use*
 2 *in pediatric patients; and*

3 “(ii) *such compounded variation pro-*
 4 *duces for the patient a clinical difference be-*
 5 *tween such compounded variation and the*
 6 *licensed biological product, as determined*
 7 *by a licensed practitioner responsible for the*
 8 *patient’s care in the hospital or health sys-*
 9 *tem.*

10 “(C) *INAPPLICABILITY.—*Clauses (ii) and
 11 (iii) of subparagraph (A) shall not apply to a
 12 *compounded allergenic product.*

13 “(D) *POOLING.—*Notwithstanding any other
 14 provision of this section, sterile pooling of a bio-
 15 logical product is not permitted.

16 “(5) *REQUIREMENT FOR DRUGS THAT HAVE*
 17 *RISK EVALUATION AND MITIGATION STRATEGIES.—*

18 “(A) *IN GENERAL.—*A copy or variation of
 19 a drug approved under section 505 or biological
 20 product licensed under section 351 of the Public
 21 Health Service Act that is the subject of a risk
 22 evaluation and mitigation strategy approved
 23 with elements to assure safe use pursuant to sec-
 24 tion 505–1, may be compounded only if—

1 “(i) the entity compounding the copy
 2 or variation receives a prescription order
 3 for an identified individual patient speci-
 4 fying that the drug or biological product
 5 may be compounded; and

6 “(ii) the entity compounding the copy
 7 or variation demonstrates to the Secretary,
 8 prior to beginning compounding, that the
 9 entity will utilize controls that are com-
 10 parable to the controls applicable under the
 11 relevant risk evaluation and mitigation
 12 strategy for the approved drug or licensed
 13 biological product.

14 “(B) *EFFECT.*—Nothing in this paragraph
 15 shall be construed to permit compounding a copy
 16 or variation of a drug other than as permitted
 17 in paragraphs (3) and (4).

18 “(e) *QUALITY OF DRUG INGREDIENTS.*—

19 “(1) *HUMAN DRUGS.*—A traditional compounder
 20 or a compounding manufacturer shall—

21 “(A) if compounding a drug from bulk drug
 22 substances (as defined in regulations of the Sec-
 23 retary published at section 207.3(a)(4) of title
 24 21, Code of Federal Regulations (or any suc-
 25 cessor regulations)), use only bulk substances—

1 “(i) that—

2 “(I) comply with the standards of
3 an applicable United States Pharma-
4 copoeia or National Formulary mono-
5 graph, if a monograph exists and has
6 not been identified under paragraph
7 (2);

8 “(II) if such a monograph does
9 not exist, are drug substances that are
10 components of drugs approved by the
11 Secretary; or

12 “(III) if such a monograph does
13 not exist and the drug substance is not
14 a component of a drug approved by the
15 Secretary, that appear on a list devel-
16 oped by the Secretary through regula-
17 tions issued by the Secretary;

18 “(ii) that are manufactured by an es-
19 tablishment that is registered under section
20 510 (including a foreign establishment that
21 is registered under section 510(i)); and

22 “(iii) that are accompanied by valid
23 certificates of analysis for each specific lot
24 of bulk drug substance;

“(B) use ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists and has not been identified under paragraph (2); and

“(C) in the case of a traditional compounder, comply with the standards of the United States Pharmacopoeia chapters on pharmacy compounding.

“(2) IDENTIFICATION BY SECRETARY.—

“(A) IN GENERAL.—Notwithstanding the existence of an applicable monograph under subparagraph (A)(i)(I) or (B) of paragraph (1), the Secretary may identify bulk substances that the Secretary determines, based on public health concerns, may not be used in compounding a drug.

“(B) PROCEDURE.—In identifying the bulk substances that may not be used in compounding, the Secretary shall—

“(i) publish a notice of such bulk substances proposed for identification in the Federal Register, including the rationale for such proposal;

1 “(ii) provide a period of not less than
 2 60 calendar days for comment on the notice;
 3 and

4 “(iii) publish a notice in the *Federal*
 5 *Register* identifying the bulk substances that
 6 may not be used in compounding a drug.

7 “(f) *REQUIREMENTS REGARDING WHOLESALING AND*
 8 *LABELING APPLICABLE TO TRADITIONAL COMPOUNDERS*
 9 *AND COMPOUNDING MANUFACTURERS.—A compounded*
 10 *drug—*

11 “(1) may not be sold by an entity other than the
 12 compounding manufacturer or traditional
 13 compounder that compounded the drug;

14 “(2) compounded by a compounding manufac-
 15 turer may not be sold or transferred to an entity
 16 other than a health care entity that provides medical
 17 services through licensed practitioners directly to pa-
 18 tients, or a network of such providers, except that a
 19 compounding manufacturer may transfer without
 20 profit a compounded sterile drug to a licensed phar-
 21 macy if—

22 “(A) as of the date of enactment of the
 23 *Pharmaceutical Compounding Quality and Ac-*
 24 *countability Act*, and at the time of such trans-
 25 fer, the licensed pharmacy falls under the same

1 *corporate ownership as the compounding manu-*
2 *facturer;*

3 “(B) *the transfer of such compounded sterile*
4 *drug is solely for the purpose of dispensing the*
5 *compounded sterile drug to the end user, who has*
6 *been instructed by the prescribing physician to*
7 *self-administer such compounded sterile drug;*

8 “(C) *as of the date of enactment of the*
9 *Pharmaceutical Compounding Quality and Ac-*
10 *countability Act, and at the time of such trans-*
11 *fer, the compounding manufacturer is an entity*
12 *wholly owned by an entity that provides phar-*
13 *macy benefits management services on behalf of*
14 *a health benefits plan;*

15 “(D) *the compounding manufacturer identi-*
16 *fies itself to the Secretary upon registering under*
17 *subsection (g)(2) as an entity that qualifies for*
18 *the exception under this paragraph, and provides*
19 *documentation of the compounding of such drugs*
20 *as of the date of enactment of the Pharma-*
21 *ceutical Compounding Quality and Account-*
22 *ability Act, in a manner described by the Sec-*
23 *retary; and*

24 “(E) *the compounding manufacturer re-*
25 *ceives confirmation from the Secretary that the*

1 *compounding manufacturer qualifies for the ex-*
 2 *ception under this paragraph and the sterile*
 3 *drug or drugs for which the exemption applies;*
 4 *and*

5 “(3) *in the case of a compounded drug offered for*
 6 *sale, shall be labeled ‘not for resale’.*

7 “(g) *OTHER REQUIREMENTS APPLICABLE TO*
 8 *COMPOUNDING MANUFACTURERS.—*

9 “(1) *LICENSED PHARMACIST OVERSIGHT.—A*
 10 *compounding manufacturer shall ensure that a phar-*
 11 *macist licensed in the State where the compounding*
 12 *manufacturer is located exercises direct supervision*
 13 *over the operations of the compounding manufacturer.*

14 “(2) *REGISTRATION OF COMPOUNDING MANUFAC-*
 15 *TURERS AND REPORTING OF DRUGS.—*

16 “(A) *REGISTRATION OF COMPOUNDING MAN-*
 17 *UFACTURERS.—*

18 “(i) *ANNUAL REGISTRATION.—During*
 19 *the period beginning on October 1 and end-*
 20 *ing on December 31 each year, each*
 21 *compounding manufacturer shall register*
 22 *with the Secretary its name, place of busi-*
 23 *ness, and unique facility identifier (which*
 24 *shall conform to the requirements for the*
 25 *unique facility identifier established under*

1 *section 510), and a point of contact e-mail*
2 *address, and shall indicate whether the*
3 *compounding manufacturer intends to com-*
4 *pound drug in shortage pursuant to sub-*
5 *section (d)(3)(A)(ii).*

6 “(ii) *NEW COMPOUNDING MANUFAC-*
7 *TURERS.—Each compounding manufac-*
8 *turer, upon first engaging in the operations*
9 *described in subsection (b)(1), shall imme-*
10 *diately register with the Secretary and pro-*
11 *vide the information described under clause*
12 *(i). The Secretary shall establish a timeline*
13 *for registration for the first year following*
14 *the effective date of the Pharmaceutical*
15 *Compounding Quality and Accountability*
16 *Act. In no case may registration be required*
17 *until at least 60 calendar days following*
18 *publication of the timeline in the Federal*
19 *Register.*

20 “(iii) *AVAILABILITY OF REGISTRATION*
21 *FOR INSPECTION.—The Secretary shall*
22 *make available for inspection, to any person*
23 *so requesting, any registration filed pursu-*
24 *ant to this subparagraph.*

1 “(B) *DRUG REPORTING BY COMPOUNDING*
2 *MANUFACTURERS.*—

3 “(i) *IN GENERAL.*—*Each compounding*
4 *manufacturer who registers with the Sec-*
5 *retary under subparagraph (A) shall submit*
6 *to the Secretary, once during the month of*
7 *June of each year and once during the*
8 *month of December of each year, a report—*

9 “(I) *identifying the drugs com-*
10 *pounded by such compounding manu-*
11 *facturer during the previous 6-month*
12 *period; and*

13 “(II) *with respect to each drug*
14 *identified under subclause (I), pro-*
15 *viding the active ingredient, the source*
16 *of such active ingredient, the National*
17 *Drug Code number, if available, of the*
18 *source drug or bulk active ingredient,*
19 *the strength of the active ingredient per*
20 *unit, the dosage form and route of ad-*
21 *ministration, the package description,*
22 *the number of individual units pro-*
23 *duced, the National Drug Code number*
24 *of the final product, if assigned.*

1 “(ii) *FORM.—Each report under clause*
2 *(i) shall be prepared in such form and man-*
3 *ner as the Secretary may prescribe by regu-*
4 *lation or guidance.*

5 “(iii) *CONFIDENTIALITY.—Reports sub-*
6 *mitted pursuant to this subparagraph shall*
7 *be exempt from inspection under subpara-*
8 *graph (A)(iii), unless the Secretary finds*
9 *that such an exemption would be incon-*
10 *sistent with the protection of the public*
11 *health.*

12 “(C) *ELECTRONIC REGISTRATION AND RE-*
13 *PORTING.—Registrations and drug reporting*
14 *under this paragraph (including the submission*
15 *of updated information) shall be submitted to the*
16 *Secretary by electronic means unless the Sec-*
17 *retary grants a request for waiver of such re-*
18 *quirement because use of electronic means is not*
19 *reasonable for the person requesting waiver.*

20 “(D) *RISK-BASED INSPECTION FRE-*
21 *QUENCY.—*

22 “(i) *IN GENERAL.—Compounding*
23 *manufacturers shall be subject to inspection*
24 *pursuant to section 704.*

1 “(ii) *RISK-BASED SCHEDULE.*—The
 2 Secretary, acting through one or more offi-
 3 cers or employees duly designated by the
 4 Secretary, shall inspect compounding man-
 5 ufacturers described in clause (i) in accord-
 6 ance with a risk-based schedule established
 7 by the Secretary.

8 “(iii) *RISK FACTORS.*—In establishing
 9 the risk-based schedule under clause (ii), the
 10 Secretary shall inspect compounding manu-
 11 facturers according to the known safety
 12 risks of such compounding manufacturers,
 13 which shall be based on the following fac-
 14 tors:

15 “(I) *The compliance history of the*
 16 *compounding manufacturer.*

17 “(II) *The record, history, and na-*
 18 *ture of recalls linked to the*
 19 *compounding manufacturer.*

20 “(III) *The inherent risk of the*
 21 *drug compounded at the compounding*
 22 *manufacturer.*

23 “(IV) *The inspection frequency*
 24 *and history of the compounding manu-*
 25 *facturer, including whether the*

1 *compounding manufacturer has been*
 2 *inspected pursuant to section 704 with-*
 3 *in the last 4 years.*

4 “(V) *Whether the compounding*
 5 *manufacturer has registered under sub-*
 6 *section (g)(2) as an entity that intends*
 7 *to compound pursuant to subsection*
 8 *(d)(3)(A)(ii).*

9 “(VI) *Any other criteria deemed*
 10 *necessary and appropriate by the Sec-*
 11 *retary for purposes of allocating in-*
 12 *spection resources.*

13 “(3) *ADVERSE EVENT REPORTING.—*

14 “(A) *DEFINITIONS.—In this paragraph:*

15 “(i) *ADVERSE EVENT.—The term ‘ad-*
 16 *verse event’ means any health-related event*
 17 *associated with the use of a compounded*
 18 *drug that is adverse, including—*

19 “(I) *an event occurring in the*
 20 *course of the use of the drug in profes-*
 21 *sional practice;*

22 “(II) *an event occurring from an*
 23 *overdose of the drug, whether acci-*
 24 *dental or intentional;*

1 “(III) an event occurring from
2 abuse of the drug;

3 “(IV) an event occurring from
4 withdrawal of the drug; and

5 “(V) any failure of expected phar-
6 macological action of the drug.

7 “(ii) *SERIOUS ADVERSE EVENT*.—The
8 term ‘serious adverse event’ means an ad-
9 verse event that—

10 “(I) results in—

11 “(aa) death;

12 “(bb) an adverse drug event
13 that places the patient at imme-
14 diate risk of death from the ad-
15 verse drug event as it occurred
16 (not including an adverse drug
17 event that might have caused
18 death had it occurred in a more
19 severe form);

20 “(cc) inpatient hospitaliza-
21 tion or prolongation of existing
22 hospitalization;

23 “(dd) a persistent or signifi-
24 cant incapacity or substantial

1 *disruption of the ability to con-*
 2 *duct normal life functions; or*

3 *“(ee) a congenital anomaly*
 4 *or birth defect; or*

5 *“(II) based on appropriate med-*
 6 *ical judgment, may jeopardize the pa-*
 7 *tient and may require a medical or*
 8 *surgical intervention to prevent an*
 9 *outcome described in subclause (I).*

10 *“(B) REPORTS.—*

11 *“(i) ADVERSE EVENT REPORTING RE-*
 12 *QUIREMENT.—*

13 *“(I) 15-DAY REPORT.—If a*
 14 *compounding manufacturer becomes*
 15 *aware of any serious adverse event,*
 16 *such manufacturer shall submit reports*
 17 *of each instance to the Secretary as*
 18 *soon as practicable, but in no case*
 19 *later than 15 calendar days after the*
 20 *initial receipt of the applicable infor-*
 21 *mation. Such manufacturer shall in-*
 22 *vestigate and submit to the Secretary*
 23 *followup reports for each such instance*
 24 *not later than 15 calendar days after*
 25 *receipt of new information or as re-*

1 *quested by the Secretary. Unless and*
2 *until the Secretary establishes the con-*
3 *tent and format of adverse event re-*
4 *ports by guidance or regulation, re-*
5 *ports shall be submitted in accordance*
6 *with the content and format require-*
7 *ments under section 310.305 of title 21,*
8 *Code of Federal Regulations (or any*
9 *successor regulations) or section 600.80*
10 *of title 21, Code of Federal Regulations*
11 *(or any successor regulations).*

12 “(II) ANNUAL REPORT.—

13 *Compounding manufacturers that re-*
14 *port serious adverse events shall submit*
15 *in December of each year a narrative*
16 *summary of any analysis of each re-*
17 *port submitted under subclause (I), in-*
18 *cluding a history of actions taken dur-*
19 *ing the year because of each report,*
20 *using the content, format, and manner*
21 *established by the Secretary by guid-*
22 *ance or regulation. Until such time as*
23 *the Secretary publishes such guidance*
24 *or regulation, each compounding man-*
25 *ufacturer shall retain such summaries*

as part of the records to be maintained
in accordance with subparagraph (C).

“(ii) *PRODUCT QUALITY REPORTING REQUIREMENT.*—Not later than 3 calendar days after the compounding manufacturer becomes aware of information pertaining to sterility, stability, or other product quality concerns that could result in serious adverse events, the compounding manufacturer shall submit to the Secretary a product quality report, in a form and manner established by the Secretary by guidance or regulation.

“(C) *MAINTENANCE OF RECORDS.*—A compounding manufacturer shall maintain for a period of 10 years records of all serious adverse drug events known to the compound manufacturer in accordance with section 314.80(i) of title 21, Code of Federal Regulations (or any successor regulation), or as otherwise directed by the Secretary in regulations.

“(4) *LABELING OF DRUGS.*—

“(A) *LABEL.*—The label of a drug compounded by a compounding manufacturer shall include—

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

6 “(ii) the name, address, and phone
7 number of the applicable compounding
8 manufacturer; and

9 “(iii) with respect to the compounded
10 drug—

11 “(I) the lot or batch number;

12 “(II) the established name of the
13 medication;

14 “(III) the dosage form and
15 strength;

16 “(IV) the statement of quantity or
17 volume, as appropriate;

18 “(V) the date that the drug was
19 compounded;

20 “(VI) the expiration date;

21 “(VII) storage and handling in-
22 structions;

23 “(VIII) the National Drug Code
24 number, if available;

1 “(IX) the ‘not for resale’ statement
2 as required by subsection (f)(3); and

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

8 “(B) CONTAINER.—The container from
9 which the individual units of a drug com-
10 pounded by a compounding manufacturer are re-
11 moved for dispensing or for administration (such
12 as a plastic bag containing individual product
13 syringes) shall include—

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

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

21 “(iii) the directions for use, including,
22 as appropriate, dosage and administration.

23 “(C) ADDITIONAL INFORMATION.—The label
24 and labeling of a drug compounded by a
25 compounding manufacturer shall include any

1 *other information as determined necessary and*
 2 *specified in regulations promulgated by the Sec-*
 3 *retary.*

4 “(h) *COMPOUNDING MANUFACTURER ESTABLISHMENT*
 5 *AND REINSPECTION FEES.—*

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

7 “(A) *the term ‘affiliate’ has the meaning*
 8 *given such term in section 735(11);*

9 “(B) *the term ‘gross annual sales’ means the*
 10 *total worldwide gross annual sales, in United*
 11 *States dollars, for a compounding manufacturer,*
 12 *including the sales of all the affiliates of the*
 13 *compounding manufacturer; and*

14 “(C) *the term ‘reinspection’ means, with re-*
 15 *spect to a compounding manufacturer, 1 or more*
 16 *inspections conducted under section 704 subse-*
 17 *quent to an inspection conducted under such*
 18 *provision which identified noncompliance mate-*
 19 *rially related to an applicable requirement of*
 20 *this Act, specifically to determine whether com-*
 21 *pliance has been achieved to the Secretary’s sat-*
 22 *isfaction.*

23 “(2) *ESTABLISHMENT AND REINSPECTION*
 24 *FEES.—*

1 “(A) *IN GENERAL.*—For fiscal year 2015
 2 and each subsequent fiscal year, the Secretary
 3 shall, in accordance with this subsection, assess
 4 and collect—

5 “(i) *an annual establishment fee from*
 6 *each compounding manufacturer; and*

7 “(ii) *a reinspection fee from each*
 8 *compounding manufacturer subject to a re-*
 9 *inspection in such fiscal year.*

10 “(B) *MULTIPLE REINSPECTIONS.*—A
 11 *compounding manufacturer subject to multiple*
 12 *reinspections in a fiscal year shall be subject to*
 13 *a reinspection fee for each reinspection.*

14 “(3) *ESTABLISHMENT AND REINSPECTION FEE*
 15 *SETTING.*—The Secretary shall establish the establish-
 16 ment and reinspection fee to be collected under this
 17 subsection for each fiscal year, based on the method-
 18 ology described in paragraph (4) and shall publish
 19 such fee in a *Federal Register* notice not later than
 20 60 calendar days before the start of each such year.

21 “(4) *AMOUNT OF ESTABLISHMENT FEE AND RE-*
 22 *INSPECTION FEE.*—

23 “(A) *IN GENERAL.*—For each compounding
 24 manufacturer in a fiscal year—

1 “(i) except as provided in subpara-
 2 graph (D), the amount of the annual estab-
 3 lishment fee under paragraph (2) shall be
 4 equal to the sum of—

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

8 “(II) the small business adjust-
 9 ment factor described in subparagraph
 10 (C); and

11 “(ii) the amount of any reinspection
 12 fee (if applicable) under paragraph (2) shall
 13 be equal to \$15,000, multiplied by the infla-
 14 tion adjustment factor described in subpara-
 15 graph (B).

16 “(B) INFLATION ADJUSTMENT FACTOR.—

17 “(i) IN GENERAL.—For fiscal year
 18 2015 and subsequent fiscal years, the fee
 19 amounts established in subparagraph (A)
 20 shall be adjusted by the Secretary by notice,
 21 published in the Federal Register, for a fis-
 22 cal year by the amount equal to the sum
 23 of—

24 “(I) one;

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

15 “(III) the average annual percent
16 change that occurred in the Consumer
17 Price Index for urban consumers (U.S.
18 City Average; Not Seasonally Adjusted;
19 All items; Annual Index) for the first
20 3 years of the preceding 4 years of
21 available data multiplied by the pro-
22 portion of all costs other than per-
23 sonnel compensation and benefits costs
24 to total costs of an average full-time
25 equivalent position of the Food and

1 *Drug Administration for the first 3*
 2 *years of the preceding 4 fiscal years.*

3 “(ii) *COMPOUNDED BASIS.—The ad-*
 4 *justment made each fiscal year under clause*
 5 *(i) shall be added on a compounded basis to*
 6 *the sum of all adjustments made each fiscal*
 7 *year after fiscal year 2014 under clause (i).*

8 “(C) *SMALL BUSINESS ADJUSTMENT FAC-*
 9 *TOR.—The small business adjustment factor re-*
 10 *ferred to subparagraph (A)(i)(II) shall be an*
 11 *amount established by the Secretary for each fis-*
 12 *cal year based on the Secretary’s estimate of—*

13 “(i) *the number of small businesses*
 14 *that will pay a reduced establishment fee for*
 15 *such fiscal year; and*

16 “(ii) *the adjustment to the establish-*
 17 *ment fee necessary to achieve total fees*
 18 *equaling the total fees that the Secretary*
 19 *would have collected if no entity qualified*
 20 *for the small business exception in subpara-*
 21 *graph (D).*

22 “(D) *EXCEPTION FOR SMALL BUSI-*
 23 *NESSES.—*

24 “(i) *IN GENERAL.—In the case of a*
 25 *compounding manufacturer with gross an-*

1 nual sales of \$1,000,000 or less in the 12
 2 months ending April 1 of the fiscal year im-
 3 mediately preceding the fiscal year in which
 4 the fees under this subsection are assessed,
 5 the amount of the establishment fee under
 6 paragraph (2) for a fiscal year shall be
 7 equal to $\frac{1}{3}$ of the amount calculated under
 8 subparagraph (A)(i)(I) in such fiscal year.

9 “(ii) *APPLICATION*.—To qualify for the
 10 exception under this subparagraph, a small
 11 business shall submit to the Secretary a
 12 written request for such exception, in a for-
 13 mat specified by the Secretary in guidance,
 14 certifying its gross annual sales for the 12
 15 months ending April 1 of the fiscal year im-
 16 mediately preceding the fiscal year in which
 17 fees under this subsection are assessed. Any
 18 such application must be submitted to the
 19 Secretary not later than April 30 for the
 20 following fiscal year. Any statement or rep-
 21 resentation made to the Secretary shall be
 22 subject to section 1001 of title 18, United
 23 States Code.

24 “(E) *CREDITING OF FEES*.—In establishing
 25 the small business adjustment factor under sub-

1 *paragraph (C) for a fiscal year, the Secretary*
2 *shall provide for the crediting of fees from the*
3 *previous year to the next year if the Secretary*
4 *overestimated the amount of the small business*
5 *adjustment factor for such previous fiscal year,*
6 *and consider the need to account for any adjust-*
7 *ment of fees and such other factors as the Sec-*
8 *retary determines appropriate.*

9 *“(5) USE OF FEES.—The Secretary shall make*
10 *all of the fees collected pursuant to clauses (i) and (ii)*
11 *of paragraph (2)(A) available solely to pay for the*
12 *costs of oversight of compounding manufacturers.*

13 *“(6) SUPPLEMENT NOT SUPPLANT.—Funds re-*
14 *ceived by the Secretary pursuant to this subsection*
15 *shall be used to supplement and not supplant any*
16 *other Federal funds available to carry out the activi-*
17 *ties described in this section.*

18 *“(7) CREDITING AND AVAILABILITY OF FEES.—*
19 *Fees authorized under this subsection shall be collected*
20 *and available for obligation only to the extent and in*
21 *the amount provided in advance in appropriations*
22 *Acts. Such fees are authorized to remain available*
23 *until expended. Such sums as may be necessary may*
24 *be transferred from the Food and Drug Administra-*
25 *tion salaries and expenses appropriation account*

1 *without fiscal year limitation to such appropriation*
 2 *account for salaries and expenses with such fiscal*
 3 *year limitation. The sums transferred shall be avail-*
 4 *able solely for the purpose of paying the costs of over-*
 5 *sight of compounding manufacturers.*

6 “(8) *COLLECTION OF FEES.*—

7 “(A) *ESTABLISHMENT FEE.*—A
 8 *compounding manufacturer shall remit the es-*
 9 *tablishment fee due under this subsection in a*
 10 *fiscal year when submitting a registration pur-*
 11 *suant to subsection (g) for such fiscal year.*

12 “(B) *REINSPECTION FEE.*—The Secretary
 13 *shall specify in the Federal Register notice de-*
 14 *scribed in paragraph (3) the manner in which*
 15 *reinspection fees assessed under this subsection*
 16 *shall be collected and the timeline for payment of*
 17 *such fees. Such a fee shall be collected after the*
 18 *Secretary has conducted a reinspection of the*
 19 *compounding manufacturer involved.*

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

21 “(i) *REGISTRATION.*—A compounding
 22 *manufacturer shall not be considered reg-*
 23 *istered under subsection (g) in a fiscal year*
 24 *until the date that the compounding manu-*

1 *facturer remits the establishment fee under*
 2 *this subsection for such fiscal year.*

3 “(ii) *MISBRANDING.*—*All drugs manu-*
 4 *factured, prepared, propagated, com-*
 5 *pounded, or processed by a compounding*
 6 *manufacturer for which any establishment*
 7 *fee or reinspection fee has not been paid as*
 8 *required by this subsection shall be deemed*
 9 *misbranded under section 502(cc) until the*
 10 *fees owed for such compounding manufac-*
 11 *turer under this subsection have been paid.*

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

19 “(9) *ANNUAL REPORT TO CONGRESS.*—*Not later*
 20 *than 120 calendar days after each fiscal year in*
 21 *which fees are assessed and collected under this sub-*
 22 *section, the Secretary shall submit a report to the*
 23 *Committee on Health Education Labor and Pensions*
 24 *of the Senate and the Committee on Energy and Com-*
 25 *merce of the House of Representatives, to include a*

1 *description of fees assessed and collected for each year,*
 2 *a summary description of entities paying the fees,*
 3 *and the number of inspections and reinspections of*
 4 *such entities performed each year.*

5 “(10) *AUTHORIZATION OF APPROPRIATIONS.—*
 6 *For fiscal year 2015 and each subsequent fiscal year,*
 7 *there is authorized to be appropriated for fees under*
 8 *this subsection an amount equivalent to the total*
 9 *amount of fees assessed for such fiscal year under this*
 10 *subsection.*

11 “(i) *ACTION BY SECRETARY REGARDING COMPLAINTS*
 12 *FROM STATE BOARDS OF PHARMACY.—*

13 “(1) *IDENTIFICATION OF COMPOUNDING MANU-*
 14 *FACTURERS.—The Secretary shall encourage States to*
 15 *identify to the Secretary facilities that are licensed by*
 16 *a State as a pharmacy that appear to be entities that*
 17 *are required to be registered with the Secretary as a*
 18 *compounding manufacturer.*

19 “(2) *DESIGNATION.—The Secretary shall des-*
 20 *ignate a point of contact and establish a format and*
 21 *procedure for a State Board of Pharmacy to notify*
 22 *the Secretary if it appears to a State Board of Phar-*
 23 *macy that an entity licensed by a State as a phar-*
 24 *macy is required to be registered with the Secretary*
 25 *as a compounding manufacturer.*

1 “(3) *DETERMINATION.*—If the Secretary deter-
 2 mines that such an entity described in paragraph (2)
 3 is required to be registered with the Secretary as a
 4 compounding manufacturer, the Secretary shall
 5 transmit such determination to the State Board of
 6 Pharmacy in the State in which the entity is located,
 7 and to the State Board of Pharmacy in the notifying
 8 State, if different, within 15 calendar days of such de-
 9 termination and shall make such determination pub-
 10 licly available on the Internet Web site of the Food
 11 and Drug Administration.

12 “(4) *EFFECT.*—The Secretary shall encourage di-
 13 rect communications between States regarding tradi-
 14 tional compounders. Nothing in this subsection shall
 15 expand the Secretary’s authority over or responsi-
 16 bility for traditional compounders.”.

17 (c) *PROHIBITED ACT.*—Section 301 (21 U.S.C. 331)
 18 is amended—

19 (1) in subsection (e), by striking “417, 416, 504”
 20 and inserting “417, 416, 503A(g), 504”; and

21 (2) by adding at the end the following:

22 “(ccc)(1) The resale of a compounded drug that is la-
 23 beled ‘not for resale’ as required by section 503A.

24 “(2) The failure to register in accordance with sub-
 25 section (g) of section 503A or the failure to submit a report

1 *as required by subsection (g)(2)(B) or (g)(3) of such sec-*
 2 *tion.”.*

3 *(d) REPORT BY GAO.—Not later than November 1,*
 4 *2016, the Comptroller General of the United States shall*
 5 *conduct a study and submit to Congress a report on the*
 6 *safety of animal drug compounding and the availability of*
 7 *safe and effective drugs for animals.*

8 **SEC. 103. OTHER REQUIREMENTS.**

9 *(a) LABELING.—Section 502 (21 U.S.C. 352) is*
 10 *amended by adding at the end the following:*

11 *“(bb) If it is a compounded drug and the labeling does*
 12 *not include the information as required by subsections (f)(3)*
 13 *and (g)(4) of section 503A, as applicable.*

14 *“(cc) If the advertising or promotion of a compounded*
 15 *drug is false or misleading in any particular.*

16 *“(dd) If it is a drug, and it was manufactured, pre-*
 17 *pared, propagated, compounded, or processed by a*
 18 *compounding manufacturer for which fees have not been*
 19 *paid as required by section 503A(g).”.*

20 *(b) APPLICATION OF INSPECTION REQUIREMENTS TO*
 21 *COMPOUNDING MANUFACTURERS.—Section 704(a)(2) (21*
 22 *U.S.C. 374(a)(2)) is amended by adding at the end the fol-*
 23 *lowing flush text:*

1 “The exemption in subparagraph (A) does not apply with
 2 respect to compounding manufacturers (as such term is de-
 3 fined in section 503A).”.

4 **SEC. 104. IMPLEMENTATION.**

5 (a) CONSULTATION WITH STAKEHOLDERS.—In imple-
 6 menting this title (and the amendments made by this title),
 7 the Secretary of Health and Human Services shall consult
 8 with relevant stakeholders including pharmacists, profes-
 9 sional associations, patient and public health advocacy
 10 groups, manufacturers and physicians.

11 (b) REGULATIONS.—In promulgating any regulations
 12 to implement this title (and the amendments made by this
 13 title), the Secretary of Health and Human Services shall—

14 (1) issue a notice of proposed rulemaking that
 15 includes the proposed regulation;

16 (2) provide a period of not less than 60 calendar
 17 days for comments on the proposed regulation; and

18 (3) publish the final regulation not more than 18
 19 months following publication of the proposed rule and
 20 not less than 30 calendar days before the effective date
 21 of such final regulation.

22 **SEC. 105. EFFECTIVE DATE.**

23 This title (and the amendments made by this title)
 24 shall take effect on the date that is 1 year after the date
 25 of enactment of this Act.

1 **TITLE II—DRUG SUPPLY CHAIN**
 2 **SECURITY**

3 **SEC. 201. SHORT TITLE.**

4 *This title may be cited as the “Drug Supply Chain*
 5 *Security Act”.*

6 **SEC. 202. PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.**

7 *Chapter V (21 U.S.C. 351 et seq.) is amended by add-*
 8 *ing at the end the following:*

9 **“Subchapter H—Pharmaceutical Distribution**
 10 **Supply Chain**

11 **“SEC. 581. DEFINITIONS.**

12 *“In this subchapter:*

13 *“(1) AUTHORIZED.—The term ‘authorized’*
 14 *means—*

15 *“(A) in the case of a manufacturer or re-*
 16 *packager, having a valid registration in accord-*
 17 *ance with section 510;*

18 *“(B) in the case of a wholesale distributor,*
 19 *having a valid license under State law or section*
 20 *583, in accordance with section 582(a)(6) and*
 21 *complying with the licensure reporting require-*
 22 *ments under section 503(e), as amended by the*
 23 *Drug Supply Chain Security Act;*

24 *“(C) in the case of a third-party logistics*
 25 *provider, having a valid license under State law*

1 or section 584(a)(1), in accordance with section
 2 582(a)(7) and complying with the licensure re-
 3 porting requirements under section 584(b); and

4 “(D) in the case of a dispenser, having a
 5 valid license under State law.

6 “(2) *DISPENSER*.—The term ‘dispenser’—

7 “(A) means a retail pharmacy, hospital
 8 pharmacy, a group of chain pharmacies under
 9 common ownership and control that do not act
 10 as a wholesale distributor, or any other person
 11 authorized by law to dispense or administer pre-
 12 scription drugs, and the affiliated warehouses or
 13 distribution centers of such entities under com-
 14 mon ownership and control that do not act as a
 15 wholesale distributor; and

16 “(B) does not include a person who dis-
 17 penses only products to be used in animals in
 18 accordance with section 512(a)(5).

19 “(3) *DISPOSITION*.—The term ‘disposition’, with
 20 respect to a product within the possession or control
 21 of an entity, means the removal of such product from
 22 the pharmaceutical distribution supply chain, which
 23 may include disposal or return of the product for dis-
 24 posal or other appropriate handling and other ac-
 25 tions, such as retaining a sample of the product for

1 *further additional physical examination or laboratory*
 2 *analysis of the product by a manufacturer or regu-*
 3 *latory or law enforcement agency.*

4 “(4) *DISTRIBUTE OR DISTRIBUTION.*—*The term*
 5 *‘distribute’ or ‘distribution’ means the sale, purchase,*
 6 *trade, delivery, handling, storage, or receipt of a*
 7 *product, and does not include the dispensing of a*
 8 *product pursuant to a prescription executed in ac-*
 9 *cordance with section 503(b)(1) or the dispensing of*
 10 *a product approved under section 512(b).*

11 “(5) *EXCLUSIVE DISTRIBUTOR.*—*The term ‘ex-*
 12 *clusive distributor’ means the wholesale distributor*
 13 *that directly purchased the product from the manu-*
 14 *facturer and is the sole distributor of that manufac-*
 15 *turer’s product to a subsequent repackager, wholesale*
 16 *distributor, or dispenser.*

17 “(6) *HOMOGENEOUS CASE.*—*The term ‘homo-*
 18 *geneous case’ means a sealed case containing only*
 19 *product that has a single National Drug Code number*
 20 *belonging to a single lot.*

21 “(7) *ILLEGITIMATE PRODUCT.*—*The term ‘illegit-*
 22 *imate product’ means a product for which credible*
 23 *evidence shows that the product—*

24 “(A) *is counterfeit, diverted, or stolen;*

1 “(B) is intentionally adulterated such that
2 the product would result in serious adverse
3 health consequences or death to humans;

4 “(C) is the subject of a fraudulent trans-
5 action; or

6 “(D) appears otherwise unfit for distribu-
7 tion such that the product could result in serious
8 adverse health consequence or death to humans.

9 “(8) *LICENSED*.—The term ‘licensed’ means—

10 “(A) in the case of a wholesale distributor,
11 having a valid license in accordance with section
12 503(e) or section 582(a)(6), as applicable;

13 “(B) in the case of a third-party logistics
14 provider, having a valid license in accordance
15 with section 584(a) or section 582(a)(7), as ap-
16 plicable; and

17 “(C) in the case of a dispenser, having a
18 valid license under State law.

19 “(9) *MANUFACTURER*.—

20 “(A) *IN GENERAL*.—The term ‘manufac-
21 turer’ means, with respect to a product—

22 “(i) a person that holds an application
23 approved under section 505 or a license
24 issued under section 351 of the Public
25 Health Service Act for such product, or if

1 *such product is not the subject of an ap-*
 2 *proved application or license, the person*
 3 *who manufactured the product;*

4 *“(ii) a co-licensed partner of the per-*
 5 *son described in clause (i) that obtains the*
 6 *product directly from a person described in*
 7 *this clause or clause (i) or (iii); or*

8 *“(iii) an affiliate of a person described*
 9 *in clause (i) or (ii) that receives the product*
 10 *directly from a person described in this*
 11 *clause or clause (i) or (ii).*

12 *“(B) AFFILIATE.—For purposes of this*
 13 *paragraph, the term ‘affiliate’ means a member*
 14 *of an affiliated group, as that term is defined in*
 15 *section 1504(a) of the Internal Revenue Code, or*
 16 *a member of a group of corporations that would*
 17 *constitute an affiliated group, as so defined, but*
 18 *for the fact that one or more members of the*
 19 *group is a corporation described in section*
 20 *1504(b)(3) of the Internal Revenue Code.*

21 *“(10) PACKAGE.—*

22 *“(A) IN GENERAL.—The term ‘package’*
 23 *means the smallest individual saleable unit of*
 24 *product for distribution by a manufacturer or*

1 *repackager that is intended by the manufacturer*
 2 *for ultimate sale to the dispenser of such product.*

3 “(B) *INDIVIDUAL SALEABLE UNIT.*—For
 4 *purposes of this paragraph, an ‘individual sale-*
 5 *able unit’ is the smallest container of product in-*
 6 *troduced into commerce by the manufacturer or*
 7 *repackager that is intended by the manufacturer*
 8 *or repackager for individual sale to a dispenser.*

9 “(11) *PRESCRIPTION DRUG.*—The term ‘prescrip-
 10 *tion drug’ means a drug for human use subject to sec-*
 11 *tion 503(b)(1).*

12 “(12) *PRODUCT.*—The term ‘product’ means a
 13 *prescription drug in a finished dosage form for ad-*
 14 *ministration to a patient without substantial further*
 15 *manufacturing (such as capsules, tablets, and*
 16 *lyophilized products before reconstitution), but for*
 17 *purposes of section 582, does not include blood or*
 18 *blood components intended for transfusion, radio-*
 19 *active drugs or radioactive biological products (as de-*
 20 *finied in section 600.3(ee) of title 21, Code of Federal*
 21 *Regulations) that are regulated by the Nuclear Regu-*
 22 *latory Commission or by a State pursuant to an*
 23 *agreement with such Commission under section 274 of*
 24 *the Atomic Energy Act of 1954 (42 U.S.C. 2021), an*
 25 *intravenous product described in clause xiv, xv, or xvi*

1 of paragraph (23), any medical gas (as defined in
2 section 575), or a drug compounded in compliance
3 with section 503A.

4 “(13) *PRODUCT IDENTIFIER*.—The term ‘product
5 identifier’ means a standardized graphic that in-
6 cludes, in both human-readable form and on a ma-
7 chine-readable data carrier that conforms to the
8 standards developed by a widely-recognized inter-
9 national standards development organization, the
10 standardized numerical identifier, lot number, and
11 expiration date of the product.

12 “(14) *QUARANTINE*.—The term ‘quarantine’
13 means the storage or identification of a product, to
14 prevent distribution or transfer of the product, in a
15 physically separate area clearly identified for such
16 use or through other procedures.

17 “(15) *REPACKAGER*.—The term ‘repackager’
18 means a person who owns or operates an establish-
19 ment that repacks and relabels a product or package
20 for further sale.

21 “(16) *RETURN*.—The term ‘return’ means pro-
22 viding product to the authorized immediate trading
23 partner from which such product was purchased, or
24 to a returns processor or reverse logistics provider for
25 handling of such product.

1 “(17) *RETURNS PROCESSOR OR REVERSE LOGIS-*
 2 *TICS PROVIDER.*—*The term ‘returns processor’ or ‘re-*
 3 *verse logistics provider’ means a person who owns or*
 4 *operates an establishment that dispositions or other-*
 5 *wise processes saleable or nonsaleable product received*
 6 *from an authorized trading partner such that the*
 7 *product may be processed for credit to the purchaser,*
 8 *manufacturer, or seller or disposed of for no further*
 9 *distribution.*

10 “(18) *SPECIFIC PATIENT NEED.*—*The term ‘spe-*
 11 *cific patient need’ refers to the transfer of a product*
 12 *from one pharmacy to another to fill a prescription*
 13 *for an identified patient. Such term does not include*
 14 *the transfer of a product from one pharmacy to an-*
 15 *other for the purpose of increasing or replenishing*
 16 *stock in anticipation of a potential need.*

17 “(19) *STANDARDIZED NUMERICAL IDENTIFIER.*—
 18 *The term ‘standardized numerical identifier’ means a*
 19 *set of numbers or characters used to uniquely identify*
 20 *each package or homogenous case that is composed of*
 21 *the National Drug Code that corresponds to the spe-*
 22 *cific product (including the particular package con-*
 23 *figuration) combined with a unique alphanumeric se-*
 24 *rial number of up to 20 characters.*

1 “(20) *SUSPECT PRODUCT.*—The term ‘suspect
2 product’ means a product for which there is reason to
3 believe that such product—

4 “(A) is potentially counterfeit, diverted, or
5 stolen;

6 “(B) is potentially intentionally adulterated
7 such that the product would result in serious ad-
8 verse health consequences or death to humans;

9 “(C) is potentially the subject of a fraudu-
10 lent transaction; or

11 “(D) appears otherwise unfit for distribu-
12 tion such that the product would result in seri-
13 ous adverse health consequences or death to hu-
14 mans.

15 “(21) *THIRD-PARTY LOGISTICS PROVIDER.*—The
16 term ‘third-party logistics provider’ means an entity
17 that provides or coordinates warehousing, or other lo-
18 gistics services of a product in interstate commerce on
19 behalf of a manufacturer, wholesale distributor, or
20 dispenser of a product, but does not take ownership
21 of the product, nor have responsibility to direct the
22 sale or disposition of the product.

23 “(22) *TRADING PARTNER.*—The term ‘trading
24 partner’ means—

1 “(A) a manufacturer, repackager, wholesale
 2 distributor, or dispenser from whom a manufac-
 3 turer, repackager, wholesale distributor, or dis-
 4 penser accepts direct ownership of a product or
 5 to whom a manufacturer, repackager, wholesale
 6 distributor, or dispenser transfers direct owner-
 7 ship of a product; or

8 “(B) a third-party logistics provider from
 9 whom a manufacturer, repackager, wholesale dis-
 10 tributor, or dispenser accepts direct possession of
 11 a product or to whom a manufacturer, repack-
 12 ager, wholesale distributor, or dispenser transfers
 13 direct possession of a product.

14 “(23) TRANSACTION.—

15 “(A) IN GENERAL.—The term ‘transaction’
 16 means the transfer of product between persons in
 17 which a change of ownership occurs.

18 “(B) EXEMPTIONS.—The term ‘transaction’
 19 does not include—

20 “(i) intracompany distribution of any
 21 product between members of an affiliated
 22 group (as defined in section 1504(a) of the
 23 Internal Revenue Code of 1986) or within a
 24 manufacturer;

1 “(ii) the distribution of a product
2 among hospitals or other health care entities
3 that are under common control;

4 “(iii) the distribution of a product for
5 emergency medical reasons including a pub-
6 lic health emergency declaration pursuant
7 to section 319 of the Public Health Service
8 Act, except that a drug shortage not caused
9 by a public health emergency shall not con-
10 stitute an emergency medical reason;

11 “(iv) the dispensing of a product pur-
12 suant to a valid prescription executed in ac-
13 cordance with section 503(b)(1);

14 “(v) the distribution of product sam-
15 ples by a manufacturer or a licensed whole-
16 sale distributor in accordance with section
17 503(d);

18 “(vi) the distribution of blood or blood
19 components intended for transfusion;

20 “(vii) the distribution of minimal
21 quantities of product by a licensed retail
22 pharmacy to a licensed practitioner for of-
23 fice use;

24 “(viii) the sale, purchase, or trade of a
25 drug or an offer to sell, purchase, or trade

1 a drug by a charitable organization de-
2 scribed in section 501(c)(3) of the Internal
3 Revenue Code of 1954 to a nonprofit affil-
4 iate of the organization to the extent other-
5 wise permitted by law;

6 “(ix) the distribution of a product pur-
7 suant to the sale or merger of a pharmacy
8 or pharmacies or a wholesale distributor or
9 wholesale distributors, except that any
10 records required to be maintained for the
11 product shall be transferred to the new
12 owner of the pharmacy or pharmacies or
13 wholesale distributor or wholesale distribu-
14 tors;

15 “(x) the dispensing of a product ap-
16 proved under section 512(b);

17 “(xi) products transferred to or from
18 any facility that is licensed by the Nuclear
19 Regulatory Commission or by a State pur-
20 suant to an agreement with such Commis-
21 sion under section 274 of the Atomic En-
22 ergy Act of 1954 (42 U.S.C. 2021);

23 “(xii) a combination product that is—

24 “(I) a product comprised of a de-
25 vice and 1 or more other regulated

1 *components (such as a drug/device, bio-*
 2 *logic/device, or drug/device/biologic)*
 3 *that are physically, chemically, or oth-*
 4 *erwise combined or mixed and pro-*
 5 *duced as a single entity;*

6 “(II) 2 or more separate products
 7 *packaged together in a single package*
 8 *or as a unit and comprised of a drug*
 9 *and device or device and biological*
 10 *product; or*

11 “(III) 2 or more finished medical
 12 *devices plus one or more drug or bio-*
 13 *logical products which are packaged to-*
 14 *gether in what is referred to as a ‘med-*
 15 *ical convenience kit’ as described in*
 16 *clause (xiii);*

17 “(xiii) the distribution of a collection
 18 *of finished medical devices or a collection of*
 19 *finished drug or biological products assem-*
 20 *bled in kit form strictly for the convenience*
 21 *of the purchaser or user (to be known as a*
 22 *‘medical convenience kit’) if—*

23 “(I) the medical convenience kit is
 24 *assembled in an establishment that is*
 25 *registered with the Food and Drug Ad-*

1 *ministration as a device manufacturer*
2 *in accordance with section 510(b)(2);*

3 “(II) *the person who manufactur-*
4 *ers a medical convenience kit pur-*
5 *chased the product contained in the*
6 *medical convenience kit directly from*
7 *the pharmaceutical manufacturer or*
8 *from a wholesale distributor that pur-*
9 *chased the product directly from the*
10 *pharmaceutical manufacturer;*

11 “(III) *the person who manufac-*
12 *turers a medical convenience kit does*
13 *not alter the primary container or*
14 *label of the product as purchased from*
15 *the manufacturer or wholesale dis-*
16 *tributor;*

17 “(IV) *the medical convenience kit*
18 *does not contain a controlled substance*
19 *that appears in a schedule contained*
20 *in the Comprehensive Drug Abuse Pre-*
21 *vention and Control Act of 1970; and*

22 “(V) *the products contained in the*
23 *medical convenience kit are—*

1 “(aa) intravenous solutions
2 intended for the replenishment of
3 fluids and electrolytes;

4 “(bb) products intended to
5 maintain the equilibrium of water
6 and minerals in the body;

7 “(cc) products intended for
8 irrigation or reconstitution;

9 “(dd) anesthetics;

10 “(ee) anticoagulants;

11 “(ff) vasopressors; or

12 “(gg) sympathicomimetics;

13 “(xiv) the distribution of an intra-
14 venous product that, by its formulation, is
15 intended for the replenishment of fluids and
16 electrolytes (such as sodium, chloride, and
17 potassium) or calories (such as dextrose and
18 amino acids);

19 “(xv) the distribution of an intra-
20 venous product used to maintain the equi-
21 librium of water and minerals in the body,
22 such as dialysis solutions;

23 “(xvi) the distribution of a product
24 that is intended for irrigation or reconstitu-

1 *tion, or sterile water, whether intended for*
 2 *such purposes or for injection;*

3 *“(xvii) the distribution of a medical*
 4 *gas (as defined in section 575); or*

5 *“(xviii) the distribution or sale of any*
 6 *licensed product under section 351 of the*
 7 *Public Health Service Act that meets the*
 8 *definition of a device under section 201(h).*

9 *“(24) TRANSACTION HISTORY.—The term ‘trans-*
 10 *action history’ means a statement in paper or elec-*
 11 *tronic form, including the transaction information for*
 12 *each prior transaction going back to the manufacturer*
 13 *of the product.*

14 *“(25) TRANSACTION INFORMATION.—The term*
 15 *‘transaction information’ means—*

16 *“(A) the proprietary or established name or*
 17 *names of the product;*

18 *“(B) the strength and dosage form of the*
 19 *product;*

20 *“(C) the National Drug Code number of the*
 21 *product;*

22 *“(D) the container size;*

23 *“(E) the number of containers;*

24 *“(F) the lot number of the product;*

25 *“(G) the date of the transaction;*

1 “(H) the date of the shipment, if different
2 from the date of the transaction;

3 “(I) the business name and address of the
4 person from whom ownership is being trans-
5 ferred; and

6 “(J) the business name and address of the
7 person to whom ownership is being transferred.

8 “(26) TRANSACTION STATEMENT.—The ‘trans-
9 action statement’ is a statement, in paper or elec-
10 tronic form, that the entity transferring ownership in
11 a transaction—

12 “(A) is authorized as required under the
13 Drug Supply Chain Security Act;

14 “(B) received the product from a person
15 that is authorized as required under the Drug
16 Supply Chain Security Act;

17 “(C) received transaction information and
18 a transaction statement from the prior owner of
19 the product, as required under section 582;

20 “(D) did not knowingly ship a suspect or il-
21 legitimate product;

22 “(E) had systems and processes in place to
23 comply with verification requirements under sec-
24 tion 582;

1 “(F) did not knowingly provide false trans-
2 action information; and

3 “(G) did not knowingly alter the trans-
4 action history.

5 “(27) VERIFICATION OR VERIFY.—The term
6 ‘verification’ or ‘verify’ means determining whether
7 the product identifier affixed to, or imprinted upon,
8 a package or homogeneous case corresponds to the
9 standardized numerical identifier or lot number and
10 expiration date assigned to the product by the manu-
11 facturer or the repackager, as applicable in accord-
12 ance with section 582.

13 “(28) WHOLESALE DISTRIBUTOR.—The term
14 ‘wholesale distributor’ means a person (other than a
15 manufacturer, a manufacturer’s co-licensed partner, a
16 third-party logistics provider, or repackager) engaged
17 in wholesale distribution (as defined in section
18 503(e)(4), as amended by the Drug Supply Chain Se-
19 curity Act).

20 **“SEC. 582. REQUIREMENTS.**

21 “(a) IN GENERAL.—

22 “(1) OTHER ACTIVITIES.—Each manufacturer,
23 repackager, wholesale distributor, third-party logistics
24 provider, and dispenser shall comply with the require-
25 ments set forth in this section with respect to the role

1 of such manufacturer, repackager, wholesale dis-
 2 tributor, third-party logistics provider, or dispenser
 3 in a transaction involving product. If an entity meets
 4 the definition of more than one of the entities listed
 5 in the preceding sentence, such entity shall comply
 6 with all applicable requirements in this section, but
 7 shall not be required to duplicate requirements.

8 “(2) INITIAL STANDARDS.—

9 “(A) IN GENERAL.—The Secretary shall, in
 10 consultation with other appropriate Federal offi-
 11 cials, manufacturers, repackagers, wholesale dis-
 12 tributors, third-party logistics providers, dis-
 13 pensers, and other pharmaceutical distribution
 14 supply chain stakeholders, issue a draft guidance
 15 document that establishes standards for the inter-
 16 operable exchange of transaction information,
 17 transaction history, and transaction statements,
 18 in paper or electronic format, for compliance
 19 with subsections (a), (b), (c), (d), (e), and (f). In
 20 establishing such standards, the Secretary shall
 21 consider the feasibility of establishing standard-
 22 ized documentation to be used by members of the
 23 pharmaceutical distribution supply chain to con-
 24 vey the transaction information, transaction his-
 25 tory, and transaction statement to the subsequent

1 *purchaser of a product and to facilitate the ex-*
 2 *change of lot level data. The standards estab-*
 3 *lished under this paragraph shall take into con-*
 4 *sideration the standards established under sec-*
 5 *tion 505D and shall comply with a form and*
 6 *format developed by a widely recognized inter-*
 7 *national standards development organization.*

8 *“(B) PUBLIC INPUT.—Prior to issuing the*
 9 *draft guidance under subparagraph (A), the Sec-*
 10 *retary shall gather comments and information*
 11 *from stakeholders and maintain such comments*
 12 *and information in a public docket for at least*
 13 *60 days prior to issuing such guidance.*

14 *“(C) PUBLICATION.—The Secretary shall*
 15 *publish the standards established under subpara-*
 16 *graph (A) not later than 1 year after the date*
 17 *of enactment of the Drug Supply Chain Security*
 18 *Act.*

19 *“(3) WAIVERS, EXCEPTIONS, AND EXEMP-*
 20 *TIONS.—*

21 *“(A) IN GENERAL.—Not later than 2 years*
 22 *after the date of enactment of the Drug Supply*
 23 *Chain Security Act, the Secretary shall, by guid-*
 24 *ance—*

1 “(i) establish a process by which an
2 authorized manufacturer, repackager, whole-
3 sale distributor, or dispenser may request a
4 waiver from any of the requirements set
5 forth in this section if the Secretary deter-
6 mines that such requirements would result
7 in an undue economic hardship or for emer-
8 gency medical reasons, including a public
9 health emergency declaration pursuant to
10 section 319 of the Public Health Service
11 Act;

12 “(ii) establish a process by which the
13 Secretary determines exceptions, and a
14 process through which a manufacturer or
15 repackager may request such an exception,
16 to the requirements relating to product
17 identifiers if a product is packaged in a
18 container too small or otherwise unable to
19 accommodate a label with sufficient space to
20 bear the information required for compli-
21 ance with this section; and

22 “(iii) establish a process by which the
23 Secretary may determine other products or
24 transactions that shall be exempt from the
25 requirements of this section.

1 “(B) *CONTENT.*—*The guidance issued under*
 2 *subparagraph (A) shall include a process for the*
 3 *biennial review and renewal of such waivers, ex-*
 4 *ceptions, and exemptions, as applicable.*

5 “(C) *PROCESS.*—*In issuing the guidance*
 6 *under this paragraph, the Secretary shall pro-*
 7 *vide an effective date that is not later than 180*
 8 *days prior to the date on which manufacturers*
 9 *are required to affix or imprint a product iden-*
 10 *tifier to each package and homogenous case of*
 11 *product intended to be introduced in a trans-*
 12 *action into commerce consistent with this sec-*
 13 *tion.*

14 “(4) *SELF-EXECUTING REQUIREMENTS.*—*Except*
 15 *where otherwise specified, the requirements of this sec-*
 16 *tion may be enforced without further regulations or*
 17 *guidance from the Secretary.*

18 “(5) *GRANDFATHERING PRODUCT.*—

19 “(A) *PRODUCT IDENTIFIER.*—*Not later than*
 20 *2 years after the date of enactment of the Drug*
 21 *Supply Chain Security Act, the Secretary shall*
 22 *finalize guidance specifying whether and under*
 23 *what circumstances product that is not labeled*
 24 *with a product identifier and that is in the*
 25 *pharmaceutical distribution supply chain at the*

1 *time of the effective date of the requirements of*
 2 *this section shall be exempted from the require-*
 3 *ments of this section.*

4 *“(B) TRACING.—For a product that entered*
 5 *the pharmaceutical distribution supply chain*
 6 *prior to the date that is 1 year after the date of*
 7 *enactment of the Drug Supply Chain Security*
 8 *Act—*

9 *“(i) authorized trading partners shall*
 10 *be exempt from providing transaction infor-*
 11 *mation as required under subsections*
 12 *(b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii), and*
 13 *(e)(1)(A)(ii);*

14 *“(ii) transaction history required*
 15 *under this section shall begin with the*
 16 *owner of such product on such date; and*

17 *“(iii) the owners of such product on*
 18 *such date shall be exempt from asserting re-*
 19 *ceipt of transaction information and trans-*
 20 *action statement from the prior owner as*
 21 *required under this section.*

22 *“(6) WHOLESALE DISTRIBUTOR LICENSES.—Not-*
 23 *withstanding section 581(8)(A), until the effective*
 24 *date of the wholesale distributor licensing regulations*
 25 *under section 583, the term ‘licensed’ or ‘authorized’,*

1 *as it relates to a wholesale distributor with respect to*
 2 *prescription drugs, shall mean a wholesale distributor*
 3 *with a valid license under State law.*

4 “(7) *THIRD-PARTY LOGISTICS PROVIDER LI-*
 5 *CENSES.*—*Until the effective date of the third-party*
 6 *logistics provider licensing regulations under section*
 7 *584, a third-party logistics provider shall be consid-*
 8 *ered ‘licensed’ under section 581(8)(B) unless the Sec-*
 9 *retary has made a finding that the third-party logis-*
 10 *tics provider does not utilize good handling and dis-*
 11 *tribution practices and publishes notice thereof.*

12 “(8) *LABEL CHANGES.*—*Changes made to pack-*
 13 *age labels solely to incorporate the product identifier*
 14 *may be submitted to the Secretary in the annual re-*
 15 *port of an establishment, in accordance with section*
 16 *314.70(d) of chapter 21, Code of Federal Regulations*
 17 *(or any successor regulation).*

18 “(9) *PRODUCT IDENTIFIERS.*—*With respect to*
 19 *any requirement relating to product identifiers under*
 20 *this subchapter—*

21 “(A) *unless the Secretary allows, through*
 22 *guidance, the use of other technologies for data*
 23 *instead of or in addition to the technologies de-*
 24 *scribed in clauses (i) and (ii), the applicable*
 25 *data—*

1 “(i) shall be included in a 2-dimen-
 2 sional data matrix barcode when affixed to,
 3 or imprinted upon, a package; and

4 “(ii) shall be included in a linear or 2-
 5 dimensional data matrix barcode when af-
 6 fixed to, or imprinted upon, a homogeneous
 7 case; and

8 “(B) verification of the product identifier
 9 may occur by using human-readable or machine-
 10 readable methods.

11 “(b) *MANUFACTURER REQUIREMENTS.*—

12 “(1) *PRODUCT TRACING.*—

13 “(A) *IN GENERAL.*—Beginning not later
 14 than 1 year after the date of enactment of the
 15 Drug Supply Chain Security Act, a manufac-
 16 turer shall—

17 “(i) prior to, or at the time of, each
 18 transaction in which such manufacturer
 19 transfers—

20 “(I) ownership of a product, pro-
 21 vide the subsequent recipient with
 22 transaction history, transaction infor-
 23 mation, and a transaction statement,
 24 in a single document in an electronic
 25 or paper format; or

1 “(II) possession of a product to a
2 third-party logistics provider for the
3 purpose of transferring ownership as
4 part of a transaction to a subsequent
5 recipient, provide to the third-party lo-
6 gistics provider the transaction history,
7 transaction information, and a trans-
8 action statement for such transaction
9 to a subsequent recipient; and

10 “(ii) maintain the transaction infor-
11 mation, transaction history, and trans-
12 action statement for each transaction for
13 not less than 6 years after the date of the
14 transaction.

15 “(B) REQUESTS FOR INFORMATION.—Upon
16 a request by the Secretary or other appropriate
17 Federal or State official, in the event of a recall
18 or for the purpose of investigating a suspect
19 product or an illegitimate product, a manufac-
20 turer shall, not later than 24 hours after receiv-
21 ing the request or in other such reasonable time
22 as determined by the Secretary, based on the cir-
23 cumstances of the request, provide the applicable
24 transaction information, transaction history,
25 and transaction statement for the product.

1 “(2) *PRODUCT IDENTIFIER.*—Beginning not
 2 *later than 4 years after the date of enactment of the*
 3 *Drug Supply Chain Security Act, a manufacturer*
 4 *shall affix or imprint a product identifier to each*
 5 *package and homogenous case of a product intended*
 6 *to be introduced in a transaction into commerce.*
 7 *Such manufacturer shall maintain the product iden-*
 8 *tifier information for such product for not less than*
 9 *6 years after the date of the transaction.*

10 “(3) *AUTHORIZED TRADING PARTNERS.*—Begin-
 11 *ning not later than 1 year after the date of enactment*
 12 *of the Drug Supply Chain Security Act, the trading*
 13 *partners of a manufacturer may be only authorized*
 14 *trading partners.*

15 “(4) *VERIFICATION.*—Beginning not later than 1
 16 *year after the date of enactment of the Drug Supply*
 17 *Chain Security Act, a manufacturer shall have sys-*
 18 *tems in place to enable the manufacturer to comply*
 19 *with the following requirements:*

20 “(A) *SUSPECT PRODUCT.*—

21 “(i) *IN GENERAL.*—Upon making a de-
 22 *termination that a product in the possession*
 23 *or control of the manufacturer is a suspect*
 24 *product, or upon receiving a request for*
 25 *verification from the Secretary that has*

1 *made a determination that a product with-*
2 *in the possession or control of a manufac-*
3 *turer is a suspect product, a manufacturer*
4 *shall—*

5 “(I) *quarantine such product*
6 *within the possession or control of the*
7 *manufacturer from product intended*
8 *for distribution until such product is*
9 *cleared or dispositioned; and*

10 “(II) *promptly conduct an inves-*
11 *tigation in coordination with trading*
12 *partners, as applicable, to determine*
13 *whether the product is an illegitimate*
14 *product, which shall include validating*
15 *any applicable transaction history and*
16 *transaction information in the posses-*
17 *sion of the manufacturer and otherwise*
18 *investigating to determine whether the*
19 *product is an illegitimate product,*
20 *and, beginning 4 years after the date*
21 *of enactment of the Drug Supply*
22 *Chain Security Act, verifying the prod-*
23 *uct at the package level, including the*
24 *standardized numerical identifier.*

1 “(ii) *CLEARED PRODUCT*.—If the man-
2 ufacturer makes the determination that a
3 suspect product is not an illegitimate prod-
4 uct, the manufacturer shall promptly notify
5 the Secretary, if applicable, of such deter-
6 mination and such product may be further
7 distributed.

8 “(iii) *RECORDS*.—A manufacturer
9 shall keep records of the investigation of a
10 suspect product for not less than 6 years
11 after the conclusion of the investigation.

12 “(B) *ILLEGITIMATE PRODUCT*.—

13 “(i) *IN GENERAL*.—Upon determining
14 that a product in the possession or control
15 of a manufacturer is an illegitimate prod-
16 uct, the manufacturer shall, in a manner
17 consistent with the systems and processes of
18 such manufacturer—

19 “(I) quarantine such product
20 within the possession or control of the
21 manufacturer from product intended
22 for distribution until such product is
23 disposed;

1 “(II) disposition the illegitimate
2 product within the possession or con-
3 trol of the manufacturer;

4 “(III) take reasonable and appro-
5 priate steps to assist a trading partner
6 to disposition an illegitimate product
7 not in the possession or control of the
8 manufacturer; and

9 “(IV) retain a sample of the prod-
10 uct for further physical examination or
11 laboratory analysis of the product by
12 the manufacturer or Secretary (or
13 other appropriate Federal or State offi-
14 cial) upon request by the Secretary (or
15 other appropriate Federal or State offi-
16 cial), as necessary and appropriate.

17 “(ii) MAKING A NOTIFICATION.—

18 “(I) ILLEGITIMATE PRODUCT.—
19 Upon determining that a product in
20 the possession or control of the manu-
21 facturer is an illegitimate product, the
22 manufacturer shall notify the Sec-
23 retary and all immediate trading part-
24 ners that the manufacturer has reason
25 to believe may have received such ille-

1 *gitimate product of such determination*
2 *not later than 24 hours after making*
3 *such determination.*

4 “(II) *HIGH RISK OF ILLEGIT-*
5 *IMACY.—A manufacturer shall notify*
6 *the Secretary and immediate trading*
7 *partners that the manufacturer has*
8 *reason to believe may have in the trad-*
9 *ing partner’s possession a product*
10 *manufactured by, or purported to be a*
11 *product manufactured by, the manu-*
12 *facturer not later than 24 hours after*
13 *determining or being notified by the*
14 *Secretary or a trading partner that*
15 *there is a high risk that such product*
16 *is an illegitimate product. For pur-*
17 *poses of this subclause, a ‘high risk’*
18 *may include a specific high-risk that*
19 *could increase the likelihood that ille-*
20 *gitimate product will enter the phar-*
21 *maceutical distribution supply chain*
22 *and other high risks as determined by*
23 *the Secretary in guidance pursuant to*
24 *subsection (i).*

1 “(iii) *RESPONDING TO A NOTIFICA-*
 2 *TION.*—Upon the receipt of a notification
 3 from the Secretary or a trading partner
 4 that a determination has been made that a
 5 product is an illegitimate product, a manu-
 6 facturer shall identify all illegitimate prod-
 7 uct subject to such notification that is in the
 8 possession or control of the manufacturer,
 9 including any product that is subsequently
 10 received, and shall perform the activities de-
 11 scribed in subparagraph (A).

12 “(iv) *TERMINATING A NOTIFICATION.*—
 13 Upon making a determination, in consulta-
 14 tion with the Secretary, that a notification
 15 is no longer necessary, a manufacturer shall
 16 promptly notify immediate trading part-
 17 ners that the manufacturer notified pursu-
 18 ant to clause (ii) that such notification has
 19 been terminated.

20 “(v) *RECORDS.*—A manufacturer shall
 21 keep records of the disposition of an illegit-
 22 imate product for not less than 6 years after
 23 the conclusion of the disposition.

24 “(C) *REQUESTS FOR VERIFICATION.*—Be-
 25 ginning 4 years after the date of enactment of

1 *the Drug Supply Chain Security Act, upon re-*
2 *ceiving a request for verification from an author-*
3 *ized repackager, wholesale distributor, or dis-*
4 *perser that is in possession or control of a prod-*
5 *uct such person believes to be manufactured by*
6 *such manufacturer, a manufacturer shall, not*
7 *later than 24 hours after receiving the*
8 *verification request or in other such reasonable*
9 *time as determined by the Secretary, based on*
10 *the circumstances of the request, notify the per-*
11 *son making the request whether the product iden-*
12 *tifier, including the standardized numerical*
13 *identifier, that is the subject of the request cor-*
14 *responds to the product identifier affixed or im-*
15 *printed by the manufacturer. If a manufacturer*
16 *responding to a verification request identifies a*
17 *product identifier that does not correspond to*
18 *that affixed or imprinted by the manufacturer,*
19 *the manufacturer shall treat such product as sus-*
20 *pect product and conduct an investigation as de-*
21 *scribed in subparagraph (A). If the manufac-*
22 *turer has reason to believe the product is an ille-*
23 *gitimate product, the manufacturer shall advise*
24 *the person making the request of such belief at*

1 *the time such manufacturer responds to the*
2 *verification request.*

3 “(D) *ELECTRONIC DATABASE.*—A manufac-
4 *turer may satisfy the requirements of this para-*
5 *graph by developing a secure electronic database*
6 *or utilizing a secure electronic database devel-*
7 *oped or operated by another entity. The owner of*
8 *such database shall establish the requirements*
9 *and processes to respond to requests and may*
10 *provide for data access to other members of the*
11 *pharmaceutical distribution supply chain, as ap-*
12 *propriate. The development and operation of*
13 *such a database shall not relieve a manufacturer*
14 *of the requirement under this paragraph to re-*
15 *spond to a verification request submitted by*
16 *means other than a secure electronic database.*

17 “(E) *SALEABLE RETURNED PRODUCT.*—Be-
18 *ginning 4 years after the date of enactment of*
19 *the Drug Supply Chain Security Act (except as*
20 *provided pursuant to subsection (a)(5)), upon re-*
21 *ceipt of a returned product that the manufac-*
22 *turer intends to further distribute, before further*
23 *distributing such product, the manufacturer*
24 *shall verify the product identifier, including the*
25 *standardized numerical identifier, for each*

1 *sealed homogeneous case of such product or, if*
 2 *such product is not in a sealed homogeneous*
 3 *case, verify the product identifier, including the*
 4 *standardized numerical identifier, on each pack-*
 5 *age.*

6 *“(F) NONSALEABLE RETURNED PRODUCT.—*

7 *A manufacturer may return a nonsaleable prod-*
 8 *uct to the manufacturer or repackager, to the*
 9 *wholesale distributor from whom such product*
 10 *was purchased, or to a person acting on behalf*
 11 *of such a person, including a returns processor,*
 12 *without providing the information described in*
 13 *paragraph (1)(A)(i).*

14 *“(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—*

15 *“(1) PRODUCT TRACING.—*

16 *“(A) IN GENERAL.—Beginning not later*
 17 *than 1 year after the date of enactment of the*
 18 *Drug Supply Chain Security Act, the following*
 19 *requirements shall apply to wholesale distribu-*
 20 *tors:*

21 *“(i) A wholesale distributor shall not*
 22 *accept ownership of a product unless the*
 23 *previous owner prior to, or at the time of,*
 24 *the transaction provides the transaction his-*
 25 *tory, transaction information, and a trans-*

1 *action statement for the product, as appli-*
2 *cable under this subparagraph.*

3 “(ii)(I)(aa) *If the wholesale distributor*
4 *purchased a product directly from the man-*
5 *ufacturer, the exclusive distributor of the*
6 *manufacturer, or a repackager that pur-*
7 *chased directly from the manufacturer, then*
8 *prior to, or at the time of, each transaction*
9 *in which the wholesale distributor transfers*
10 *ownership of a product, the wholesale dis-*
11 *tributor shall provide to the subsequent pur-*
12 *chaser—*

13 “(AA) *a transaction statement,*
14 *which shall state that such wholesale*
15 *distributor, or a member of the affili-*
16 *ated group of such wholesale dis-*
17 *tributor, purchased the product di-*
18 *rectly from the manufacturer, exclusive*
19 *distributor of the manufacturer, or re-*
20 *packager that purchased directly from*
21 *the manufacturer; and*

22 “(BB) *subject to subclause (II),*
23 *the transaction history and transaction*
24 *information.*

1 “(bb) *The wholesale distributor shall*
2 *provide the transaction history, transaction*
3 *information, and transaction statement*
4 *under item (aa)—*

5 “(AA) *if provided to a dis-*
6 *perser, on a single document in*
7 *an electronic or paper format;*
8 *and*

9 “(BB) *if provided to a whole-*
10 *sale distributor, through any com-*
11 *bination of self-generated paper,*
12 *electronic data, or manufacturer-*
13 *provided information on the prod-*
14 *uct package.*

15 “(II) *For purposes of transactions de-*
16 *scribed in subclause (I), transaction history*
17 *and transaction information shall not be re-*
18 *quired to include the lot number of the*
19 *product, the initial transaction date, or the*
20 *initial shipment date from the manufac-*
21 *turer (as defined in subparagraphs (F), (G),*
22 *and (H) of section 581(25)).*

23 “(iii) *If the wholesale distributor did*
24 *not purchase a product directly from the*
25 *manufacturer, the exclusive distributor of*

1 the manufacturer, or a repackager that pur-
2 chased directly from the manufacturer, as
3 described in clause (ii), then prior to, or at
4 the time of, each transaction or subsequent
5 transaction, the wholesale distributor shall
6 provide to the subsequent purchaser a trans-
7 action statement, transaction history, and
8 transaction information, in a paper or elec-
9 tronic format that complies with the guid-
10 ance document issued under subsection
11 (a)(2).

12 “(iv) For the purposes of clause (iii),
13 the transaction history supplied shall begin
14 only with the wholesale distributor described
15 in clause (ii)(I), but the wholesale dis-
16 tributor described in clause (iii) shall in-
17 form the subsequent purchaser that such
18 wholesale distributor received a direct pur-
19 chase statement from a wholesale distributor
20 described in clause (ii)(I).

21 “(v) A wholesale distributor shall
22 maintain the transaction information,
23 transaction history, and transaction state-
24 ment for each transaction described in

1 *clauses (i), (ii), and (iii) for not less than*
2 *6 years after the date of the transaction.*

3 *“(B) RETURNS.—*

4 *“(i) SALEABLE RETURNS.—Notwith-*
5 *standing subparagraph (A)(i), the following*
6 *shall apply:*

7 *“(I) REQUIREMENTS.—Until the*
8 *date that is 6 years after the date of*
9 *enactment of the Drug Supply Chain*
10 *Security Act (except as provided pur-*
11 *suant to subsection (a)(5)), a wholesale*
12 *distributor may accept returned prod-*
13 *uct from a dispenser pursuant to the*
14 *terms and conditions of any agreement*
15 *between the parties, and, notwith-*
16 *standing subparagraph (A)(ii), may*
17 *distribute such returned product with-*
18 *out providing the transaction history.*
19 *For transactions subsequent to the re-*
20 *turn, the transaction history of such*
21 *product shall begin with the wholesale*
22 *distributor that accepted the returned*
23 *product, consistent with the require-*
24 *ments of this subsection.*

1 “(II) *ENHANCED REQUIRE-*
2 *MENTS.—Beginning 6 years after the*
3 *date of enactment of the Drug Supply*
4 *Chain Security Act (except as provided*
5 *pursuant to subsection (a)(5)), a*
6 *wholesale distributor may accept re-*
7 *turned product from a dispenser only*
8 *if the wholesale distributor can asso-*
9 *ciate returned product with the trans-*
10 *action information and transaction*
11 *statement associated with that product.*
12 *For all transactions after such date,*
13 *the transaction history, as applicable,*
14 *of such product shall begin with the*
15 *wholesale distributor that accepted and*
16 *verified the returned product. For pur-*
17 *poses of this subparagraph, the trans-*
18 *action information and transaction*
19 *history, as applicable, need not include*
20 *transaction dates if it is not reason-*
21 *ably practicable to obtain such dates.*

22 “(ii) *NONSALEABLE RETURNS.—A*
23 *wholesale distributor may return a nonsale-*
24 *able prescription drug to the manufacturer*
25 *or repackager, to the wholesale distributor*

1 *from whom such prescription drug was pur-*
 2 *chased, or to a person acting on behalf of*
 3 *such a person, including a returns proc-*
 4 *essor, without providing the information re-*
 5 *quired under subparagraph (A)(i).*

6 “(C) *REQUESTS FOR INFORMATION.*—*Upon*
 7 *a request by the Secretary or other appropriate*
 8 *Federal or State official, in the event of a recall*
 9 *or for the purpose of investigating a suspect*
 10 *product or an illegitimate product a wholesale*
 11 *distributor shall, not later than 24 hours after*
 12 *receiving the request or in other such reasonable*
 13 *time as determined by the Secretary, based on*
 14 *the circumstances of the request, provide the ap-*
 15 *plicable transaction information, transaction*
 16 *history, and transaction statement for the prod-*
 17 *uct.*

18 “(2) *PRODUCT IDENTIFIER.*—*Beginning 6 years*
 19 *after the date of enactment of the Drug Supply Chain*
 20 *Security Act, a wholesale distributor may engage in*
 21 *transactions involving a product only if such product*
 22 *is encoded with a product identifier (except as pro-*
 23 *vided pursuant to subsection (a)(5)).*

24 “(3) *AUTHORIZED TRADING PARTNERS.*—*Begin-*
 25 *ning not later than 1 year after the date of enactment*

1 *of the Drug Supply Chain Security Act, the trading*
 2 *partners of a wholesale distributor may be only au-*
 3 *thorized trading partners.*

4 “(4) *VERIFICATION.*—*Beginning not later than 1*
 5 *year after the date of enactment of the Drug Supply*
 6 *Chain Security Act, a wholesale distributor shall have*
 7 *systems in place to enable the wholesale distributor to*
 8 *comply with the following requirements:*

9 “(A) *SUSPECT PRODUCT.*—

10 “(i) *IN GENERAL.*—*Upon making a de-*
 11 *termination that a product in the possession*
 12 *or control of the wholesale distributor is a*
 13 *suspect product, or upon receiving a request*
 14 *for verification from the Secretary that has*
 15 *made a determination that a product with-*
 16 *in the possession or control of a wholesale*
 17 *distributor is a suspect product, a wholesale*
 18 *distributor shall—*

19 “(I) *quarantine such product*
 20 *within the possession or control of the*
 21 *wholesale distributor from product in-*
 22 *tended for distribution until such prod-*
 23 *uct is cleared or dispositioned; and*

24 “(II) *promptly conduct an inves-*
 25 *tigation in coordination with trading*

1 *partners, as applicable, to determine*
2 *whether the product is an illegitimate*
3 *product, which shall include validating*
4 *any applicable transaction history and*
5 *transaction information in the posses-*
6 *sion of the wholesale distributor and*
7 *otherwise investigating to determine*
8 *whether the product is an illegitimate*
9 *product, and, beginning 6 years after*
10 *the date of enactment of the Drug Sup-*
11 *ply Chain Security Act (except as pro-*
12 *vided pursuant to subsection (a)(5)),*
13 *verifying the product at the package*
14 *level, including the standardized nu-*
15 *merical identifier.*

16 “(ii) *CLEARED PRODUCT.*—*If the*
17 *wholesale distributor determines that a sus-*
18 *pect product is not an illegitimate product,*
19 *the wholesale distributor shall promptly no-*
20 *tify the Secretary, if applicable, of such de-*
21 *termination and such product may be fur-*
22 *ther distributed.*

23 “(iii) *RECORDS.*—*A wholesale dis-*
24 *tributor shall keep records of the investiga-*
25 *tion of a suspect product for not less than*

1 *6 years after the conclusion of the investiga-*
2 *tion.*

3 “(B) *ILLEGITIMATE PRODUCT.*—

4 “(i) *IN GENERAL.*—Upon determining,
5 *in coordination with the manufacturer, that*
6 *a product in the possession or control of a*
7 *wholesale distributor is an illegitimate*
8 *product, the wholesale distributor shall, in a*
9 *manner that is consistent with the systems*
10 *and processes of such wholesale dis-*
11 *tributor—*

12 “(I) *quarantine such product*
13 *within the possession or control of the*
14 *wholesale distributor from product in-*
15 *tended for distribution until such prod-*
16 *uct is dispositioned;*

17 “(II) *disposition the illegitimate*
18 *product within the possession or con-*
19 *trol of the wholesale distributor;*

20 “(III) *take reasonable and appro-*
21 *priate steps to assist a trading partner*
22 *to disposition an illegitimate product*
23 *not in the possession or control of the*
24 *wholesale distributor; and*

1 “(IV) retain a sample of the prod-
2 uct for further physical examination or
3 laboratory analysis of the product by
4 the manufacturer or Secretary (or
5 other appropriate Federal or State offi-
6 cial) upon request by the manufacturer
7 or Secretary (or other appropriate
8 Federal or State official), as necessary
9 and appropriate.

10 “(ii) *MAKING A NOTIFICATION.*—Upon
11 determining that a product in the posses-
12 sion or control of the wholesale distributor
13 is an illegitimate product, the wholesale dis-
14 tributor shall notify the Secretary and all
15 immediate trading partners that the whole-
16 sale distributor has reason to believe may
17 have received such illegitimate product of
18 such determination not later than 24 hours
19 after making such determination.

20 “(iii) *RESPONDING TO A NOTIFICA-*
21 *TION.*—Upon the receipt of a notification
22 from the Secretary or a trading partner
23 that a determination has been made that a
24 product is an illegitimate product, a whole-
25 sale distributor shall identify all illegit-

1 *imate product subject to such notification*
 2 *that is in the possession or control of the*
 3 *wholesale distributor, including any product*
 4 *that is subsequently received, and shall per-*
 5 *form the activities described in subpara-*
 6 *graph (A).*

7 “(iv) *TERMINATING A NOTIFICATION.*—
 8 *Upon a determination, in consultation with*
 9 *the Secretary, that a notification is no*
 10 *longer necessary, a wholesale distributor*
 11 *shall promptly notify immediate trading*
 12 *partners that the wholesale distributor noti-*
 13 *fied pursuant to clause (ii) that such notifi-*
 14 *cation has been terminated.*

15 “(v) *RECORDS.*—*A wholesale dis-*
 16 *tributor shall keep records of the disposition*
 17 *of an illegitimate product for not less than*
 18 *6 years after the conclusion of the disposi-*
 19 *tion.*

20 “(C) *ELECTRONIC DATABASE.*—*A wholesale*
 21 *distributor may satisfy the requirements of this*
 22 *paragraph by developing a secure electronic*
 23 *database or utilizing a secure electronic database*
 24 *developed or operated by another entity. The*
 25 *owner of such database shall establish the re-*

quirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a wholesale distributor of the requirement under this paragraph to respond to a verification request submitted by means other than a secure electronic database.

“(D) VERIFICATION OF SALEABLE RETURNED PRODUCT.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, upon receipt of a returned product that the wholesale distributor intends to further distribute, before further distributing such product, the wholesale distributor shall verify the product identifier, including the standardized numerical identifier, for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier, including the standardized numerical identifier, on each package.

“(d) DISPENSER REQUIREMENTS.—

“(1) PRODUCT TRACING.—

1 “(A) *IN GENERAL.*—Beginning 1 year after
2 the date of enactment of the Drug Supply Chain
3 Security Act, a dispenser—

4 “(i) shall not accept ownership of a
5 product, unless the previous owner prior to,
6 or at the time of, the transaction, provides
7 transaction history, transaction informa-
8 tion, and a transaction statement;

9 “(ii) prior to, or at the time of, each
10 transaction in which the dispenser transfers
11 ownership of a product (but not including
12 dispensing to a patient or returns) shall
13 provide the subsequent owner with trans-
14 action history, transaction information,
15 and a transaction statement for the product,
16 except that the requirements of this clause
17 shall not apply to sales by a dispenser to
18 another dispenser to fulfill a specific patient
19 need; and

20 “(iii) shall maintain transaction infor-
21 mation, transaction history, and trans-
22 action statements, as necessary to inves-
23 tigate a suspect product, for not less than 6
24 years after the transaction.

1 “(B) *AGREEMENTS WITH THIRD PARTIES.*—

2 *A dispenser may enter into a written agreement*
 3 *with a third party, including an authorized*
 4 *wholesale distributor, under which the third*
 5 *party confidentially maintains the transaction*
 6 *information, transaction history, and trans-*
 7 *action statements required to be maintained*
 8 *under this subsection on behalf of the dispenser.*
 9 *If a dispenser enters into such an agreement, the*
 10 *dispenser shall maintain a copy of the written*
 11 *agreement and shall not be relieved of the obliga-*
 12 *tions of the dispenser under this subsection.*

13 “(C) *RETURNS.*—

14 “(i) *SALEABLE RETURNS.*—*A dispenser*
 15 *may return product to the trading partner*
 16 *from which the dispenser obtained the prod-*
 17 *uct without providing the information re-*
 18 *quired under subparagraph (A).*

19 “(ii) *NONSALEABLE RETURNS.*—*A dis-*
 20 *penster may return a nonsaleable product to*
 21 *the manufacturer or repackager, to the*
 22 *wholesale distributor from whom such prod-*
 23 *uct was purchased, to a returns processor,*
 24 *or to a person acting on behalf of such a*

1 *person without providing the information*
2 *required under subparagraph (A)(i).*

3 “(D) *REQUESTS FOR INFORMATION.*—Upon
4 *a request by the Secretary or other appropriate*
5 *Federal or State official, in the event of a recall*
6 *or for the purpose of investigating a suspect or*
7 *an illegitimate product, a dispenser shall, not*
8 *later than 2 business days after receiving the re-*
9 *quest or in another such reasonable time as de-*
10 *termined by the Secretary, based on the cir-*
11 *cumstances of the request, provide the applicable*
12 *transaction information, transaction statement,*
13 *and transaction history which the dispenser re-*
14 *ceived from the previous owner, which shall not*
15 *include the lot number of the product, the initial*
16 *transaction date, or the initial shipment date*
17 *from the manufacturer unless such information*
18 *was included in the transaction information,*
19 *transaction statement, and transaction history*
20 *provided by the manufacturer or wholesale dis-*
21 *tributor to the dispenser. The dispenser may re-*
22 *spond to the request by providing the applicable*
23 *information in either paper or electronic format.*

24 “(2) *PRODUCT IDENTIFIER.*—Beginning not
25 *later than 7 years after the date of enactment of the*

1 *Drug Supply Chain Security Act, a dispenser may*
 2 *engage in transactions involving a product only if*
 3 *such product is encoded with a product identifier (ex-*
 4 *cept as provided pursuant to subsection (a)(5)).*

5 “(3) *AUTHORIZED TRADING PARTNERS.*—*Begin-*
 6 *ning not later than 1 year after the date of enactment*
 7 *of the Drug Supply Chain Security Act, the trading*
 8 *partners of a dispenser may be only authorized trad-*
 9 *ing partners.*

10 “(4) *VERIFICATION.*—*Beginning not later than 1*
 11 *year after the date of enactment of the Drug Supply*
 12 *Chain Security Act, a dispenser shall have systems in*
 13 *place to enable the dispenser to comply with the fol-*
 14 *lowing requirements:*

15 “(A) *SUSPECT PRODUCT.*—

16 “(i) *IN GENERAL.*—*Upon making a de-*
 17 *termination that a product in the possession*
 18 *or control of the dispenser is a suspect prod-*
 19 *uct, or upon receiving a request for*
 20 *verification from the Secretary that has*
 21 *made a determination that a product with-*
 22 *in the possession or control of a dispenser is*
 23 *a suspect product, a dispenser shall—*

24 “(I) *quarantine such product*
 25 *within the possession or control of the*

1 dispenser from product intended for
2 distribution until such product is
3 cleared or dispositioned; and

4 “(II) promptly conduct an inves-
5 tigation in coordination with trading
6 partners, as applicable, to determine
7 whether the product is an illegitimate
8 product.

9 “(ii) INVESTIGATION.—An investiga-
10 tion conducted under clause (i)(II) shall in-
11 clude—

12 “(I) beginning 7 years after the
13 date of enactment of the Drug Supply
14 Chain Security Act, verifying whether
15 the lot number of a suspect product
16 corresponds with the lot number for
17 such product;

18 “(II) beginning 7 years after the
19 date of enactment of such Act,
20 verifying that the product identifier,
21 including the standardized numerical
22 identifier, of at least 3 packages or 10
23 percent of such suspect product, which-
24 ever is greater, or all packages, if there

1 are fewer than 3, corresponds with the
2 product identifier for such product;

3 “(III) validating any applicable
4 transaction history and transaction in-
5 formation in the possession of the dis-
6 penser; and

7 “(IV) otherwise investigating to
8 determine whether the product is an il-
9 legitimate product.

10 “(iii) *CLEARED PRODUCT.*—If the dis-
11 penser makes the determination that a sus-
12 pect product is not an illegitimate product,
13 the dispenser shall promptly notify the Sec-
14 retary, if applicable, of such determination
15 and such product may be further distributed
16 or dispensed.

17 “(iv) *RECORDS.*—A dispenser shall
18 keep records of the investigation of a suspect
19 product for not less than 6 years after the
20 conclusion of the investigation.

21 “(B) *ILLEGITIMATE PRODUCT.*—

22 “(i) *IN GENERAL.*—Upon determining,
23 in coordination with the manufacturer, that
24 a product in the possession or control of a

1 *dispenser is an illegitimate product, the dis-*
 2 *dispenser shall—*

3 “(I) *disposition the illegitimate*
 4 *product within the possession or con-*
 5 *trol of the dispenser;*

6 “(II) *take reasonable and appro-*
 7 *priate steps to assist a trading partner*
 8 *to disposition an illegitimate product*
 9 *not in the possession or control of the*
 10 *dispenser; and*

11 “(III) *retain a sample of the*
 12 *product for further physical examina-*
 13 *tion or laboratory analysis of the prod-*
 14 *uct by the manufacturer or Secretary*
 15 *(or other appropriate Federal or State*
 16 *official) upon request by the manufac-*
 17 *turer or Secretary (or other appro-*
 18 *priate Federal or State official), as*
 19 *necessary and appropriate.*

20 “(ii) *MAKING A NOTIFICATION.—Upon*
 21 *determining that a product in the posses-*
 22 *sion or control of the dispenser is an illegit-*
 23 *imate product, the dispenser shall notify the*
 24 *Secretary and all immediate trading part-*
 25 *ners that the dispenser has reason to believe*

1 *may have received such illegitimate product*
2 *of such determination not later than 24*
3 *hours after making such determination.*

4 “(iii) *RESPONDING TO A NOTIFICA-*
5 *TION.—Upon the receipt of a notification*
6 *from the Secretary or a trading partner*
7 *that a determination has been made that a*
8 *product is an illegitimate product, a dis-*
9 *perser shall identify all illegitimate product*
10 *subject to such notification that is in the*
11 *possession or control of the dispenser, in-*
12 *cluding any product that is subsequently re-*
13 *ceived, and shall perform the activities de-*
14 *scribed in subparagraph (A).*

15 “(iv) *TERMINATING A NOTIFICATION.—*
16 *Upon making a determination, in consulta-*
17 *tion with the Secretary, that a notification*
18 *is no longer necessary, a dispenser shall*
19 *promptly notify immediate trading part-*
20 *ners that the dispenser notified pursuant to*
21 *clause (ii) that such notification has been*
22 *terminated.*

23 “(v) *RECORDS.—A dispenser shall keep*
24 *records of the disposition of an illegitimate*

1 *product for not less than 6 years after the*
 2 *conclusion of the disposition.*

3 “(C) *ELECTRONIC DATABASE.—A dispenser*
 4 *may satisfy the requirements of this paragraph*
 5 *by developing a secure electronic database or uti-*
 6 *lizing a secure electronic database developed or*
 7 *operated by another entity.*

8 “(e) *REPACKAGER REQUIREMENTS.—*

9 “(1) *PRODUCT TRACING.—*

10 “(A) *IN GENERAL.—Beginning not later*
 11 *than 1 year after the date of enactment of the*
 12 *Drug Supply Chain Security Act, a repackager*
 13 *shall—*

14 “(i) *not accept ownership of a product*
 15 *unless the previous owner, prior to, or at*
 16 *the time of, the transaction, provides trans-*
 17 *action history, transaction information,*
 18 *and a transaction statement for the product;*

19 “(ii) *prior to, or at the time of, each*
 20 *transaction in which the repackager trans-*
 21 *fers ownership of a product, or transfers*
 22 *possession of a product to a third-party lo-*
 23 *gistics provider, provide the subsequent*
 24 *owner with transaction history, transaction*

1 *information, and a transaction statement;*
2 *and*

3 *“(iii) maintain the transaction infor-*
4 *mation, transaction history, and trans-*
5 *action statement for each transaction de-*
6 *scribed in clauses (i) and (ii) for not less*
7 *than 6 years after the transaction.*

8 *“(B) NONSALEABLE RETURNS.—A repack-*
9 *ager may return a nonsaleable product to the*
10 *manufacturer or repackager, or to the wholesale*
11 *distributor from whom such product was pur-*
12 *chased, or to a person acting on behalf of such*
13 *a person, including a returns processor, without*
14 *providing the information required under sub-*
15 *paragraph (A)(ii).*

16 *“(C) REQUESTS FOR INFORMATION.—Upon*
17 *a request by the Secretary or other appropriate*
18 *Federal or State official, in the event of a recall*
19 *or for the purpose of investigating a suspect*
20 *product or an illegitimate product, a repackager*
21 *shall, not later than 24 hours after receiving the*
22 *request or in other such reasonable time as deter-*
23 *mined by the Secretary, based on the cir-*
24 *cumstances of the request, provide the applicable*

1 *transaction information, transaction history and*
2 *transaction statement for the product.*

3 “(2) *PRODUCT IDENTIFIER.*—*Beginning not*
4 *later than 5 years after the date of enactment of the*
5 *Drug Supply Chain Security Act, a repackager—*

6 “(A) *shall affix or imprint a product iden-*
7 *tifier to each package and homogenous case of*
8 *product intended to be introduced in a trans-*
9 *action in commerce;*

10 “(B) *shall maintain the product identifier*
11 *information for such product for not less than 6*
12 *years after the date of the transaction;*

13 “(C) *may engage in transactions involving*
14 *a product only if such product is encoded with*
15 *a product identifier (except as provided pursu-*
16 *ant to subsection (a)(5)); and*

17 “(D) *maintain records for not less than 6*
18 *years to allow the repackager to associate the*
19 *product identifier the repackager affixes or im-*
20 *prints with the product identifier assigned by the*
21 *original manufacturer of the product.*

22 “(3) *AUTHORIZED TRADING PARTNERS.*—*Begin-*
23 *ning 1 year after the date of enactment of the Drug*
24 *Supply Chain Security Act, the trading partners of*

1 *a repackager may be only authorized trading part-*
2 *ners.*

3 “(4) *VERIFICATION.*—*Beginning not later than 1*
4 *year after the date of enactment of the Drug Supply*
5 *Chain Security Act, a repackager shall have systems*
6 *in place to enable the repackager to comply with the*
7 *following requirements:*

8 “(A) *SUSPECT PRODUCT.*—

9 “(i) *IN GENERAL.*—*Upon making a de-*
10 *termination that a product in the possession*
11 *or control of the repackager is a suspect*
12 *product, or upon receiving a request for*
13 *verification from the Secretary that has*
14 *made a determination that a product with-*
15 *in the possession or control of a repackager*
16 *is a suspect product, a repackager shall—*

17 “(I) *quarantine such product*
18 *within the possession or control of the*
19 *repackager from product intended for*
20 *distribution until such product is*
21 *cleared or dispositioned; and*

22 “(II) *promptly conduct an inves-*
23 *tigation in coordination with trading*
24 *partners, as applicable, to determine*
25 *whether the product is an illegitimate*

1 *product, which shall include validating*
 2 *any applicable transaction history and*
 3 *transaction information in the posses-*
 4 *sion of the repackager and otherwise*
 5 *investigating to determine whether the*
 6 *product is an illegitimate product,*
 7 *and, beginning 5 years after the date*
 8 *of enactment of the Drug Supply*
 9 *Chain Security Act (except as provided*
 10 *pursuant to subsection (a)(5)),*
 11 *verifying the product at the package*
 12 *level, including the standardized nu-*
 13 *merical identifier.*

14 *“(ii) CLEARED PRODUCT.—If the re-*
 15 *packager makes the determination that a*
 16 *suspect product is not an illegitimate prod-*
 17 *uct, the repackager shall promptly notify*
 18 *the Secretary, if applicable, of such deter-*
 19 *mination and such product may be further*
 20 *distributed.*

21 *“(iii) RECORDS.—A repackager shall*
 22 *keep records of the investigation of a suspect*
 23 *product for not less than 6 years after the*
 24 *conclusion of the investigation.*

25 *“(B) ILLEGITIMATE PRODUCT.—*

1 “(i) *IN GENERAL.*—Upon determining,
2 *in coordination with the manufacturer, that*
3 *a product in the possession or control of a*
4 *repackager is an illegitimate product, the*
5 *repackager shall, in a manner that is con-*
6 *sistent with the systems and processes of*
7 *such repackager—*

8 “(I) *quarantine such product*
9 *within the possession or control of the*
10 *repackager from product intended for*
11 *distribution until such product is*
12 *disposed;*

13 “(II) *dispose the illegitimate*
14 *product within the possession or con-*
15 *trol of the repackager;*

16 “(III) *take reasonable and appro-*
17 *priate steps to assist a trading partner*
18 *to dispose an illegitimate product*
19 *not in the possession or control of the*
20 *repackager; and*

21 “(IV) *retain a sample of the prod-*
22 *uct for further physical examination or*
23 *laboratory analysis of the product by*
24 *the manufacturer or Secretary (or*
25 *other appropriate Federal or State offi-*

1 cial) upon request by the manufacturer
2 or Secretary (or other appropriate
3 Federal or State official), as necessary
4 and appropriate.

5 “(ii) *MAKING A NOTIFICATION.*—Upon
6 determining that a product in the posses-
7 sion or control of the repackager is an ille-
8 gitimate product, the repackager shall no-
9 tify the Secretary and all immediate trad-
10 ing partners that the repackager has reason
11 to believe may have received the illegitimate
12 product of such determination not later
13 than 24 hours after making such determina-
14 tion.

15 “(iii) *RESPONDING TO A NOTIFICA-*
16 *TION.*—Upon the receipt of a notification
17 from the Secretary or a trading partner, a
18 repackager shall identify all illegitimate
19 product subject to such notification that is
20 in the possession or control of the repack-
21 ager, including any product that is subse-
22 quently received, and shall perform the ac-
23 tivities described in subparagraph (A).

24 “(iv) *TERMINATING A NOTIFICATION.*—
25 Upon a determination, in consultation with

1 the Secretary, that a notification is no
2 longer necessary, a repackager shall
3 promptly notify immediate trading part-
4 ners that the repackager notified pursuant
5 to clause (ii) that such notification has been
6 terminated.

7 “(v) *RECORDS*.—A repackager shall
8 keep records of the disposition of an illegit-
9 imate product for not less than 6 years after
10 the conclusion of the disposition.

11 “(C) *REQUESTS FOR VERIFICATION*.—Be-
12 ginning 5 years after the date of enactment of
13 the Drug Supply Chain Security Act, upon re-
14 ceiving a request for verification from an author-
15 ized manufacturer, wholesale distributor, or dis-
16 penser that is in possession or control of a prod-
17 uct they believe to be repackaged by such repack-
18 ager, a repackager shall, not later than 24 hours
19 after receiving the verification request or in other
20 such reasonable time as determined by the Sec-
21 retary, based on the circumstances of the request,
22 notify the person making the request whether the
23 product identifier, including the standardized
24 numerical identifier, that is the subject of the re-
25 quest corresponds to the product identifier af-

1 *fixed or imprinted by the repackager. If a re-*
2 *packager responding to a verification request*
3 *identifies a product identifier that does not cor-*
4 *respond to that affixed or imprinted by the re-*
5 *packager, the repackager shall treat such product*
6 *as suspect product and conduct an investigation*
7 *as described in subparagraph (A). If the repack-*
8 *ager has reason to believe the product is an ille-*
9 *gitimate product, the repackager shall advise the*
10 *person making the request of such belief at the*
11 *time such manufacturer responds to the*
12 *verification request.*

13 “(D) *ELECTRONIC DATABASE.*—A repack-
14 *ager may satisfy the requirements of paragraph*
15 *(4) by developing a secure electronic database or*
16 *utilizing a secure electronic database developed*
17 *or operated by another entity. The owner of such*
18 *database shall establish the requirements and*
19 *processes to respond to requests and may provide*
20 *for data access to other members of the pharma-*
21 *ceutical distribution supply chain, as appro-*
22 *priate. The development and operation of such a*
23 *database shall not relieve a repackager of the re-*
24 *quirement under subparagraph (C) to respond to*

1 *a verification request submitted by means other*
 2 *than a secure electronic database.*

3 “(E) VERIFICATION OF SALEABLE RE-
 4 *TURNED PRODUCT.—Beginning 5 years after the*
 5 *date of enactment of the Drug Supply Chain Se-*
 6 *curity Act, upon receipt of a returned product*
 7 *that the repackager intends to further distribute,*
 8 *before further distributing such product, the re-*
 9 *packager shall verify the product identifier for*
 10 *each sealed homogeneous case of such product or,*
 11 *if such product is not in a sealed homogeneous*
 12 *case, verify the product identifier on each pack-*
 13 *age.*

14 “(f) THIRD-PARTY LOGISTICS PROVIDER REQUIRE-
 15 MENTS.—

16 “(1) IN GENERAL.—Beginning not later than 1
 17 *year after the date of enactment of the Drug Supply*
 18 *Chain Security Act, a third-party logistics provider*
 19 *shall—*

20 “(A) not accept possession of a product un-
 21 *less the owner of the product provides the trans-*
 22 *action history, transaction information, and a*
 23 *transaction statement for the product;*

1 “(B) maintain a copy of the information
2 described in subparagraph (A) for not less than
3 6 years after the transfer of possession; and

4 “(C) upon a request by the Secretary or
5 other appropriate Federal or State official, in
6 the event of a recall or for the purpose of inves-
7 tigating a suspect product or an illegitimate
8 product, not later than 24 hours after receiving
9 the request or in other such reasonable time as
10 determined by the Secretary based on the cir-
11 cumstances of the request, provide the applicable
12 transaction information, transaction history,
13 and transaction statement for the product.

14 “(2) *PRODUCT TRACING*.—Beginning not later
15 than 6 years after the date of enactment of the Drug
16 Supply Chain Security Act, a third-party logistics
17 provider may accept possession of product only if
18 such product is encoded with a product identifier (ex-
19 cept as provided pursuant to subsection (a)(5)).

20 “(3) *AUTHORIZED TRADING PARTNERS*.—Begin-
21 ning 1 year after the date of enactment of the Drug
22 Supply Chain Security Act, the trading partners of
23 a third-party logistics provider may be only author-
24 ized trading partners.

1 “(4) *VERIFICATION.*—*Beginning not later than 1*
 2 *year after the date of enactment of the Drug Supply*
 3 *Chain Security Act, a third-party logistics provider*
 4 *shall have systems in place to enable the third-party*
 5 *logistics provider to comply with the following re-*
 6 *quirements:*

7 “(A) *SUSPECT PRODUCT.*—

8 “(i) *IN GENERAL.*—*Upon making a de-*
 9 *termination that a product in the possession*
 10 *or control of a third-party logistics provider*
 11 *is a suspect product, a third-party logistics*
 12 *provider shall—*

13 “(I) *quarantine such product*
 14 *within the possession or control of the*
 15 *third-party logistics provider from*
 16 *product intended for distribution until*
 17 *such product is cleared or transferred*
 18 *to the owner of such product for dis-*
 19 *position of the product; and*

20 “(II) *promptly notify the owner of*
 21 *such product of the need to conduct an*
 22 *investigation to determine whether the*
 23 *product is an illegitimate product.*

24 “(ii) *CLEARED PRODUCT.*—*If the*
 25 *owner of the product notifies the third-party*

1 *logistics provider of the determination that*
 2 *a suspect product is not an illegitimate*
 3 *product, such product may be further dis-*
 4 *tributed.*

5 “(iii) *RECORDS.*—*A third-party logis-*
 6 *tics provider shall keep records of the activi-*
 7 *ties described in subclauses (I) and (II) of*
 8 *clause (i), as such subclauses relate to a sus-*
 9 *pect product, for not less than 6 years after*
 10 *the conclusion of the investigation.*

11 “(B) *ILLEGITIMATE PRODUCT.*—

12 “(i) *IN GENERAL.*—*Upon determining,*
 13 *in coordination with the manufacturer, that*
 14 *a product in the possession or control of a*
 15 *third-party logistics provider is an illegit-*
 16 *imate product, the third-party logistics pro-*
 17 *vider shall—*

18 “(I) *promptly notify the owner of*
 19 *such product of the need to disposition*
 20 *such product; and*

21 “(II) *promptly transfer possession*
 22 *of the product to the owner of such*
 23 *product to disposition the product.*

24 “(ii) *MAKING A NOTIFICATION.*—*Upon*
 25 *determining that a product in the posses-*

1 *sion or control of the third-party logistics*
 2 *provider is an illegitimate product, the*
 3 *third-party logistics provider shall notify*
 4 *the Secretary not later than 24 hours after*
 5 *making such determination.*

6 “(iii) *RESPONDING TO A NOTIFICA-*
 7 *TION.—Upon the receipt of a notification*
 8 *from the Secretary, a third-party logistics*
 9 *provider shall identify all illegitimate prod-*
 10 *uct subject to such notification that is in the*
 11 *possession or control of the third-party lo-*
 12 *gistics provider, including any product that*
 13 *is subsequently received, and shall perform*
 14 *the activities described in subparagraph*
 15 *(A).*

16 “(iv) *TERMINATING A NOTIFICATION.—*
 17 *Upon making a determination, in consulta-*
 18 *tion with the Secretary and the owner of*
 19 *such product, that a notification is no*
 20 *longer necessary, a third-party logistics pro-*
 21 *vider shall promptly terminate such notifi-*
 22 *cation.*

23 “(v) *RECORDS.—A third-party logis-*
 24 *tics provider shall keep records of the activi-*
 25 *ties described in subclauses (I) and (II) of*

1 *clause (i) as such subclauses relate to an il-*
 2 *legitimate product for not less than 6 years*
 3 *after the conclusion of the disposition.*

4 “(g) *DROP SHIPMENTS.*—

5 “(1) *IN GENERAL.*—A wholesale distributor that
 6 *does not physically handle or store product shall be*
 7 *exempt from the provisions of this section, except the*
 8 *notification requirements under clauses (ii), (iii), and*
 9 *(iv) of subsection (c)(4)(B), provided that the manu-*
 10 *facturer, repackager, or other wholesale distributor*
 11 *that distributes the product to the dispenser by means*
 12 *of drop shipment for such wholesale distributor in-*
 13 *cludes on the transaction information and trans-*
 14 *action history to the dispenser the contact informa-*
 15 *tion of such wholesale distributor and provides the*
 16 *transaction information, transaction history, and*
 17 *transaction statement directly to the dispenser.*

18 “(2) *CLARIFICATION.*—For purposes of this sub-
 19 *section, providing administrative services, including*
 20 *processing of orders and payments, shall not by itself,*
 21 *be construed as being involved in the handling, dis-*
 22 *tribution, or storage of a product.”.*

23 **SEC. 203. ENHANCED DRUG DISTRIBUTION SECURITY.**

24 *Section 582, as added by section 202, is amended by*
 25 *adding at the end the following:*

1 “(h) *ENHANCED DRUG DISTRIBUTION SECURITY.*—

2 “(1) *IN GENERAL.*—On the date that is 10 years
3 after the date of enactment of the Drug Supply Chain
4 Security Act, the following interoperable, electronic
5 tracing of product at the package level requirements
6 shall go into effect:

7 “(A) *The transaction information and the*
8 *transaction statements as required under this*
9 *section shall be exchanged in a secure, interoper-*
10 *able, electronic manner in accordance with the*
11 *standards established under the guidance issued*
12 *pursuant to paragraphs (3) and (4) of subsection*
13 *(i), including any revision of such guidance*
14 *issued in accordance with paragraph (5) of such*
15 *subsection.*

16 “(B) *The transaction information required*
17 *under this section shall include the product iden-*
18 *tifier at the package level for each package in-*
19 *cluded in the transaction.*

20 “(C) *Systems and processes for verification*
21 *of product at the package level, including the*
22 *standardized numerical identifier, shall be re-*
23 *quired in accordance with the standards estab-*
24 *lished under the guidance issued pursuant to*
25 *subsection (a)(2) and the guidances issued pur-*

1 *suant to paragraphs (2), (3), and (4) of sub-*
2 *section (i), including any revision of such guid-*
3 *ances issued in accordance with paragraph (5) of*
4 *such subsection, which may include the use of ag-*
5 *gregation and inference as necessary.*

6 *“(D) The systems and processes necessary to*
7 *promptly respond with the transaction informa-*
8 *tion and transaction statement for a product*
9 *upon a request by the Secretary (or other appro-*
10 *priate Federal or State official) in the event of*
11 *a recall or for the purposes of investigating a*
12 *suspect product or an illegitimate product shall*
13 *be required.*

14 *“(E) The systems and processes necessary to*
15 *promptly facilitate gathering the information*
16 *necessary to produce the transaction information*
17 *for each transaction going back to the manufac-*
18 *turer, as applicable, shall be required—*

19 *“(i) in the event of a request by the*
20 *Secretary (or other appropriate Federal or*
21 *State official), on account of a recall or for*
22 *the purposes of investigating a suspect prod-*
23 *uct or an illegitimate product; or*

24 *“(ii) in the event of a request by an*
25 *authorized trading partner, in a secure*

1 *manner that ensures the protection of con-*
 2 *fidential commercial information and trade*
 3 *secrets, for purposes of investigating a sus-*
 4 *pect product or assisting the Secretary (or*
 5 *other appropriate Federal or State official)*
 6 *with a request described in clause (i).*

7 “(F) Each person accepting a saleable re-
 8 turn shall have systems and processes in place to
 9 allow acceptance of such product and may accept
 10 saleable returns only if such person can associate
 11 the saleable return product with the transaction
 12 information and transaction statement associ-
 13 ated with that product.

14 “(2) COMPLIANCE.—

15 “(A) INFORMATION MAINTENANCE AGREE-
 16 MENT.—A dispenser may enter into a written
 17 agreement with a third party, including an au-
 18 thorized wholesale distributor, under which the
 19 third party shall confidentially maintain any
 20 information and statements required to be main-
 21 tained under this section. If a dispenser enters
 22 into such an agreement, the dispenser shall
 23 maintain a copy of the written agreement and
 24 shall not be relieved of the obligations of the dis-
 25 penser under this subsection.

1 “(B) *ALTERNATIVE METHODS.*—*The Sec-*
2 *retary, taking into consideration the assessment*
3 *conducted under paragraph (3), shall provide for*
4 *alternative methods of compliance with any of*
5 *the requirements set forth in paragraph (1), in-*
6 *cluding—*

7 “(i) *establishing timelines for compli-*
8 *ance by small businesses (including small*
9 *business dispensers with 25 or fewer full*
10 *time employees) with such requirements, in*
11 *order to ensure that such requirements do*
12 *not impose undue economic hardship for*
13 *small businesses, including small business*
14 *dispensers for whom the criteria set forth in*
15 *the assessment under paragraph (3) is not*
16 *met, if the Secretary determines that such*
17 *requirements under paragraph (1) would*
18 *result in undue economic hardship; and*

19 “(ii) *establishing a process by which a*
20 *dispenser may request a waiver from any of*
21 *the requirements set forth in paragraph (1)*
22 *if the Secretary determines that such re-*
23 *quirements would result in an undue eco-*
24 *nomie hardship, which shall include a proc-*

1 *ess for the biennial review and renewal of*
2 *any such waiver.*

3 “(3) *ASSESSMENT.*—

4 “(A) *IN GENERAL.*—Not later than the date
5 *that is 18 months after the Secretary issues the*
6 *final guidance required under subsection (i), the*
7 *Secretary shall enter into contract with a pri-*
8 *vate, independent consulting firm with expertise*
9 *to conduct a technology and software assessment*
10 *that looks at the feasibility of dispensers with 25*
11 *or fewer full-time employees conducting inter-*
12 *operable, electronic tracing of products at the*
13 *package level. In no case may such assessment*
14 *commence later than 7½ years after the date of*
15 *enactment of the Drug Supply Chain Security*
16 *Act.*

17 “(B) *CONDITION.*—As a condition of the
18 *award of the contract under subparagraph (A),*
19 *the private, independent consulting firm shall*
20 *agree to consult with dispensers with 25 or fewer*
21 *full-time employees when conducting the assess-*
22 *ment under such subparagraph.*

23 “(C) *CONTENT.*—The assessment conducted
24 *under subparagraph (A) shall assess whether—*

1 “(i) the necessary software and hard-
2 ware is readily accessible to such dispensers;

3 “(ii) the necessary software and hard-
4 ware is prohibitively expensive to obtain,
5 install, and maintain for such dispensers;
6 and

7 “(iii) the necessary hardware and soft-
8 ware can be integrated into business prac-
9 tices, such as interoperability with whole-
10 sale distributors, for such dispensers.

11 “(D) PUBLICATION.—The Secretary shall—

12 “(i) publish the statement of work for
13 the assessment conducted under subpara-
14 graph (A) for public comment prior to be-
15 ginning the assessment;

16 “(ii) publish the final assessment for
17 public comment not later than 30 calendar
18 days after receiving such assessment; and

19 “(iii) hold a public meeting not later
20 than 180 calendar days after receiving the
21 final assessment at which public stake-
22 holders may present their views on the as-
23 sessment.

24 “(4) PROCEDURE.—Notwithstanding section 553
25 of title 5, United States Code, the Secretary, in pro-

1 *mulgating any regulation pursuant to this section,*
2 *shall—*

3 *“(A) provide appropriate flexibility by—*

4 *“(i) not requiring the adoption of spe-*
5 *cific business systems for the maintenance*
6 *and transmission of data;*

7 *“(ii) prescribing alternative methods of*
8 *compliance for any of the requirements set*
9 *forth in paragraph (1) or set forth in regu-*
10 *lations implementing such requirements, in-*
11 *cluding timelines—*

12 *“(I) for small businesses to com-*
13 *ply with the requirements set forth in*
14 *the regulations in order to ensure that*
15 *such requirements do not impose undue*
16 *economic hardship for small businesses*
17 *(including small business dispensers*
18 *for whom the criteria set forth in the*
19 *assessment under paragraph (3) is not*
20 *met), if the Secretary determines that*
21 *such requirements would result in*
22 *undue economic hardship; and*

23 *“(II) which shall include estab-*
24 *lishing a process by which a dispenser*
25 *may request a waiver from any of the*

1 *requirements set forth in such regula-*
2 *tions if the Secretary determines that*
3 *such requirements would result in an*
4 *undue economic hardship; and*
5 *“(iii) taking into consideration—*

6 *“(I) the results of pilot projects,*
7 *including pilot projects pursuant to*
8 *this section;*

9 *“(II) the public meetings held and*
10 *related guidance documents issued*
11 *under this section;*

12 *“(III) the public health benefits of*
13 *any additional regulations in compari-*
14 *son to the cost of compliance with such*
15 *requirements, including on entities of*
16 *varying sizes and capabilities;*

17 *“(IV) the diversity of the pharma-*
18 *ceutical distribution supply chain by*
19 *providing appropriate flexibility for*
20 *each sector, including both large and*
21 *small businesses; and*

22 *“(V) the assessment pursuant to*
23 *paragraph (3) with respect to small*
24 *business dispensers, including related*
25 *public comment and the public meet-*

1 *ing, and requirements under this sec-*
 2 *tion;*

3 *“(B) issue a notice of proposed rulemaking*
 4 *that includes a copy of the proposed regulation;*

5 *“(C) provide a period of not less than 60*
 6 *days for comments on the proposed regulation;*
 7 *and*

8 *“(D) publish the final regulation not less*
 9 *than 2 years prior to the effective date of the reg-*
 10 *ulation.*

11 *“(i) GUIDANCE DOCUMENTS.—*

12 *“(1) IN GENERAL.—For the purposes of facili-*
 13 *tating the successful and efficient adoption of secure,*
 14 *interoperable product tracing at the package level in*
 15 *order to enhance drug distribution security and fur-*
 16 *ther protect the public health, the Secretary shall issue*
 17 *the guidance documents as provided for in this sub-*
 18 *section.*

19 *“(2) SUSPECT AND ILLEGITIMATE PRODUCT.—*

20 *“(A) IN GENERAL.—Not later than 180*
 21 *days after the date of enactment of the Drug*
 22 *Supply Chain Security Act, the Secretary shall*
 23 *issue a guidance document to aid trading part-*
 24 *ners in the identification of a suspect product*

1 *and notification termination. Such guidance*
2 *document shall—*

3 “(i) *identify specific scenarios that*
4 *could significantly increase the risk of a*
5 *suspect product entering the pharmaceutical*
6 *distribution supply chain;*

7 “(ii) *provide recommendation on how*
8 *trading partners may identify such product*
9 *and make a determination if the product is*
10 *a suspect product as soon as practicable;*
11 *and*

12 “(iii) *set forth the process by which*
13 *manufacturers, repackagers, wholesale dis-*
14 *tributors, dispensers, and third-party logis-*
15 *tics providers shall terminate notifications*
16 *in consultation with the Secretary regard-*
17 *ing illegitimate product pursuant to sub-*
18 *sections (b)(4)(B), (c)(4)(B), (d)(4)(B),*
19 *(e)(4)(B), and (f)(4)(B).*

20 “(B) *REVISED GUIDANCE.—If the Secretary*
21 *revises the guidance issued under subparagraph*
22 *(A), the Secretary shall follow the procedure set*
23 *forth in paragraph (5).*

24 “(3) *UNIT LEVEL TRACING.—*

1 “(A) *IN GENERAL.*—*In order to enhance*
2 *drug distribution security at the package level,*
3 *not later than 18 months after conducting a pub-*
4 *lic meeting on the system attributes necessary to*
5 *enable secure tracing of product at the package*
6 *level, including allowing for the use of*
7 *verification, inference, and aggregation, as nec-*
8 *essary, the Secretary shall issue a final guidance*
9 *document that outlines and makes recommenda-*
10 *tions with respect to the system attributes nec-*
11 *essary to enable secure tracing at the package*
12 *level as required under the requirements estab-*
13 *lished under subsection (h). Such guidance docu-*
14 *ment shall—*

15 “(i) *define the circumstances under*
16 *which the sectors within the pharmaceutical*
17 *distribution supply chain may, in the most*
18 *efficient manner practicable, infer the con-*
19 *tents of a case, pallet, tote, or other aggre-*
20 *gate of individual packages or containers of*
21 *product, from a product identifier associ-*
22 *ated with the case, pallet, tote, or other ag-*
23 *gregate, without opening each case, pallet,*
24 *tote, or other aggregate or otherwise individ-*
25 *ually scanning each package;*

1 “(ii) identify methods and processes to
 2 enhance secure tracing of product at the
 3 package level, such as secure processes to fa-
 4 cilitate the use of inference, enhanced
 5 verification activities, the use of aggregation
 6 and inference, processes that utilize the
 7 product identifiers to enhance tracing of
 8 product at the package level, including the
 9 standardized numerical identifier, or pack-
 10 age security features; and

11 “(iii) ensure the protection of confiden-
 12 tial commercial information and trade se-
 13 crets.

14 “(B) *PROCEDURE*.—In issuing the guidance
 15 under subparagraph (A), and in revising such
 16 guidance, if applicable, the Secretary shall follow
 17 the procedure set forth in paragraph (5).

18 “(4) *STANDARDS FOR INTEROPERABLE DATA EX-*
 19 *CHANGE*.—

20 “(A) *IN GENERAL*.—In order to enhance se-
 21 cure tracing of a product at the package level,
 22 the Secretary, not later than 18 months after
 23 conducting a public meeting on the interoperable
 24 standards necessary to enhance the security of
 25 the pharmaceutical distribution supply chain,

1 *shall update the guidance issued pursuant to*
2 *subsection (a)(2), as necessary and appropriate,*
3 *and finalize such guidance document so that the*
4 *guidance document—*

5 “(i) identifies and makes recommenda-
6 tions with respect to the standards nec-
7 essary for adoption in order to support the
8 secure, interoperable electronic data ex-
9 change among the pharmaceutical distribu-
10 tion supply chain that comply with a form
11 and format developed by a widely recog-
12 nized international standards development
13 organization;

14 “(ii) takes into consideration stand-
15 ards established pursuant to subsection
16 (a)(2) and section 505D;

17 “(iii) facilitates the creation of a uni-
18 form process or methodology for product
19 tracing; and

20 “(iv) ensures the protection of con-
21 fidential commercial information and trade
22 secrets.

23 “(B) *PROCEDURE.*—In issuing the guidance
24 under subparagraph (A), and in revising such

1 *guidance, if applicable, the Secretary shall follow*
2 *the procedure set forth in paragraph (5).*

3 “(5) *PROCEDURE.—In issuing or revising any*
4 *guidance issued pursuant to this subsection or sub-*
5 *section (h), except the initial guidance issued under*
6 *paragraph (2)(A), the Secretary shall—*

7 “(A) *publish a notice in the Federal Reg-*
8 *ister for a period not less than 30 days announc-*
9 *ing that the draft or revised draft guidance is*
10 *available;*

11 “(B) *post the draft guidance document on*
12 *the Internet Web site of the Food and Drug Ad-*
13 *ministration and make such draft guidance doc-*
14 *ument available in hard copy;*

15 “(C) *provide an opportunity for comment*
16 *and review and take into consideration any com-*
17 *ments received;*

18 “(D) *revise the draft guidance, as appro-*
19 *priate;*

20 “(E) *publish a notice in the Federal Reg-*
21 *ister for a period not less than 30 days announc-*
22 *ing that the final guidance or final revised guid-*
23 *ance is available;*

24 “(F) *post the final guidance document on*
25 *the Internet Website of the Food and Drug Ad-*

1 *ministration and make such final guidance doc-*
 2 *ument available in hard copy; and*

3 “(G) *provide for an effective date of not ear-*
 4 *lier than 1 year after such guidance becomes*
 5 *final.*

6 “(j) *PUBLIC MEETINGS.—*

7 “(1) *IN GENERAL.—The Secretary shall hold not*
 8 *less than 3 public meetings to enhance the safety and*
 9 *security of the pharmaceutical distribution supply*
 10 *chain and provide for comment. The Secretary may*
 11 *hold the first such public meeting not earlier than 1*
 12 *year after the date of enactment of the Drug Supply*
 13 *Chain Security Act. In carrying out the public meet-*
 14 *ings described in this paragraph, the Secretary*
 15 *shall—*

16 “(A) *prioritize topics necessary to inform*
 17 *the issuance of the guidance described in para-*
 18 *graphs (3) and (4) of subsection (i); and*

19 “(B) *take all measures reasonable and prac-*
 20 *ticable to ensure the protection of confidential*
 21 *commercial information and trade secrets.*

22 “(2) *CONTENT.—Each of the following topics*
 23 *shall be addressed in at least one of the public meet-*
 24 *ings described in paragraph (1):*

1 “(A) *An assessment of the steps taken under*
 2 *subsections (b) through (f) to build capacity for*
 3 *a unit-level system, including the impact of the*
 4 *requirements of such subsections on—*

5 “(i) *the ability of the health care sys-*
 6 *tem collectively to maintain patient access*
 7 *to medicines;*

8 “(ii) *the scalability of such require-*
 9 *ments, including as it relates to product*
 10 *lines; and*

11 “(iii) *the capability of different sectors*
 12 *and subsectors, including both large and*
 13 *small businesses, to affix and utilize the*
 14 *product identifier.*

15 “(B) *The system attributes necessary to sup-*
 16 *port the requirements set forth under subsection*
 17 *(h), including the standards necessary for adop-*
 18 *tion in order to support the secure, interoperable*
 19 *electronic data exchange among sectors within*
 20 *the pharmaceutical distribution supply chain.*

21 “(C) *Best practices in each of the different*
 22 *sectors within the pharmaceutical distribution*
 23 *supply chain to implement the requirements of*
 24 *this section.*

1 “(D) *The costs and benefits of the imple-*
2 *mentation of this section, including the impact*
3 *on each pharmaceutical distribution supply*
4 *chain sector and on public health.*

5 “(E) *Whether electronic tracing require-*
6 *ments, including tracing of product at the pack-*
7 *age level, are feasible, cost-effective, and needed*
8 *to protect the public health.*

9 “(F) *The systems and processes needed to*
10 *utilize the product identifiers to enhance tracing*
11 *of product at the package level, including allow-*
12 *ing for verification, aggregation, and inference,*
13 *as necessary.*

14 “(G) *The technical capabilities and legal*
15 *authorities, if any, needed to establish an inter-*
16 *operable, electronic system that provides for trac-*
17 *ing of product at the package level.*

18 “(H) *The impact that such additional re-*
19 *quirements would have on patient safety, the*
20 *drug supply, cost and regulatory burden, and*
21 *timely patient access to prescription drugs.*

22 “(I) *Other topics, as determined appro-*
23 *priate by the Secretary.*

24 “(k) *PILOT PROJECTS.—*

1 “(1) *IN GENERAL.*—*The Secretary shall establish*
2 *1 or more pilot projects, in coordination with author-*
3 *ized manufacturers, repackagers, wholesale distribu-*
4 *tors, third-party logistics providers, and dispensers, to*
5 *explore and evaluate methods to enhance the safety*
6 *and security of the pharmaceutical distribution sup-*
7 *ply chain. Such projects shall build upon efforts, in*
8 *existence as of the date of enactment of the Drug Sup-*
9 *ply Chain Security Act, to enhance the safety and se-*
10 *curity of the pharmaceutical distribution supply*
11 *chain, take into consideration any pilot projects con-*
12 *ducted prior to such date of enactment, and inform*
13 *the draft and final guidance under paragraphs (3)*
14 *and (4) of subsection (i).*

15 “(2) *CONTENT.*—

16 “(A) *IN GENERAL.*—*The Secretary shall en-*
17 *sure that the pilot projects under paragraph (1)*
18 *reflect the diversity of the pharmaceutical dis-*
19 *tribution supply chain and that the pilot*
20 *projects, when taken as a whole, include partici-*
21 *pants representative of every sector, including*
22 *both large and small businesses.*

23 “(B) *PROJECT DESIGN.*—*The pilot projects*
24 *under paragraph (1) shall be designed to—*

1 “(i) *utilize the product identifier for*
 2 *tracing of a product, which may include*
 3 *verification of the product identifier of a*
 4 *product, including the use of aggregation*
 5 *and inference;*

6 “(ii) *improve the technical capabilities*
 7 *of each sector and subsector to comply with*
 8 *systems and processes needed to utilize the*
 9 *product identifiers to enhance tracing of a*
 10 *product;*

11 “(iii) *identify system attributes that*
 12 *are necessary to implement the requirements*
 13 *established under this section; and*

14 “(iv) *complete other activities as deter-*
 15 *mined by the Secretary.*

16 “(l) *SUNSET.—The following requirements shall have*
 17 *no force or effect beginning on the date that is 10 years*
 18 *after the date of enactment of the Drug Supply Chain Secu-*
 19 *rity Act:*

20 “(1) *The provision and receipt of transaction*
 21 *history under this section.*

22 “(2) *The requirements set forth for returns under*
 23 *subsections (b)(4)(E), (c)(1)(B)(i), (d)(1)(C)(i), and*
 24 *(e)(4)(E).*

1 “(m) *RULE OF CONSTRUCTION.*—*The requirements set*
 2 *forth in subsections (h)(4), (j), and (k) shall not be con-*
 3 *strued as a condition, prohibition, or precedent for pre-*
 4 *cluding or delaying the provisions becoming effective pursu-*
 5 *ant to subsection (h).’’.*

6 **SEC. 204. NATIONAL LICENSURE STANDARDS FOR PRE-**
 7 **SCRIPTION DRUG WHOLESALE DISTRIBUTU-**
 8 **TORS.**

9 (a) *AMENDMENTS.*—

10 (1) *LICENSE REQUIREMENT.*—*Section 503(e) (21*
 11 *U.S.C. 353(e)) is amended by striking paragraphs*
 12 *(1), (2), and (3) and inserting the following:*

13 “(1) *LICENSE REQUIREMENT.*—*Subject to section*
 14 *583:*

15 “(A) *IN GENERAL.*—*No person may engage*
 16 *in wholesale distribution of a drug subject to*
 17 *subsection (b)(1) in any State unless such per-*
 18 *son—*

19 “(i)(I) *is licensed by the State from*
 20 *which the drug is distributed; or*

21 “(II) *if the State from which the drug*
 22 *distributed has not established a licensure*
 23 *requirement, is licensed by the Secretary;*
 24 *and*

1 “(ii) if the drug is distributed inter-
 2 state, is licensed by the State into which the
 3 drug is distributed if the State into which
 4 the drug is distributed requires the licensure
 5 of a person that distributes drugs into the
 6 State.

7 “(B) *LICENSE STANDARDS.*—Each Federal
 8 and State license described in subparagraph (A)
 9 shall meet the standards, terms, and conditions
 10 established by the Secretary under section 583.

11 “(2) *LICENSURE REPORTING AND DATABASE.*—

12 “(A) *LICENSURE REPORTING.*—Beginning 1
 13 year after the date of enactment of the Drug
 14 Supply Chain Security Act, any person who
 15 owns or operates an establishment that engages
 16 in wholesale distribution shall report to the Sec-
 17 retary, on an annual basis pursuant to a sched-
 18 ule determined by the Secretary—

19 “(i) each State by which the person is
 20 licensed and the appropriate identification
 21 number of each such license; and

22 “(ii) the name, address, and contact
 23 information of each facility at which, and
 24 all trade names under which, the person
 25 conducts business.

1 “(B) *DATABASE.*—*Not later than 1 year*
 2 *after the date of enactment of the Drug Supply*
 3 *Chain Security Act, the Secretary shall establish*
 4 *a database of licensed wholesale distributors.*
 5 *Such database shall—*

6 “(i) *identify each wholesale distributor*
 7 *by name, contact information, and each*
 8 *State where such wholesale distributor is*
 9 *appropriately licensed to engage in whole-*
 10 *sale distribution;*

11 “(ii) *be available to the public on the*
 12 *Internet Web site of the Food and Drug Ad-*
 13 *ministration; and*

14 “(iii) *be regularly updated on a sched-*
 15 *ule determined by the Secretary.*

16 “(3) *COSTS.*—

17 “(A) *AUTHORIZED LICENSURE FEES OF*
 18 *SECRETARY.*—*If a State does not establish a li-*
 19 *censing program for persons engaged in the*
 20 *wholesale distribution of a drug subject to sub-*
 21 *section (b), the Secretary shall license a person*
 22 *engaged in wholesale distribution located in such*
 23 *State and may collect a reasonable fee in such*
 24 *amount necessary to reimburse the Secretary for*
 25 *costs associated with establishing and admin-*

1 *istering the licensure program and conducting*
 2 *periodic inspections under this section. The Sec-*
 3 *retary shall adjust fee rates as needed on an an-*
 4 *nual basis to generate only the amount of rev-*
 5 *enue needed to perform this service. Fees author-*
 6 *ized under this paragraph shall be collected and*
 7 *available for obligation only to the extent and in*
 8 *the amount provided in advance in appropria-*
 9 *tions Acts. Such fees are authorized to remain*
 10 *available until expended.*

11 *“(B) STATE LICENSING FEES.—Nothing in*
 12 *this Act shall prohibit States from collecting fees*
 13 *from wholesale distributors in connection with*
 14 *State licensing of such distributors.”.*

15 *(2) WHOLESALE DISTRIBUTION.—Section 503(e)*
 16 *(21 U.S.C. 353(e)), as amended by paragraph (1), is*
 17 *further amended by adding at the end the following:*

18 *“(4) For the purposes of this subsection and sub-*
 19 *section (d), the term ‘wholesale distribution’ means*
 20 *the distribution of a drug subject to subsection (b) to*
 21 *a person other than a consumer or patient, or receipt*
 22 *of a drug subject to subsection (b) by a person other*
 23 *than the consumer or patient, but does not include—*

24 *“(A) intracompany distribution of any*
 25 *drug between members of an affiliated group (as*

1 *defined in section 1504(a) of the Internal Rev-*
2 *enue Code of 1986) or within a manufacturer;*

3 *“(B) the distribution of a drug, or an offer*
4 *to distribute a drug among hospitals or other*
5 *health care entities which are under common*
6 *control;*

7 *“(C) the distribution of a drug or an offer*
8 *to distribute a drug for emergency medical rea-*
9 *sons, including a public health emergency dec-*
10 *laration pursuant to section 319 of the Public*
11 *Health Service Act, except that, for purposes of*
12 *this paragraph, a drug shortage not caused by a*
13 *public health emergency shall not constitute an*
14 *emergency medical reason;*

15 *“(D) the dispensing of a drug pursuant to*
16 *a valid prescription executed in accordance with*
17 *section 503(b)(1);*

18 *“(E) the distribution of minimal quantities*
19 *of drug by a licensed retail pharmacy to a li-*
20 *censed practitioner for office use;*

21 *“(F) the distribution of a drug or an offer*
22 *to distribute a drug by a charitable organization*
23 *to a nonprofit affiliate of the organization to the*
24 *extent otherwise permitted by law;*

1 “(G) the purchase or other acquisition by a
2 dispenser, hospital, or other health care entity of
3 a drug for use by such dispenser, hospital, or
4 other health care entity;

5 “(H) the distribution of a drug by the man-
6 ufacturer of such drug;

7 “(I) the receipt or transfer of a drug by an
8 authorized third-party logistics provider pro-
9 vided that such third-party logistics provider
10 does not take ownership of the drug;

11 “(J) a common carrier that transports a
12 drug, provided that the common carrier does not
13 take ownership of the drug;

14 “(K) the distribution of a drug, or an offer
15 to distribute a drug by an authorized repackager
16 that has taken ownership or possession of the
17 drug and repacks it in accordance with section
18 582(e);

19 “(L) salable drug returns when conducted
20 by a dispenser;

21 “(M) the distribution of a medical conven-
22 ience kit which is a collection of finished medical
23 devices or a collection of drug or biologic prod-
24 ucts assembled in kit form strictly for the con-
25 venience of the purchaser or user if—

1 “(i) the medical convenience kit is as-
2 sembled in an establishment that is reg-
3 istered with the Food and Drug Adminis-
4 tration as a device manufacturer in accord-
5 ance with section 510(b)(2);

6 “(ii) the person who manufacturers the
7 medical convenience kit purchased the fin-
8 ished drug or biologic product contained in
9 the medical convenience kit directly from
10 the pharmaceutical manufacturer or from a
11 wholesale distributor that purchased the
12 product directly from the pharmaceutical
13 manufacturer;

14 “(iii) the person who manufacturers a
15 medical convenience kit does not alter the
16 primary container or label of the product as
17 purchased from the manufacturer or whole-
18 sale distributor;

19 “(iv) the medical convenience kit does
20 not contain a controlled substance that ap-
21 pears in a schedule contained in the Com-
22 prehensive Drug Abuse Prevention and Con-
23 trol Act of 1970 (21 U.S.C. 801, et seq); and

24 “(v) the products contained in the
25 medical convenience kit are—

1 “(I) intravenous solutions in-
2 tended for the replenishment of fluids
3 and electrolytes;

4 “(II) drugs intended to maintain
5 the equilibrium of water and minerals
6 in the body;

7 “(III) drugs intended for irriga-
8 tion or reconstitution;

9 “(IV) anesthetics;

10 “(V) anticoagulants;

11 “(VI) vasopressors; or

12 “(VII) sympathicomimetics;

13 “(N) the distribution of an intravenous
14 drug that, by its formulation, is intended for the
15 replenishment of fluids and electrolytes (such as
16 sodium, chloride, and potassium) or calories
17 (such as dextrose and amino acids);

18 “(O) the distribution of an intravenous
19 drug used to maintain the equilibrium of water
20 and minerals in the body, such as dialysis solu-
21 tions;

22 “(P) the distribution of a drug that is in-
23 tended for irrigation or reconstitution, or sterile
24 water, whether intended for such purposes or for
25 injection;

1 “(Q) the distribution of medical gas, as de-
2 fined in section 575;

3 “(R) facilitating the distribution of a prod-
4 uct by providing solely administrative services,
5 including processing of orders and payments; or

6 “(S) the transfer of a product by a hospital
7 or other health care entity to a repackager reg-
8 istered under section 510 for the purpose of re-
9 packaging the drug for use by that hospital, or
10 other health care entity and other health care en-
11 tities that are under common control, if owner-
12 ship of the drug remains with the hospital or
13 other health care entity at all times.”.

14 (3) *THIRD-PARTY LOGISTICS PROVIDERS.*—Sec-
15 tion 503(e)(21 U.S.C. 353(e)), as amended by para-
16 graph (2), is further amended by adding at the end
17 the following:

18 “(5) *THIRD-PARTY LOGISTICS PROVIDERS.*—Not-
19 withstanding paragraphs (1) through (4), each entity
20 that meets the definition of a third-party logistics
21 provider under section 581(21) shall obtain a license
22 as a third-party logistics provider as described in sec-
23 tion 584(a) and is not required to obtain a license as
24 a wholesale distributor if the entity never assumes an
25 ownership interest in the product it handles.”.

1 (4) *LICENSURE STANDARDS.*—Subchapter H of
 2 chapter V, as added by section 202, is amended by
 3 adding at the end the following:

4 **“SEC. 583. NATIONAL LICENSURE STANDARDS FOR PRE-**
 5 **SCRIPTION DRUG WHOLESALE DISTRIBUTU-**
 6 **TORS.**

7 “(a) *IN GENERAL.*—The Secretary shall, not later than
 8 2 years after the date of enactment of the Drug Supply
 9 Chain Security Act, establish by regulation minimum
 10 standards, terms, and conditions for the licensing of persons
 11 under section 503(e)(1) (as amended by the Drug Supply
 12 Chain Security Act), including the revocation, reissuance,
 13 and renewal of such license.

14 “(b) *CONTENT.*—The standards established under sub-
 15 section (a) shall apply to all State and Federal licenses de-
 16 scribed under section 503(e)(1) (as amended by the Drug
 17 Supply Chain Security Act) and shall prescribe minimum
 18 requirements for the following:

19 “(1) *The storage and handling of such drugs, in-*
 20 *cluding facility requirements.*

21 “(2) *The establishment and maintenance of*
 22 *records of the distributions of such drugs.*

23 “(3) *The furnishing of a bond or other equivalent*
 24 *means of security, as follows:*

1 “(A)(i) *For the issuance or renewal of a*
2 *wholesale distributor license, an applicant that*
3 *is not a government owned and operated whole-*
4 *sale distributor shall submit a surety bond of*
5 *\$100,000 or other equivalent means of security*
6 *acceptable to the State.*

7 “(ii) *For purposes of clause (i), the State or*
8 *other applicable authority may accept a surety*
9 *bond in the amount of \$25,000 if the annual*
10 *gross receipts of the previous tax year for the*
11 *wholesaler is \$10,000,000 or less.*

12 “(B) *If a wholesale distributor can provide*
13 *evidence that it possesses the required bond in a*
14 *State, the requirement for a bond in another*
15 *State shall be waived.*

16 “(4) *Mandatory background checks and*
17 *fingerprinting of facility managers or designated rep-*
18 *resentatives.*

19 “(5) *The establishment and implementation of*
20 *qualifications for key personnel.*

21 “(6) *The mandatory physical inspection of any*
22 *facility to be used in wholesale distribution within a*
23 *reasonable time frame from the initial application of*
24 *the facility and to be conducted by the licensing au-*
25 *thority or by the State, consistent with subsection (c).*

1 “(7) *In accordance with subsection (d), the pro-*
2 *hibition of certain persons from receiving or main-*
3 *taining licensure for wholesale distribution.*

4 “(c) *INSPECTIONS.—To satisfy the inspection require-*
5 *ment under subsection (b)(6), the Federal or State licensing*
6 *authority may conduct the inspection or may accept an in-*
7 *spection by the State in which the facility is located, or*
8 *by a third-party accreditation or inspection service ap-*
9 *proved by the Secretary or the State licensing such whole-*
10 *sale distributor.*

11 “(d) *PROHIBITED PERSONS.—The standards estab-*
12 *lished under subsection (a) shall include requirements to*
13 *prohibit a person from receiving or maintaining licensure*
14 *for wholesale distribution if the person—*

15 “(1) *has been convicted of any felony for conduct*
16 *relating to wholesale distribution, any felony viola-*
17 *tion of subsection (i) or (k) of section 301, or any fel-*
18 *ony violation of section 1365 of title 18, United*
19 *States Code, relating to product tampering; or*

20 “(2) *has engaged in a pattern of violating the re-*
21 *quirements of this section, or State requirements for*
22 *licensure, that presents a threat of serious adverse*
23 *health consequences or death to humans.*

1 “(e) *REQUIREMENTS.*—*The Secretary, in promul-*
 2 *gating any regulation pursuant to this section, shall, not-*
 3 *withstanding section 553 of title 5, United States Code—*

4 “(1) *issue a notice of proposed rulemaking that*
 5 *includes a copy of the proposed regulation;*

6 “(2) *provide a period of not less than 60 days*
 7 *for comments on the proposed regulation; and*

8 “(3) *provide that the final regulation take effect*
 9 *on the date that is 2 years after the date such final*
 10 *regulation is published.”.*

11 “(b) *AUTHORIZED DISTRIBUTORS OF RECORD.*—*Sec-*
 12 *tion 503(d) (21 U.S.C. 353(d)) is amended by adding at*
 13 *the end the following:*

14 “(4) *In this subsection, the term ‘authorized dis-*
 15 *tributors of record’ means those distributors with*
 16 *whom a manufacturer has established an ongoing re-*
 17 *lationship to distribute such manufacturer’s prod-*
 18 *ucts.”.*

19 “(c) *EFFECTIVE DATE.*—*The amendments made by sub-*
 20 *sections (a) and (b) shall take effect on the day that is 1*
 21 *year after the date of enactment of this Act.*

1 **SEC. 205. NATIONAL LICENSURE STANDARDS FOR THIRD-**
 2 **PARTY LOGISTICS PROVIDERS; UNIFORM NA-**
 3 **TIONAL POLICY.**

4 *Subchapter H of chapter V, as amended by section 204,*
 5 *is further amended by adding at the end the following:*

6 **“SEC. 584. NATIONAL LICENSURE STANDARDS FOR THIRD-**
 7 **PARTY LOGISTICS PROVIDERS.**

8 *“(a) LICENSE REQUIREMENTS.—No third-party logis-*
 9 *tics provider in any State may conduct activities in any*
 10 *State unless each facility of such third-party logistics pro-*
 11 *vider—*

12 *“(1)(A) is licensed by the State from which the*
 13 *drug is distributed by the third-party logistics pro-*
 14 *vider, in accordance with the regulations promulgated*
 15 *under subsection (d); or*

16 *“(B) if the State from which the drug distributed*
 17 *by the third-party logistics provider has not estab-*
 18 *lished a licensure requirement, is licensed by the Sec-*
 19 *retary, in accordance with the regulations promul-*
 20 *gated under subsection (d); and*

21 *“(2) if the drug is distributed interstate, is li-*
 22 *censed by the State into which the drug is distributed*
 23 *by the third-party logistics provider if such State li-*
 24 *censes third-party logistics providers that distribute*
 25 *drugs into the State and the third-party logistics pro-*

1 *vider is not licensed by the Secretary as described in*
 2 *paragraph (1)(B).*

3 *“(b) LICENSURE REPORTING.—Beginning 1 year after*
 4 *the date of enactment of the Drug Supply Chain Security*
 5 *Act, a facility of a third-party logistics provider shall re-*
 6 *port to the Secretary, on an annual basis pursuant to a*
 7 *schedule determined by the Secretary—*

8 *“(1) the State by which the facility is licensed*
 9 *and the appropriate identification number of such li-*
 10 *cence; and*

11 *“(2) the name and address of the facility, and all*
 12 *trade names under which, such facility conducts busi-*
 13 *ness.*

14 *“(c) COSTS.—*

15 *“(1) AUTHORIZED LICENSURE FEES OF SEC-*
 16 *RETARY.—If a State does not establish a licensing*
 17 *program for a third-party logistics provider, the Sec-*
 18 *retary shall license the third-party logistics provider*
 19 *located in such State and may collect a reasonable fee*
 20 *in such amount necessary to reimburse the Secretary*
 21 *for costs associated with establishing and admin-*
 22 *istering the licensure program and conducting peri-*
 23 *odic inspections under this section. The Secretary*
 24 *shall adjust fee rates as needed on an annual basis to*
 25 *generate only the amount of revenue needed to per-*

1 *form this service. Fees authorized under this para-*
 2 *graph shall be collected and available for obligation*
 3 *only to the extent and in the amount provided in ad-*
 4 *vance in appropriations Acts. Such fees are author-*
 5 *ized to remain available until expended.*

6 *“(2) STATE LICENSING FEES.—*

7 *“(A) STATE ESTABLISHED PROGRAM.—*
 8 *Nothing in this Act shall prohibit a State that*
 9 *has established a program to license a third-*
 10 *party logistics provider from collecting fees from*
 11 *a third-party logistics provider for such a li-*
 12 *cense.*

13 *“(B) NO STATE ESTABLISHED PROGRAM.—*
 14 *A State that does not establish a program to li-*
 15 *cense a third-party logistics provider in accord-*
 16 *ance with this section shall be prohibited from*
 17 *collecting a State licensing fee from a third-*
 18 *party logistics provider.*

19 *“(d) LICENSE REGULATIONS.—*

20 *“(1) IN GENERAL.—Not later than 2 years after*
 21 *the date of enactment of the Drug Supply Chain Se-*
 22 *curity Act, the Secretary shall issue regulations re-*
 23 *garding the minimum issuance and eligibility re-*
 24 *quirements for licensing under subsection (a), includ-*

1 *ing the revocation and reissuance of such license, to*
2 *third-party logistics providers under this section.*

3 *“(2) CONTENT.—Such regulations shall—*

4 *“(A) establish a process by which a third-*
5 *party accreditation program approved by the*
6 *Secretary shall, upon request by a third-party*
7 *logistics provider, issue a license to each third-*
8 *party logistics provider that meets the minimum*
9 *requirements set forth in this section;*

10 *“(B) establish a process by which the Sec-*
11 *retary shall issue a license to each third-party*
12 *logistics provider that meets the minimum re-*
13 *quirements set forth in this section if the Sec-*
14 *retary is not able to approve a third-party ac-*
15 *creditation program because no such program*
16 *meets the Secretary’s requirements necessary for*
17 *approval of such a third-party accreditation pro-*
18 *gram;*

19 *“(C) require that the entity complies with*
20 *storage practices, as determined by the Secretary*
21 *for such facility, including—*

22 *“(i) maintaining access to warehouse*
23 *space of suitable size to facilitate safe oper-*
24 *ations, including a suitable area to quar-*
25 *antine suspect product;*

1 “(ii) maintaining adequate security;

2 *and*

3 “(iii) having written policies and pro-

4 *cedures to—*

5 “(I) address receipt, security, stor-

6 *age, inventory, shipment, and distribu-*

7 *tion of a product;*

8 “(II) identify, record, and report

9 *confirmed losses or thefts in the United*

10 *States;*

11 “(III) correct errors and inac-

12 *curacies in inventories;*

13 “(IV) provide support for manu-

14 *facturer recalls;*

15 “(V) prepare for, protect against,

16 *and address any reasonably foreseeable*

17 *crisis that affects security or operation*

18 *at the facility, such as a strike, fire, or*

19 *flood;*

20 “(VI) ensure that any expired

21 *product is segregated from other prod-*

22 *ucts and returned to the manufacturer*

23 *or re-packager or destroyed;*

24 “(VII) maintain the capability to

25 *trace the receipt and outbound dis-*

1 *tribution of a product, and supplies*
2 *and records of inventory; and*

3 *“(VIII) quarantine or destroy a*
4 *suspect product if directed to do so by*
5 *the respective manufacturer, wholesale*
6 *distributor, dispenser or an authorized*
7 *government agency;*

8 *“(D) provide for periodic inspection by the*
9 *licensing authority, as determined by the Sec-*
10 *retary, of such facility warehouse space to ensure*
11 *compliance with this section;*

12 *“(E) prohibit a facility from having as a*
13 *manager or designated representative anyone*
14 *convicted of any felony violation of subsection (i)*
15 *or (k) of section 301 or any violation of section*
16 *1365 of title 18, United States Code relating to*
17 *product tampering;*

18 *“(F) provide for mandatory background*
19 *checks of a facility manager or a designated rep-*
20 *resentative of such manager; and*

21 *“(G) require a third-party logistics provider*
22 *to provide the Secretary, upon a request by the*
23 *Secretary, a list of all product manufacturers,*
24 *wholesale distributors, and dispensers for whom*

1 *the third-party logistics provider provides serv-*
 2 *ices at such facility.*

3 “(3) *PROCEDURE.—In promulgating the regula-*
 4 *tions under this subsection, the Secretary shall, not-*
 5 *withstanding section 553 of title 5, United States*
 6 *Code—*

7 “(A) *issue a notice of proposed rulemaking*
 8 *that includes a copy of the proposed regulation;*

9 “(B) *provide a period of not less than 60*
 10 *days for comments on the proposed regulation;*
 11 *and*

12 “(C) *provide that the final regulation takes*
 13 *effect upon the expiration of 1 year after the date*
 14 *that such final regulation is issued.*

15 “(e) *RENEWAL OF LICENSES.—The Secretary shall de-*
 16 *velop procedures for license renewal. Licenses issued under*
 17 *this section shall expire on the date that is 3 years after*
 18 *issuance of the license. Such an expired license may be re-*
 19 *newed for additional 3-year periods according to procedures*
 20 *developed by the Secretary.*

21 **“SEC. 585. UNIFORM NATIONAL POLICY.**

22 “(a) *PRODUCT TRACING AND OTHER REQUIRE-*
 23 *MENTS.—Beginning on the date of enactment of the Drug*
 24 *Supply Chain Security Act, no State or political subdivi-*
 25 *sion of a State may establish or continue in effect any re-*

1 *quirements for tracing products through the distribution*
 2 *system (including any requirements with respect to state-*
 3 *ments of distribution history, transaction history, trans-*
 4 *action information, or transaction statement of a product*
 5 *as such product changes ownership in the supply chain, or*
 6 *verification, investigation, disposition, notification, or*
 7 *record-keeping relating to such systems, including paper or*
 8 *electronic pedigree systems or for tracking and tracing*
 9 *drugs throughout the distribution system) which are incon-*
 10 *sistent with, more stringent than, or in addition to, any*
 11 *requirements applicable under section 503(e) (as amended*
 12 *by such Act) or this subchapter (or regulations issued there-*
 13 *under), or which are inconsistent with—*

14 “(1) *any waiver, exception, or exemption pursu-*
 15 *ant to section 581 or 582; or*

16 “(2) *any restrictions specified in section 582.*

17 “(b) *DISTRIBUTION AND LICENSING STANDARDS.—*

18 “(1) *IN GENERAL.—Beginning on the date of en-*
 19 *actment of the Drug Supply Chain Security Act, no*
 20 *State or political subdivision of a State may establish*
 21 *or continue any standards, requirements, or regula-*
 22 *tions with respect to wholesale prescription drug dis-*
 23 *tributor or third-party logistics provider licensure*
 24 *that are less stringent than the standards and re-*
 25 *quirements applicable under section 503(e) (as*

1 *amended by such Act), in the case of a wholesale dis-*
 2 *tributor, or section 584, in the case of a third-party*
 3 *logistics provider.*

4 “(2) *STATE REGULATION OF THIRD-PARTY LO-*
 5 *GISTICS PROVIDERS.—No State shall regulate third-*
 6 *party logistics providers as wholesale distributors.*

7 “(3) *ADMINISTRATION FEES.—Notwithstanding*
 8 *paragraph (1), a State may administer fee collections*
 9 *for effectuating the wholesale drug distributor and*
 10 *third-party logistics provider licensure requirements*
 11 *under sections 503(e) (as amended by the Drug Sup-*
 12 *ply Chain Security Act), 583, and 584.*

13 “(4) *ENFORCEMENT, SUSPENSION, AND REVOCA-*
 14 *TION OF LICENSES.—Notwithstanding paragraph (1),*
 15 *a State—*

16 “(A) *may take administrative action, in-*
 17 *cluding fines, to enforce a licensure requirement*
 18 *promulgated by the State in accordance with sec-*
 19 *tion 503(e) (as amended by the Drug Supply*
 20 *Chain Security Act) or this subchapter;*

21 “(B) *may provide for the suspension or rev-*
 22 *ocation of licenses issued by the State for viola-*
 23 *tions of the laws of such State;*

24 “(C) *upon conviction of violations of Fed-*
 25 *eral, State, or local drug laws or regulations,*

1 may provide for fines, imprisonment, or civil
2 penalties; and

3 “(D) may regulate activities of licensed en-
4 tities in a manner that is consistent with prod-
5 uct tracing requirements under section 582.

6 “(c) *EXCEPTION.*—Nothing in subsection (a) or (b)
7 shall be construed to preempt State requirements related to
8 the distribution of prescription drugs if such requirements
9 are not related to product tracing as described in subsection
10 (a), including any requirements applicable under section
11 503(e) (as amended by the Drug Supply Chain Security
12 Act) or this subchapter (or regulations issued thereunder).”.

13 **SEC. 206. PENALTIES.**

14 (a) *PROHIBITED ACT.*—Section 301(t)(21 U.S.C.
15 331(t)), is amended—

16 (1) by striking “or” after “the requirements of
17 section 503(d),”; and

18 (2) by inserting “, failure to comply with the re-
19 quirements under section 582, the failure to comply
20 with the requirements under section 584, as applica-
21 ble,” after “in violation of section 503(e)”.

22 (b) *MISBRANDING.*—Section 502 (21 U.S.C. 352), as
23 amended by section 103, is further amended by adding at
24 the end the following:

1 “(ee) If it is a drug and it fails to bear the product
2 identifier as required by section 582.”.

3 **SEC. 207. CONFORMING AMENDMENT.**

4 (a) *IN GENERAL.*—Section 303(b)(1)(D)(21 U.S.C.
5 333(b)(1)(D)) is amended by striking “503(e)(2)(A)” and
6 inserting “503(e)(1)”.

7 (b) *EFFECTIVE DATE.*—The amendment made by sub-
8 section (a) shall take effect on the day that is 1 year after
9 the date of enactment of this Act.

10 **SEC. 208. SAVINGS CLAUSE.**

11 *Except as provided in the amendments made by para-*
12 *graphs (1), (2), and (3) of section 204(a) and by section*
13 *206(a), nothing in this title (including the amendments*
14 *made by this title) shall be construed as altering any au-*
15 *thority of the Secretary of Health and Human Services with*
16 *respect to a drug subject to section 503(b)(1) of the Federal*
17 *Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)) under*
18 *any other provision of such Act or the Public Health Service*
19 *Act (42 U.S.C. 201 et seq.).*

Amend the title so as to read: “A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to compounding drugs and the pharmaceutical distribution supply chain.”.

Calendar No. 89

113TH CONGRESS
1ST Session

S. 959

A BILL

To amend the Federal Food, Drug, and Cosmetic
Act with respect to compounding drugs.

JUNE 19, 2013

Reported with an amendment and an amendment to the
title