

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—113th Cong., 1st Sess.

S. 959

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pharmaceutical Qual-
5 ity, Security, and Accountability Act”.

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

7 (a) REFERENCES IN ACT.—Except as otherwise spec-
8 ified, amendments made by this Act to a section or other
9 provision of law are amendments to such section or other
10 provision of the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 301 et seq.).

1 (b) TABLE OF CONTENTS.—The table of contents of
 2 this 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 distributors.
 Sec. 205. National licensure standards for third-party logistics providers; uniform national policy.
 Sec. 206. Penalties.
 Sec. 207. Conforming amendment.
 Sec. 208. Savings clause.

3 TITLE I—HUMAN DRUG 4 COMPOUNDING

5 SEC. 101. SHORT TITLE.

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

8 SEC. 102. REGULATION OF HUMAN DRUG COMPOUNDING.

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

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

4 **“SEC. 503A. HUMAN DRUG COMPOUNDING.**

5 “(a) SCOPE.—

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

8 “(A) include—

9 “(i) the combining, admixing, mixing,
10 diluting, reconstituting, or otherwise alter-
11 ing of a marketed drug;

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

14 “(iii) repackaging; and

15 “(B) exclude mixing, reconstituting, or
16 other such acts with respect to a marketed drug
17 that are limited to and performed in accordance
18 with specific directions for such acts contained
19 in approved labeling provided by a drug’s man-
20 ufacturer, when performed based upon a pre-
21 scription for an identified individual patient or
22 when such mixing, reconstituting, or other such
23 acts with respect to a marketed drug are per-
24 formed within a health care entity by a practi-
25 tioner, or other licensed individual under the

1 supervision or direction of such practitioner, for
2 administration within the same day within such
3 health care entity.

4 “(2) ADMINISTRATION AND DISPENSING NOT A
5 SALE.—In this section, the terms ‘sale’, ‘sell’, and
6 ‘resale’ do not include—

7 “(A) circumstances in which drug is ad-
8 ministered to a patient or provided to a patient
9 who has been instructed to self-administer the
10 drug;

11 “(B) the dispensing of a drug by—

12 “(i) the entity that compounded the
13 drug pursuant to a prescription executed
14 in accordance with section 503(b)(1); or

15 “(ii) a hospital or health system, as
16 defined in subsection (b)(11)(B), to a pa-
17 tient of such hospital or health system; or

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

20 “(3) EXCLUSIONS.—For purposes of this sec-
21 tion, the activities described in paragraph (1) shall
22 not be considered ‘compounding’ if such activities
23 are conducted in whole or in part with respect to—

24 “(A) blood or blood components for trans-
25 fusion;

1 “(B) medical gases, as defined in section
2 575; or

3 “(C) human cells, tissues, or cellular or tis-
4 sue-based products.

5 “(4) ANIMAL DRUGS FOR HUMAN USE.—Noth-
6 ing in this section shall be construed to permit the
7 use of animal drugs in compounding a drug for
8 human use.

9 “(b) DEFINITIONS.—In this section:

10 “(1) COMPOUNDING MANUFACTURER.—

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

14 “(i) that compounds any sterile drug
15 without receiving a prescription for an
16 identified individual patient for such sterile
17 drug prior to beginning compounding, and
18 distributes or offers to sell such com-
19 pounded sterile drug in interstate com-
20 merce; or

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

24 “(B) EXCLUSIONS.—

1 “(i) EXCLUDED ACTIVITIES.—Not-
2 withstanding subparagraph (A)(ii), a facil-
3 ity 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 “(iii) INFUSION PHARMACY.—The
18 term ‘compounding manufacturer’ shall
19 not include an infusion pharmacy, unless
20 the infusion pharmacy compounds as de-
21 scribed in subparagraph (A)(i).

22 “(C) EFFECT.—Nothing in this paragraph
23 requires a compounding manufacturer to re-
24 ceive a prescription before or after
25 compounding or pooling a drug. Compounding

1 for which a prescription is required under this
2 section may not be performed by a
3 compounding manufacturer.

4 “(2) COMPOUNDING NUCLEAR PHARMACY.—
5 The term ‘compounding nuclear pharmacy’ means
6 an entity that—

7 “(A) is a State-licensed pharmacy or a
8 Federal facility;

9 “(B) holds a license currently in effect
10 from the Nuclear Regulatory Commission or
11 from a State pursuant to an agreement with
12 such commission under section 274 of the
13 Atomic Energy Act of 1954;

14 “(C) does not compound non-radioactive
15 drugs that would cause the entity to be a
16 compounding manufacturer described in para-
17 graph (1)(A); and

18 “(D) meets the requirements of this sec-
19 tion applicable to drugs compounded by tradi-
20 tional compounders with respect to any non-
21 radioactive drug compounding conducted at
22 such pharmacy or facility.

23 “(3) COPY.—The term ‘copy’ means an iden-
24 tical or nearly identical version of a drug.

1 “(4) INFUSION PHARMACY.—The term ‘infusion
2 pharmacy’ means an entity that—

3 “(A) is a State-licensed pharmacy or a
4 Federal facility;

5 “(B) is accredited to provide infusion phar-
6 macy services by a national accreditation body
7 approved by the Secretary for purposes of this
8 section;

9 “(C) provides infusion therapy, pursuant
10 to a prescription for an identified individual pa-
11 tient received prior to beginning compounding
12 and pooling, for administration in the patient’s
13 home, or in a health care entity wherein infu-
14 sion products are administered directly to pa-
15 tients; and

16 “(D) does not compound drugs, other than
17 as provided for in subparagraph (C), that would
18 cause the entity to be a compounding manufac-
19 turer described in paragraph (1)(A).

20 “(5) PRACTITIONER.—The term ‘practitioner’
21 includes a physician or any other person that is au-
22 thorized to prescribe medication under State law.

23 “(6) PRACTITIONER ORDER.—

1 “(A) IN GENERAL.—The term ‘practitioner
2 order’ means an order for a compounded pre-
3 scription drug—

4 “(i) issued by an identified practi-
5 tioner—

6 “(I) who has determined that a
7 compounded drug is necessary to meet
8 the clinical need of the patients of
9 such practitioner; and

10 “(II) for use by such practitioner
11 in administering the drug to such
12 practitioner’s patients in a health care
13 setting (referred to in this section as
14 ‘office use’); and

15 “(ii) that includes a statement speci-
16 fying that such drug may be compounded.

17 “(B) EXCLUSIONS.—The term ‘practi-
18 tioner order’ does not include—

19 “(i) a purchase order, through which
20 hospitals or health systems order drugs for
21 use in a healthcare setting; or

22 “(ii) any other type of order pursuant
23 to which a drug is dispensed to a patient
24 for use or administration by the patient in
25 the patient’s home.

1 “(7) RADIOACTIVE DRUG.—The term ‘radio-
2 active drug’—

3 “(A) means any substance defined as a
4 drug in section 201(g)(1) that exhibits sponta-
5 neous disintegration of unstable nuclei with the
6 emission of nuclear particles or photons and in-
7 cludes any nonradioactive reagent kit or nuclide
8 regenerator which is intended to be used in the
9 preparation of any such substance but does not
10 include drugs such as carbon-containing com-
11 pounds or potassium-containing salts which
12 contain trace quantities of naturally occurring
13 radionuclides; and

14 “(B) includes a ‘radioactive biological
15 product,’ which means a biological product
16 which is labeled with a radionuclide or intended
17 solely to be labeled with a radionuclide.

18 “(8) REPACKAGE OR REPACKAGING.—The term
19 ‘repackage’ or ‘repackaging’—

20 “(A) means taking a drug approved under
21 section 505 or licensed under section 351 of the
22 Public Health Service Act from the container in
23 which it is distributed by the original manufac-
24 turer and placing it in a different container of
25 the same or smaller size without further manip-

1 ulating the drug (such as by diluting it or mix-
2 ing it with another, different drug or drugs);
3 and

4 “(B) does not include removing the drug
5 from its original container for immediate ad-
6 ministration to an identified individual patient,
7 such as withdrawing a drug into a syringe for
8 immediate injection or removing the drug from
9 its original container within a health care entity
10 by a practitioner, or other licensed individual
11 under the supervision or direction of such prac-
12 titioner, for administration within the same day
13 within such health care entity.

14 “(9) STERILE DRUG.—The term ‘sterile drug’
15 means a drug that is—

16 “(A) intended for parenteral administra-
17 tion;

18 “(B) an ophthalmic or oral inhalation drug
19 in aqueous format; or

20 “(C) required to be sterile under Federal
21 or State law.

22 “(10) STERILE POOLING.—The term ‘sterile
23 pooling’—

24 “(A) means taking a single sterile drug ap-
25 proved under section 505 from the container in

1 which it is distributed by the original manufac-
2 turer and combining it with the same sterile
3 drug from one or more other containers without
4 or before further manipulating the product
5 (such as by diluting it or mixing it with an-
6 other, different drug or drugs);

7 “(B) does not include combining the drug
8 from 2 or more separate containers of the same
9 drug to prepare a single dose for administration
10 to an individual patient when a single container
11 of the drug is not sufficient; and

12 “(C) does not include combining a single
13 drug from 2 or more separate containers of
14 component products of a parenteral nutrition
15 product, for use the same day within the health
16 care entity that performs such pooling.

17 “(11) TRADITIONAL COMPOUNDER.—

18 “(A) IN GENERAL.—The term ‘traditional
19 compounder’ means a facility that does not
20 meet the definition of a compounding manufac-
21 turer under paragraph (1) and wherein each
22 drug compounded in that facility is com-
23 pounded—

24 “(i) by—

1 “(I) a licensed pharmacist, or a
2 pharmacy technician working under
3 the supervision of such pharmacist,
4 where permitted by State law, in a
5 State-licensed pharmacy or a licensed
6 Federal facility; or

7 “(II) a licensed physician or
8 other individual working under the su-
9 pervision or direction of such physi-
10 cian, where permitted by State law;
11 and

12 “(ii)(I) upon receipt of a prescription
13 for an identified individual patient;

14 “(II) before receipt of a prescription
15 for an identified individual patient, only in
16 limited quantities based on a history of the
17 licensed pharmacist or licensed physician
18 receiving a prescription for the
19 compounding of the drug, which orders
20 have been generated solely within an estab-
21 lished relationship between the licensed
22 pharmacist or licensed physician and—

23 “(aa) such individual patient for
24 whom the prescription will be pro-
25 vided; or

1 “(bb) the licensed physician or
2 other licensed practitioner who will
3 write such prescription; or

4 “(III) for administration within the
5 health care entity where the drug was com-
6 pounded within the same day, if the drug
7 is compounded by an individual as de-
8 scribed in clause (i)(II).

9 “(B) EXCEPTION REGARDING HOSPITALS
10 AND HEALTH SYSTEMS.—

11 “(i) HOSPITALS AND HEALTH SYS-
12 TEMS.—A pharmacy within a hospital or
13 health system shall be considered a tradi-
14 tional compounder and shall be subject to
15 the requirements of traditional
16 compounders under this section if such
17 pharmacy meets the definition under sub-
18 paragraph (A)(i) (without regard to clause
19 (ii)) and if, with respect to a drug com-
20 pounded or pooled by such pharmacy, the
21 only activity conducted by the pharmacy is
22 to dispense or administer such drug (which
23 may include interstate shipment) solely to
24 a patient of such hospital or health system.

1 “(ii) HEALTH SYSTEM DEFINED.—In
2 this subparagraph, the term ‘health sys-
3 tem’—

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

6 “(aa) one hospital; or

7 “(bb) two or more hospitals
8 that have common access to
9 databases with drug order infor-
10 mation for patients; and

11 “(II) includes only the inpatient,
12 outpatient, and ambulatory facilities
13 wholly owned and operated by such
14 entity, and accredited by a national
15 accreditation body approved by the
16 Secretary for purposes of this section.

17 “(C) EXCEPTION REGARDING OFFICE
18 USE.—

19 “(i) IN GENERAL.—A pharmacy that
20 compounds a drug for office use (other
21 than a pharmacy that is considered a tra-
22 ditional compounder pursuant to subpara-
23 graph (B)) and that otherwise meets the
24 definition in subparagraph (A), is a tradi-
25 tional compounder if—

1 “(I) in lieu of the prescription for
2 an identified individual patient as de-
3 scribed in subparagraph (A)(ii), the
4 pharmacy receives a practitioner
5 order; and

6 “(II) the pharmacy complies with
7 the requirements described in sub-
8 section (g).

9 “(ii) LIMITATION.—Notwithstanding
10 clause (i), a pharmacy that compounds a
11 sterile drug for office use is not a tradi-
12 tional compounder if the pharmacy does
13 not receive a prescription for an identified
14 individual patient for such sterile drug
15 prior to beginning compounding, and dis-
16 tributes or offers to sell such a com-
17 pounded sterile drug in interstate com-
18 merce.

19 “(D) EXCEPTION REGARDING INFUSION
20 PHARMACIES.—An infusion pharmacy shall be
21 considered a traditional compounder if such
22 pharmacy meets the definition under paragraph
23 (4) and drugs compounded or pooled by such
24 pharmacy, other than as described in subpara-
25 graph (C) of such paragraph, shall be subject

1 to the requirements of traditional compounders
2 under this section.

3 “(c) EXEMPTIONS FROM CERTAIN REQUIRE-
4 MENTS.—

5 “(1) IN GENERAL.—Except as otherwise pro-
6 vided in paragraphs (2), (3), and (4), a compounded
7 drug shall be subject to all the requirements of this
8 Act applicable to new drugs.

9 “(2) DRUGS COMPOUNDED BY TRADITIONAL
10 COMPOUNDERS.—Sections 501(a)(2)(B), 502(f)(1),
11 505, and 582 of this Act and section 351 of the
12 Public Health Service Act shall not apply to a com-
13 pounded drug if such drug—

14 “(A) is compounded by a traditional
15 compounder that is in compliance with this sec-
16 tion with respect to all drugs compounded at
17 the facility; and

18 “(B) meets the requirements of this sec-
19 tion applicable to drugs compounded by tradi-
20 tional compounders.

21 “(3) DRUGS COMPOUNDED BY COMPOUNDING
22 MANUFACTURERS.—Sections 502(f)(1), 505, and
23 582 of this Act and section 351 of the Public Health
24 Service Act shall not apply to a compounded pre-
25 scription drug, if such prescription drug—

1 “(A) is compounded by a compounding
2 manufacturer—

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

5 “(ii) that is in compliance with this
6 section; and

7 “(B) meets the requirements of this sec-
8 tion applicable to drugs compounded by
9 compounding manufacturers.

10 “(4) DRUGS COMPOUNDED BY COMPOUNDING
11 NUCLEAR PHARMACIES.—Sections 501(a)(2)(B),
12 502(f)(1), and 505 of this Act and section 351 of
13 the Public Health Service Act shall not apply to a
14 compounded drug if such drug is compounded in a
15 compounding nuclear pharmacy wherein—

16 “(A) each radioactive drug is com-
17 pounded—

18 “(i) by a licensed pharmacist;

19 “(ii) solely using one or more radio-
20 active drugs approved under section 505 or
21 licensed under section 351 of the Public
22 Health Service Act, or solely using such
23 drugs and one or more ingredients in com-
24 pliance with subsection (e)(1)(B); and

1 “(iii) in compliance with the United
2 States Pharmacopoeia chapters on phar-
3 macy compounding; and

4 “(B) each nonradioactive drug—

5 “(i) is compounded in compliance with
6 the requirements of this section that apply
7 to a traditional compounder with respect to
8 all nonradioactive drugs compounded at
9 the facility; and

10 “(ii) meets the requirements of this
11 section applicable to drugs compounded by
12 traditional compounders.

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

14 “(1) IN GENERAL.—The following drugs may
15 not be compounded by a compounding manufacturer
16 or traditional compounder:

17 “(A) DRUGS THAT ARE DEMONSTRABLY
18 DIFFICULT TO COMPOUND.—A drug or category
19 of drugs that presents demonstrable difficulties
20 for compounding that are reasonably likely to
21 lead to an adverse effect on the safety or effec-
22 tiveness of that drug or category of drugs tak-
23 ing into account the risks and benefits to pa-
24 tients, which may include a complex dosage

1 form or biological product, as designated by the
2 Secretary pursuant to paragraph (2).

3 “(B) MARKETED DRUGS.—A drug (other
4 than a biological product) compounded from
5 bulk drug substances that is a copy of a mar-
6 keted drug approved under section 505 or a
7 variation of such drug, except as provided in
8 paragraph (3).

9 “(C) BIOLOGICAL PRODUCTS.—A drug
10 that is a biological product, except as provided
11 in paragraph (4).

12 “(D) DRUGS SUBJECT TO RISK EVALUA-
13 TION AND MITIGATION STRATEGY.—A copy or
14 variation of a drug approved under section 505
15 or licensed under section 351 of the Public
16 Health Service Act that is the subject of a risk
17 evaluation and mitigation strategy approved
18 with elements to assure safe use pursuant to
19 section 505–1, except provided in paragraph
20 (5).

21 “(E) DRUGS REMOVED FOR SAFETY AND
22 EFFICACY.—A drug that appears on a list pub-
23 lished by the Secretary in the Federal Register
24 of drugs that have been withdrawn or removed
25 from the market because such drug or compo-

1 nents of such drug have been found to be un-
2 safe or not effective.

3 “(2) DRUGS THAT ARE DEMONSTRABLY DIF-
4 FICULT TO COMPOUND.—

5 “(A) IN GENERAL.—The Secretary may
6 promulgate a regulation that designates drugs
7 or categories of drugs described in subpara-
8 graph (C).

9 “(B) INTERIM LIST.—

10 “(i) IN GENERAL.—Before the effec-
11 tive date of the regulation promulgated
12 under subparagraph (A), the Secretary
13 may designate drugs or categories of drugs
14 described in subparagraph (C), by—

15 “(I) publishing a notice of such
16 drugs or categories of drugs proposed
17 for designation, including the ration-
18 ale for such designation, in the Fed-
19 eral Register;

20 “(II) providing a period of not
21 less than 60 calendar days for com-
22 ment on the notice; and

23 “(III) publishing a notice in the
24 Federal Register designating such
25 drugs or categories of drugs that can-

1 not be compounded, including the ra-
2 tionale for such designation.

3 “(ii) SUNSET.—Any notice provided
4 under clause (i) shall cease to have force or
5 effect on the date that is 5 years after the
6 date of enactment of the Pharmaceutical
7 Compounding Quality and Accountability
8 Act or on the effective date of the final
9 regulation under subparagraph (A), which-
10 ever is earlier.

11 “(C) DRUGS OR CATEGORIES OF DRUGS.—
12 A drug or category of drugs described in this
13 subparagraph is a drug or category of drugs
14 that may not be compounded, or that may be
15 compounded only under conditions specified by
16 the Secretary, because such drug or category of
17 drugs presents demonstrable difficulties for
18 compounding that are reasonably likely to lead
19 to an adverse effect on the safety or effective-
20 ness of that drug or category of drugs taking
21 into account the risks and benefits to patients.
22 Drugs or categories of drugs that may be so
23 designated include drugs that are complex dos-
24 age forms or biological products, such as ex-
25 tended release products (as defined by the

1 United States Pharmacopoeia), metered dose
2 inhalers, transdermal patches, and sterile
3 liposomal products.

4 “(D) CONSULTATION WITH STAKE-
5 HOLDERS.—Prior to making a designation
6 under subparagraph (A) or (B), the Secretary
7 shall consult with relevant stakeholders includ-
8 ing pharmacists, professional associations, pa-
9 tient and public health advocacy groups, manu-
10 facturers and physicians about the need for the
11 compounded drugs to be included or excluded
12 from the lists of drugs so designated.

13 “(E) UPDATES TO LIST.—Five years after
14 the effective date of the regulation described in
15 subparagraph (A), and every 5 years thereafter,
16 the Secretary shall publish a Federal Register
17 notice seeking public input about the need for
18 the compounded drugs to be included or ex-
19 cluded from the list of drugs designated under
20 subparagraph (A). Nothing in the previous sen-
21 tence prohibits notifications or submissions be-
22 fore or during any 5-year period described
23 under such sentence regarding the need for the
24 compounded drugs to be included or excluded
25 from such list.

1 “(3) EXCEPTIONS REGARDING MARKETED
2 DRUGS.—

3 “(A) COMPOUNDING VARIATIONS FROM
4 BULK DRUG SUBSTANCES.—A drug (other than
5 a biological product) that is a variation of a
6 marketed drug approved under section 505 may
7 be compounded from one or more bulk drug
8 substances only if—

9 “(i) such compounding is conducted
10 by a traditional compounder;

11 “(ii) the compounded variation pro-
12 duces for the identified individual patient a
13 clinical difference between the compounded
14 drug and such marketed drug, as deter-
15 mined by the prescribing practitioner; and

16 “(iii) prior to compounding such vari-
17 ation, the traditional compounder receives
18 a prescription order for an identified indi-
19 vidual patient specifying that the variation
20 may be compounded.

21 “(B) COPYING MARKETED DRUGS FROM
22 BULK DRUG SUBSTANCES.—

23 “(i) IN GENERAL.—A drug (other
24 than a biological product) that is a copy of
25 a marketed drug approved under section

1 compounding manufacturer has reg-
2 istered under subsection (h)(3) as an
3 entity that intends to compound pur-
4 suant to this subparagraph; and

5 “(IV) at the time of
6 compounding and at the time of dis-
7 tribution of the compounded drug, the
8 drug does not appear on a list of re-
9 solved drug shortages established and
10 made publicly available by the Sec-
11 retary.

12 “(ii) SINGLE NOTICE.—A single notice
13 submitted under clause (i)(II) shall fulfill
14 such notice requirement until the drug ap-
15 pears on the list described in clause (i)(IV)
16 or for one year after the notice, whichever
17 is sooner. If a drug for which a notice was
18 submitted under clause (i)(II) still fulfills
19 the requirements of clause (i)(I) one year
20 after the notice was submitted, an entity
21 wishing to continue compounding the drug
22 shall submit a new notice in accordance
23 with clause (i)(II).

1 “(C) NOTICE WAIVER.—The Secretary
2 may waive the notice required under subpara-
3 graph (B)(i)(II).”

4 “(D) LIMITATION REGARDING OFFICE
5 USE.—Notwithstanding subsections (b)(11)(C)
6 and (g), if compounding a variation from bulk
7 drug substances of a marketed drug as de-
8 scribed in subparagraph (A), a traditional
9 compounder shall require a prescription for an
10 identified individual patient.

11 “(E) EXCLUSION.—For purposes of this
12 subsection, repackaging a marketed drug ap-
13 proved under section 505 does not make the re-
14 packaged drug a copy of such marketed drug,
15 unless the repackaged drug is also a copy of a
16 marketed approved drug.

17 “(4) EXCEPTIONS REGARDING BIOLOGICAL
18 PRODUCTS.—

19 “(A) IN GENERAL.—A drug that is a bio-
20 logical product may be compounded only if—

21 “(i)(I) such compounded drug is com-
22 pounded solely using a licensed biological
23 product, or solely using a licensed biologi-
24 cal product and one or more ingredients in
25 compliance with subsection (e)(1)(B), in-

1 tended to dilute the licensed biological
2 product; or

3 “(II) in the case of a licensed aller-
4 genic product, such drug is compounded
5 solely using one or more licensed allergenic
6 products, or solely using one or more li-
7 censed allergenic products and one or more
8 ingredients in compliance with subsection
9 (e)(1)(B);

10 “(ii)(I) such compounded drug pro-
11 duces for the patient a clinical difference
12 between such compounded drug and the li-
13 censed biological product, as determined
14 by—

15 “(aa) the prescribing practitioner
16 (in the case of a drug compounded by
17 a traditional compounder); or

18 “(bb) a licensed practitioner re-
19 sponsible for the patient’s care in a
20 health care entity that provides med-
21 ical services through licensed practi-
22 tioners directly to patients (in the
23 case of a drug compounded by a
24 compounding manufacturer); or

1 “(II) such compounded drug is re-
2 packaged from a licensed biological prod-
3 uct by a compounding manufacturer;

4 “(iii) prior to beginning
5 compounding—

6 “(I) except as provided in sub-
7 paragraph (B), the traditional
8 compounder receives a prescription for
9 an identified individual patient speci-
10 fying that the biological product may
11 be compounded for an identified indi-
12 vidual patient; or

13 “(II) the compounding manufac-
14 turer receives a practitioner order
15 from a health care entity that pro-
16 vides medical services through li-
17 censed practitioners directly to pa-
18 tients, specifying that the biological
19 product may be compounded; and

20 “(iv) in the case of a radioactive bio-
21 logical product, the compounded drug is
22 compounded by a compounding nuclear
23 pharmacy in accordance with subsection
24 (b)(2).

1 “(B) SPECIAL RULE FOR PEDIATRIC
2 USES.—An entity described in subsection
3 (b)(11)(B) may begin compounding a drug that
4 is a variation of a licensed biological product
5 prior to receiving a prescription as required
6 under subparagraph (A)(iii) if—

7 “(i) such compounded drug is a di-
8 luted or repackaged variation of the li-
9 censed biological product for emergent use
10 in pediatric patients; and

11 “(ii) such compounded drug produces
12 for the patient a clinical difference between
13 such compounded variation and the li-
14 censed biological product, as determined by
15 a licensed practitioner responsible for the
16 patient’s care in the hospital or health sys-
17 tem.

18 “(C) INAPPLICABILITY.—Clauses (ii) and
19 (iii) of subparagraph (A) shall not apply to a
20 compounded allergenic product.

21 “(D) POOLING.—Notwithstanding any
22 other provision of this section, sterile pooling of
23 a biological product is not permitted.

24 “(5) REQUIREMENT FOR DRUGS THAT HAVE
25 RISK EVALUATION AND MITIGATION STRATEGIES.—

1 “(A) IN GENERAL.—A copy or variation of
2 a drug approved under section 505 or biological
3 product licensed under section 351 of the Pub-
4 lic Health Service Act that is the subject of a
5 risk evaluation and mitigation strategy ap-
6 proved with elements to assure safe use pursu-
7 ant to section 505–1, may be compounded only
8 if—

9 “(i) the entity compounding the copy
10 or variation receives a prescription for an
11 identified individual patient specifying that
12 the drug or biological product may be com-
13 pounded; and

14 “(ii) the entity compounding the copy
15 or variation demonstrates to the Secretary,
16 prior to beginning compounding, that the
17 entity will utilize controls that are com-
18 parable to the controls applicable under
19 the relevant risk evaluation and mitigation
20 strategy for the approved drug or licensed
21 biological product.

22 “(B) EFFECT.—Nothing in this paragraph
23 shall be construed to permit compounding a
24 copy or variation of a drug other than as per-
25 mitted in paragraphs (3) and (4).

1 “(e) QUALITY OF DRUG INGREDIENTS.—

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

4 “(A) if compounding a drug from bulk
5 drug substances (as defined in regulations of
6 the Secretary published at section 207.3(a)(4)
7 of title 21, Code of Federal Regulations (or any
8 successor regulations)), use only bulk drug sub-
9 stances—

10 “(i) that—

11 “(I) comply with the standards of
12 the applicable United States Pharma-
13 copoeia or National Formulary mono-
14 graph, if such monograph exists and
15 has not been identified under para-
16 graph (2);

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

21 “(III) if such a monograph does
22 not exist and the drug substance is
23 not a component of a drug approved
24 by the Secretary that appears on a
25 list developed by the Secretary

1 through regulations issued by the Sec-
2 retary;

3 “(ii) that are manufactured by an es-
4 tablishment that is registered under sec-
5 tion 510 (including a foreign establishment
6 that is registered under section 510(i));
7 and

8 “(iii) that are accompanied by valid
9 certificates of analysis for each specific lot
10 of bulk drug substance; and

11 “(B) use ingredients (other than bulk drug
12 substances) that comply with the standards of
13 the applicable United States Pharmacopoeia or
14 National Formulary monograph, if such mono-
15 graph exists and has not been identified under
16 paragraph (2).

17 “(2) IDENTIFICATION BY SECRETARY.—

18 “(A) IN GENERAL.—Notwithstanding the
19 existence of an applicable monograph under
20 subparagraph (A)(i)(I) or (B) of paragraph (1),
21 the Secretary may identify bulk drug sub-
22 stances and ingredients (other than bulk drug
23 substances) that the Secretary determines,
24 based on public health concerns taking into ac-
25 count historical use, reports in peer-reviewed

1 literature, or other criteria identified by the
2 Secretary, may not be used in compounding a
3 drug.

4 “(B) PROCEDURE.—In identifying the bulk
5 drug substances and ingredients (other than
6 bulk drug substances) that may not be used in
7 compounding, the Secretary shall—

8 “(i) publish a notice of the bulk drug
9 substances and ingredients (other than
10 bulk drug substances) proposed for identi-
11 fication in the Federal Register, including
12 the rationale for such proposal;

13 “(ii) provide a period of not less than
14 60 calendar days for comment on the no-
15 tice; and

16 “(iii) publish a notice in the Federal
17 Register identifying the bulk drug sub-
18 stances and ingredients (other than bulk
19 drug substances) that may not be used in
20 compounding a drug.

21 “(f) REQUIREMENTS REGARDING WHOLESALING
22 AND LABELING APPLICABLE TO TRADITIONAL
23 COMPOUNDERS AND COMPOUNDING MANUFACTURERS.—
24 A compounded drug—

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

4 “(2) compounded by a compounding manufac-
5 turer may not be sold or transferred to an entity
6 other than a health care entity that provides medical
7 services through licensed practitioners directly to pa-
8 tients, or a network of such providers, except that
9 a compounding manufacturer may transfer without
10 profit a compounded sterile drug to a licensed phar-
11 macy if—

12 “(A) as of the date of enactment of the
13 Pharmaceutical Compounding Quality and Ac-
14 countability Act, and at the time of such trans-
15 fer, the licensed pharmacy falls under the same
16 corporate ownership as the compounding manu-
17 facturer;

18 “(B) the transfer of such compounded
19 sterile drug is solely for the purpose of dis-
20 pensing the compounded sterile drug to the end
21 user, who has been instructed by the pre-
22 scribing physician to self-administer such com-
23 pounded sterile drug;

24 “(C) as of the date of enactment of the
25 Pharmaceutical Compounding Quality and Ac-

1 countability Act, and at the time of such trans-
2 fer, the compounding manufacturer is an entity
3 wholly owned by an entity that provides phar-
4 macy benefits management services on behalf of
5 a health benefits plan;

6 “(D) the compounding manufacturer iden-
7 tifies itself to the Secretary upon registering
8 under subsection (h)(3) as an entity that quali-
9 fies for the exception under this paragraph, and
10 provides documentation of the compounding of
11 such drugs as of the date of enactment of the
12 Pharmaceutical Compounding Quality and Ac-
13 countability Act, in a manner described by the
14 Secretary; and

15 “(E) the compounding manufacturer re-
16 ceives confirmation from the Secretary that the
17 compounding manufacturer qualifies for the ex-
18 ception under this paragraph and the sterile
19 drug or drugs for which the exemption applies;
20 and

21 “(3) offered for sale shall be labeled ‘not for re-
22 sale’.

23 “(g) OFFICE USE REQUIREMENTS APPLICABLE TO
24 CERTAIN TRADITIONAL COMPOUNDERS.—

1 “(1) IN GENERAL.—Pursuant to subsection
2 (b)(11)(C), a traditional compounder may not dis-
3 pense a compounded drug to a health care entity for
4 office use unless such traditional compounder meets
5 the following requirements:

6 “(A) In any 30 day period, of the total
7 drugs dispensed pursuant to practitioner orders
8 and prescriptions for identified individual pa-
9 tients, no more than 10 percent may be dis-
10 pensed pursuant to practitioner orders.

11 “(B) The traditional compounder shall re-
12 ceive the names of each patient who received a
13 drug dispensed to a provider pursuant to a
14 practitioner order, or, if not all of the drug was
15 administered, confirmation that the remaining
16 drug was not administered, not later than 14
17 days after such drug was dispensed to such pro-
18 vider.

19 “(C) The traditional compounder shall
20 maintain records relating to the dispensing of
21 drugs pursuant to a practitioner order for the
22 6-year period following such dispensing.

23 “(D) The label of a drug compounded pur-
24 suant to a practitioner order shall include—

1 “(i) the statement ‘Office Use Only’
2 and the statement ‘Not for Resale’ (as re-
3 quired under subsection (f)(3)); and

4 “(ii) the statement ‘Use within 14
5 days of _____’ with the date of
6 dispensing filled in the blank, unless a
7 shorter beyond use or expiration date ap-
8 plies, in which case such shorter period
9 shall be included on the label.

10 “(2) SAFE HARBOR.—

11 “(A) TOTAL DRUGS DISPENSED.—For pur-
12 poses of paragraph (1)(A), the total drugs dis-
13 pensed and the amount of drugs dispensed via
14 practitioner orders shall be determined based on
15 the number of identified individual patient pre-
16 scriptions and a reasonable estimate of the
17 number of patients to whom each drug dis-
18 pensed pursuant to a practitioner order would
19 be administered.

20 “(B) GOOD FAITH.—A traditional
21 compounder shall not be considered in violation
22 of paragraph (1)(B) if the drug was dispensed
23 in good faith and a reasonable effort was made
24 to receive the names or confirmation described
25 in paragraph (1)(B), unless the traditional

1 compounder fails to receive names or confirma-
2 tion described in paragraph (1)(B) for practi-
3 tioner orders that were filled for the same prac-
4 titioner on multiple occasions.

5 “(3) STATE FLEXIBILITY REGARDING OFFICE
6 USE.—Nothing in this section shall prohibit a State
7 from establishing standards relating to compounding
8 drugs for office use that are more stringent than the
9 requirements relating to such use established under
10 this section.

11 “(4) PUBLIC HEALTH EMERGENCY.—The Sec-
12 retary may waive the requirements under paragraph
13 (1)(B) for emergency medical reasons, including a
14 public health emergency declaration pursuant to sec-
15 tion 319 of the Public Health Service Act.

16 “(h) OTHER REQUIREMENTS APPLICABLE TO
17 COMPOUNDING MANUFACTURERS.—

18 “(1) LICENSED PHARMACIST OVERSIGHT.—A
19 compounding manufacturer shall ensure that a phar-
20 macist licensed in the State where the compounding
21 manufacturer is located exercises direct supervision
22 over the operations of the compounding manufac-
23 turer.

24 “(2) COMPOUNDING OF NON-STERILE DRUGS.—

1 “(A) IN GENERAL.—A compounding man-
2 ufacturer may not compound a non-sterile drug,
3 except as provided in this paragraph.

4 “(B) LIST BY SECRETARY.—The Secretary
5 shall establish a list of non-sterile drugs that
6 may be compounded by a compounding manu-
7 facturer.

8 “(C) CONSIDERATIONS.—In establishing
9 and updating the list under this paragraph, the
10 Secretary shall—

11 “(i) reference the drugs and other in-
12 formation identified under subclauses (I)
13 and (II) of paragraph (3)(B)(i) and sub-
14 mitted in an initial registration report
15 under such paragraph; and

16 “(ii) consider whether the non-sterile
17 drug fulfills a clinical need that cannot be
18 filled by a marketed drug.

19 “(D) PROCEDURE.—In identifying the
20 non-sterile drugs that may be compounded by a
21 compounding manufacturer, the Secretary
22 shall—

23 “(i) publish a notice of such non-ster-
24 ile drugs proposed for identification in the

1 Federal Register, including the rationale
2 for such proposal;

3 “(ii) provide a period of not less than
4 60 calendar days for comment on the no-
5 tice; and

6 “(iii) publish a notice in the Federal
7 Register identifying the non-sterile drugs
8 that may be compounded by a
9 compounding manufacturer.

10 “(E) TRANSITION RULE.—Until the date
11 the Secretary publishes the first notice de-
12 scribed under subparagraph (D)(iii), a
13 compounding manufacturer may compound a
14 non-sterile drug.

15 “(F) UPDATES TO LIST.—Five years after
16 the establishment of the initial list under sub-
17 paragraph (B), and every 5 years thereafter,
18 the Secretary shall publish a Federal Register
19 notice seeking public input about the need for
20 non-sterile drugs to be included or excluded
21 from the list under this paragraph. Nothing in
22 the previous sentence prohibits notifications or
23 submissions before or during any 5-year period
24 described under such sentence regarding the

1 need for non-sterile drugs to be included or ex-
2 cluded from the list.

3 “(G) EFFECT OF PARAGRAPH.—Nothing
4 about this paragraph alters the definition of a
5 compounding manufacturer in subsection (b)(1)
6 or the authority of the Secretary to regulate
7 compounding manufacturers under this Act.

8 “(3) REGISTRATION OF COMPOUNDING MANU-
9 FACTURERS AND REPORTING OF DRUGS.—

10 “(A) REGISTRATION OF COMPOUNDING
11 MANUFACTURERS.—

12 “(i) ANNUAL REGISTRATION.—During
13 the period beginning on October 1 and
14 ending on December 31 each year, each
15 compounding manufacturer shall register
16 with the Secretary its name, place of busi-
17 ness, and unique facility identifier (which
18 shall conform to the requirements for the
19 unique facility identifier established under
20 section 510), and a point of contact e-mail
21 address, and shall indicate whether the
22 compounding manufacturer intends to
23 compound a drug in shortage pursuant to
24 subsection (d)(3)(A)(ii).

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 cal-
13 endar days following publication of the
14 timeline in the Federal Register.

15 “(iii) AVAILABILITY OF REGISTRATION
16 FOR INSPECTION; LIST.—

17 “(I) REGISTRATIONS.—The Sec-
18 retary shall make available for inspec-
19 tion, to any person so requesting, any
20 registration filed pursuant to this sub-
21 paragraph.

22 “(II) LIST.—The Secretary shall
23 make available on the Internet Web
24 site of the Food and Drug Adminis-
25 tration a list of the name of each fa-

1 cility registered under this subsection
2 as a compounding manufacturer, the
3 State in which each such
4 compounding manufacturer is located,
5 whether the compounding manufac-
6 turer compounds from bulk drug sub-
7 stances as described in subsection
8 (e)(1)(A), and whether any such
9 compounding from bulk drug sub-
10 stances is for sterile or non-sterile
11 drugs.

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

14 “(i) IN GENERAL.—Each
15 compounding manufacturer who registers
16 with the Secretary under subparagraph (A)
17 shall submit to the Secretary, upon ini-
18 tially registering as a compounding manu-
19 facturer under subparagraph (A)(ii) and
20 once during the month of June of each
21 year and once during the month of Decem-
22 ber of each year, a report—

23 “(I) identifying the drugs com-
24 pounded by such compounding manu-

1 facturer during the previous 6-month
2 period; and

3 “(II) with respect to each drug
4 identified under subclause (I), pro-
5 viding the active ingredient, the
6 source of such active ingredient, the
7 National Drug Code number, if avail-
8 able, of the source drug or bulk active
9 ingredient, the strength of the active
10 ingredient per unit, the dosage form
11 and route of administration, the pack-
12 age description, the number of indi-
13 vidual units produced, and the Na-
14 tional Drug Code number of the final
15 product, if assigned.

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

20 “(iii) CONFIDENTIALITY.—Reports
21 submitted pursuant to this subparagraph
22 shall be exempt from inspection under sub-
23 paragraph (A)(iii), unless the Secretary
24 finds that such an exemption would be in-

1 manufacturers according to the known
2 safety risks of such compounding manufac-
3 turers, which shall be based on the fol-
4 lowing factors:

5 “(I) The compliance history of
6 the compounding manufacturer.

7 “(II) The record, history, and na-
8 ture of recalls linked to the
9 compounding manufacturer.

10 “(III) The inherent risk of the
11 drug compounded at the compounding
12 manufacturer.

13 “(IV) The inspection frequency
14 and history of the compounding man-
15 ufacturer, including whether the
16 compounding manufacturer has been
17 inspected pursuant to section 704
18 within the last 4 years.

19 “(V) Whether the compounding
20 manufacturer has registered under
21 this paragraph as an entity that in-
22 tends to compound pursuant to sub-
23 section (d)(3)(A)(ii).

24 “(VI) Any other criteria deemed
25 necessary and appropriate by the Sec-

1 retary for purposes of allocating in-
2 spection resources.

3 “(4) ADVERSE EVENT REPORTING.—

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

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

9 “(I) an event occurring in the
10 course of the use of the drug in pro-
11 fessional practice;

12 “(II) an event occurring from an
13 overdose of the drug, whether acci-
14 dental or intentional;

15 “(III) an event occurring from
16 abuse of the drug;

17 “(IV) an event occurring from
18 withdrawal of the drug; and

19 “(V) any failure of expected
20 pharmacological action of the drug.

21 “(ii) SERIOUS ADVERSE EVENT.—The
22 term ‘serious adverse event’ means an ad-
23 verse event that—

24 “(I) results in—

25 “(aa) death;

1 “(bb) an adverse drug event
2 that places the patient at imme-
3 diate risk of death from the ad-
4 verse drug event as it occurred
5 (not including an adverse drug
6 event that might have caused
7 death had it occurred in a more
8 severe form);

9 “(cc) inpatient hospitaliza-
10 tion or prolongation of existing
11 hospitalization;

12 “(dd) a persistent or signifi-
13 cant incapacity or substantial
14 disruption of the ability to con-
15 duct normal life functions; or

16 “(ee) a congenital anomaly
17 or birth defect; or

18 “(II) based on appropriate med-
19 ical judgment, may jeopardize the pa-
20 tient and may require a medical or
21 surgical intervention to prevent an
22 outcome described in subclause (I).

23 “(B) REPORTS.—

24 “(i) SERIOUS ADVERSE EVENT RE-
25 PORTING REQUIREMENT.—

1 “(I) 15-DAY REPORT.—If a
2 compounding manufacturer becomes
3 aware of any serious adverse event,
4 such manufacturer shall submit re-
5 ports of each instance to the Sec-
6 retary as soon as practicable, but in
7 no case later than 15 calendar days
8 after the initial receipt of the applica-
9 ble information. Such manufacturer
10 shall investigate and submit to the
11 Secretary followup reports for each
12 such instance not later than 15 cal-
13 endar days after receipt of new infor-
14 mation or as requested by the Sec-
15 retary. Unless and until the Secretary
16 establishes the content and format of
17 adverse event reports by guidance or
18 regulation, reports shall be submitted
19 in accordance with the content and
20 format requirements under section
21 310.305 of title 21, Code of Federal
22 Regulations (or any successor regula-
23 tions) or section 600.80 of title 21,
24 Code of Federal Regulations (or any
25 successor regulations).

1 “(II) ANNUAL REPORT.—

2 Compounding manufacturers that re-
3 port serious adverse events shall sub-
4 mit in December of each year a nar-
5 rative summary of any analysis of
6 each report submitted under subclause
7 (I), including a history of actions
8 taken during the year because of each
9 report, using the content, format, and
10 manner established by the Secretary
11 by guidance or regulation. Until such
12 time as the Secretary publishes such
13 guidance or regulation, each
14 compounding manufacturer shall re-
15 tain such summaries as part of the
16 records to be maintained in accord-
17 ance with subparagraph (C).

18 “(ii) PRODUCT QUALITY REPORTING
19 REQUIREMENT.—Not later than 3 calendar
20 days after the compounding manufacturer
21 becomes aware of information pertaining
22 to sterility, stability, or other product qual-
23 ity concerns that could result in serious
24 adverse events, the compounding manufac-
25 turer shall submit to the Secretary a prod-

1 uct quality report, in a form and manner
2 established by the Secretary by guidance or
3 regulation.

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

12 “(5) LABELING OF DRUGS.—

13 “(A) LABEL.—The label of a drug com-
14 pounded by a compounding manufacturer shall
15 include—

16 “(i) the statement ‘This is a com-
17 pounded drug.’ or a reasonable comparable
18 alternative statement (as specified by the
19 Secretary) that prominently identifies the
20 drug as a compounded drug;

21 “(ii) the name, address, and phone
22 number of the applicable compounding
23 manufacturer; and

24 “(iii) with respect to the compounded
25 drug—

- 1 “(I) the lot or batch number;
- 2 “(II) the established name of the
- 3 medication;
- 4 “(III) the dosage form and
- 5 strength;
- 6 “(IV) the statement of quantity
- 7 or volume, as appropriate;
- 8 “(V) the date that the drug was
- 9 compounded;
- 10 “(VI) the expiration date;
- 11 “(VII) storage and handling in-
- 12 structions;
- 13 “(VIII) the National Drug Code
- 14 number, if available;
- 15 “(IX) the ‘not for resale’ state-
- 16 ment as required by subsection (f)(3);
- 17 and
- 18 “(X) 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

1 removed for dispensing or for administration
2 (such as a plastic bag containing individual
3 product syringes) shall include—

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

7 “(ii) the following information to fa-
8 cilitate adverse event reporting:
9 www.fda.gov/medwatch and 1-800-FDA-
10 1088; and

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

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

19 “(i) COMPOUNDING MANUFACTURER ESTABLISH-
20 MENT AND REINSPECTION FEES.—

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

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

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

1 United States dollars, for a compounding man-
2 ufacturer, including the sales of all the affiliates
3 of the compounding manufacturer; and

4 “(C) the term ‘reinspection’ means, with
5 respect to a compounding manufacturer, 1 or
6 more inspections conducted under section 704
7 subsequent to an inspection conducted under
8 such provision which identified noncompliance
9 materially related to an applicable requirement
10 of this Act, specifically to determine whether
11 compliance has been achieved to the Secretary’s
12 satisfaction.

13 “(2) ESTABLISHMENT AND REINSPECTION
14 FEES.—

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

19 “(i) an annual establishment fee from
20 each compounding manufacturer; and

21 “(ii) a reinspection fee from each
22 compounding manufacturer subject to a re-
23 inspection in such fiscal year.

24 “(B) MULTIPLE REINSPECTIONS.—A
25 compounding manufacturer subject to multiple

1 reinspections in a fiscal year shall be subject to
2 a reinspection fee for each reinspection.

3 “(3) ESTABLISHMENT AND REINSPECTION FEE
4 SETTING.—The Secretary shall establish the estab-
5 lishment and reinspection fee to be collected under
6 this subsection for each fiscal year, based on the
7 methodology described in paragraph (4) and shall
8 publish such fee in a Federal Register notice not
9 later than 60 calendar days before the start of each
10 such year.

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

13 “(A) IN GENERAL.—For each
14 compounding manufacturer in a fiscal year—

15 “(i) except as provided in subpara-
16 graph (D), the amount of the annual es-
17 tablishment fee under paragraph (2) shall
18 be equal to the sum of—

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

22 “(II) the small business adjust-
23 ment factor described in subpara-
24 graph (C); and

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

6 “(B) INFLATION ADJUSTMENT FACTOR.—

7 “(i) IN GENERAL.—For fiscal year
8 2015 and subsequent fiscal years, the fee
9 amounts established in subparagraph (A)
10 shall be adjusted by the Secretary by no-
11 tice, published in the Federal Register, for
12 a fiscal year by the amount equal to the
13 sum of—

14 “(I) one;

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

1 and Drug Administration for the first
2 3 years of the preceding 4 fiscal
3 years; and

4 “(III) the average annual percent
5 change that occurred in the Consumer
6 Price Index for urban consumers
7 (U.S. City Average; Not Seasonally
8 Adjusted; All items; Annual Index) for
9 the first 3 years of the preceding 4
10 years of available data multiplied by
11 the proportion of all costs other than
12 personnel compensation and benefits
13 costs to total costs of an average full-
14 time equivalent position of the Food
15 and Drug Administration for the first
16 3 years of the preceding 4 fiscal
17 years.

18 “(ii) COMPOUNDED BASIS.—The ad-
19 justment made each fiscal year under
20 clause (i) shall be added on a compounded
21 basis to the sum of all adjustments made
22 each fiscal year after fiscal year 2014
23 under clause (i).

24 “(C) SMALL BUSINESS ADJUSTMENT FAC-
25 TOR.—The small business adjustment factor re-

1 ferred to in subparagraph (A)(i)(II) shall be an
2 amount established by the Secretary for each
3 fiscal year based on the Secretary's estimate
4 of—

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

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

14 “(D) EXCEPTION FOR SMALL BUSI-
15 NESSES.—

16 “(i) IN GENERAL.—In the case of a
17 compounding manufacturer with gross an-
18 nual sales of \$1,000,000 or less in the 12
19 months ending April 1 of the fiscal year
20 immediately preceding the fiscal year in
21 which the fees under this subsection are
22 assessed, the amount of the establishment
23 fee under paragraph (2) for a fiscal year
24 shall be equal to $\frac{1}{3}$ of the amount cal-

1 culated under subparagraph (A)(i)(I) in
2 such fiscal year.

3 “(ii) APPLICATION.—To qualify for
4 the exception under this subparagraph, a
5 small business shall submit to the Sec-
6 retary a written request for such exception,
7 in a format specified by the Secretary in
8 guidance, certifying its gross annual sales
9 for the 12 months ending April 1 of the
10 fiscal year immediately preceding the fiscal
11 year in which fees under this subsection
12 are assessed. Any such application must be
13 submitted to the Secretary not later than
14 April 30 for the following fiscal year. Any
15 statement or representation made to the
16 Secretary shall be subject to section 1001
17 of title 18, United States Code.

18 “(E) CREDITING OF FEES.—In estab-
19 lishing the small business adjustment factor
20 under subparagraph (C) for a fiscal year, the
21 Secretary shall provide for the crediting of fees
22 from the previous year to the next year if the
23 Secretary overestimated the amount of the
24 small business adjustment factor for such pre-
25 vious fiscal year, and consider the need to ac-

1 count for any adjustment of fees and such other
2 factors as the Secretary determines appropriate.

3 “(5) USE OF FEES.—The Secretary shall make
4 all of the fees collected pursuant to clauses (i) and
5 (ii) of paragraph (2)(A) available solely to pay for
6 the costs of oversight of compounding manufactur-
7 ers.

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

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

1 “(8) COLLECTION OF FEES.—

2 “(A) ESTABLISHMENT FEE.—A
3 compounding manufacturer shall remit the es-
4 tablishment fee due under this subsection in a
5 fiscal year when submitting a registration pur-
6 suant to subsection (h) for such fiscal year.

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

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

16 “(i) REGISTRATION.—A compounding
17 manufacturer shall not be considered reg-
18 istered under subsection (h) in a fiscal
19 year until the date that the compounding
20 manufacturer remits the establishment fee
21 under this subsection for such fiscal year.

22 “(ii) MISBRANDING.—All drugs manu-
23 factured, prepared, propagated, com-
24 pounded, or processed by a compounding
25 manufacturer for which any establishment

1 fee or reinspection fee has not been paid as
2 required by this subsection shall be deemed
3 misbranded under section 502(cc) until the
4 fees owed for such compounding manufac-
5 turer under this subsection have been paid.

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

13 “(9) ANNUAL REPORT TO CONGRESS.—Not
14 later than 120 calendar days after each fiscal year
15 in which fees are assessed and collected under this
16 subsection, the Secretary shall submit a report to
17 the Committee on Health, Education, Labor, and
18 Pensions of the Senate and the Committee on En-
19 ergy and Commerce of the House of Representa-
20 tives, to include a description of fees assessed and
21 collected for each year, a summary description of en-
22 tities paying the fees, a description of the hiring and
23 placement of new staff, a description of the use of
24 fee resources to support inspecting compounding

1 manufacturers, and the number of inspections and
2 reinspections of such entities performed each year.

3 “(10) AUTHORIZATION OF APPROPRIATIONS.—

4 For fiscal year 2015 and each subsequent fiscal
5 year, there is authorized to be appropriated for fees
6 under this subsection an amount equivalent to the
7 total amount of fees assessed for such fiscal year
8 under this subsection.

9 “(j) ACTION BY SECRETARY REGARDING COM-
10 PLAINS FROM STATE BOARDS OF PHARMACY.—

11 “(1) IDENTIFICATION OF COMPOUNDING MANU-
12 FACTURERS.—The Secretary shall encourage States
13 to identify to the Secretary any facility that is li-
14 censed by a State as a pharmacy that appears to be
15 an entity that is required to be registered with the
16 Secretary as a compounding manufacturer.

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

24 “(3) DETERMINATION.—If the Secretary deter-
25 mines that such an entity described in paragraph (2)

1 is required to be registered with the Secretary as a
2 compounding manufacturer, the Secretary shall
3 transmit such determination to the State Board of
4 Pharmacy in the State in which the entity is located,
5 and to the State Board of Pharmacy in the notifying
6 State, if different, within 15 calendar days of such
7 determination and shall make such determination
8 publicly available on the Internet Web site of the
9 Food and Drug Administration.

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

15 (c) REPORTS BY GAO.—

16 (1) REPORT ON HEALTH SYSTEM
17 COMPOUNDING.—

18 (A) STUDY.—The Comptroller General of
19 the United States shall conduct a study on the
20 quality of non-sterile and sterile drugs com-
21 pounded within hospitals and health systems.

22 (B) CONSIDERATION.—In conducting the
23 study under this paragraph, the Comptroller
24 General shall consider the following questions:

1 (i) What types of drugs are com-
2 pounded in high volumes inside hospitals
3 and health systems? And of those drugs,
4 which are sterile?

5 (ii) How many hospitals and health
6 systems produce sterile drugs in advance of
7 a prescription and ship such drugs across
8 State lines within a given month? Has this
9 increased since the effective date of this
10 Act?

11 (iii) How often are hospital and health
12 system pharmacies being inspected by Fed-
13 eral or State authorities, or the applicable
14 designees of those authorities? How does
15 this compare to the inspection frequency of
16 other traditional pharmacies?

17 (iv) How do hospital and health sys-
18 tems monitor the quality and effectiveness
19 of their internally compounded drugs?

20 (v) How many adverse events, viola-
21 tions, or citations were issued associated
22 with drugs compounded under section
23 503A(b)(11)(B) of the Federal Food,
24 Drug, and Cosmetic Act (as added by this
25 Act).

1 (vi) Are hospitals or health systems
2 taking ownership of stand-alone sterile
3 compounding operations, which would oth-
4 erwise be compounding manufacturers,
5 that compound drugs for the use in such
6 hospital or health system?

7 (C) CONSULTATION WITH STAKE-
8 HOLDERS.—In conducting the study under this
9 paragraph, the Comptroller General shall con-
10 sult with relevant stakeholders, including physi-
11 cians, compounding manufacturers, phar-
12 macists, hospitals, patients, public health
13 groups, professional associations, and other
14 health providers.

15 (D) REPORT.—Not later than July 31,
16 2016, the Comptroller General shall submit a
17 report to the Committee on Energy and Com-
18 merce of the House of Representatives and the
19 Committee on Health, Education, Labor, and
20 Pensions of the Senate on the results of the
21 study under this paragraph, including a sum-
22 mary of any trends in the quantity and sources
23 of compounded drugs used in hospitals (includ-
24 ing the number of hospitals that contract with
25 external pharmacies).

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

7 (d) PROHIBITED ACT.—Section 301 (21 U.S.C. 331)
8 is amended—

9 (1) in subsection (e), by striking “417, 416,
10 504” and inserting “417, 416, 503A(h), 504”; and

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

12 “(ccc)(1) The resale of a compounded drug that is
13 labeled ‘not for resale’ as required by section 503A.

14 “(2) The failure to register in accordance with sub-
15 section (h) of section 503A or the failure to submit a re-
16 port as required by subsection (h)(3)(B) or (h)(4) of such
17 section.

18 “(3) With respect to a drug to be compounded under
19 section 503A, the intentional falsification of a prescrip-
20 tion, a practitioner order (as defined in subsection (b)(6)
21 of such section), or name required under subsection
22 (g)(1)(B) of such section 503A.

23 “(4) With respect to a drug compounded for office
24 use (as described in subsection (b)(6) of section 503A),

1 the dispensing of such compounded drug in a manner in-
2 consistent with subsection (g)(1) of such section.”.

3 **SEC. 103. OTHER REQUIREMENTS.**

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

6 “(bb) If it is a compounded drug and the labeling
7 does not include the information as required by sub-
8 sections (f)(3), (g)(1), and (h)(5) of section 503A, as ap-
9 plicable.

10 “(cc) If the advertising or promotion of a com-
11 pounded drug is false or misleading in any particular.

12 “(dd) If it is a drug, and it was manufactured, pre-
13 pared, propagated, compounded, or processed by a
14 compounding manufacturer for which fees have not been
15 paid as required by section 503A(h).”.

16 (b) APPLICATION OF INSPECTION REQUIREMENTS TO
17 COMPOUNDING MANUFACTURERS.—Section 704(a)(2)
18 (21 U.S.C. 374(a)(2)) is amended by adding at the end
19 the following flush text:

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

23 **SEC. 104. IMPLEMENTATION.**

24 (a) CONSULTATION WITH STAKEHOLDERS.—In im-
25 plementing this title (and the amendments made by this

1 title), the Secretary of Health and Human Services shall
2 consult with relevant stakeholders including pharmacists,
3 professional associations, patient and public health advo-
4 cacy groups, manufacturers and physicians.

5 (b) REGULATIONS.—In promulgating any regulations
6 to implement this title (and the amendments made by this
7 title), the Secretary of Health and Human Services
8 shall—

9 (1) issue a notice of proposed rulemaking that
10 includes the proposed regulation;

11 (2) provide a period of not less than 60 cal-
12 endar days for comments on the proposed regula-
13 tion; and

14 (3) publish the final regulation not more than
15 18 months following publication of the proposed rule
16 and not less than 30 calendar days before the effec-
17 tive date of such final regulation.

18 **SEC. 105. EFFECTIVE DATE.**

19 This title (and the amendments made by this title)
20 shall take effect on the date that is 1 year after the date
21 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**
7 **CHAIN.**

8 Chapter V (21 U.S.C. 351 et seq.) is amended by
9 adding at the end the following:

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

12 **“SEC. 581. DEFINITIONS.**

13 “In this subchapter:

14 “(1) **AFFILIATE.**—The term ‘affiliate’ means a
15 business entity that has a relationship with a second
16 business entity if, directly or indirectly—

17 “(A) one business entity controls, or has
18 the power to control, the other business entity;

19 or

20 “(B) a third party controls, or has the
21 power to control, both of the business entities.

22 “(2) **AUTHORIZED.**—The term ‘authorized’
23 means—

1 “(A) in the case of a manufacturer or re-
2 packager, having a valid registration in accord-
3 ance with section 510;

4 “(B) in the case of a wholesale distributor,
5 having a valid license under State law or sec-
6 tion 583, in accordance with section 582(a)(6)
7 and complying with the licensure reporting re-
8 quirements under section 503(e), as amended
9 by the Drug Supply Chain Security Act;

10 “(C) in the case of a third-party logistics
11 provider, having a valid license under State law
12 or section 584(a)(1), in accordance with section
13 582(a)(7) and complying with the licensure re-
14 porting requirements under section 584(b); and

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

17 “(3) DISPENSER.—The term ‘dispenser’—

18 “(A) means a retail pharmacy, hospital
19 pharmacy, a group of chain pharmacies under
20 common ownership and control that do not act
21 as a wholesale distributor, or any other person
22 authorized by law to dispense or administer
23 prescription drugs, and the affiliated ware-
24 houses or distribution centers of such entities

1 under common ownership and control that do
2 not act as a wholesale distributor; and

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

6 “(4) DISPOSITION.—The term ‘disposition’,
7 with respect to a product within the possession or
8 control of an entity, means the removal of such
9 product from the pharmaceutical distribution supply
10 chain, which may include disposal or return of the
11 product for disposal or other appropriate handling
12 and other actions, such as retaining a sample of the
13 product for further additional physical examination
14 or laboratory analysis of the product by a manufac-
15 turer or regulatory or law enforcement agency.

16 “(5) DISTRIBUTE OR DISTRIBUTION.—The
17 term ‘distribute’ or ‘distribution’ means the sale,
18 purchase, trade, delivery, handling, storage, or re-
19 ceipt of a product, and does not include the dis-
20 pensing of a product pursuant to a prescription exe-
21 cuted in accordance with section 503(b)(1) or the
22 dispensing of a product approved under section
23 512(b).

24 “(6) EXCLUSIVE DISTRIBUTOR.—The term ‘ex-
25 clusive distributor’ means the wholesale distributor

1 that directly purchased the product from the manu-
2 facturer and is the sole distributor of that manufac-
3 turer's product to a subsequent repackager, whole-
4 sale distributor, or dispenser.

5 “(7) HOMOGENEOUS CASE.—The term ‘homo-
6 geneous case’ means a sealed case containing only
7 product that has a single National Drug Code num-
8 ber belonging to a single lot.

9 “(8) ILLEGITIMATE PRODUCT.—The term ‘ille-
10 gitimate product’ means a product for which credible
11 evidence shows that the product—

12 “(A) is counterfeit, diverted, or stolen;

13 “(B) is intentionally adulterated such that
14 the product would result in serious adverse
15 health consequences or death to humans;

16 “(C) is the subject of a fraudulent trans-
17 action; or

18 “(D) appears otherwise unfit for distribu-
19 tion such that the product could result in seri-
20 ous adverse health consequence or death to hu-
21 mans.

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

23 “(A) in the case of a wholesale distributor,
24 having a valid license in accordance with section
25 503(e) or section 582(a)(6), as applicable;

1 “(B) in the case of a third-party logistics
2 provider, having a valid license in accordance
3 with section 584(a) or section 582(a)(7), as ap-
4 plicable; and

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

7 “(10) MANUFACTURER.—The term ‘manufac-
8 turer’ means, with respect to a product—

9 “(A) a person that holds an application ap-
10 proved under section 505 or a license issued
11 under section 351 of the Public Health Service
12 Act for such product, or if such product is not
13 the subject of an approved application or li-
14 cense, the person who manufactured the prod-
15 uct;

16 “(B) a co-licensed partner of the person
17 described in subparagraph (A) that obtains the
18 product directly from a person described in this
19 subparagraph or subparagraph (A) or (C); or

20 “(C) an affiliate of a person described in
21 subparagraph (A) or (B) that receives the prod-
22 uct directly from a person described in this sub-
23 paragraph or subparagraph (A) or (B).

24 “(11) PACKAGE.—

1 “(A) IN GENERAL.—The term ‘package’
2 means the smallest individual saleable unit of
3 product for distribution by a manufacturer or
4 repackager that is intended by the manufac-
5 turer for ultimate sale to the dispenser of such
6 product.

7 “(B) INDIVIDUAL SALEABLE UNIT.—For
8 purposes of this paragraph, an ‘individual sale-
9 able unit’ is the smallest container of product
10 introduced into commerce by the manufacturer
11 or repackager that is intended by the manufac-
12 turer or repackager for individual sale to a dis-
13 penser.

14 “(12) PRESCRIPTION DRUG.—The term ‘pre-
15 scription drug’ means a drug for human use subject
16 to section 503(b)(1).

17 “(13) PRODUCT.—The term ‘product’ means a
18 prescription drug in a finished dosage form for ad-
19 ministration to a patient without substantial further
20 manufacturing (such as capsules, tablets, and
21 lyophilized products before reconstitution), but for
22 purposes of section 582, does not include blood or
23 blood components intended for transfusion, radio-
24 active drugs or radioactive biological products (as
25 defined in section 600.3(ee) of title 21, Code of Fed-

1 eral Regulations) that are regulated by the Nuclear
2 Regulatory Commission or by a State pursuant to
3 an agreement with such Commission under section
4 274 of the Atomic Energy Act of 1954 (42 U.S.C.
5 2021), an intravenous product described in clause
6 xiv, xv, or xvi of paragraph (23), any medical gas
7 (as defined in section 575),), homeopathic drugs
8 marketed in accordance with applicable guidance
9 under this Act, or a drug compounded in compliance
10 with section 503A.

11 “(14) PRODUCT IDENTIFIER.—The term ‘prod-
12 uct identifier’ means a standardized graphic that in-
13 cludes, in both human-readable form and on a ma-
14 chine-readable data carrier that conforms to the
15 standards developed by a widely-recognized inter-
16 national standards development organization, the
17 standardized numerical identifier, lot number, and
18 expiration date of the product.

19 “(15) QUARANTINE.—The term ‘quarantine’
20 means the storage or identification of a product, to
21 prevent distribution or transfer of the product, in a
22 physically separate area clearly identified for such
23 use or through other procedures.

24 “(16) REPACKAGER.—The term ‘repackager’
25 means a person who owns or operates an establish-

1 ment that repacks and relabels a product or package
2 for—

3 “(A) further sale; or

4 “(B) distribution without a further trans-
5 action.

6 “(17) RETURN.—The term ‘return’ means pro-
7 viding product to the authorized immediate trading
8 partner from which such product was purchased or
9 received, or to a returns processor or reverse logis-
10 tics provider for handling of such product.

11 “(18) RETURNS PROCESSOR OR REVERSE LO-
12 GISTICS PROVIDER.—The term ‘returns processor’ or
13 ‘reverse logistics provider’ means a person who owns
14 or operates an establishment that disposes or
15 otherwise processes saleable or nonsaleable product
16 received from an authorized trading partner such
17 that the product may be processed for credit to the
18 purchaser, manufacturer, or seller or disposed of for
19 no further distribution.

20 “(19) SPECIFIC PATIENT NEED.—The term
21 ‘specific patient need’ refers to the transfer of a
22 product from one pharmacy to another to fill a pre-
23 scription for an identified patient. Such term does
24 not include the transfer of a product from one phar-

1 macy to another for the purpose of increasing or re-
2 replenishing stock in anticipation of a potential need.

3 “(20) STANDARDIZED NUMERICAL IDENTIFI-
4 FIER.—The term ‘standardized numerical identifier’
5 means a set of numbers or characters used to
6 uniquely identify each package or homogenous case
7 that is composed of the National Drug Code that
8 corresponds to the specific product (including the
9 particular package configuration) combined with a
10 unique alphanumeric serial number of up to 20
11 characters.

12 “(21) SUSPECT PRODUCT.—The term ‘suspect
13 product’ means a product for which there is reason
14 to believe that such product—

15 “(A) is potentially counterfeit, diverted, or
16 stolen;

17 “(B) is potentially intentionally adulterated
18 such that the product would result in serious
19 adverse health consequences or death to hu-
20 mans;

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

23 “(D) appears otherwise unfit for distribu-
24 tion such that the product would result in seri-

1 ous adverse health consequences or death to hu-
2 mans.

3 “(22) THIRD-PARTY LOGISTICS PROVIDER.—

4 The term ‘third-party logistics provider’ means an
5 entity that provides or coordinates warehousing, or
6 other logistics services of a product in interstate
7 commerce on behalf of a manufacturer, wholesale
8 distributor, or dispenser of a product, but does not
9 take ownership of the product, nor have responsi-
10 bility to direct the sale or disposition of the product.

11 “(23) TRADING PARTNER.—The term ‘trading
12 partner’ means—

13 “(A) a manufacturer, repackager, whole-
14 sale distributor, or dispenser from whom a
15 manufacturer, repackager, wholesale dis-
16 tributor, or dispenser accepts direct ownership
17 of a product or to whom a manufacturer, re-
18 packager, wholesale distributor, or dispenser
19 transfers direct ownership of a product; or

20 “(B) a third-party logistics provider from
21 whom a manufacturer, repackager, wholesale
22 distributor, or dispenser accepts direct posses-
23 sion of a product or to whom a manufacturer,
24 repackager, wholesale distributor, or dispenser
25 transfers direct possession of a product.

1 “(24) TRANSACTION.—

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

5 “(B) EXEMPTIONS.—The term ‘trans-
6 action’ does not include—

7 “(i) intracompany distribution of any
8 product between members of an affiliated
9 group or within a manufacturer;

10 “(ii) the distribution of a product
11 among hospitals or other health care enti-
12 ties that are under common control;

13 “(iii) the distribution of a product for
14 emergency medical reasons including a
15 public health emergency declaration pursu-
16 ant to section 319 of the Public Health
17 Service Act, except that a drug shortage
18 not caused by a public health emergency
19 shall not constitute an emergency medical
20 reason;

21 “(iv) the dispensing of a product pur-
22 suant to a prescription executed in accord-
23 ance with section 503(b)(1);

24 “(v) the distribution of product sam-
25 ples by a manufacturer or a licensed

1 wholesale distributor in accordance with
2 section 503(d);

3 “(vi) the distribution of blood or blood
4 components intended for transfusion;

5 “(vii) the distribution of minimal
6 quantities of product by a licensed retail
7 pharmacy to a licensed practitioner for of-
8 fice use;

9 “(viii) the sale, purchase, or trade of
10 a drug or an offer to sell, purchase, or
11 trade a drug by a charitable organization
12 described in section 501(c)(3) of the Inter-
13 nal Revenue Code of 1986 to a nonprofit
14 affiliate of the organization to the extent
15 otherwise permitted by law;

16 “(ix) the distribution of a product
17 pursuant to the sale or merger of a phar-
18 macy or pharmacies or a wholesale dis-
19 tributor or wholesale distributors, except
20 that any records required to be maintained
21 for the product shall be transferred to the
22 new owner of the pharmacy or pharmacies
23 or wholesale distributor or wholesale dis-
24 tributors;

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

3 “(xi) products transferred to or from
4 any facility that is licensed by the Nuclear
5 Regulatory Commission or by a State pur-
6 suant to an agreement with such Commis-
7 sion under section 274 of the Atomic En-
8 ergy Act of 1954 (42 U.S.C. 2021);

9 “(xii) a combination product that is
10 not subject to approval under section 505
11 or licensure under section 351 of the Pub-
12 lic Health Service Act, and that is—

13 “(I) a product comprised of a de-
14 vice and 1 or more other regulated
15 components (such as a drug/device,
16 biologic/device, or drug/device/biologic)
17 that are physically, chemically, or oth-
18 erwise combined or mixed and pro-
19 duced as a single entity;

20 “(II) 2 or more separate prod-
21 ucts packaged together in a single
22 package or as a unit and comprised of
23 a drug and device or device and bio-
24 logical product; or

1 “(III) 2 or more finished medical
2 devices plus one or more drug or bio-
3 logical products which are packaged
4 together in what is referred to as a
5 ‘medical convenience kit’ as described
6 in clause (xiii);

7 “(xiii) the distribution of a collection
8 of finished medical devices, which may in-
9 clude a product or biological product, as-
10 sembled in kit form strictly for the conven-
11 ience of the purchaser or user (referred to
12 in this clause as a ‘medical convenience
13 kit’) if—

14 “(I) the medical convenience kit
15 is assembled in an establishment that
16 is registered with the Food and Drug
17 Administration as a device manufac-
18 turer in accordance with section
19 510(b)(2);

20 “(II) the medical convenience kit
21 does not contain a controlled sub-
22 stance that appears in a schedule con-
23 tained in the Comprehensive Drug
24 Abuse Prevention and Control Act of
25 1970;

1 “(III) in the case of a medical
2 convenience kit that includes a prod-
3 uct, the person that manufacturers
4 the kit—

5 “(aa) purchased such prod-
6 uct directly from the pharma-
7 ceutical manufacturer or from a
8 wholesale distributor that pur-
9 chased the product directly from
10 the pharmaceutical manufac-
11 turer; and

12 “(bb) does not alter the pri-
13 mary container or label of the
14 product as purchased from the
15 manufacturer or wholesale dis-
16 tributor; and

17 “(IV) in the case of a medical
18 convenience kit that includes a prod-
19 uct, the product is—

20 “(aa) intravenous solution
21 intended for the replenishment of
22 fluids and electrolytes;

23 “(bb) a product intended to
24 maintain the equilibrium of water
25 and minerals in the body;

1 “(cc) a product intended for
2 irrigation or reconstitution;

3 “(dd) an anesthetic;

4 “(ee) an anticoagulant;

5 “(ff) a vasopressor; or

6 “(gg) a sympathicomimetic;

7 “(xiv) the distribution of an intra-
8 venous product that, by its formulation, is
9 intended for the replenishment of fluids
10 and electrolytes (such as sodium, chloride,
11 and potassium) or calories (such as dex-
12 trose and amino acids);

13 “(xv) the distribution of an intra-
14 venous product used to maintain the equi-
15 librium of water and minerals in the body,
16 such as dialysis solutions;

17 “(xvi) the distribution of a product
18 that is intended for irrigation, or sterile
19 water, whether intended for such purposes
20 or for injection;

21 “(xvii) the distribution of a medical
22 gas (as defined in section 575); or

23 “(xviii) the distribution or sale of any
24 licensed product under section 351 of the

1 Public Health Service Act that meets the
2 definition of a device under section 201(h).

3 “(25) TRANSACTION HISTORY.—The term
4 ‘transaction history’ means a statement in paper or
5 electronic form, including the transaction informa-
6 tion for each prior transaction going back to the
7 manufacturer of the product.

8 “(26) TRANSACTION INFORMATION.—The term
9 ‘transaction information’ means—

10 “(A) the proprietary or established name
11 or names of the product;

12 “(B) the strength and dosage form of the
13 product;

14 “(C) the National Drug Code number of
15 the product;

16 “(D) the container size;

17 “(E) the number of containers;

18 “(F) the lot number of the product;

19 “(G) the date of the transaction;

20 “(H) the date of the shipment, if different
21 from the date of the transaction;

22 “(I) the business name and address of the
23 person from whom ownership is being trans-
24 ferred; and

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

3 “(27) TRANSACTION STATEMENT.—The ‘trans-
4 action statement’ is a statement, in paper or elec-
5 tronic form, that the entity transferring ownership
6 in a transaction—

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

9 “(B) received the product from a person
10 that is authorized as required under the Drug
11 Supply Chain Security Act;

12 “(C) received transaction information and
13 a transaction statement from the prior owner of
14 the product, as required under section 582;

15 “(D) did not knowingly ship a suspect or
16 illegitimate product;

17 “(E) had systems and processes in place to
18 comply with verification requirements under
19 section 582;

20 “(F) did not knowingly provide false trans-
21 action information; and

22 “(G) did not knowingly alter the trans-
23 action history.

24 “(28) VERIFICATION OR VERIFY.—The term
25 ‘verification’ or ‘verify’ means determining whether

1 the product identifier affixed to, or imprinted upon,
2 a package or homogeneous case corresponds to the
3 standardized numerical identifier or lot number and
4 expiration date assigned to the product by the man-
5 ufacturer or the repackager, as applicable in accord-
6 ance with section 582.

7 “(29) WHOLESALE DISTRIBUTOR.—The term
8 ‘wholesale distributor’ means a person (other than a
9 manufacturer, a manufacturer’s co-licensed partner,
10 a third-party logistics provider, or repackager) en-
11 gaged in wholesale distribution (as defined in section
12 503(e)(4), as amended by the Drug Supply Chain
13 Security Act).

14 **“SEC. 582. REQUIREMENTS.**

15 “(a) IN GENERAL.—

16 “(1) OTHER ACTIVITIES.—Each manufacturer,
17 repackager, wholesale distributor, third-party logis-
18 tics provider, and dispenser shall comply with the re-
19 quirements set forth in this section with respect to
20 the role of such manufacturer, repackager, wholesale
21 distributor, third-party logistics provider, or dis-
22 penser in a transaction involving product. If an enti-
23 ty meets the definition of more than one of the enti-
24 ties listed in the preceding sentence, such entity
25 shall comply with all applicable requirements in this

1 section, but shall not be required to duplicate re-
2 quirements.

3 “(2) INITIAL STANDARDS.—

4 “(A) IN GENERAL.—The Secretary shall,
5 in consultation with other appropriate Federal
6 officials, manufacturers, repackagers, wholesale
7 distributors, third-party logistics providers, dis-
8 pensers, and other pharmaceutical distribution
9 supply chain stakeholders, issue a draft guid-
10 ance document that establishes standards for
11 the interoperable exchange of transaction infor-
12 mation, transaction history, and transaction
13 statements, in paper or electronic format, for
14 compliance with subsections (a), (b), (c), (d),
15 (e), and (f). In establishing such standards, the
16 Secretary shall consider the feasibility of estab-
17 lishing standardized documentation to be used
18 by members of the pharmaceutical distribution
19 supply chain to convey the transaction informa-
20 tion, transaction history, and transaction state-
21 ment to the subsequent purchaser of a product
22 and to facilitate the exchange of lot level data.
23 The standards established under this paragraph
24 shall take into consideration the standards es-
25 tablished under section 505D and shall comply

1 with a form and format developed by a widely
2 recognized international standards development
3 organization.

4 “(B) PUBLIC INPUT.—Prior to issuing the
5 draft guidance under subparagraph (A), the
6 Secretary shall gather comments and informa-
7 tion from stakeholders and maintain such com-
8 ments and information in a public docket for at
9 least 60 days prior to issuing such guidance.

10 “(C) PUBLICATION.—The Secretary shall
11 publish the standards established under sub-
12 paragraph (A) not later than 1 year after the
13 date of enactment of the Drug Supply Chain
14 Security Act.

15 “(3) WAIVERS, EXCEPTIONS, AND EXEMP-
16 TIONS.—

17 “(A) IN GENERAL.—Not later than 2 years
18 after the date of enactment of the Drug Supply
19 Chain Security Act, the Secretary shall, by
20 guidance—

21 “(i) establish a process by which an
22 authorized manufacturer, repackager,
23 wholesale distributor, or dispenser may re-
24 quest a waiver from any of the require-
25 ments set forth in this section if the Sec-

1 retary determines that such requirements
2 would result in an undue economic hard-
3 ship or for emergency medical reasons, in-
4 cluding a public health emergency declara-
5 tion pursuant to section 319 of the Public
6 Health Service Act;

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

17 “(iii) establish a process by which the
18 Secretary may determine other products or
19 transactions that shall be exempt from the
20 requirements of this section.

21 “(B) CONTENT.—The guidance issued
22 under subparagraph (A) shall include a process
23 for the biennial review and renewal of such
24 waivers, exceptions, and exemptions, as applica-
25 ble.

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

10 “(4) SELF-EXECUTING REQUIREMENTS.—Ex-
11 cept where otherwise specified, the requirements of
12 this section may be enforced without further regula-
13 tions or guidance from the Secretary.

14 “(5) GRANDFATHERING PRODUCT.—

15 “(A) PRODUCT IDENTIFIER.—Not later
16 than 2 years after the date of enactment of the
17 Drug Supply Chain Security Act, the Secretary
18 shall finalize guidance specifying whether and
19 under what circumstances product that is not
20 labeled with a product identifier and that is in
21 the pharmaceutical distribution supply chain at
22 the time of the effective date of the require-
23 ments of this section shall be exempted from
24 the requirements of this section.

1 “(B) TRACING.—For a product that en-
2 tered the pharmaceutical distribution supply
3 chain prior to the date that is 1 year after the
4 date of enactment of the Drug Supply Chain
5 Security Act—

6 “(i) authorized trading partners shall
7 be exempt from providing transaction in-
8 formation as required under subsections
9 (b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii),
10 and (e)(1)(A)(ii);

11 “(ii) transaction history required
12 under this section shall begin with the
13 owner of such product on such date; and

14 “(iii) the owners of such product on
15 such date shall be exempt from asserting
16 receipt of transaction information and
17 transaction statement from the prior owner
18 as required under this section.

19 “(6) WHOLESALE DISTRIBUTOR LICENSES.—
20 Notwithstanding section 581(9)(A), until the effec-
21 tive date of the wholesale distributor licensing regu-
22 lations under section 583, the term ‘licensed’ or ‘au-
23 thorized’, as it relates to a wholesale distributor with
24 respect to prescription drugs, shall mean a wholesale
25 distributor with a valid license under State law.

1 “(ii) shall be included in a linear or 2-
2 dimensional data matrix barcode when af-
3 fixed to, or imprinted upon, a homo-
4 geneous case; and

5 “(B) verification of the product identifier
6 may occur by using human-readable or ma-
7 chine-readable methods.

8 “(b) MANUFACTURER 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 manufac-
13 turer shall—

14 “(i)(I) prior to, or at the time of, each
15 transaction in which such manufacturer
16 transfers ownership of a product, provide
17 the subsequent recipient with transaction
18 history, transaction information, and a
19 transaction statement, in a single docu-
20 ment in an electronic or paper format; and

21 “(II) prior to, or at the time of, each
22 transaction in which such manufacturer
23 transfers possession of a product to a
24 third-party logistics provider for the pur-
25 pose of transferring ownership as part of a

1 transaction to a subsequent recipient, pro-
2 vide to the third-party logistics provider
3 the transaction history, transaction infor-
4 mation, and a transaction statement for
5 such transaction to a subsequent recipient;
6 and

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

12 “(B) REQUESTS FOR INFORMATION.—
13 Upon a request by the Secretary or other ap-
14 propriate Federal or State official, in the event
15 of a recall or for the purpose of investigating a
16 suspect product or an illegitimate product, a
17 manufacturer shall, not later than 24 hours
18 after receiving the request or in other such rea-
19 sonable time as determined by the Secretary,
20 based on the circumstances of the request, pro-
21 vide the applicable transaction information,
22 transaction history, and transaction statement
23 for the product.

24 “(C) ELECTRONIC FORMAT.—Beginning
25 not later than 4 years after the date of enact-

1 ment of the Drug Supply Chain Security Act,
2 a manufacturer shall provide the transaction in-
3 formation, transaction history, and transaction
4 statement required under subclauses (I) and
5 (II) of subparagraph (A)(i) in electronic form.

6 “(2) PRODUCT IDENTIFIER.—

7 “(A) IN GENERAL.—Beginning not later
8 than 4 years after the date of enactment of the
9 Drug Supply Chain Security Act, a manufac-
10 turer shall affix or imprint a product identifier
11 to each package and homogenous case of a
12 product intended to be introduced in a trans-
13 action into commerce. Such manufacturer shall
14 maintain the product identifier information for
15 such product for not less than 6 years after the
16 date of the transaction.

17 “(B) EXCEPTION.—A package that is re-
18 quired to have a standardized numerical identi-
19 fier is not required to have a unique device
20 identifier.

21 “(3) AUTHORIZED TRADING PARTNERS.—Be-
22 ginning not later than 1 year after the date of enact-
23 ment of the Drug Supply Chain Security Act, the
24 trading partners of a manufacturer may be only au-
25 thorized trading partners.

1 any applicable transaction history and
2 transaction information in the posses-
3 sion of the manufacturer and other-
4 wise investigating to determine wheth-
5 er the product is an illegitimate prod-
6 uct, and, beginning 4 years after the
7 date of enactment of the Drug Supply
8 Chain Security Act, verifying the
9 product at the package level, including
10 the standardized numerical identifier.

11 “(ii) CLEARED PRODUCT.—If the
12 manufacturer makes the determination
13 that a suspect product is not an illegit-
14 imate product, the manufacturer shall
15 promptly notify the Secretary, if applica-
16 ble, of such determination and such prod-
17 uct may be further distributed.

18 “(iii) RECORDS.—A manufacturer
19 shall keep records of the investigation of a
20 suspect product for not less than 6 years
21 after the conclusion of the investigation.

22 “(B) ILLEGITIMATE PRODUCT.—

23 “(i) IN GENERAL.—Upon determining
24 that a product in the possession or control
25 of a manufacturer is an illegitimate prod-

1 uct, the manufacturer shall, in a manner
2 consistent with the systems and processes
3 of such manufacturer—

4 “(I) quarantine such product
5 within the possession or control of the
6 manufacturer from product intended
7 for distribution until such product is
8 disposed;

9 “(II) disposition the illegitimate
10 product within the possession or con-
11 trol of the manufacturer;

12 “(III) take reasonable and appro-
13 priate steps to assist a trading part-
14 ner to disposition an illegitimate prod-
15 uct not in the possession or control of
16 the manufacturer; and

17 “(IV) retain a sample of the
18 product for further physical examina-
19 tion or laboratory analysis of the
20 product by the manufacturer or Sec-
21 retary (or other appropriate Federal
22 or State official) upon request by the
23 Secretary (or other appropriate Fed-
24 eral or State official), as necessary
25 and appropriate.

1 “(ii) MAKING A NOTIFICATION.—

2 “(I) ILLEGITIMATE PRODUCT.—

3 Upon determining that a product in
4 the possession or control of the manu-
5 facturer is an illegitimate product, the
6 manufacturer shall notify the Sec-
7 retary and all immediate trading part-
8 ners that the manufacturer has reason
9 to believe may have received such ille-
10 gitimate product of such determina-
11 tion not later than 24 hours after
12 making such determination.

13 “(II) HIGH RISK OF ILLEGIT-
14 IMACY.—A manufacturer shall notify
15 the Secretary and immediate trading
16 partners that the manufacturer has
17 reason to believe may have in the
18 trading partner’s possession a product
19 manufactured by, or purported to be a
20 product manufactured by, the manu-
21 facturer not later than 24 hours after
22 determining or being notified by the
23 Secretary or a trading partner that
24 there is a high risk that such product
25 is an illegitimate product. For pur-

1 poses of this subclause, a ‘high risk’
2 may include a specific high-risk that
3 could increase the likelihood that ille-
4 gitimate product will enter the phar-
5 maceutical distribution supply chain
6 and other high risks as determined by
7 the Secretary in guidance pursuant to
8 subsection (i).

9 “(iii) RESPONDING TO A NOTIFICA-
10 TION.—Upon the receipt of a notification
11 from the Secretary or a trading partner
12 that a determination has been made that a
13 product is an illegitimate product, a manu-
14 facturer shall identify all illegitimate prod-
15 uct subject to such notification that is in
16 the possession or control of the manufac-
17 turer, including any product that is subse-
18 quently received, and shall perform the ac-
19 tivities described in subparagraph (A).

20 “(iv) TERMINATING A NOTIFICA-
21 TION.—Upon making a determination, in
22 consultation with the Secretary, that a no-
23 tification is no longer necessary, a manu-
24 facturer shall promptly notify immediate
25 trading partners that the manufacturer no-

1 tified pursuant to clause (ii) that such no-
2 tification has been terminated.

3 “(v) RECORDS.—A manufacturer shall
4 keep records of the disposition of an illegit-
5 imate product for not less than 6 years
6 after the conclusion of the disposition.

7 “(C) REQUESTS FOR VERIFICATION.—Be-
8 ginning 4 years after the date of enactment of
9 the Drug Supply Chain Security Act, upon re-
10 ceiving a request for verification from an au-
11 thorized repackager, wholesale distributor, or
12 dispenser that is in possession or control of a
13 product such person believes to be manufac-
14 tured by such manufacturer, a manufacturer
15 shall, not later than 24 hours after receiving
16 the verification request or in other such reason-
17 able time as determined by the Secretary, based
18 on the circumstances of the request, notify the
19 person making the request whether the product
20 identifier, including the standardized numerical
21 identifier, that is the subject of the request cor-
22 responds to the product identifier affixed or im-
23 printed by the manufacturer. If a manufacturer
24 responding to a verification request identifies a
25 product identifier that does not correspond to

1 that affixed or imprinted by the manufacturer,
2 the manufacturer shall treat such product as
3 suspect product and conduct an investigation as
4 described in subparagraph (A). If the manufac-
5 turer has reason to believe the product is an il-
6 legitimate product, the manufacturer shall ad-
7 vise the person making the request of such be-
8 lief at the time such manufacturer responds to
9 the verification request.

10 “(D) ELECTRONIC DATABASE.—A manu-
11 facturer may satisfy the requirements of this
12 paragraph by developing a secure electronic
13 database or utilizing a secure electronic data-
14 base developed or operated by another entity.
15 The owner of such database shall establish the
16 requirements and processes to respond to re-
17 quests and may provide for data access to other
18 members of the pharmaceutical distribution
19 supply chain, as appropriate. The development
20 and operation of such a database shall not re-
21 lieve a manufacturer of the requirement under
22 this paragraph to respond to a verification re-
23 quest submitted by means other than a secure
24 electronic database.

1 “(E) SALEABLE RETURNED PRODUCT.—
2 Beginning 4 years after the date of enactment
3 of the Drug Supply Chain Security Act (except
4 as provided pursuant to subsection (a)(5)),
5 upon receipt of a returned product that the
6 manufacturer intends to further distribute, be-
7 fore further distributing such product, the man-
8 ufacturer shall verify the product identifier, in-
9 cluding the standardized numerical identifier,
10 for each sealed homogeneous case of such prod-
11 uct or, if such product is not in a sealed homo-
12 geneous case, verify the product identifier, in-
13 cluding the standardized numerical identifier,
14 on each package.

15 “(F) NONSALEABLE RETURNED PROD-
16 UCT.—A manufacturer may return a nonsale-
17 able product to the manufacturer or repack-
18 ager, to the wholesale distributor from whom
19 such product was purchased, or to a person act-
20 ing on behalf of such a person, including a re-
21 turns processor, without providing the informa-
22 tion described in paragraph (1)(A)(i).

23 “(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

24 “(1) PRODUCT TRACING.—

1 “(A) IN GENERAL.—Beginning not later
2 than 1 year after the date of enactment of the
3 Drug Supply Chain Security Act, the following
4 requirements shall apply to wholesale distribu-
5 tors:

6 “(i) A wholesale distributor shall not
7 accept ownership of a product unless the
8 previous owner prior to, or at the time of,
9 the transaction provides the transaction
10 history, transaction information, and a
11 transaction statement for the product, as
12 applicable under this subparagraph.

13 “(ii)(I)(aa) If the wholesale dis-
14 tributor purchased a product directly from
15 the manufacturer, the exclusive distributor
16 of the manufacturer, or a repackager that
17 purchased directly from the manufacturer,
18 then prior to, or at the time of, each trans-
19 action in which the wholesale distributor
20 transfers ownership of a product, the
21 wholesale distributor shall provide to the
22 subsequent purchaser—

23 “(AA) a transaction statement,
24 which shall state that such wholesale
25 distributor, or a member of the affili-

1 ated group of such wholesale dis-
2 tributor, purchased the product di-
3 rectly from the manufacturer, exclu-
4 sive distributor of the manufacturer,
5 or repackager that purchased directly
6 from the manufacturer; and

7 “(BB) subject to subclause (II),
8 the transaction history and trans-
9 action information.

10 “(bb) The wholesale distributor shall
11 provide the transaction history, transaction
12 information, and transaction statement
13 under item (aa)—

14 “(AA) if provided to a dis-
15 penser, on a single document in
16 an electronic or paper format;
17 and

18 “(BB) if provided to a
19 wholesale distributor, through
20 any combination of self-generated
21 paper, electronic data, or manu-
22 facturer-provided information on
23 the product package.

24 “(II) For purposes of transactions de-
25 scribed in subclause (I), transaction his-

1 tory and transaction information shall not
2 be required to include the lot number of
3 the product, the initial transaction date, or
4 the initial shipment date from the manu-
5 facturer (as defined in subparagraphs (F),
6 (G), and (H) of section 581(26)).

7 “(iii) If the wholesale distributor did
8 not purchase a product directly from the
9 manufacturer, the exclusive distributor of
10 the manufacturer, or a repackager that
11 purchased directly from the manufacturer,
12 as described in clause (ii), then prior to, or
13 at the time of, each transaction or subse-
14 quent transaction, the wholesale distributor
15 shall provide to the subsequent purchaser a
16 transaction statement, transaction history,
17 and transaction information, in a paper or
18 electronic format that complies with the
19 guidance document issued under sub-
20 section (a)(2).

21 “(iv) For the purposes of clause (iii),
22 the transaction history supplied shall begin
23 only with the wholesale distributor de-
24 scribed in clause (ii)(I), but the wholesale
25 distributor described in clause (iii) shall in-

1 form the subsequent purchaser that such
2 wholesale distributor received a direct pur-
3 chase statement from a wholesale dis-
4 tributor described in clause (ii)(I).

5 “(v) A wholesale distributor shall—

6 “(I) maintain the transaction in-
7 formation, transaction history, and
8 transaction statement for each trans-
9 action described in clauses (i), (ii),
10 and (iii) for not less than 6 years
11 after the date of the transaction; and

12 “(II) maintain the confidentiality
13 of the transaction information (includ-
14 ing any lot level information con-
15 sistent with the requirements of this
16 section), transaction history, and
17 transaction statement for a product in
18 a manner that prohibits disclosure to
19 any person, except to comply with
20 clauses (ii) and (iii) pursuant to an
21 agreement under subparagraph (D) or
22 as required under subparagraph (C).

23 “(B) RETURNS.—

1 “(i) SALEABLE RETURNS.—Notwith-
2 standing subparagraph (A)(i), the fol-
3 lowing shall apply:

4 “(I) REQUIREMENTS.—Until the
5 date that is 6 years after the date of
6 enactment of the Drug Supply Chain
7 Security Act (except as provided pur-
8 suant to subsection (a)(5)), a whole-
9 sale distributor may accept returned
10 product from a dispenser or repack-
11 ager pursuant to the terms and condi-
12 tions of any agreement between the
13 parties, and, notwithstanding sub-
14 paragraph (A)(ii), may distribute such
15 returned product without providing
16 the transaction history. For trans-
17 actions subsequent to the return, the
18 transaction history of such product
19 shall begin with the wholesale dis-
20 tributor that accepted the returned
21 product, consistent with the require-
22 ments of this subsection.

23 “(II) ENHANCED REQUIRE-
24 MENTS.—Beginning 6 years after the
25 date of enactment of the Drug Supply

1 Chain Security Act (except as pro-
2 vided pursuant to subsection (a)(5)),
3 a wholesale distributor may accept re-
4 turned product from a dispenser or
5 repackager only if the wholesale dis-
6 tributor can associate returned prod-
7 uct with the transaction information
8 and transaction statement associated
9 with that product. For all trans-
10 actions after such date, the trans-
11 action history, as applicable, of such
12 product shall begin with the wholesale
13 distributor that accepted and verified
14 the returned product. For purposes of
15 this subparagraph, the transaction in-
16 formation and transaction history, as
17 applicable, need not include trans-
18 action dates if it is not reasonably
19 practicable to obtain such dates.

20 “(ii) NONSALEABLE RETURNS.—A
21 wholesale distributor may return a non-
22 saleable prescription drug to the manufac-
23 turer or repackager, to the wholesale dis-
24 tributor from whom such prescription drug
25 was purchased, or to a person acting on

1 behalf of such a person, including a re-
2 turns processor, without providing the in-
3 formation required under subparagraph
4 (A)(i).

5 “(C) REQUESTS FOR INFORMATION.—

6 Upon a request by the Secretary or other ap-
7 propriate Federal or State official, in the event
8 of a recall or for the purpose of investigating a
9 suspect product or an illegitimate product a
10 wholesale distributor shall, not later than 24
11 hours after receiving the request or in other
12 such reasonable time as determined by the Sec-
13 retary, based on the circumstances of the re-
14 quest, provide the applicable transaction infor-
15 mation, transaction history, and transaction
16 statement for the product.

17 “(D) TRADING PARTNER AGREEMENTS.—

18 Beginning 6 years after the date of enactment
19 of the Drug Supply Chain Security Act, a
20 wholesale distributor may disclose the trans-
21 action information, including lot level informa-
22 tion, transaction history, or transaction state-
23 ment of a product to the subsequent purchaser
24 of the product, pursuant to a written agreement

1 product within the possession or control of
2 a wholesale distributor is a suspect prod-
3 uct, a wholesale distributor shall—

4 “(I) quarantine such product
5 within the possession or control of the
6 wholesale distributor from product in-
7 tended for distribution until such
8 product is cleared or dispositioned;
9 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 wholesale distributor and
18 otherwise investigating to determine
19 whether the product is an illegitimate
20 product, and, beginning 6 years after
21 the date of enactment of the Drug
22 Supply Chain Security Act (except as
23 provided pursuant to subsection
24 (a)(5)), verifying the product at the

1 package level, including the standard-
2 ized numerical identifier.

3 “(ii) CLEARED PRODUCT.—If the
4 wholesale distributor determines that a
5 suspect product is not an illegitimate prod-
6 uct, the wholesale distributor shall prompt-
7 ly notify the Secretary, if applicable, of
8 such determination and such product may
9 be further distributed.

10 “(iii) RECORDS.—A wholesale dis-
11 tributor shall keep records of the investiga-
12 tion of a suspect product for not less than
13 6 years after the conclusion of the inves-
14 tigation.

15 “(B) ILLEGITIMATE PRODUCT.—

16 “(i) IN GENERAL.—Upon deter-
17 mining, in coordination with the manufac-
18 turer, that a product in the possession or
19 control of a wholesale distributor is an ille-
20 gitimate product, the wholesale distributor
21 shall, in a manner that is consistent with
22 the systems and processes of such whole-
23 sale distributor—

24 “(I) quarantine such product
25 within the possession or control of the

1 wholesale distributor from product in-
2 tended for distribution until such
3 product is dispositioned;

4 “(II) disposition the illegitimate
5 product within the possession or con-
6 trol of the wholesale distributor;

7 “(III) take reasonable and appro-
8 priate steps to assist a trading part-
9 ner to disposition an illegitimate prod-
10 uct not in the possession or control of
11 the wholesale distributor; and

12 “(IV) retain a sample of the
13 product for further physical examina-
14 tion or laboratory analysis of the
15 product by the manufacturer or Sec-
16 retary (or other appropriate Federal
17 or State official) upon request by the
18 manufacturer or Secretary (or other
19 appropriate Federal or State official),
20 as necessary and appropriate.

21 “(ii) MAKING A NOTIFICATION.—

22 Upon determining that a product in the
23 possession or control of the wholesale dis-
24 tributor is an illegitimate product, the
25 wholesale distributor shall notify the Sec-

1 retary and all immediate trading partners
2 that the wholesale distributor has reason
3 to believe may have received such illegit-
4 imate product of such determination not
5 later than 24 hours after making such de-
6 termination.

7 “(iii) RESPONDING TO A NOTIFICA-
8 TION.—Upon the receipt of a notification
9 from the Secretary or a trading partner
10 that a determination has been made that a
11 product is an illegitimate product, a whole-
12 sale distributor shall identify all illegit-
13 imate product subject to such notification
14 that is in the possession or control of the
15 wholesale distributor, including any prod-
16 uct that is subsequently received, and shall
17 perform the activities described in subpara-
18 graph (A).

19 “(iv) TERMINATING A NOTIFICA-
20 TION.—Upon a determination, in consulta-
21 tion with the Secretary, that a notification
22 is no longer necessary, a wholesale dis-
23 tributor shall promptly notify immediate
24 trading partners that the wholesale dis-

1 tributor notified pursuant to clause (ii)
2 that such notification has been terminated.

3 “(v) RECORDS.—A wholesale dis-
4 tributor shall keep records of the dispo-
5 sition of an illegitimate product for not less
6 than 6 years after the conclusion of the
7 disposition.

8 “(C) ELECTRONIC DATABASE.—A whole-
9 sale distributor may satisfy the requirements of
10 this paragraph by developing a secure electronic
11 database or utilizing a secure electronic data-
12 base developed or operated by another entity.
13 The owner of such database shall establish the
14 requirements and processes to respond to re-
15 quests and may provide for data access to other
16 members of the pharmaceutical distribution
17 supply chain, as appropriate. The development
18 and operation of such a database shall not re-
19 lieve a wholesale distributor of the requirement
20 under this paragraph to respond to a
21 verification request submitted by means other
22 than a secure electronic database.

23 “(D) VERIFICATION OF SALEABLE RE-
24 TURNED PRODUCT.—Beginning 6 years after
25 the date of enactment of the Drug Supply

1 Chain Security Act, upon receipt of a returned
2 product that the wholesale distributor intends
3 to further distribute, before further distributing
4 such product, the wholesale distributor shall
5 verify the product identifier, including the
6 standardized numerical identifier, for each
7 sealed homogeneous case of such product or, if
8 such product is not in a sealed homogeneous
9 case, verify the product identifier, including the
10 standardized numerical identifier, on each pack-
11 age.

12 “(d) DISPENSER REQUIREMENTS.—

13 “(1) PRODUCT TRACING.—

14 “(A) IN GENERAL.—Beginning 1 year
15 after the date of enactment of the Drug Supply
16 Chain Security Act, a dispenser—

17 “(i) shall not accept ownership of a
18 product, unless the previous owner prior
19 to, or at the time of, the transaction, pro-
20 vides transaction history, transaction infor-
21 mation, and a transaction statement;

22 “(ii) prior to, or at the time of, each
23 transaction in which the dispenser trans-
24 fers ownership of a product (but not in-
25 cluding dispensing to a patient or returns)

1 shall provide the subsequent owner with
2 transaction history, transaction informa-
3 tion, and a transaction statement for the
4 product, except that the requirements of
5 this clause shall not apply to sales by a
6 dispenser to another dispenser to fulfill a
7 specific patient need; and

8 “(iii) shall maintain transaction infor-
9 mation, transaction history, and trans-
10 action statements, as necessary to inves-
11 tigate a suspect product, for not less than
12 6 years after the transaction.

13 “(B) AGREEMENTS WITH THIRD PAR-
14 TIES.—A dispenser may enter into a written
15 agreement with a third party, including an au-
16 thorized wholesale distributor, under which the
17 third party confidentially maintains the trans-
18 action information, transaction history, and
19 transaction statements required to be main-
20 tained under this subsection on behalf of the
21 dispenser. If a dispenser enters into such an
22 agreement, the dispenser shall maintain a copy
23 of the written agreement and shall not be re-
24 lieved of the obligations of the dispenser under
25 this subsection.

1 “(C) RETURNS.—

2 “(i) SALEABLE RETURNS.—A dis-
3 penser may return product to the trading
4 partner from which the dispenser obtained
5 the product without providing the informa-
6 tion required under subparagraph (A).

7 “(ii) NONSALEABLE RETURNS.—A
8 dispenser may return a nonsaleable prod-
9 uct to the manufacturer or repackager, to
10 the wholesale distributor from whom such
11 product was purchased, to a returns proc-
12 essor, or to a person acting on behalf of
13 such a person without providing the infor-
14 mation required under subparagraph
15 (A)(i).

16 “(D) REQUESTS FOR INFORMATION.—

17 “(i) IN GENERAL.—Upon a request by
18 the Secretary or other appropriate Federal
19 or State official, in the event of a recall or
20 for the purpose of investigating a suspect
21 or an illegitimate product, a dispenser
22 shall, not later than 2 business days after
23 receiving the request or in another such
24 reasonable time as determined by the Sec-
25 retary, based on the circumstances of the

1 request, provide the applicable transaction
2 information, transaction statement, and
3 transaction history which the dispenser re-
4 ceived from the previous owner, which shall
5 not include the lot number of the product,
6 the initial transaction date, or the initial
7 shipment date from the manufacturer un-
8 less such information was included in the
9 transaction information, transaction state-
10 ment, and transaction history provided by
11 the manufacturer or wholesale distributor
12 to the dispenser. The dispenser may re-
13 spond to the request by providing the ap-
14 plicable information in either paper or elec-
15 tronic format.

16 “(ii) EXCEPTION.—Until the date
17 that is 4 years after the date of enactment
18 of the Drug Supply Chain Security Act,
19 the Secretary shall grant a dispenser addi-
20 tional time, as necessary, only with respect
21 to a request described in clause (i) to pro-
22 vide lot level information that was provided
23 to the dispenser in paper 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
4 (except as provided pursuant to subsection (a)(5)).

5 “(3) AUTHORIZED TRADING PARTNERS.—Be-
6 ginning not later than 1 year after the date of enact-
7 ment of the Drug Supply Chain Security Act, the
8 trading partners of a dispenser may be only author-
9 ized trading partners.

10 “(4) VERIFICATION.—Beginning not later than
11 1 year after the date of enactment of the Drug Sup-
12 ply Chain Security Act, a dispenser shall have sys-
13 tems in place to enable the dispenser to comply with
14 the following requirements:

15 “(A) SUSPECT PRODUCT.—

16 “(i) IN GENERAL.—Upon making a
17 determination that a product in the posses-
18 sion or control of the dispenser is a suspect
19 product, 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
23 is 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,
24 whichever is greater, or all packages,
25 if there are fewer than 3, corresponds

1 with the product identifier for such
2 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
9 illegitimate 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
14 Secretary, if applicable, of such determina-
15 tion and such product may be further dis-
16 tributed or dispensed.

17 “(iv) RECORDS.—A dispenser shall
18 keep records of the investigation of a sus-
19 pect product for not less than 6 years after
20 the conclusion of the investigation.

21 “(B) ILLEGITIMATE PRODUCT.—

22 “(i) IN GENERAL.—Upon deter-
23 mining, in coordination with the manufac-
24 turer, that a product in the possession or

1 control of a dispenser is an illegitimate
2 product, the 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 part-
8 ner to disposition an illegitimate prod-
9 uct not in the possession or control of
10 the dispenser; and

11 “(III) retain a sample of the
12 product for further physical examina-
13 tion or laboratory analysis of the
14 product by the manufacturer or Sec-
15 retary (or other appropriate Federal
16 or State official) upon request by the
17 manufacturer or Secretary (or other
18 appropriate Federal or State official),
19 as necessary and appropriate.

20 “(ii) MAKING A NOTIFICATION.—
21 Upon determining that a product in the
22 possession or control of the dispenser is an
23 illegitimate product, the dispenser shall no-
24 tify the Secretary and all immediate trad-
25 ing partners that the dispenser has reason

1 to believe may have received such illegit-
2 imate product of such determination not
3 later than 24 hours after making such de-
4 termination.

5 “(iii) RESPONDING TO A NOTIFICA-
6 TION.—Upon the receipt of a notification
7 from the Secretary or a trading partner
8 that a determination has been made that a
9 product is an illegitimate product, a dis-
10 penser shall identify all illegitimate product
11 subject to such notification that is in the
12 possession or control of the dispenser, in-
13 cluding any product that is subsequently
14 received, and shall perform the activities
15 described in subparagraph (A).

16 “(iv) TERMINATING A NOTIFICA-
17 TION.—Upon making a determination, in
18 consultation with the Secretary, that a no-
19 tification is no longer necessary, a dis-
20 penser shall promptly notify immediate
21 trading partners that the dispenser notified
22 pursuant to clause (ii) that such notifica-
23 tion has been terminated.

24 “(v) RECORDS.—A dispenser shall
25 keep records of the disposition of an illegit-

1 imate product for not less than 6 years
2 after the conclusion of the disposition.

3 “(C) ELECTRONIC DATABASE.—A dis-
4 penser may satisfy the requirements of this
5 paragraph by developing a secure electronic
6 database or utilizing a secure electronic data-
7 base developed or 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 described in section 581(16)(A) 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
17 transaction history, transaction informa-
18 tion, and a transaction statement for the
19 product;

20 “(ii) prior to, or at the time of, each
21 transaction in which the repackager trans-
22 fers ownership of a product, or transfers
23 possession of a product to a third-party lo-
24 gistics provider, provide the subsequent
25 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) RETURNS.—

9 “(i) NONSALEABLE PRODUCT.—A re-
10 packager described in section 581(16)(A)
11 may return a nonsaleable product to the
12 manufacturer or repackager, or to the
13 wholesale distributor from whom such
14 product was purchased, or to a person act-
15 ing on behalf of such a person, including
16 a returns processor, without providing the
17 information required under subparagraph
18 (A)(ii).

19 “(ii) SALEABLE OR NONSALEABLE
20 PRODUCT.—A repackager described in sec-
21 tion 581(16)(B) may return a saleable or
22 nonsaleable product to the manufacturer,
23 repackager, or to the wholesale distributor
24 from whom such product was received
25 without providing the information required

1 under subparagraph (A)(ii) on behalf of
2 the hospital or other health care entity
3 that took ownership of such product pursu-
4 ant to the terms and conditions of any
5 agreement between such repackager and
6 the entity that owns the product.

7 “(C) REQUESTS FOR INFORMATION.—
8 Upon a request by the Secretary or other ap-
9 propriate Federal or State official, in the event
10 of a recall or for the purpose of investigating a
11 suspect product or an illegitimate product, a re-
12 packager described in section 581(16)(A) shall,
13 not later than 24 hours after receiving the re-
14 quest or in other such reasonable time as deter-
15 mined by the Secretary, based on the cir-
16 cumstances of the request, provide the applica-
17 ble transaction information, transaction history
18 and transaction statement for the product.

19 “(2) PRODUCT IDENTIFIER.—

20 “(A) IN GENERAL.—Beginning not later
21 than 5 years after the date of enactment of the
22 Drug Supply Chain Security Act, a repackager
23 described in section 581(16)(A)—

24 “(i) shall affix or imprint a product
25 identifier to each package and homogenous

1 case of product intended to be introduced
2 in a transaction in commerce;

3 “(ii) shall maintain the product iden-
4 tifier information for such product for not
5 less than 6 years after the date of the
6 transaction;

7 “(iii) may engage in transactions in-
8 volving a product only if such product is
9 encoded with a product identifier (except
10 as provided pursuant to subsection (a)(5));
11 and

12 “(iv) maintain records for not less
13 than 6 years to allow the repackager to as-
14 sociate the product identifier the repack-
15 ager affixes or imprints with the product
16 identifier assigned by the original manu-
17 facturer of the product.

18 “(B) EXCEPTION.—A package that is re-
19 quired to have a standardized numerical identi-
20 fier is not required to have a unique device
21 identifier.

22 “(3) AUTHORIZED TRADING PARTNERS.—Be-
23 ginning 1 year after the date of enactment of the
24 Drug Supply Chain Security Act, the trading part-

1 ners of a repackager described in section 581(16)
2 may be only authorized trading partners.

3 “(4) VERIFICATION.—Beginning not later than
4 1 year after the date of enactment of the Drug Sup-
5 ply Chain Security Act, a repackager described in
6 section 581(16)(A) shall have systems in place to en-
7 able the repackager to comply with the following re-
8 quirements:

9 “(A) SUSPECT PRODUCT.—

10 “(i) IN GENERAL.—Upon making a
11 determination that a product in the posses-
12 sion or control of the repackager is a sus-
13 pect 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 repack-
17 ager is a suspect product, a repackager
18 shall—

19 “(I) quarantine such product
20 within the possession or control of the
21 repackager from product intended for
22 distribution until such product is
23 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 repackager and otherwise
7 investigating to determine whether the
8 product is an illegitimate product,
9 and, beginning 5 years after the date
10 of enactment of the Drug Supply
11 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 re-
17 packager makes the determination that a
18 suspect product is not an illegitimate prod-
19 uct, the repackager shall promptly notify
20 the Secretary, if applicable, of such deter-
21 mination and such product may be further
22 distributed.

23 “(iii) RECORDS.—A repackager shall
24 keep records of the investigation of a sus-

1 pect product for not less than 6 years after
2 the conclusion of the investigation.

3 “(B) ILLEGITIMATE PRODUCT.—

4 “(i) IN GENERAL.—Upon deter-
5 mining, in coordination with the manufac-
6 turer, that a product in the possession or
7 control of a repackager is an illegitimate
8 product, the repackager shall, in a manner
9 that is consistent with the systems and
10 processes of such repackager—

11 “(I) quarantine such product
12 within the possession or control of the
13 repackager from product intended for
14 distribution until such product is
15 disposed;

16 “(II) disposition the illegitimate
17 product within the possession or con-
18 trol of the repackager;

19 “(III) take reasonable and appro-
20 priate steps to assist a trading part-
21 ner to disposition an illegitimate prod-
22 uct not in the possession or control of
23 the repackager; and

24 “(IV) retain a sample of the
25 product for further physical examina-

1 tion or laboratory analysis of the
2 product by the manufacturer or Sec-
3 retary (or other appropriate Federal
4 or State official) upon request by the
5 manufacturer or Secretary (or other
6 appropriate Federal or State official),
7 as necessary and appropriate.

8 “(ii) MAKING A NOTIFICATION.—
9 Upon determining that a product in the
10 possession or control of the repackager is
11 an illegitimate product, the repackager
12 shall notify the Secretary and all imme-
13 diate trading partners that the repackager
14 has reason to believe may have received the
15 illegitimate product of such determination
16 not later than 24 hours after making such
17 determination.

18 “(iii) RESPONDING TO A NOTIFICA-
19 TION.—Upon the receipt of a notification
20 from the Secretary or a trading partner, a
21 repackager shall identify all illegitimate
22 product subject to such notification that is
23 in the possession or control of the repack-
24 ager, including any product that is subse-

1 frequently received, and shall perform the ac-
2 tivities described in subparagraph (A).

3 “(iv) TERMINATING A NOTIFICA-
4 TION.—Upon a determination, in consulta-
5 tion with the Secretary, that a notification
6 is no longer necessary, a repackager shall
7 promptly notify immediate trading part-
8 ners that the repackager notified pursuant
9 to clause (ii) that such notification has
10 been terminated.

11 “(v) RECORDS.—A repackager shall
12 keep records of the disposition of an illegit-
13 imate product for not less than 6 years
14 after the conclusion of the disposition.

15 “(C) REQUESTS FOR VERIFICATION.—Be-
16 ginning 5 years after the date of enactment of
17 the Drug Supply Chain Security Act, upon re-
18 ceiving a request for verification from an au-
19 thorized manufacturer, wholesale distributor, or
20 dispenser that is in possession or control of a
21 product they believe to be repackaged by such
22 repackager, a repackager shall, not later than
23 24 hours after receiving the verification request
24 or in other such reasonable time as determined
25 by the Secretary, based on the circumstances of

1 the request, notify the person making the re-
2 quest whether the product identifier, including
3 the standardized numerical identifier, that is
4 the subject of the request corresponds to the
5 product identifier affixed or imprinted by the
6 repackager. If a repackager responding to a
7 verification request identifies a product identi-
8 fier that does not correspond to that affixed or
9 imprinted by the repackager, the repackager
10 shall treat such product as suspect product and
11 conduct an investigation as described in sub-
12 paragraph (A). If the repackager has reason to
13 believe the product is an illegitimate product,
14 the repackager shall advise the person making
15 the request of such belief at the time such re-
16 packager responds to the verification request.

17 “(D) ELECTRONIC DATABASE.—A repack-
18 ager may satisfy the requirements of paragraph
19 (4) by developing a secure electronic database
20 or utilizing a secure electronic database devel-
21 oped or operated by another entity. The owner
22 of such database shall establish the require-
23 ments and processes to respond to requests and
24 may provide for data access to other members
25 of the pharmaceutical distribution supply chain,

1 as appropriate. The development and operation
2 of such a database shall not relieve a repack-
3 ager of the requirement under subparagraph
4 (C) to respond to a verification request sub-
5 mitted by means other than a secure electronic
6 database.

7 “(E) VERIFICATION OF SALEABLE RE-
8 TURNED PRODUCT.—Beginning 5 years after
9 the date of enactment of the Drug Supply
10 Chain Security Act, upon receipt of a returned
11 product that the repackager intends to further
12 distribute, before further distributing such
13 product, the repackager shall verify the product
14 identifier for each sealed homogeneous case of
15 such product or, if such product is not in a
16 sealed homogeneous case, verify the product
17 identifier on each package.

18 “(f) THIRD-PARTY LOGISTICS PROVIDER REQUIRE-
19 MENTS.—

20 “(1) IN GENERAL.—Beginning not later than 1
21 year after the date of enactment of the Drug Supply
22 Chain Security Act, a third-party logistics provider
23 shall—

24 “(A) not accept possession of a product
25 unless the owner of the product provides the

1 transaction history, transaction information,
2 and a transaction statement for the product;

3 “(B) maintain a copy of the information
4 described in subparagraph (A) for not less than
5 6 years after the transfer of possession; and

6 “(C) upon a request by the Secretary or
7 other appropriate Federal or State official, in
8 the event of a recall or for the purpose of inves-
9 tigating a suspect product or an illegitimate
10 product, not later than 24 hours after receiving
11 the request or in other such reasonable time as
12 determined by the Secretary based on the cir-
13 cumstances of the request, provide the applica-
14 ble transaction information, transaction history,
15 and transaction statement for the product.

16 “(2) PRODUCT TRACING.—Beginning not later
17 than 6 years after the date of enactment of the
18 Drug Supply Chain Security Act, a third-party logis-
19 tics provider may accept possession of product only
20 if such product is encoded with a product identifier
21 (except as provided pursuant to subsection (a)(5)).

22 “(3) AUTHORIZED TRADING PARTNERS.—Be-
23 ginning 1 year after the date of enactment of the
24 Drug Supply Chain Security Act, the trading part-

1 ners of a third-party logistics provider may be only
2 authorized trading partners.

3 “(4) VERIFICATION.—Beginning not later than
4 1 year after the date of enactment of the Drug Sup-
5 ply Chain Security Act, a third-party logistics pro-
6 vider shall have systems in place to enable the third-
7 party logistics provider to comply with the following
8 requirements:

9 “(A) SUSPECT PRODUCT.—

10 “(i) IN GENERAL.—Upon making a
11 determination that a product in the posses-
12 sion or control of a third-party logistics
13 provider is a suspect product, a third-party
14 logistics provider shall—

15 “(I) quarantine such product
16 within the possession or control of the
17 third-party logistics provider from
18 product intended for distribution until
19 such product is cleared or transferred
20 to the owner of such product for dis-
21 position of the product; and

22 “(II) promptly notify the owner
23 of such product of the need to conduct
24 an investigation to determine whether
25 the product is an illegitimate product.

1 “(ii) CLEARED PRODUCT.—If the
2 owner of the product notifies the third-
3 party logistics provider of the determina-
4 tion that a suspect product is not an ille-
5 gitimate product, such product may be fur-
6 ther distributed.

7 “(iii) RECORDS.—A third-party logis-
8 tics provider shall keep records of the ac-
9 tivities described in subclauses (I) and (II)
10 of clause (i), as such subclauses relate to
11 a suspect product, for not less than 6
12 years after the conclusion of the investiga-
13 tion.

14 “(B) ILLEGITIMATE PRODUCT.—

15 “(i) IN GENERAL.—Upon deter-
16 mining, in coordination with the manufac-
17 turer, that a product in the possession or
18 control of a third-party logistics provider is
19 an illegitimate product, the third-party lo-
20 gistics provider shall—

21 “(I) promptly notify the owner of
22 such product of the need to dispo-
23 sition such product; and

24 “(II) promptly transfer posses-
25 sion of the product to the owner of

1 such product to disposition the prod-
2 uct.

3 “(ii) MAKING A NOTIFICATION.—

4 Upon determining that a product in the
5 possession or control of the third-party lo-
6 gistics provider is an illegitimate product,
7 the third-party logistics provider shall no-
8 tify the Secretary not later than 24 hours
9 after making such determination.

10 “(iii) RESPONDING TO A NOTIFICA-

11 TION.—Upon the receipt of a notification
12 from the Secretary, a third-party logistics
13 provider shall identify all illegitimate prod-
14 uct subject to such notification that is in
15 the possession or control of the third-party
16 logistics provider, including any product
17 that is subsequently received, and shall
18 perform the activities described in subpara-
19 graph (A).

20 “(iv) TERMINATING A NOTIFICA-

21 TION.—Upon making a determination, in
22 consultation with the Secretary and the
23 owner of such product, that a notification
24 is no longer necessary, a third-party logis-

1 ties provider shall promptly terminate such
2 notification.

3 “(v) RECORDS.—A third-party logis-
4 tics provider shall keep records of the ac-
5 tivities described in subclauses (I) and (II)
6 of clause (i) as such subclauses relate to
7 an illegitimate product for not less than 6
8 years after the conclusion of the disposi-
9 tion.

10 “(g) DROP SHIPMENTS.—

11 “(1) IN GENERAL.—A wholesale distributor
12 that does not physically handle or store product
13 shall be exempt from the provisions of this section,
14 except the notification requirements under clauses
15 (ii), (iii), and (iv) of subsection (c)(4)(B), provided
16 that the manufacturer, repackager, or other whole-
17 sale distributor that distributes the product to the
18 dispenser by means of drop shipment for such
19 wholesale distributor includes on the transaction in-
20 formation and transaction history to the dispenser
21 the contact information of such wholesale distributor
22 and provides the transaction information, trans-
23 action history, and transaction statement directly to
24 the dispenser.

1 “(2) CLARIFICATION.—For purposes of this
2 subsection, providing administrative services, includ-
3 ing processing of orders and payments, shall not by
4 itself, be construed as being involved in the han-
5 dling, distribution, or storage of a product.”.

6 **SEC. 203. ENHANCED DRUG DISTRIBUTION SECURITY.**

7 Section 582, as added by section 202, is amended by
8 adding at the end the following:

9 “(h) ENHANCED DRUG DISTRIBUTION SECURITY.—

10 “(1) IN GENERAL.—On the date that is 10
11 years after the date of enactment of the Drug Sup-
12 ply Chain Security Act, the following interoperable,
13 electronic tracing of product at the package level re-
14 quirements shall go into effect:

15 “(A) The transaction information and the
16 transaction statements as required under this
17 section shall be exchanged in a secure, inter-
18 operable, electronic manner in accordance with
19 the standards established under the guidance
20 issued pursuant to paragraphs (3) and (4) of
21 subsection (i), including any revision of such
22 guidance issued in accordance with paragraph
23 (5) of such subsection.

24 “(B) The transaction information required
25 under this section shall include the product

1 identifier at the package level for each package
2 included in the transaction.

3 “(C) Systems and processes for verification
4 of product at the package level, including the
5 standardized numerical identifier, shall be re-
6 quired in accordance with the standards estab-
7 lished under the guidance issued pursuant to
8 subsection (a)(2) and the guidances issued pur-
9 suant to paragraphs (2), (3), and (4) of sub-
10 section (i), including any revision of such guid-
11 ances issued in accordance with paragraph (5)
12 of such subsection, which may include the use
13 of aggregation and inference as necessary.

14 “(D) The systems and processes necessary
15 to promptly respond with the transaction infor-
16 mation and transaction statement for a product
17 upon a request by the Secretary (or other ap-
18 propriate Federal or State official) in the event
19 of a recall or for the purposes of investigating
20 a suspect product or an illegitimate product
21 shall be required.

22 “(E) The systems and processes necessary
23 to promptly facilitate gathering the information
24 necessary to produce the transaction informa-

1 tion for each transaction going back to the
2 manufacturer, as applicable, shall be required—

3 “(i) in the event of a request by the
4 Secretary (or other appropriate Federal or
5 State official), on account of a recall or for
6 the purposes of investigating a suspect
7 product or an illegitimate product; or

8 “(ii) in the event of a request by an
9 authorized trading partner, in a secure
10 manner that ensures the protection of con-
11 fidential commercial information and trade
12 secrets, for purposes of investigating a sus-
13 pect product or assisting the Secretary (or
14 other appropriate Federal or State official)
15 with a request described in clause (i).

16 “(F) Each person accepting a saleable re-
17 turn shall have systems and processes in place
18 to allow acceptance of such product and may
19 accept saleable returns only if such person can
20 associate the saleable return product with the
21 transaction information and transaction state-
22 ment associated with that product.

23 “(2) COMPLIANCE.—

24 “(A) INFORMATION MAINTENANCE AGREE-
25 MENT.—A dispenser may enter into a written

1 agreement with a third party, including an au-
2 thorized wholesale distributor, under which the
3 third party shall confidentially maintain any in-
4 formation and statements required to be main-
5 tained under this section. If a dispenser enters
6 into such an agreement, the dispenser shall
7 maintain a copy of the written agreement and
8 shall not be relieved of the obligations of the
9 dispenser under this subsection.

10 “(B) ALTERNATIVE METHODS.—The Sec-
11 retary, taking into consideration the assessment
12 conducted under paragraph (3), shall provide
13 for alternative methods of compliance with any
14 of the requirements set forth in paragraph (1),
15 including—

16 “(i) establishing timelines for compli-
17 ance by small businesses (including small
18 business dispensers with 25 or fewer full
19 time employees) with such requirements, in
20 order to ensure that such requirements do
21 not impose undue economic hardship for
22 small businesses, including small business
23 dispensers for whom the criteria set forth
24 in the assessment under paragraph (3) is
25 not met, if the Secretary determines that

1 such requirements under paragraph (1)
2 would result in undue economic hardship;
3 and

4 “(ii) establishing a process by which a
5 dispenser may request a waiver from any
6 of the requirements set forth in paragraph
7 (1) if the Secretary determines that such
8 requirements would result in an undue eco-
9 nomic hardship, which shall include a proc-
10 ess for the biennial review and renewal of
11 any such waiver.

12 “(3) ASSESSMENT.—

13 “(A) IN GENERAL.—Not later than the
14 date that is 18 months after the Secretary
15 issues the final guidance required under sub-
16 section (i), the Secretary shall enter into con-
17 tract with a private, independent consulting
18 firm with expertise to conduct a technology and
19 software assessment that looks at the feasibility
20 of dispensers with 25 or fewer full-time employ-
21 ees conducting interoperable, electronic tracing
22 of products at the package level. In no case
23 may such assessment commence later than 7½
24 years after the date of enactment of the Drug
25 Supply Chain Security Act.

1 graph (A) for public comment prior to be-
2 ginning the assessment;

3 “(ii) publish the final assessment for
4 public comment not later than 30 calendar
5 days after receiving such assessment; and

6 “(iii) hold a public meeting not later
7 than 180 calendar days after receiving the
8 final assessment at which public stake-
9 holders may present their views on the as-
10 sessment.

11 “(4) PROCEDURE.—Notwithstanding section
12 553 of title 5, United States Code, the Secretary, in
13 promulgating any regulation pursuant to this sec-
14 tion, shall—

15 “(A) provide appropriate flexibility by—

16 “(i) not requiring the adoption of spe-
17 cific business systems for the maintenance
18 and transmission of data;

19 “(ii) prescribing alternative methods
20 of compliance for any of the requirements
21 set forth in paragraph (1) or set forth in
22 regulations implementing such require-
23 ments, including timelines—

24 “(I) for small businesses to com-
25 ply with the requirements set forth in

1 the regulations in order to ensure that
2 such requirements do not impose
3 undue economic hardship for small
4 businesses (including small business
5 dispensers for whom the criteria set
6 forth in the assessment under para-
7 graph (3) is not met), if the Secretary
8 determines that such requirements
9 would result in undue economic hard-
10 ship; and

11 “(II) which shall include estab-
12 lishing a process by which a dispenser
13 may request a waiver from any of the
14 requirements set forth in such regula-
15 tions if the Secretary determines that
16 such requirements would result in an
17 undue economic hardship; and

18 “(iii) taking into consideration—

19 “(I) the results of pilot projects,
20 including pilot projects pursuant to
21 this section and private sector pilot
22 projects, including those involving the
23 use of aggregation and inference;

1 “(II) the public meetings held
2 and related guidance documents
3 issued under this section;

4 “(III) the public health benefits
5 of any additional regulations in com-
6 parison to the cost of compliance with
7 such requirements, including on enti-
8 ties of varying sizes and capabilities;

9 “(IV) the diversity of the phar-
10 maceutical distribution supply chain
11 by providing appropriate flexibility for
12 each sector, including both large and
13 small businesses; and

14 “(V) the assessment pursuant to
15 paragraph (3) with respect to small
16 business dispensers, including related
17 public comment and the public meet-
18 ing, and requirements under this sec-
19 tion;

20 “(B) issue a notice of proposed rulemaking
21 that includes a copy of the proposed regulation;

22 “(C) provide a period of not less than 60
23 days for comments on the proposed regulation;
24 and

1 “(D) publish the final regulation not less
2 than 2 years prior to the effective date of the
3 regulation.

4 “(i) GUIDANCE DOCUMENTS.—

5 “(1) IN GENERAL.—For the purposes of facili-
6 tating the successful and efficient adoption of se-
7 cure, interoperable product tracing at the package
8 level in order to enhance drug distribution security
9 and further protect the public health, the Secretary
10 shall issue the guidance documents as provided for
11 in this subsection.

12 “(2) SUSPECT AND ILLEGITIMATE PRODUCT.—

13 “(A) IN GENERAL.—Not later than 180
14 days after the date of enactment of the Drug
15 Supply Chain Security Act, the Secretary shall
16 issue a guidance document to aid trading part-
17 ners in the identification of a suspect product
18 and notification termination. Such guidance
19 document shall—

20 “(i) identify specific scenarios that
21 could significantly increase the risk of a
22 suspect product entering the pharma-
23 ceutical distribution supply chain;

24 “(ii) provide recommendation on how
25 trading partners may identify such product

1 and make a determination if the product is
2 a suspect product as soon as practicable;
3 and

4 “(iii) set forth the process by which
5 manufacturers, repackagers, wholesale dis-
6 tributors, dispensers, and third-party logis-
7 tics providers shall terminate notifications
8 in consultation with the Secretary regard-
9 ing illegitimate product pursuant to sub-
10 sections (b)(4)(B), (c)(4)(B), (d)(4)(B),
11 (e)(4)(B), and (f)(4)(B).

12 “(B) REVISED GUIDANCE.—If the Sec-
13 retary revises the guidance issued under sub-
14 paragraph (A), the Secretary shall follow the
15 procedure set forth in paragraph (5).

16 “(3) UNIT LEVEL TRACING.—

17 “(A) IN GENERAL.—In order to enhance
18 drug distribution security at the package level,
19 not later than 18 months after conducting a
20 public meeting on the system attributes nec-
21 essary to enable secure tracing of product at
22 the package level, including allowing for the use
23 of verification, inference, and aggregation, as
24 necessary, the Secretary shall issue a final guid-
25 ance document that outlines and makes rec-

1 ommendations with respect to the system at-
2 tributes necessary to enable secure tracing at
3 the package level as required under the require-
4 ments established under subsection (h). Such
5 guidance document shall—

6 “(i) define the circumstances under
7 which the sectors within the pharma-
8 ceutical distribution supply chain may, in
9 the most efficient manner practicable, infer
10 the contents of a case, pallet, tote, or other
11 aggregate of individual packages or con-
12 tainers of product, from a product identi-
13 fier associated with the case, pallet, tote,
14 or other aggregate, without opening each
15 case, pallet, tote, or other aggregate or
16 otherwise individually scanning each pack-
17 age;

18 “(ii) identify methods and processes
19 to enhance secure tracing of product at the
20 package level, such as secure processes to
21 facilitate the use of inference, enhanced
22 verification activities, the use of aggrega-
23 tion and inference, processes that utilize
24 the product identifiers to enhance tracing
25 of product at the package level, including

1 the standardized numerical identifier, or
2 package security features; and

3 “(iii) ensure the protection of con-
4 fidential commercial information and trade
5 secrets.

6 “(B) PROCEDURE.—In issuing the guid-
7 ance under subparagraph (A), and in revising
8 such guidance, if applicable, the Secretary shall
9 follow the procedure set forth in paragraph (5).

10 “(4) STANDARDS FOR INTEROPERABLE DATA
11 EXCHANGE.—

12 “(A) IN GENERAL.—In order to enhance
13 secure tracing of a product at the package level,
14 the Secretary, not later than 18 months after
15 conducting a public meeting on the interoper-
16 able standards necessary to enhance the secu-
17 rity of the pharmaceutical distribution supply
18 chain, shall update the guidance issued pursu-
19 ant to subsection (a)(2), as necessary and ap-
20 propriate, and finalize such guidance document
21 so that the guidance document—

22 “(i) identifies and makes rec-
23 ommendations with respect to the stand-
24 ards necessary for adoption in order to
25 support the secure, interoperable electronic

1 data exchange among the pharmaceutical
2 distribution supply chain that comply with
3 a form and format developed by a widely
4 recognized international standards develop-
5 ment organization;

6 “(ii) takes into consideration stand-
7 ards established pursuant to subsection
8 (a)(2) and section 505D;

9 “(iii) facilitates the creation of a uni-
10 form process or methodology for product
11 tracing; and

12 “(iv) ensures the protection of con-
13 fidential commercial information and trade
14 secrets.

15 “(B) PROCEDURE.—In issuing the guid-
16 ance under subparagraph (A), and in revising
17 such guidance, if applicable, the Secretary shall
18 follow the procedure set forth in paragraph (5).

19 “(5) PROCEDURE.—In issuing or revising any
20 guidance issued pursuant to this subsection or sub-
21 section (h), except the initial guidance issued under
22 paragraph (2)(A), the Secretary shall—

23 “(A) publish a notice in the Federal Reg-
24 ister for a period not less than 30 days an-

1 nouncing that the draft or revised draft guid-
2 ance is available;

3 “(B) post the draft guidance document on
4 the Internet Web site of the Food and Drug
5 Administration and make such draft guidance
6 document available in hard copy;

7 “(C) provide an opportunity for comment
8 and review and take into consideration any
9 comments received;

10 “(D) revise the draft guidance, as appro-
11 priate;

12 “(E) publish a notice in the Federal Reg-
13 ister for a period not less than 30 days an-
14 nouncing that the final guidance or final revised
15 guidance is available;

16 “(F) post the final guidance document on
17 the Internet Website of the Food and Drug Ad-
18 ministration and make such final guidance doc-
19 ument available in hard copy; and

20 “(G) provide for an effective date of not
21 earlier than 1 year after such guidance becomes
22 final.

23 “(j) PUBLIC MEETINGS.—

24 “(1) IN GENERAL.—The Secretary shall hold
25 not less than 3 public meetings to enhance the safe-

1 ty and security of the pharmaceutical distribution
2 supply chain and provide for comment. The Sec-
3 retary may hold the first such public meeting not
4 earlier than 1 year after the date of enactment of
5 the Drug Supply Chain Security Act. In carrying
6 out the public meetings described in this paragraph,
7 the Secretary shall—

8 “(A) prioritize topics necessary to inform
9 the issuance of the guidance described in para-
10 graphs (3) and (4) of subsection (i); and

11 “(B) take all measures reasonable and
12 practicable to ensure the protection of confiden-
13 tial commercial information and trade secrets.

14 “(2) CONTENT.—Each of the following topics
15 shall be addressed in at least one of the public meet-
16 ings described in paragraph (1):

17 “(A) An assessment of the steps taken
18 under subsections (b) through (f) to build ca-
19 pacity for a unit-level system, including the im-
20 pact of the requirements of such subsections
21 on—

22 “(i) the ability of the health care sys-
23 tem collectively to maintain patient access
24 to medicines;

1 “(ii) the scalability of such require-
2 ments, including as it relates to product
3 lines; and

4 “(iii) the capability of different sec-
5 tors and subsectors, including both large
6 and small businesses, to affix and utilize
7 the product identifier.

8 “(B) The system attributes necessary to
9 support the requirements set forth under sub-
10 section (h), including the standards necessary
11 for adoption in order to support the secure,
12 interoperable electronic data exchange among
13 sectors within the pharmaceutical distribution
14 supply chain.

15 “(C) Best practices in each of the different
16 sectors within the pharmaceutical distribution
17 supply chain to implement the requirements of
18 this section.

19 “(D) The costs and benefits of the imple-
20 mentation of this section, including the impact
21 on each pharmaceutical distribution supply
22 chain sector and on public health.

23 “(E) Whether electronic tracing require-
24 ments, including tracing of product at the pack-

1 age level, are feasible, cost-effective, and needed
2 to protect the public health.

3 “(F) The systems and processes needed to
4 utilize the product identifiers to enhance tracing
5 of product at the package level, including allow-
6 ing for verification, aggregation, and inference,
7 as necessary.

8 “(G) The technical capabilities and legal
9 authorities, if any, needed to establish an inter-
10 operable, electronic system that provides for
11 tracing of product at the package level.

12 “(H) The impact that such additional re-
13 quirements would have on patient safety, the
14 drug supply, cost and regulatory burden, and
15 timely patient access to prescription drugs.

16 “(I) Other topics, as determined appro-
17 priate by the Secretary.

18 “(k) PILOT PROJECTS.—

19 “(1) IN GENERAL.—The Secretary shall estab-
20 lish 1 or more pilot projects, in coordination with
21 authorized manufacturers, repackagers, wholesale
22 distributors, third-party logistics providers, and dis-
23 pensers, to explore and evaluate methods to enhance
24 the safety and security of the pharmaceutical dis-
25 tribution supply chain. Such projects shall build

1 upon efforts, in existence as of the date of enact-
2 ment of the Drug Supply Chain Security Act, to en-
3 hance the safety and security of the pharmaceutical
4 distribution supply chain, take into consideration
5 any pilot projects conducted prior to such date of
6 enactment, including any pilot projects that use ag-
7 gregation and inference, and inform the draft and
8 final guidance under paragraphs (3) and (4) of sub-
9 section (i).

10 “(2) CONTENT.—

11 “(A) IN GENERAL.—The Secretary shall
12 ensure that the pilot projects under paragraph
13 (1) reflect the diversity of the pharmaceutical
14 distribution supply chain and that the pilot
15 projects, when taken as a whole, include partici-
16 pants representative of every sector, including
17 both large and small businesses.

18 “(B) PROJECT DESIGN.—The pilot
19 projects under paragraph (1) shall be designed
20 to—

21 “(i) utilize the product identifier for
22 tracing of a product, which may include
23 verification of the product identifier of a
24 product, including the use of aggregation
25 and inference;

1 “(ii) improve the technical capabilities
2 of each sector and subsector to comply
3 with systems and processes needed to uti-
4 lize the product identifiers to enhance trac-
5 ing of a product;

6 “(iii) identify system attributes that
7 are necessary to implement the require-
8 ments established under this section; and

9 “(iv) complete other activities as de-
10 termined by the Secretary.

11 “(1) SUNSET.—The following requirements shall have
12 no force or effect beginning on the date that is 10 years
13 after the date of enactment of the Drug Supply Chain Se-
14 curity Act:

15 “(1) The provision and receipt of transaction
16 history under this section.

17 “(2) The requirements set forth for returns
18 under subsections (b)(4)(E), (c)(1)(B)(i),
19 (d)(1)(C)(i), and (e)(4)(E).

20 “(3) The requirements set forth under subpara-
21 graphs (A)(v)(II) and (D) of subsection (c)(1), as
22 applied to lot level information only.

23 “(m) RULE OF CONSTRUCTION.—The requirements
24 set forth in subsections (h)(4), (j), and (k) shall not be
25 construed as a condition, prohibition, or precedent for pre-

1 cluding or delaying the provisions becoming effective pur-
2 suant to subsection (h).”.

3 **SEC. 204. NATIONAL LICENSURE STANDARDS FOR PRE-**
4 **SCRIPTION DRUG WHOLESALE DISTRIBUTORS.**
5 **TORS.**

6 (a) AMENDMENTS.—

7 (1) LICENSE REQUIREMENT.—Section 503(e)
8 (21 U.S.C. 353(e)) is amended by striking para-
9 graphs (1), (2), and (3) and inserting the following:

10 “(1) LICENSE REQUIREMENT.—Subject to sec-
11 tion 583:

12 “(A) IN GENERAL.—No person may en-
13 gage in wholesale distribution of a drug subject
14 to subsection (b)(1) in any State unless such
15 person—

16 “(i)(I) is licensed by the State from
17 which the drug is distributed; or

18 “(II) if the State from which the drug
19 distributed has not established a licensure
20 requirement, is licensed by the Secretary;
21 and

22 “(ii) if the drug is distributed inter-
23 state, is licensed by the State into which
24 the drug is distributed if the State into
25 which the drug is distributed requires the

1 licensure of a person that distributes drugs
2 into the State.

3 “(B) LICENSE STANDARDS.—Each Federal
4 and State license described in subparagraph (A)
5 shall meet the standards, terms, and conditions
6 established by the Secretary under section 583.

7 “(2) LICENSURE REPORTING AND DATABASE.—

8 “(A) LICENSURE REPORTING.—Beginning
9 1 year after the date of enactment of the Drug
10 Supply Chain Security Act, any person who
11 owns or operates an establishment that engages
12 in wholesale distribution shall report to the Sec-
13 retary, on an annual basis pursuant to a sched-
14 ule determined by the Secretary—

15 “(i) each State by which the person is
16 licensed and the appropriate identification
17 number of each such license; and

18 “(ii) the name, address, and contact
19 information of each facility at which, and
20 all trade names under which, the person
21 conducts business.

22 “(B) DATABASE.—Not later than 1 year
23 after the date of enactment of the Drug Supply
24 Chain Security Act, the Secretary shall estab-

1 lish a database of licensed wholesale distribu-
2 tors. Such database shall—

3 “(i) identify each wholesale distributor
4 by name, contact information, and each
5 State where such wholesale distributor is
6 appropriately licensed to engage in whole-
7 sale distribution;

8 “(ii) be available to the public on the
9 Internet Web site of the Food and Drug
10 Administration; and

11 “(iii) be regularly updated on a sched-
12 ule determined by the Secretary.

13 “(3) COSTS.—

14 “(A) AUTHORIZED LICENSURE FEES OF
15 SECRETARY.—If a State does not establish a li-
16 censing program for persons engaged in the
17 wholesale distribution of a drug subject to sub-
18 section (b), the Secretary shall license a person
19 engaged in wholesale distribution located in
20 such State and may collect a reasonable fee in
21 such amount necessary to reimburse the Sec-
22 retary for costs associated with establishing and
23 administering the licensure program and con-
24 ducting periodic inspections under this section.
25 The Secretary shall adjust fee rates as needed

1 on an annual basis to generate only the amount
2 of revenue needed to perform this service. Fees
3 authorized under this paragraph shall be col-
4 lected and available for obligation only to the
5 extent and in the amount provided in advance
6 in appropriations Acts. Such fees are authorized
7 to remain available until expended.

8 “(B) STATE LICENSING FEES.—Nothing in
9 this Act shall prohibit States from collecting
10 fees from wholesale distributors in connection
11 with State licensing of such distributors.”.

12 (2) WHOLESALE DISTRIBUTION.—Section
13 503(e) (21 U.S.C. 353(e)), as amended by para-
14 graph (1), is further amended by adding at the end
15 the following:

16 “(4) For the purposes of this subsection and
17 subsection (d), the term ‘wholesale distribution’
18 means the distribution of a drug subject to sub-
19 section (b) to a person other than a consumer or pa-
20 tient, or receipt of a drug subject to subsection (b)
21 by a person other than the consumer or patient, but
22 does not include—

23 “(A) intracompany distribution of any
24 drug between members of an affiliated group or
25 within a manufacturer;

1 “(B) the distribution of a drug, or an offer
2 to distribute a drug among hospitals or other
3 health care entities which are under common
4 control;

5 “(C) the distribution of a drug or an offer
6 to distribute a drug for emergency medical rea-
7 sons, including a public health emergency dec-
8 laration pursuant to section 319 of the Public
9 Health Service Act, except that, for purposes of
10 this paragraph, a drug shortage not caused by
11 a public health emergency shall not constitute
12 an emergency medical reason;

13 “(D) the dispensing of a drug pursuant to
14 a prescription executed in accordance with sec-
15 tion 503(b)(1);

16 “(E) the distribution of minimal quantities
17 of drug by a licensed retail pharmacy to a li-
18 censed practitioner for office use;

19 “(F) the distribution of a drug or an offer
20 to distribute a drug by a charitable organization
21 to a nonprofit affiliate of the organization to
22 the extent otherwise permitted by law;

23 “(G) the purchase or other acquisition by
24 a dispenser, hospital, or other health care entity

1 of a drug for use by such dispenser, hospital, or
2 other health care entity;

3 “(H) the distribution of a drug by the
4 manufacturer of such drug;

5 “(I) the receipt or transfer of a drug by an
6 authorized third-party logistics provider pro-
7 vided that such third-party logistics provider
8 does not take ownership of the drug;

9 “(J) a common carrier that transports a
10 drug, provided that the common carrier does
11 not take ownership of the drug;

12 “(K) the distribution of a drug, or an offer
13 to distribute a drug by an authorized repack-
14 ager that has taken ownership or possession of
15 the drug and repacks it in accordance with sec-
16 tion 582(e);

17 “(L) salable drug returns when conducted
18 by a dispenser;

19 “(M) the distribution of a collection of fin-
20 ished medical devices, which may include a
21 product or biological product, assembled in kit
22 form strictly for the convenience of the pur-
23 chaser or user (referred to in this subparagraph
24 as a ‘medical convenience kit’) 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 medical convenience kit does
7 not contain a controlled substance that ap-
8 pears in a schedule contained in the Com-
9 prehensive Drug Abuse Prevention and
10 Control Act of 1970;

11 “(iii) in the case of a medical conven-
12 ience kit that includes a product, the per-
13 son that manufactures the kit—

14 “(I) purchased such product di-
15 rectly from the pharmaceutical manu-
16 facturer or from a wholesale dis-
17 tributor that purchased the product
18 directly from the pharmaceutical man-
19 ufacturer; and

20 “(II) does not alter the primary
21 container or label of the product as
22 purchased from the manufacturer or
23 wholesale distributor; and

1 “(iv) in the case of a medical conven-
2 ience kit that includes a product, the prod-
3 uct is—

4 “(I) intravenous solution in-
5 tended for the replenishment of fluids
6 and electrolytes;

7 “(II) a product intended to main-
8 tain the equilibrium of water and min-
9 erals in the body;

10 “(III) a product intended for irri-
11 gation or reconstitution;

12 “(IV) an anesthetic;

13 “(V) an anticoagulant;

14 “(VI) a vasopressor; or

15 “(VII) a sympathicomimetic;

16 “(N) the distribution of an intravenous
17 drug that, by its formulation, is intended for
18 the replenishment of fluids and electrolytes
19 (such as sodium, chloride, and potassium) or
20 calories (such as dextrose and amino acids);

21 “(O) the distribution of an intravenous
22 drug used to maintain the equilibrium of water
23 and minerals in the body, such as dialysis solu-
24 tions;

1 “(P) the distribution of a drug that is in-
2 tended for irrigation, or sterile water, whether
3 intended for such purposes or for injection;

4 “(Q) the distribution of medical gas, as de-
5 fined in section 575;

6 “(R) facilitating the distribution of a prod-
7 uct by providing solely administrative services,
8 including processing of orders and payments; or

9 “(S) the transfer of a product by a hos-
10 pital or other health care entity, or by a whole-
11 sale distributor or manufacturer operating at
12 the direction of the hospital or other health care
13 entity, to a repackager described in section
14 581(16)(B) and registered under section 510
15 for the purpose of repackaging the drug for use
16 by that hospital, or other health care entity and
17 other health care entities that are under com-
18 mon control, if ownership of the drug remains
19 with the hospital or other health care entity at
20 all times.”.

21 (3) **THIRD-PARTY LOGISTICS PROVIDERS.**—Sec-
22 tion 503(e)(21 U.S.C. 353(e)), as amended by para-
23 graph (2), is further amended by adding at the end
24 the following:

1 “(5) THIRD-PARTY LOGISTICS PROVIDERS.—
2 Notwithstanding paragraphs (1) through (4), each
3 entity that meets the definition of a third-party lo-
4 gistics provider under section 581(22) shall obtain a
5 license as a third-party logistics provider as de-
6 scribed in section 584(a) and is not required to ob-
7 tain a license as a wholesale distributor if the entity
8 never assumes an ownership interest in the product
9 it handles.”.

10 (4) AFFILIATE.—Section 503(e) (21 U.S.C.
11 353(e)), as amended by paragraph (3), is further
12 amended by adding at the end the following:

13 “(6) AFFILIATE.—For purposes of this sub-
14 section, the term ‘affiliate’ means a business entity
15 that has a relationship with a second business entity
16 if, directly or indirectly—

17 “(A) one business entity controls, or has
18 the power to control, the other business entity;
19 or

20 “(B) a third party controls, or has the
21 power to control, both of the business entities.”.

22 (5) LICENSURE STANDARDS.—Subchapter H of
23 chapter V, as added by section 202, is amended by
24 adding at the end the following:

1 **“SEC. 583. NATIONAL LICENSURE STANDARDS FOR PRE-**
2 **SCRIPTION DRUG WHOLESALE DISTRIBUTORS.**
3 **TORS.**

4 “(a) IN GENERAL.—The Secretary shall, not later
5 than 2 years after the date of enactment of the Drug Sup-
6 ply Chain Security Act, establish by regulation minimum
7 standards, terms, and conditions for the licensing of per-
8 sons under section 503(e)(1) (as amended by the Drug
9 Supply Chain Security Act), including the revocation,
10 reissuance, and renewal of such license.

11 “(b) CONTENT.—The standards established under
12 subsection (a) shall apply to all State and Federal licenses
13 described under section 503(e)(1) (as amended by the
14 Drug Supply Chain Security Act) and shall prescribe min-
15 imum requirements for the following:

16 “(1) The storage and handling of such drugs,
17 including facility requirements.

18 “(2) The establishment and maintenance of
19 records of the distributions of such drugs.

20 “(3) The furnishing of a bond or other equiva-
21 lent means of security, as follows:

22 “(A)(i) For the issuance or renewal of a
23 wholesale distributor license, an applicant that
24 is not a government owned and operated whole-
25 sale distributor shall submit a surety bond of

1 \$100,000 or other equivalent means of security
2 acceptable to the State.

3 “(ii) For purposes of clause (i), the State
4 or other applicable authority may accept a sur-
5 ety bond in the amount of \$25,000 if the an-
6 nual gross receipts of the previous tax year for
7 the wholesaler is \$10,000,000 or less.

8 “(B) If a wholesale distributor can provide
9 evidence that it possesses the required bond in
10 a State, the requirement for a bond in another
11 State shall be waived.

12 “(4) Mandatory background checks and
13 fingerprinting of facility managers or designated
14 representatives.

15 “(5) The establishment and implementation of
16 qualifications for key personnel.

17 “(6) The mandatory physical inspection of any
18 facility to be used in wholesale distribution within a
19 reasonable time frame from the initial application of
20 the facility and to be conducted by the licensing au-
21 thority or by the State, consistent with subsection
22 (c).

23 “(7) In accordance with subsection (d), the pro-
24 hibition of certain persons from receiving or main-
25 taining licensure for wholesale distribution.

1 “(c) INSPECTIONS.—To satisfy the inspection re-
2 quirement under subsection (b)(6), the Federal or State
3 licensing authority may conduct the inspection or may ac-
4 cept an inspection by the State in which the facility is lo-
5 cated, or by a third-party accreditation or inspection serv-
6 ice approved by the Secretary or the State licensing such
7 wholesale distributor.

8 “(d) PROHIBITED PERSONS.—The standards estab-
9 lished under subsection (a) shall include requirements to
10 prohibit a person from receiving or maintaining licensure
11 for wholesale distribution if the person—

12 “(1) has been convicted of any felony for con-
13 duct relating to wholesale distribution, any felony
14 violation of subsection (i) or (k) of section 301, or
15 any felony violation of section 1365 of title 18,
16 United States Code, relating to product tampering;
17 or

18 “(2) has engaged in a pattern of violating the
19 requirements of this section, or State requirements
20 for licensure, that presents a threat of serious ad-
21 verse health consequences or death to humans.

22 “(e) REQUIREMENTS.—The Secretary, in promul-
23 gating any regulation pursuant to this section, shall, not-
24 withstanding section 553 of title 5, United States Code—

1 “(1) issue a notice of proposed rulemaking that
2 includes a copy of the proposed regulation;

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

5 “(3) provide that the final regulation take effect
6 on the date that is 2 years after the date such final
7 regulation is published.”.

8 (b) AUTHORIZED DISTRIBUTORS OF RECORD.—Sec-
9 tion 503(d) (21 U.S.C. 353(d)) is amended by adding at
10 the end the following:

11 “(4) In this subsection, the term ‘authorized
12 distributors of record’ means those distributors with
13 whom a manufacturer has established an ongoing re-
14 lationship to distribute such manufacturer’s prod-
15 ucts.”.

16 (c) EFFECTIVE DATE.—The amendments made by
17 subsections (a) and (b) shall take effect on the day that
18 is 1 year after the date of enactment of this Act.

19 **SEC. 205. NATIONAL LICENSURE STANDARDS FOR THIRD-**
20 **PARTY LOGISTICS PROVIDERS; UNIFORM NA-**
21 **TIONAL POLICY.**

22 Subchapter H of chapter V, as amended by section
23 204, is further amended by adding at the end the fol-
24 lowing:

1 **“SEC. 584. NATIONAL LICENSURE STANDARDS FOR THIRD-**
2 **PARTY LOGISTICS PROVIDERS.**

3 “(a) **LICENSE REQUIREMENTS.**—No third-party lo-
4 gistics provider in any State may conduct activities in any
5 State unless each facility of such third-party logistics pro-
6 vider—

7 “(1)(A) is licensed by the State from which the
8 drug is distributed by the third-party logistics pro-
9 vider, in accordance with the regulations promul-
10 gated under subsection (d); or

11 “(B) if the State from which the drug distrib-
12 uted by the third-party logistics provider has not es-
13 tablished a licensure requirement, is licensed by the
14 Secretary, in accordance with the regulations pro-
15 mulgated under subsection (d); and

16 “(2) if the drug is distributed interstate, is li-
17 censed by the State into which the drug is distrib-
18 uted by the third-party logistics provider if such
19 State licenses third-party logistics providers that dis-
20 tribute drugs into the State and the third-party lo-
21 gistics provider is not licensed by the Secretary as
22 described in paragraph (1)(B).

23 “(b) **LICENSURE REPORTING.**—Beginning 1 year
24 after the date of enactment of the Drug Supply Chain Se-
25 curity Act, a facility of a third-party logistics provider

1 shall report to the Secretary, on an annual basis pursuant
2 to a schedule determined by the Secretary—

3 “(1) the State by which the facility is licensed
4 and the appropriate identification number of such li-
5 cense; and

6 “(2) the name and address of the facility, and
7 all trade names under which, such facility conducts
8 business.

9 “(c) COSTS.—

10 “(1) AUTHORIZED LICENSURE FEES OF SEC-
11 RETARY.—If a State does not establish a licensing
12 program for a third-party logistics provider, the Sec-
13 retary shall license the third-party logistics provider
14 located in such State and may collect a reasonable
15 fee in such amount necessary to reimburse the Sec-
16 retary for costs associated with establishing and ad-
17 ministering the licensure program and conducting
18 periodic inspections under this section. The Sec-
19 retary shall adjust fee rates as needed on an annual
20 basis to generate only the amount of revenue needed
21 to perform this service. Fees authorized under this
22 paragraph shall be collected and available for obliga-
23 tion only to the extent and in the amount provided
24 in advance in appropriations Acts. Such fees are au-
25 thorized to remain available until expended.

1 “(2) STATE LICENSING FEES.—

2 “(A) STATE ESTABLISHED PROGRAM.—

3 Nothing in this Act shall prohibit a State that
4 has established a program to license a third-
5 party logistics provider from collecting fees
6 from a third-party logistics provider for such a
7 license.

8 “(B) NO STATE ESTABLISHED PRO-

9 GRAM.—A State that does not establish a pro-
10 gram to license a third-party logistics provider
11 in accordance with this section shall be prohib-
12 ited from collecting a State licensing fee from
13 a third-party logistics provider.

14 “(d) LICENSE REGULATIONS.—

15 “(1) IN GENERAL.—Not later than 2 years
16 after the date of enactment of the Drug Supply
17 Chain Security Act, the Secretary shall issue regula-
18 tions regarding the minimum issuance and eligibility
19 requirements for licensing under subsection (a), in-
20 cluding the revocation and reissuance of such li-
21 cense, to third-party logistics providers under this
22 section.

23 “(2) CONTENT.—Such regulations shall—

24 “(A) establish a process by which a third-
25 party accreditation program approved by the

1 Secretary shall, upon request by a third-party
2 logistics provider, issue a license to each third-
3 party logistics provider that meets the min-
4 imum requirements set forth in this section;

5 “(B) establish a process by which the Sec-
6 retary shall issue a license to each third-party
7 logistics provider that meets the minimum re-
8 quirements set forth in this section if the Sec-
9 retary is not able to approve a third-party ac-
10 creditation program because no such program
11 meets the Secretary’s requirements necessary
12 for approval of such a third-party accreditation
13 program;

14 “(C) require that the entity complies with
15 storage practices, as determined by the Sec-
16 retary for such facility, including—

17 “(i) maintaining access to warehouse
18 space of suitable size to facilitate safe op-
19 erations, including a suitable area to quar-
20 antine suspect product;

21 “(ii) maintaining adequate security;
22 and

23 “(iii) having written policies and pro-
24 cedures to—

1 “(I) address receipt, security,
2 storage, inventory, shipment, and dis-
3 tribution of a product;

4 “(II) identify, record, and report
5 confirmed losses or thefts in the
6 United States;

7 “(III) correct errors and inac-
8 curacies in inventories;

9 “(IV) provide support for manu-
10 facturer recalls;

11 “(V) prepare for, protect against,
12 and address any reasonably foresee-
13 able crisis that affects security or op-
14 eration at the facility, such as a
15 strike, fire, or flood;

16 “(VI) ensure that any expired
17 product is segregated from other
18 products and returned to the manu-
19 facturer or re-packager or destroyed;

20 “(VII) maintain the capability to
21 trace the receipt and outbound dis-
22 tribution of a product, and supplies
23 and records of inventory; and

24 “(VIII) quarantine or destroy a
25 suspect product if directed to do so by

1 the respective manufacturer, wholesale
2 distributor, dispenser or an authorized
3 government agency;

4 “(D) provide for periodic inspection by the
5 licensing authority, as determined by the Sec-
6 retary, of such facility warehouse space to en-
7 sure compliance with this section;

8 “(E) prohibit a facility from having as a
9 manager or designated representative anyone
10 convicted of any felony violation of subsection
11 (i) or (k) of section 301 or any violation of sec-
12 tion 1365 of title 18, United States Code relat-
13 ing to product tampering;

14 “(F) provide for mandatory background
15 checks of a facility manager or a designated
16 representative of such manager; and

17 “(G) require a third-party logistics pro-
18 vider to provide the Secretary, upon a request
19 by the Secretary, a list of all product manufac-
20 turers, wholesale distributors, and dispensers
21 for whom the third-party logistics provider pro-
22 vides services at such facility.

23 “(3) PROCEDURE.—In promulgating the regula-
24 tions under this subsection, the Secretary shall, not-

1 withstanding section 553 of title 5, United States
2 Code—

3 “(A) issue a notice of proposed rulemaking
4 that includes a copy of the proposed regulation;

5 “(B) provide a period of not less than 60
6 days for comments on the proposed regulation;
7 and

8 “(C) provide that the final regulation takes
9 effect upon the expiration of 1 year after the
10 date that such final regulation is issued.

11 “(e) RENEWAL OF LICENSES.—The Secretary shall
12 develop procedures for license renewal. Licenses issued
13 under this section shall expire on the date that is 3 years
14 after issuance of the license. Such an expired license may
15 be renewed for additional 3-year periods according to pro-
16 cedures developed by the Secretary.

17 **“SEC. 585. UNIFORM NATIONAL POLICY.**

18 “(a) PRODUCT TRACING AND OTHER REQUIRE-
19 MENTS.—Beginning on the date of enactment of the Drug
20 Supply Chain Security Act, no State or political subdivi-
21 sion of a State may establish or continue in effect any
22 requirements for tracing products through the distribution
23 system (including any requirements with respect to state-
24 ments of distribution history, transaction history, trans-
25 action information, or transaction statement of a product

1 as such product changes ownership in the supply chain,
2 or verification, investigation, disposition, notification, or
3 record-keeping relating to such systems, including paper
4 or electronic pedigree systems or for tracking and tracing
5 drugs throughout the distribution system) which are in-
6 consistent with, more stringent than, or in addition to, any
7 requirements applicable under section 503(e) (as amended
8 by such Act) or this subchapter (or regulations issued
9 thereunder), or which are inconsistent with—

10 “(1) any waiver, exception, or exemption pursu-
11 ant to section 581 or 582; or

12 “(2) any restrictions specified in section 582.

13 “(b) DISTRIBUTION AND LICENSING STANDARDS.—

14 “(1) IN GENERAL.—Beginning on the date of
15 enactment of the Drug Supply Chain Security Act,
16 no State or political subdivision of a State may es-
17 tablish or continue any standards, requirements, or
18 regulations with respect to wholesale prescription
19 drug distributor or third-party logistics provider li-
20 censure that are less stringent than the standards
21 and requirements applicable under section 503(e)
22 (as amended by such Act), in the case of a wholesale
23 distributor, or section 584, in the case of a third-
24 party logistics provider.

1 “(2) STATE REGULATION OF THIRD-PARTY LO-
2 GISTICS PROVIDERS.—No State shall regulate third-
3 party logistics providers as wholesale distributors.

4 “(3) ADMINISTRATION FEES.—Notwithstanding
5 paragraph (1), a State may administer fee collec-
6 tions for effectuating the wholesale drug distributor
7 and third-party logistics provider licensure require-
8 ments under sections 503(e) (as amended by the
9 Drug Supply Chain Security Act), 583, and 584.

10 “(4) ENFORCEMENT, SUSPENSION, AND REV-
11 OCATION OF LICENSES.—Notwithstanding paragraph
12 (1), a State—

13 “(A) may take administrative action, in-
14 cluding fines, to enforce a licensure requirement
15 promulgated by the State in accordance with
16 section 503(e) (as amended by the Drug Supply
17 Chain Security Act) or this subchapter;

18 “(B) may provide for the suspension or
19 revocation of licenses issued by the State for
20 violations of the laws of such State;

21 “(C) upon conviction of violations of Fed-
22 eral, State, or local drug laws or regulations,
23 may provide for fines, imprisonment, or civil
24 penalties; and

1 “(D) may regulate activities of licensed en-
2 tities in a manner that is consistent with prod-
3 uct tracing requirements under section 582.

4 “(c) EXCEPTION.—Nothing in subsection (a) or (b)
5 shall be construed to preempt State requirements related
6 to the distribution of prescription drugs if such require-
7 ments are not related to product tracing as described in
8 subsection (a), including any requirements applicable
9 under section 503(e) (as amended by the Drug Supply
10 Chain Security Act) or this subchapter (or regulations
11 issued thereunder).”.

12 **SEC. 206. PENALTIES.**

13 (a) PROHIBITED ACT.—Section 301(t)(21 U.S.C.
14 331(t)), is amended—

15 (1) by striking “or” after “the requirements of
16 section 503(d),”; and

17 (2) by inserting “, failure to comply with the
18 requirements under section 582, the failure to com-
19 ply with the requirements under section 584, as ap-
20 plicable,” after “in violation of section 503(e)”.

21 (b) MISBRANDING.—Section 502 (21 U.S.C. 352), as
22 amended by section 103, is further amended by adding
23 at the end the following:

24 “(ee) If it is a drug and it fails to bear the product
25 identifier as required by section 582.”.

1 **SEC. 207. CONFORMING AMENDMENT.**

2 (a) IN GENERAL.—Section 303(b)(1)(D)(21 U.S.C.
3 333(b)(1)(D)) is amended by striking “503(e)(2)(A)” and
4 inserting “503(e)(1)”.

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

8 **SEC. 208. SAVINGS CLAUSE.**

9 Except as provided in the amendments made by para-
10 graphs (1), (2), and (3) of section 204(a) and by section
11 206(a), nothing in this title (including the amendments
12 made by this title) shall be construed as altering any au-
13 thority of the Secretary of Health and Human Services
14 with respect to a drug subject to section 503(b)(1) of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 353(b)(1)) under any other provision of such Act or the
17 Public Health Service Act (42 U.S.C. 201 et seq.).