

Calendar No. 236

113TH CONGRESS
1ST SESSION

H. R. 3204

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 30, 2013

Received

NOVEMBER 4, 2013

Read the first time

NOVEMBER 5, 2013

Read the second time and placed on the calendar

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Drug Quality and Se-
5 curity Act”.

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

2 (a) REFERENCES IN ACT.—Except as otherwise spec-
 3 ified, amendments made by this Act to a section or other
 4 provision of law are amendments to such section or other
 5 provision of the Federal Food, Drug, and Cosmetic Act
 6 (21 U.S.C. 301 et seq.).

7 (b) TABLE OF CONTENTS.—The table of contents of
 8 this Act is as follows:

Sec. 1. Short title.
 Sec. 2. References in Act; table of contents.

TITLE I—DRUG COMPOUNDING

Sec. 101. Short title.
 Sec. 102. Voluntary outsourcing facilities.
 Sec. 103. Penalties.
 Sec. 104. Regulations.
 Sec. 105. Enhanced communication.
 Sec. 106. Severability.
 Sec. 107. GAO study.

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 standards for prescription drug wholesale distributors.
 Sec. 205. National standards for third-party logistics providers; uniform na-
 tional policy.
 Sec. 206. Penalties.
 Sec. 207. Conforming amendment.
 Sec. 208. Savings clause.

9 **TITLE I—DRUG COMPOUNDING**

10 **SEC. 101. SHORT TITLE.**

11 This Act may be cited as the “Compounding Quality
 12 Act”.

13 **SEC. 102. VOLUNTARY OUTSOURCING FACILITIES.**

14 (a) IN GENERAL.—Subchapter A of chapter V (21
 15 U.S.C. 351 et seq.) is amended—

1 (1) by redesignating section 503B as section
2 503C; and

3 (2) by inserting after section 503A the fol-
4 lowing new section:

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

6 “(a) IN GENERAL.—Sections 502(f)(1), 505, and 582
7 shall not apply to a drug compounded by or under the
8 direct supervision of a licensed pharmacist in a facility
9 that elects to register as an outsourcing facility if each
10 of the following conditions is met:

11 “(1) REGISTRATION AND REPORTING.—The
12 drug is compounded in an outsourcing facility that
13 is in compliance with the requirements of subsection
14 (b).

15 “(2) BULK DRUG SUBSTANCES.—The drug is
16 compounded in an outsourcing facility that does not
17 compound using bulk drug substances (as defined in
18 section 207.3(a)(4) of title 21, Code of Federal Reg-
19 ulations (or any successor regulation)), unless—

20 “(A)(i) the bulk drug substance appears on
21 a list established by the Secretary identifying
22 bulk drug substances for which there is a clin-
23 ical need, by—

24 “(I) publishing a notice in the Federal
25 Register proposing bulk drug substances to

1 be included on the list, including the ra-
2 tionale for such proposal;

3 “(II) providing a period of not less
4 than 60 calendar days for comment on the
5 notice; and

6 “(III) publishing a notice in the Fed-
7 eral Register designating bulk drug sub-
8 stances for inclusion on the list; or

9 “(ii) the drug compounded from such bulk
10 drug substance appears on the drug shortage
11 list in effect under section 506E at the time of
12 compounding, distribution, and dispensing;

13 “(B) if an applicable monograph exists
14 under the United States Pharmacopeia, the Na-
15 tional Formulary, or another compendium or
16 pharmacopeia recognized by the Secretary for
17 purposes of this paragraph, the bulk drug sub-
18 stances each comply with the monograph;

19 “(C) the bulk drug substances are each
20 manufactured by an establishment that is reg-
21 istered under section 510 (including a foreign
22 establishment that is registered under section
23 510(i)); and

24 “(D) the bulk drug substances are each ac-
25 companied by a valid certificate of analysis.

1 “(3) INGREDIENTS (OTHER THAN BULK DRUG
2 SUBSTANCES).—If any ingredients (other than bulk
3 drug substances) are used in compounding the drug,
4 such ingredients comply with the standards of the
5 applicable United States Pharmacopeia or National
6 Formulary monograph, if such monograph exists, or
7 of another compendium or pharmacopeia recognized
8 by the Secretary for purposes of this paragraph if
9 any.

10 “(4) DRUGS WITHDRAWN OR REMOVED BE-
11 CAUSE UNSAFE OR NOT EFFECTIVE.—The drug does
12 not appear on a list published by the Secretary of
13 drugs that have been withdrawn or removed from
14 the market because such drugs or components of
15 such drugs have been found to be unsafe or not ef-
16 fective.

17 “(5) ESSENTIALLY A COPY OF AN APPROVED
18 DRUG.—The drug is not essentially a copy of one or
19 more approved drugs.

20 “(6) DRUGS PRESENTING DEMONSTRABLE DIF-
21 FICULTIES FOR COMPOUNDING.—The drug—

22 “(A) is not identified (directly or as part
23 of a category of drugs) on a list published by
24 the Secretary, through the process described in
25 subsection (c), of drugs or categories of drugs

1 that present demonstrable difficulties for
2 compounding that are reasonably likely to lead
3 to an adverse effect on the safety or effective-
4 ness of the drug or category of drugs, taking
5 into account the risks and benefits to patients;
6 or

7 “(B) is compounded in accordance with all
8 applicable conditions identified on the list de-
9 scribed in subparagraph (A) as conditions that
10 are necessary to prevent the drug or category of
11 drugs from presenting the demonstrable dif-
12 ficulties described in subparagraph (A).

13 “(7) ELEMENTS TO ASSURE SAFE USE.—In the
14 case of a drug that is compounded from a drug that
15 is the subject of a risk evaluation and mitigation
16 strategy approved with elements to assure safe use
17 pursuant to section 505–1, or from a bulk drug sub-
18 stance that is a component of such drug, the out-
19 sourcing facility demonstrates to the Secretary prior
20 to beginning compounding that such facility will uti-
21 lize controls comparable to the controls applicable
22 under the relevant risk evaluation and mitigation
23 strategy.

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

1 other than the outsourcing facility that compounded
2 such drug. This paragraph does not prohibit admin-
3 istration of a drug in a health care setting or dis-
4 pensing a drug pursuant to a prescription executed
5 in accordance with section 503(b)(1).

6 “(9) FEES.—The drug is compounded in an
7 outsourcing facility that has paid all fees owed by
8 such facility pursuant to section 744K.

9 “(10) LABELING OF DRUGS.—

10 “(A) LABEL.—The label of the drug in-
11 cludes—

12 “(i) the statement ‘This is a com-
13 pounded drug.’ or a reasonable comparable
14 alternative statement (as specified by the
15 Secretary) that prominently identifies the
16 drug as a compounded drug;

17 “(ii) the name, address, and phone
18 number of the applicable outsourcing facil-
19 ity; and

20 “(iii) with respect to the drug—

21 “(I) the lot or batch number;

22 “(II) the established name of the
23 drug;

24 “(III) the dosage form and
25 strength;

1 “(IV) the statement of quantity
2 or volume, as appropriate;

3 “(V) the date that the drug was
4 compounded;

5 “(VI) the expiration date;

6 “(VII) storage and handling in-
7 structions;

8 “(VIII) the National Drug Code
9 number, if available;

10 “(IX) the statement ‘Not for re-
11 sale’, and, if the drug is dispensed or
12 distributed other than pursuant to a
13 prescription for an individual identi-
14 fied patient, the statement ‘Office Use
15 Only’; and

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

21 “(B) CONTAINER.—The container from
22 which the individual units of the drug are re-
23 moved for dispensing or for administration
24 (such as a plastic bag containing individual
25 product syringes) shall include—

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

4 “(ii) the following information to fa-
5 cilitate adverse event reporting:
6 www.fda.gov/medwatch and 1-800-FDA-
7 1088 (or any successor Internet Web site
8 or phone number); and

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

11 “(C) ADDITIONAL INFORMATION.—The
12 label and labeling of the drug shall include any
13 other information as determined necessary and
14 specified in regulations promulgated by the Sec-
15 retary.

16 “(11) OUTSOURCING FACILITY REQUIRE-
17 MENT.—The drug is compounded in an outsourcing
18 facility in which the compounding of drugs occurs
19 only in accordance with this section.

20 “(b) REGISTRATION OF OUTSOURCING FACILITIES
21 AND REPORTING OF DRUGS.—

22 “(1) REGISTRATION OF OUTSOURCING FACILI-
23 TIES.—

24 “(A) ANNUAL REGISTRATION.—Upon
25 electing and in order to become an outsourcing

1 facility, and during the period beginning on Oc-
2 tober 1 and ending on December 31 of each
3 year thereafter, a facility—

4 “(i) shall register with the Secretary
5 its name, place of business, and unique fa-
6 cility identifier (which shall conform to the
7 requirements for the unique facility identi-
8 fier established under section 510), and a
9 point of contact email address; and

10 “(ii) shall indicate whether the out-
11 sourcing facility intends to compound a
12 drug that appears on the list in effect
13 under section 506E during the subsequent
14 calendar year.

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

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

21 “(ii) LIST.—The Secretary shall make
22 available on the public Internet Web site of
23 the Food and Drug Administration a list
24 of the name of each facility registered
25 under this subsection as an outsourcing fa-

1 cility, the State in which each such facility
2 is located, whether the facility compounds
3 from bulk drug substances, and whether
4 any such compounding from bulk drug
5 substances is for sterile or nonsterile
6 drugs.

7 “(2) DRUG REPORTING BY OUTSOURCING FA-
8 CILITIES.—

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

16 “(i) identifying the drugs compounded
17 by such outsourcing facility during the pre-
18 vious 6-month period; and

19 “(ii) with respect to each drug identi-
20 fied under clause (i), providing the active
21 ingredient, the source of such active ingre-
22 dient, the National Drug Code number of
23 the source drug or bulk active ingredient,
24 if available, the strength of the active in-
25 gredient per unit, the dosage form and

1 route of administration, the package de-
2 scription, the number of individual units
3 produced, and the National Drug Code
4 number of the final product, if assigned.

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

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

15 “(3) ELECTRONIC REGISTRATION AND REPORT-
16 ING.—Registrations and drug reporting under this
17 subsection (including the submission of updated in-
18 formation) shall be submitted to the Secretary by
19 electronic means unless the Secretary grants a re-
20 quest for waiver of such requirement because use of
21 electronic means is not reasonable for the person re-
22 questing waiver.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 “(c) REGULATIONS.—

19 “(1) IN GENERAL.—The Secretary shall imple-
20 ment the list described in subsection (a)(6) through
21 regulations.

22 “(2) ADVISORY COMMITTEE ON
23 COMPOUNDING.—Before issuing regulations to im-
24 plement subsection (a)(6), the Secretary shall con-
25 vene and consult an advisory committee on

1 compounding. The advisory committee shall include
2 representatives from the National Association of
3 Boards of Pharmacy, the United States Pharma-
4 copeia, pharmacists with current experience and ex-
5 pertise in compounding, physicians with background
6 and knowledge in compounding, and patient and
7 public health advocacy organizations.

8 “(3) INTERIM LIST.—

9 “(A) IN GENERAL.—Before the effective
10 date of the regulations finalized to implement
11 subsection (a)(6), the Secretary may designate
12 drugs, categories of drugs, or conditions as de-
13 scribed such subsection by—

14 “(i) publishing a notice of such sub-
15 stances, drugs, categories of drugs, or con-
16 ditions proposed for designation, including
17 the rationale for such designation, in the
18 Federal Register;

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

22 “(iii) publishing a notice in the Fed-
23 eral Register designating such drugs, cat-
24 egories of drugs, or conditions.

1 “(B) SUNSET OF NOTICE.—Any notice
2 provided under subparagraph (A) shall not be
3 effective after the earlier of—

4 “(i) the date that is 5 years after the
5 date of enactment of the Compounding
6 Quality Act; or

7 “(ii) the effective date of the final reg-
8 ulations issued to implement subsection
9 (a)(6).

10 “(4) UPDATES.—The Secretary shall review,
11 and update as necessary, the regulations containing
12 the lists of drugs, categories of drugs, or conditions
13 described in subsection (a)(6) regularly, but not less
14 than once every 4 years. Nothing in the previous
15 sentence prohibits submissions to the Secretary, be-
16 fore or during any 4-year period described in such
17 sentence, requesting updates to such lists.

18 “(d) DEFINITIONS.—In this section:

19 “(1) The term ‘compounding’ includes the com-
20 bining, admixing, mixing, diluting, pooling, reconsti-
21 tuting, or otherwise altering of a drug or bulk drug
22 substance to create a drug.

23 “(2) The term ‘essentially a copy of an ap-
24 proved drug’ means—

1 “(A) a drug that is identical or nearly
2 identical to an approved drug, or a marketed
3 drug not subject to section 503(b) and not sub-
4 ject to approval in an application submitted
5 under section 505, unless, in the case of an ap-
6 proved drug, the drug appears on the drug
7 shortage list in effect under section 506E at the
8 time of compounding, distribution, and dis-
9 pensing; or

10 “(B) a drug, a component of which is a
11 bulk drug substance that is a component of an
12 approved drug or a marketed drug that is not
13 subject to section 503(b) and not subject to ap-
14 proval in an application submitted under sec-
15 tion 505, unless there is a change that produces
16 for an individual patient a clinical difference, as
17 determined by the prescribing practitioner, be-
18 tween the compounded drug and the com-
19 parable approved drug.

20 “(3) The term ‘approved drug’ means a drug
21 that is approved under section 505 and does not ap-
22 pear on the list described in subsection (a)(4) of
23 drugs that have been withdrawn or removed from
24 the market because such drugs or components of

1 such drugs have been found to be unsafe or not ef-
2 fective.

3 “(4)(A) The term ‘outsourcing facility’ means a
4 facility at one geographic location or address that—

5 “(i) is engaged in the compounding of ster-
6 ile drugs;

7 “(ii) has elected to register as an outsource-
8 ing facility; and

9 “(iii) complies with all of the requirements
10 of this section.

11 “(B) An outsourcing facility is not required to
12 be a licensed pharmacy.

13 “(C) An outsourcing facility may or may not
14 obtain prescriptions for identified individual pa-
15 tients.

16 “(5) The term ‘sterile drug’ means a drug that
17 is intended for parenteral administration, an oph-
18 thalmic or oral inhalation drug in aqueous format,
19 or a drug that is required to be sterile under Federal
20 or State law.”.

21 “(d) OBLIGATION TO PAY FEES.—Payment of the fee
22 under section 744K, as described in subsection (a)(9),
23 shall not relieve an outsourcing facility that is licensed as
24 a pharmacy in any State that requires pharmacy licensing
25 fees of its obligation to pay such State fees.”.

1 (b) FEES.—Subchapter C of chapter VII (21 U.S.C.
2 379f et seq.) is amended by adding at the end the fol-
3 lowing:

4 **“PART 9—FEES RELATING TO OUTSOURCING**
5 **FACILITIES**

6 **“SEC. 744J. DEFINITIONS.**

7 “In this part:

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

10 “(2) The term ‘gross annual sales’ means the
11 total worldwide gross annual sales, in United States
12 dollars, for an outsourcing facility, including the
13 sales of all the affiliates of the outsourcing facility.

14 “(3) The term ‘outsourcing facility’ has the
15 meaning given to such term in section 503B(d)(4).

16 “(4) The term ‘reinspection’ means, with re-
17 spect to an outsourcing facility, 1 or more inspec-
18 tions conducted under section 704 subsequent to an
19 inspection conducted under such provision which
20 identified noncompliance materially related to an ap-
21 plicable requirement of this Act, specifically to deter-
22 mine whether compliance has been achieved to the
23 Secretary’s satisfaction.

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

3 “(a) ESTABLISHMENT AND REINSPECTION FEES.—

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

7 “(A) an annual establishment fee from
8 each outsourcing facility; and

9 “(B) a reinspection fee from each out-
10 sourcing facility subject to a reinspection in
11 such fiscal year.

12 “(2) MULTIPLE REINSPECTIONS.—An outsource-
13 ing facility subject to multiple reinspections in a fis-
14 cal year shall be subject to a reinspection fee for
15 each reinspection.

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

18 “(1) establish the amount of the establishment
19 fee and reinspection fee to be collected under this
20 section for each fiscal year based on the method-
21 ology described in subsection (c); and

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

25 “(c) AMOUNT OF ESTABLISHMENT FEE AND REIN-
26 SPECTION FEE.—

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

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

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

10 “(ii) the small business adjustment
11 factor described in paragraph (3); and

12 “(B) the amount of any reinspection fee (if
13 applicable) under subsection (b) shall be equal
14 to \$15,000, multiplied by the inflation adjust-
15 ment factor described in paragraph (2).

16 “(2) INFLATION ADJUSTMENT FACTOR.—

17 “(A) IN GENERAL.—For fiscal year 2015
18 and subsequent fiscal years, the fee amounts es-
19 tablished in paragraph (1) shall be adjusted by
20 the Secretary by notice, published in the Fed-
21 eral Register, for a fiscal year by the amount
22 equal to the sum of—

23 “(i) 1;

24 “(ii) the average annual percent
25 change in the cost, per full-time equivalent

1 position of the Food and Drug Administra-
2 tion, of all personnel compensation and
3 benefits paid with respect to such positions
4 for the first 3 years of the preceding 4 fis-
5 cal years, multiplied by the proportion of
6 personnel compensation and benefits costs
7 to total costs of an average full-time equiv-
8 alent position of the Food and Drug Ad-
9 ministration for the first 3 years of the
10 preceding 4 fiscal years; plus

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

23 “(B) COMPOUNDED BASIS.—The adjust-
24 ment made each fiscal year under subparagraph
25 (A) shall be added on a compounded basis to

1 the sum of all adjustments made each fiscal
2 year after fiscal year 2014 under subparagraph
3 (A).

4 “(3) SMALL BUSINESS ADJUSTMENT FACTOR.—
5 The small business adjustment factor described in
6 this paragraph shall be an amount established by
7 the Secretary for each fiscal year based on the Sec-
8 retary’s estimate of—

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

12 “(B) the adjustment to the establishment
13 fee necessary to achieve total fees equaling the
14 total fees that the Secretary would have col-
15 lected if no entity qualified for the small busi-
16 ness exception in paragraph (4).

17 “(4) EXCEPTION FOR SMALL BUSINESSES.—

18 “(A) IN GENERAL.—In the case of an out-
19 sourcing facility with gross annual sales of
20 \$1,000,000 or less in the 12 months ending
21 April 1 of the fiscal year immediately preceding
22 the fiscal year in which the fees under this sec-
23 tion are assessed, the amount of the establish-
24 ment fee under subsection (b) for a fiscal year

1 shall be equal to $\frac{1}{3}$ of the amount calculated
2 under paragraph (1)(A)(i) for such fiscal year.

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

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

17 “(A) provide for the crediting of fees from
18 the previous year to the next year if the Sec-
19 retary overestimated the amount of the small
20 business adjustment factor for such previous
21 fiscal year; and

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

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

5 “(e) SUPPLEMENT NOT SUPPLANT.—Funds received
6 by the Secretary pursuant to this section shall be used
7 to supplement and not supplant any other Federal funds
8 available to carry out the activities described in this sec-
9 tion.

10 “(f) CREDITING AND AVAILABILITY OF FEES.—Fees
11 authorized under this section shall be collected and avail-
12 able for obligation only to the extent and in the amount
13 provided in advance in appropriations Acts. Such fees are
14 authorized to remain available until expended. Such sums
15 as may be necessary may be transferred from the Food
16 and Drug Administration salaries and expenses appropria-
17 tion account without fiscal year limitation to such appro-
18 priation account for salaries and expenses with such fiscal
19 year limitation. The sums transferred shall be available
20 solely for the purpose of paying the costs of oversight of
21 outsourcing facilities.

22 “(g) COLLECTION OF FEES.—

23 “(1) ESTABLISHMENT FEE.—An outsourcing
24 facility shall remit the establishment fee due under
25 this section in a fiscal year when submitting a reg-

1 istration pursuant to section 503B(b) for such fiscal
2 year.

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

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

12 “(A) REGISTRATION.—An outsourcing fa-
13 cility shall not be considered registered under
14 section 503B(b) in a fiscal year until the date
15 that the outsourcing facility remits the estab-
16 lishment fee under this subsection for such fis-
17 cal year.

18 “(B) MISBRANDING.—All drugs manufac-
19 tured, prepared, propagated, compounded, or
20 processed by an outsourcing facility for which
21 any establishment fee or reinspection fee has
22 not been paid, as required by this section, shall
23 be deemed misbranded under section 502 until
24 the fees owed for such outsourcing facility
25 under this section have been paid.

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

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

21 “(i) AUTHORIZATION OF APPROPRIATIONS.—For fis-
22 cal year 2014 and each subsequent fiscal year, there is
23 authorized to be appropriated for fees under this section
24 an amount equivalent to the total amount of fees assessed
25 for such fiscal year under this section.”.

1 **SEC. 103. PENALTIES.**

2 (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.
3 331) is amended by adding at the end the following:

4 “(ccc)(1) The resale of a compounded drug that is
5 labeled ‘not for resale’ in accordance with section 503B.

6 “(2) With respect to a drug to be compounded pursu-
7 ant to section 503A or 503B, the intentional falsification
8 of a prescription, as applicable.

9 “(3) The failure to report drugs or adverse events
10 by an entity that is registered in accordance with sub-
11 section (b) of section 503B.”.

12 (b) MISBRANDED DRUGS.—Section 502 (21 U.S.C.
13 352) is amended by adding at the end the following:

14 “(bb) If the advertising or promotion of a com-
15 pounded drug is false or misleading in any particular.”.

16 **SEC. 104. REGULATIONS.**

17 In promulgating any regulations to implement this
18 title (and the amendments made by this title), the Sec-
19 retary of Health and Human Services shall—

20 (1) issue a notice of proposed rulemaking that
21 includes the proposed regulation;

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

25 (3) publish the final regulation not more than
26 18 months following publication of the proposed rule

1 and not less than 30 calendar days before the effective date of such final regulation.

3 **SEC. 105. ENHANCED COMMUNICATION.**

4 (a) SUBMISSIONS FROM STATE BOARDS OF PHARMACY.—In a manner specified by the Secretary of Health
5 and Human Services (referred to in this section as the
6 “Secretary”), the Secretary shall receive submissions from
7 State boards of pharmacy—

9 (1) describing actions taken against
10 compounding pharmacies, as described in subsection
11 (b); or

12 (2) expressing concerns that a compounding
13 pharmacy may be acting contrary to section 503A of
14 the Federal Food, Drug, and Cosmetic Act (21
15 U.S.C. 353a).

16 (b) CONTENT OF SUBMISSIONS FROM STATE
17 BOARDS OF PHARMACY.—An action referred to in sub-
18 section (a)(1) is, with respect to a pharmacy that com-
19 pounds drugs, any of the following:

20 (1) The issuance of a warning letter, or the im-
21 position of sanctions or penalties, by a State for vio-
22 lations of a State’s pharmacy regulations pertaining
23 to compounding.

24 (2) The suspension or revocation of a State-
25 issued pharmacy license or registration for violations

1 of a State’s pharmacy regulations pertaining to
2 compounding.

3 (3) The recall of a compounded drug due to
4 concerns relating to the quality or purity of such
5 drug.

6 (c) CONSULTATION.—The Secretary shall implement
7 subsection (a) in consultation with the National Associa-
8 tion of Boards of Pharmacy.

9 (d) NOTIFYING STATE BOARDS OF PHARMACY.—The
10 Secretary shall immediately notify State boards of phar-
11 macy when—

12 (1) the Secretary receives a submission under
13 subsection (a)(1); or

14 (2) the Secretary makes a determination that a
15 pharmacy is acting contrary to section 503A of the
16 Federal Food, Drug, and Cosmetic Act.

17 **SEC. 106. SEVERABILITY.**

18 (a) IN GENERAL.—Section 503A (21 U.S.C. 353a)
19 is amended —

20 (1) in subsection (a), in the matter preceding
21 paragraph (1), by striking “unsolicited”;

22 (2) by striking subsection (c);

23 (3) by redesignating subsections (d) through (f)
24 as subsections (c) through (e), respectively; and

1 (4) in subsection (b)(1)(A)(i)(III), by striking
2 “subsection (d)” and inserting “subsection (e)”.

3 (b) SEVERABILITY.—If any provision of this Act (in-
4 cluding the amendments made by this Act) is declared un-
5 constitutional, or the applicability of this Act (including
6 the amendments made by this Act) to any person or cir-
7 cumstance is held invalid, the constitutionality of the re-
8 mainder of this Act (including the amendments made by
9 this Act) and the applicability thereof to other persons and
10 circumstances shall not be affected.

11 **SEC. 107. GAO STUDY.**

12 (a) STUDY.—Not later than 36 months after the date
13 of the enactment of this Act, the Comptroller General of
14 the United States shall submit to Congress a report on
15 pharmacy compounding and the adequacy of State and
16 Federal efforts to assure the safety of compounded drugs.

17 (b) CONTENTS.—The report required under this sec-
18 tion shall include—

19 (1) a review of pharmacy compounding in each
20 State, and the settings in which such compounding
21 occurs;

22 (2) a review of the State laws and policies gov-
23 erning pharmacy compounding, including enforce-
24 ment of State laws and policies;

1 (3) an assessment of the available tools to per-
2 mit purchasers of compounded drugs to determine
3 the safety and quality of such drugs;

4 (4) an evaluation of the effectiveness of the
5 communication among States and between States
6 and the Food and Drug Administration regarding
7 compounding; and

8 (5) an evaluation of the Food and Drug Admin-
9 istration’s implementation of sections 503A and
10 503B of the Federal Food, Drug, and Cosmetic Act.

11 **TITLE II—DRUG SUPPLY CHAIN**
12 **SECURITY**

13 **SEC. 201. SHORT TITLE.**

14 This title may be cited as the “Drug Supply Chain
15 Security Act”.

16 **SEC. 202. PHARMACEUTICAL DISTRIBUTION SUPPLY**
17 **CHAIN.**

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

20 **“Subchapter H—Pharmaceutical Distribution**
21 **Supply Chain**

22 **“SEC. 581. DEFINITIONS.**

23 “In this subchapter:

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

4 “(A) one business entity controls, or has
5 the power to control, the other business entity;
6 or

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

9 “(2) AUTHORIZED.—The term ‘authorized’
10 means—

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

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

20 “(C) in the case of a third-party logistics
21 provider, having a valid license under State law
22 or section 584(a)(1), in accordance with section
23 582(a)(7), and complying with the licensure re-
24 porting requirements under section 584(b); and

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

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

4 “(A) means a retail pharmacy, hospital
5 pharmacy, a group of chain pharmacies under
6 common ownership and control that do not act
7 as a wholesale distributor, or any other person
8 authorized by law to dispense or administer
9 prescription drugs, and the affiliated ware-
10 houses or distribution centers of such entities
11 under common ownership and control that do
12 not act as a wholesale distributor; and

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

16 “(4) DISPOSITION.—The term ‘disposition’,
17 with respect to a product within the possession or
18 control of an entity, means the removal of such
19 product from the pharmaceutical distribution supply
20 chain, which may include disposal or return of the
21 product for disposal or other appropriate handling
22 and other actions, such as retaining a sample of the
23 product for further additional physical examination
24 or laboratory analysis of the product by a manufac-
25 turer or regulatory or law enforcement agency.

1 “(5) DISTRIBUTE OR DISTRIBUTION.—The
2 term ‘distribute’ or ‘distribution’ means the sale,
3 purchase, trade, delivery, handling, storage, or re-
4 ceipt of a product, and does not include the dis-
5 pensing of a product pursuant to a prescription exe-
6 cuted in accordance with section 503(b)(1) or the
7 dispensing of a product approved under section
8 512(b).

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

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

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

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

23 “(B) is intentionally adulterated such that
24 the product would result in serious adverse
25 health consequences or death to humans;

1 “(C) is the subject of a fraudulent trans-
2 action; or

3 “(D) appears otherwise unfit for distribu-
4 tion such that the product would be reasonably
5 likely to result in serious adverse health con-
6 sequences or death to humans.

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

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

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

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

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

19 “(A) a person that holds an application ap-
20 proved under section 505 or a license issued
21 under section 351 of the Public Health Service
22 Act for such product, or if such product is not
23 the subject of an approved application or li-
24 cense, the person who manufactured the prod-
25 uct;

1 “(B) a co-licensed partner of the person
2 described in subparagraph (A) that obtains the
3 product directly from a person described in this
4 subparagraph or subparagraph (A) or (C); or

5 “(C) an affiliate of a person described in
6 subparagraph (A) or (B) that receives the prod-
7 uct directly from a person described in this sub-
8 paragraph or subparagraph (A) or (B).

9 “(11) PACKAGE.—

10 “(A) IN GENERAL.—The term ‘package’
11 means the smallest individual saleable unit of
12 product for distribution by a manufacturer or
13 repackager that is intended by the manufac-
14 turer for ultimate sale to the dispenser of such
15 product.

16 “(B) INDIVIDUAL SALEABLE UNIT.—For
17 purposes of this paragraph, an ‘individual sale-
18 able unit’ is the smallest container of product
19 introduced into commerce by the manufacturer
20 or repackager that is intended by the manufac-
21 turer or repackager for individual sale to a dis-
22 penser.

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

1 “(13) PRODUCT.—The term ‘product’ means a
2 prescription drug in a finished dosage form for ad-
3 ministration to a patient without substantial further
4 manufacturing (such as capsules, tablets, and
5 lyophilized products before reconstitution), but for
6 purposes of section 582, does not include blood or
7 blood components intended for transfusion, radio-
8 active drugs or radioactive biological products (as
9 defined in section 600.3(ee) of title 21, Code of Fed-
10 eral Regulations) that are regulated by the Nuclear
11 Regulatory Commission or by a State pursuant to
12 an agreement with such Commission under section
13 274 of the Atomic Energy Act of 1954 (42 U.S.C.
14 2021), imaging drugs, an intravenous product de-
15 scribed in clause (xiv), (xv), or (xvi) of paragraph
16 (24)(B), any medical gas (as defined in section 575),
17 homeopathic drugs marketed in accordance with ap-
18 plicable guidance under this Act, or a drug com-
19 pounded in compliance with section 503A or 503B.

20 “(14) PRODUCT IDENTIFIER.—The term ‘prod-
21 uct identifier’ means a standardized graphic that in-
22 cludes, in both human-readable form and on a ma-
23 chine-readable data carrier that conforms to the
24 standards developed by a widely recognized inter-
25 national standards development organization, the

1 standardized numerical identifier, lot number, and
2 expiration date of the product.

3 “(15) QUARANTINE.—The term ‘quarantine’
4 means the storage or identification of a product, to
5 prevent distribution or transfer of the product, in a
6 physically separate area clearly identified for such
7 use or through other procedures.

8 “(16) REPACKAGER.—The term ‘repackager’
9 means a person who owns or operates an establish-
10 ment that repacks and relabels a product or package
11 for—

12 “(A) further sale; or

13 “(B) distribution without a further trans-
14 action.

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

20 “(18) RETURNS PROCESSOR OR REVERSE LO-
21 GISTICS PROVIDER.—The term ‘returns processor’ or
22 ‘reverse logistics provider’ means a person who owns
23 or operates an establishment that disposes or
24 otherwise processes saleable or nonsaleable product
25 received from an authorized trading partner such

1 that the product may be processed for credit to the
2 purchaser, manufacturer, or seller or disposed of for
3 no further distribution.

4 “(19) SPECIFIC PATIENT NEED.—The term
5 ‘specific patient need’ refers to the transfer of a
6 product from one pharmacy to another to fill a pre-
7 scription for an identified patient. Such term does
8 not include the transfer of a product from one phar-
9 macy to another for the purpose of increasing or re-
10 plenishing stock in anticipation of a potential need.

11 “(20) STANDARDIZED NUMERICAL IDENTI-
12 FIER.—The term ‘standardized numerical identifier’
13 means a set of numbers or characters used to
14 uniquely identify each package or homogenous case
15 that is composed of the National Drug Code that
16 corresponds to the specific product (including the
17 particular package configuration) combined with a
18 unique alphanumeric serial number of up to 20
19 characters.

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

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

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

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

7 “(D) appears otherwise unfit for distribu-
8 tion such that the product would result in seri-
9 ous adverse health consequences or death to hu-
10 mans.

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

12 The term ‘third-party logistics provider’ means an
13 entity that provides or coordinates warehousing, or
14 other logistics services of a product in interstate
15 commerce on behalf of a manufacturer, wholesale
16 distributor, or dispenser of a product, but does not
17 take ownership of the product, nor have responsi-
18 bility to direct the sale or disposition of the product.

19 “(23) TRADING PARTNER.—The term ‘trading
20 partner’ means—

21 “(A) a manufacturer, repackager, whole-
22 sale distributor, or dispenser from whom a
23 manufacturer, repackager, wholesale dis-
24 tributor, or dispenser accepts direct ownership
25 of a product or to whom a manufacturer, re-

1 packager, wholesale distributor, or dispenser
2 transfers direct ownership of a product; or

3 “(B) a third-party logistics provider from
4 whom a manufacturer, repackager, wholesale
5 distributor, or dispenser accepts direct posses-
6 sion of a product or to whom a manufacturer,
7 repackager, wholesale distributor, or dispenser
8 transfers direct possession of a product.

9 “(24) TRANSACTION.—

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

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

15 “(i) intracompany distribution of any
16 product between members of an affiliate or
17 within a manufacturer;

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

21 “(iii) the distribution of a product for
22 emergency medical reasons including a
23 public health emergency declaration pursu-
24 ant to section 319 of the Public Health
25 Service Act, except that a drug shortage

1 not caused by a public health emergency
2 shall not constitute an emergency medical
3 reason;

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

7 “(v) the distribution of product sam-
8 ples by a manufacturer or a licensed
9 wholesale distributor in accordance with
10 section 503(d);

11 “(vi) the distribution of blood or blood
12 components intended for transfusion;

13 “(vii) the distribution of minimal
14 quantities of product by a licensed retail
15 pharmacy to a licensed practitioner for of-
16 fice use;

17 “(viii) the sale, purchase, or trade of
18 a drug or an offer to sell, purchase, or
19 trade a drug by a charitable organization
20 described in section 501(c)(3) of the Inter-
21 nal Revenue Code of 1986 to a nonprofit
22 affiliate of the organization to the extent
23 otherwise permitted by law;

24 “(ix) the distribution of a product
25 pursuant to the sale or merger of a phar-

1 macy or pharmacies or a wholesale dis-
2 tributor or wholesale distributors, except
3 that any records required to be maintained
4 for the product shall be transferred to the
5 new owner of the pharmacy or pharmacies
6 or wholesale distributor or wholesale dis-
7 tributors;

8 “(x) the dispensing of a product ap-
9 proved under section 512(c);

10 “(xi) products transferred to or from
11 any facility that is licensed by the Nuclear
12 Regulatory Commission or by a State pur-
13 suant to an agreement with such Commis-
14 sion under section 274 of the Atomic En-
15 ergy Act of 1954 (42 U.S.C. 2021);

16 “(xii) a combination product that is
17 not subject to approval under section 505
18 or licensure under section 351 of the Pub-
19 lic Health Service Act, and that is—

20 “(I) a product comprised of a de-
21 vice and 1 or more other regulated
22 components (such as a drug/device,
23 biologic/device, or drug/device/biologic)
24 that are physically, chemically, or oth-

1 erwise combined or mixed and pro-
2 duced as a single entity;

3 “(II) 2 or more separate prod-
4 ucts packaged together in a single
5 package or as a unit and comprised of
6 a drug and device or device and bio-
7 logical product; or

8 “(III) 2 or more finished medical
9 devices plus one or more drug or bio-
10 logical products that are packaged to-
11 gether in what is referred to as a
12 ‘medical convenience kit’ as described
13 in clause (xiii);

14 “(xiii) the distribution of a collection
15 of finished medical devices, which may in-
16 clude a product or biological product, as-
17 sembled in kit form strictly for the conven-
18 ience of the purchaser or user (referred to
19 in this clause as a ‘medical convenience
20 kit’) if—

21 “(I) the medical convenience kit
22 is assembled in an establishment that
23 is registered with the Food and Drug
24 Administration as a device manufac-

1 turer in accordance with section
2 510(b)(2);

3 “(II) the medical convenience kit
4 does not contain a controlled sub-
5 stance that appears in a schedule con-
6 tained in the Comprehensive Drug
7 Abuse Prevention and Control Act of
8 1970;

9 “(III) in the case of a medical
10 convenience kit that includes a prod-
11 uct, the person that manufactures
12 the kit—

13 “(aa) purchased such prod-
14 uct directly from the pharma-
15 ceutical manufacturer or from a
16 wholesale distributor that pur-
17 chased the product directly from
18 the pharmaceutical manufac-
19 turer; and

20 “(bb) does not alter the pri-
21 mary container or label of the
22 product as purchased from the
23 manufacturer or wholesale dis-
24 tributor; and

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

4 “(aa) an intravenous solu-
5 tion intended for the replenish-
6 ment of fluids and electrolytes;

7 “(bb) a product intended to
8 maintain the equilibrium of water
9 and minerals in the body;

10 “(cc) a product intended for
11 irrigation or reconstitution;

12 “(dd) an anesthetic;

13 “(ee) an anticoagulant;

14 “(ff) a vasopressor; or

15 “(gg) a sympathomimetic;

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

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

1 “(xvi) the distribution of a product
2 that is intended for irrigation, or sterile
3 water, whether intended for such purposes
4 or for injection;

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

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

11 “(25) TRANSACTION HISTORY.—The term
12 ‘transaction history’ means a statement in paper or
13 electronic form, including the transaction informa-
14 tion for each prior transaction going back to the
15 manufacturer of the product.

16 “(26) TRANSACTION INFORMATION.—The term
17 ‘transaction information’ means—

18 “(A) the proprietary or established name
19 or names of the product;

20 “(B) the strength and dosage form of the
21 product;

22 “(C) the National Drug Code number of
23 the product;

24 “(D) the container size;

25 “(E) the number of containers;

1 “(F) the lot number of the product;

2 “(G) the date of the transaction;

3 “(H) the date of the shipment, if more
4 than 24 hours after the date of the transaction;

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

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

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

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

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

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

22 “(D) did not knowingly ship a suspect or
23 illegitimate product;

1 “(E) had systems and processes in place to
2 comply with verification requirements under
3 section 582;

4 “(F) did not knowingly provide false trans-
5 action information; and

6 “(G) did not knowingly alter the trans-
7 action history.

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

16 “(29) WHOLESALE DISTRIBUTOR.—The term
17 ‘wholesale distributor’ means a person (other than a
18 manufacturer, a manufacturer’s co-licensed partner,
19 a third-party logistics provider, or repackager) en-
20 gaged in wholesale distribution (as defined in section
21 503(e)(4), as amended by the Drug Supply Chain
22 Security Act).

23 **“SEC. 582. REQUIREMENTS.**

24 “(a) IN GENERAL.—

1 “(1) OTHER ACTIVITIES.—Each manufacturer,
2 repackager, wholesale distributor, and dispenser
3 shall comply with the requirements set forth in this
4 section with respect to the role of such manufac-
5 turer, repackager, wholesale distributor, or dispenser
6 in a transaction involving product. If an entity meets
7 the definition of more than one of the entities listed
8 in the preceding sentence, such entity shall comply
9 with all applicable requirements in this section, but
10 shall not be required to duplicate requirements.

11 “(2) INITIAL STANDARDS.—

12 “(A) IN GENERAL.—The Secretary shall,
13 in consultation with other appropriate Federal
14 officials, manufacturers, repackagers, wholesale
15 distributors, dispensers, and other pharma-
16 ceutical distribution supply chain stakeholders,
17 issue a draft guidance document that estab-
18 lishes standards for the interoperable exchange
19 of transaction information, transaction history,
20 and transaction statements, in paper or elec-
21 tronic format, for compliance with this sub-
22 section and subsections (b), (c), (d), and (e). In
23 establishing such standards, the Secretary shall
24 consider the feasibility of establishing standard-
25 ized documentation to be used by members of

1 the pharmaceutical distribution supply chain to
2 convey the transaction information, transaction
3 history, and transaction statement to the subse-
4 quent purchaser of a product and to facilitate
5 the exchange of lot level data. The standards
6 established under this paragraph shall take into
7 consideration the standards established under
8 section 505D and shall comply with a form and
9 format developed by a widely recognized inter-
10 national standards development organization.

11 “(B) PUBLIC INPUT.—Prior to issuing the
12 draft guidance under subparagraph (A), the
13 Secretary shall gather comments and informa-
14 tion from stakeholders and maintain such com-
15 ments and information in a public docket for at
16 least 60 days prior to issuing such guidance.

17 “(C) PUBLICATION.—The Secretary shall
18 publish the standards established under sub-
19 paragraph (A) not later than 1 year after the
20 date of enactment of the Drug Supply Chain
21 Security Act.

22 “(3) WAIVERS, EXCEPTIONS, AND EXEMP-
23 TIONS.—

24 “(A) IN GENERAL.—Not later than 2 years
25 after the date of enactment of the Drug Supply

1 Chain Security Act, the Secretary shall, by
2 guidance—

3 “(i) establish a process by which an
4 authorized manufacturer, repackager,
5 wholesale distributor, or dispenser may re-
6 quest a waiver from any of the require-
7 ments set forth in this section, which the
8 Secretary may grant if the Secretary deter-
9 mines that such requirements would result
10 in an undue economic hardship or for
11 emergency medical reasons, including a
12 public health emergency declaration pursu-
13 ant to section 319 of the Public Health
14 Service Act;

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

1 “(iii) establish a process by which the
2 Secretary may determine other products or
3 transactions that shall be exempt from the
4 requirements of this section.

5 “(B) CONTENT.—The guidance issued
6 under subparagraph (A) shall include a process
7 for the biennial review and renewal of such
8 waivers, exceptions, and exemptions, as applica-
9 ble.

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

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

23 “(5) GRANDFATHERING PRODUCT.—

24 “(A) PRODUCT IDENTIFIER.—Not later
25 than 2 years after the date of enactment of the

1 Drug Supply Chain Security Act, the Secretary
2 shall finalize guidance specifying whether and
3 under what circumstances product that is not
4 labeled with a product identifier and that is in
5 the pharmaceutical distribution supply chain at
6 the time of the effective date of the require-
7 ments of this section shall be exempted from
8 the requirements of this section.

9 “(B) TRACING.—For a product that en-
10 tered the pharmaceutical distribution supply
11 chain prior to January 1, 2015—

12 “(i) authorized trading partners shall
13 be exempt from providing transaction in-
14 formation as required under subsections
15 (b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii),
16 and (e)(1)(A)(ii);

17 “(ii) transaction history required
18 under this section shall begin with the
19 owner of such product on such date; and

20 “(iii) the owners of such product on
21 such date shall be exempt from asserting
22 receipt of transaction information and
23 transaction statement from the prior owner
24 as required under this section.

1 “(6) WHOLESALE DISTRIBUTOR LICENSES.—
2 Notwithstanding section 581(9)(A), until the effec-
3 tive date of the wholesale distributor licensing regu-
4 lations under section 583, the term ‘licensed’ or ‘au-
5 thorized’, as it relates to a wholesale distributor with
6 respect to prescription drugs, shall mean a wholesale
7 distributor with a valid license under State law.

8 “(7) THIRD-PARTY LOGISTICS PROVIDER LI-
9 CENSES.—Until the effective date of the third-party
10 logistics provider licensing regulations under section
11 584, a third-party logistics provider shall be consid-
12 ered ‘licensed’ under section 581(9)(B) unless the
13 Secretary has made a finding that the third-party lo-
14 gistics provider does not utilize good handling and
15 distribution practices and publishes notice thereof.

16 “(8) LABEL CHANGES.—Changes made to pack-
17 age labels solely to incorporate the product identifier
18 may be submitted to the Secretary in the annual re-
19 port of an establishment, in accordance with section
20 314.70(d) of chapter 21, Code of Federal Regula-
21 tions (or any successor regulation).

22 “(9) PRODUCT IDENTIFIERS.—With respect to
23 any requirement relating to product identifiers under
24 this subchapter—

1 “(A) unless the Secretary allows, through
2 guidance, the use of other technologies for data
3 instead of or in addition to the technologies de-
4 scribed in clauses (i) and (ii), the applicable
5 data—

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

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

13 “(B) verification of the product identifier
14 may occur by using human-readable or ma-
15 chine-readable methods.

16 “(b) MANUFACTURER REQUIREMENTS.—

17 “(1) PRODUCT TRACING.—

18 “(A) IN GENERAL.—Beginning not later
19 than January 1, 2015, a manufacturer shall—

20 “(i) prior to, or at the time of, each
21 transaction in which such manufacturer
22 transfers ownership of a product, provide
23 the subsequent owner with transaction his-
24 tory, transaction information, and a trans-

1 action statement, in a single document in
2 an paper or electronic format; and

3 “(ii) capture the transaction informa-
4 tion (including lot level information),
5 transaction history, and transaction state-
6 ment for each transaction and maintain
7 such information, history, and statement
8 for not less than 6 years after the date of
9 the transaction.

10 “(B) REQUESTS FOR INFORMATION.—

11 Upon a request by the Secretary or other ap-
12 propriate Federal or State official, in the event
13 of a recall or for the purpose of investigating a
14 suspect product or an illegitimate product, a
15 manufacturer shall, not later than 1 business
16 day, and not to exceed 48 hours, after receiving
17 the request, or in other such reasonable time as
18 determined by the Secretary, based on the cir-
19 cumstances of the request, provide the applica-
20 ble transaction information, transaction history,
21 and transaction statement for the product.

22 “(C) ELECTRONIC FORMAT.—

23 “(i) IN GENERAL.—Beginning not
24 later than 4 years after the date of enact-
25 ment of the Drug Supply Chain Security

1 Act, except as provided under clause (ii), a
2 manufacturer shall provide the transaction
3 information, transaction history, and
4 transaction statement required under sub-
5 paragraph (A)(i) in electronic format.

6 “(ii) EXCEPTION.—A manufacturer
7 may continue to provide the transaction in-
8 formation, transaction history, and trans-
9 action statement required under subpara-
10 graph (A)(i) in a paper format to a li-
11 censed health care practitioner authorized
12 to prescribe medication under State law or
13 other licensed individual under the super-
14 vision or direction of such a practitioner
15 who dispenses product in the usual course
16 of professional practice.

17 “(2) PRODUCT IDENTIFIER.—

18 “(A) IN GENERAL.—Beginning not later
19 than 4 years after the date of enactment of the
20 Drug Supply Chain Security Act, a manufac-
21 turer shall affix or imprint a product identifier
22 to each package and homogenous case of a
23 product intended to be introduced in a trans-
24 action into commerce. Such manufacturer shall
25 maintain the product identifier information for

1 such product for not less than 6 years after the
2 date of the transaction.

3 “(B) EXCEPTION.—A package that is re-
4 quired to have a standardized numerical identi-
5 fier is not required to have a unique device
6 identifier.

7 “(3) AUTHORIZED TRADING PARTNERS.—Be-
8 ginning not later than January 1, 2015, the trading
9 partners of a manufacturer may be only authorized
10 trading partners.

11 “(4) VERIFICATION.—Beginning not later than
12 January 1, 2015, a manufacturer shall have systems
13 in place to enable the manufacturer 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 manufacturer is a
19 suspect product, or upon receiving a re-
20 quest for verification from the Secretary
21 that has made a determination that a
22 product within the possession or control of
23 a manufacturer is a suspect product, a
24 manufacturer shall—

1 “(I) quarantine such product
2 within the possession or control of the
3 manufacturer from product intended
4 for distribution until such product is
5 cleared or dispositioned; and

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

21 “(ii) CLEARED PRODUCT.—If the
22 manufacturer makes the determination
23 that a suspect product is not an illegit-
24 imate product, the manufacturer shall
25 promptly notify the Secretary, if applica-

1 ble, of such determination and such prod-
2 uct may be further distributed.

3 “(iii) RECORDS.—A manufacturer
4 shall keep records of the investigation of a
5 suspect product for not less than 6 years
6 after the conclusion of the investigation.

7 “(B) ILLEGITIMATE PRODUCT.—

8 “(i) IN GENERAL.—Upon determining
9 that a product in the possession or control
10 of a manufacturer is an illegitimate prod-
11 uct, the manufacturer shall, in a manner
12 consistent with the systems and processes
13 of such manufacturer—

14 “(I) quarantine such product
15 within the possession or control of the
16 manufacturer from product intended
17 for distribution until such product is
18 disposed;

19 “(II) disposition the illegitimate
20 product within the possession or con-
21 trol of the manufacturer;

22 “(III) take reasonable and appro-
23 priate steps to assist a trading part-
24 ner to disposition an illegitimate prod-

1 uct not in the possession or control of
2 the manufacturer; and

3 “(IV) retain a sample of the
4 product for further physical examina-
5 tion or laboratory analysis of the
6 product by the manufacturer or Sec-
7 retary (or other appropriate Federal
8 or State official) upon request by the
9 Secretary (or other appropriate Fed-
10 eral or State official), as necessary
11 and appropriate.

12 “(ii) MAKING A NOTIFICATION.—

13 “(I) ILLEGITIMATE PRODUCT.—
14 Upon determining that a product in
15 the possession or control of the manu-
16 facturer is an illegitimate product, the
17 manufacturer shall notify the Sec-
18 retary and all immediate trading part-
19 ners that the manufacturer has reason
20 to believe may have received such ille-
21 gitimate product of such determina-
22 tion not later than 24 hours after
23 making such determination.

24 “(II) HIGH RISK OF ILLEGIT-
25 IMACY.—A manufacturer shall notify

1 the Secretary and immediate trading
2 partners that the manufacturer has
3 reason to believe may have in the
4 trading partner's possession a product
5 manufactured by, or purported to be a
6 product manufactured by, the manu-
7 facturer not later than 24 hours after
8 determining or being notified by the
9 Secretary or a trading partner that
10 there is a high risk that such product
11 is an illegitimate product. For pur-
12 poses of this subclause, a 'high risk'
13 may include a specific high risk that
14 could increase the likelihood that ille-
15 gitimate product will enter the phar-
16 maceutical distribution supply chain
17 and other high risks as determined by
18 the Secretary in guidance pursuant to
19 subsection (h).

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

1 uct subject to such notification that is in
2 the possession or control of the manufac-
3 turer, including any product that is subse-
4 quently received, and shall perform the ac-
5 tivities described in subparagraph (A).

6 “(iv) TERMINATING A NOTIFICA-
7 TION.—Upon making a determination, in
8 consultation with the Secretary, that a no-
9 tification is no longer necessary, a manu-
10 facturer shall promptly notify immediate
11 trading partners that the manufacturer no-
12 tified pursuant to clause (ii) that such no-
13 tification has been terminated.

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

18 “(C) REQUESTS FOR VERIFICATION.—Be-
19 ginning 4 years after the date of enactment of
20 the Drug Supply Chain Security Act, upon re-
21 ceiving a request for verification from an au-
22 thorized repackager, wholesale distributor, or
23 dispenser that is in possession or control of a
24 product such person believes to be manufac-
25 tured by such manufacturer, a manufacturer

1 shall, not later than 24 hours after receiving
2 the request for verification or in other such rea-
3 sonable time as determined by the Secretary,
4 based on the circumstances of the request, no-
5 tify the person making the request whether the
6 product identifier, including the standardized
7 numerical identifier, that is the subject of the
8 request corresponds to the product identifier af-
9 fixed or imprinted by the manufacturer. If a
10 manufacturer responding to a request for
11 verification identifies a product identifier that
12 does not correspond to that affixed or imprinted
13 by the manufacturer, the manufacturer shall
14 treat such product as suspect product and con-
15 duct an investigation as described in subpara-
16 graph (A). If the manufacturer has reason to
17 believe the product is an illegitimate product,
18 the manufacturer shall advise the person mak-
19 ing the request of such belief at the time such
20 manufacturer responds to the request for
21 verification.

22 “(D) ELECTRONIC DATABASE.—A manu-
23 facturer may satisfy the requirements of this
24 paragraph by developing a secure electronic
25 database or utilizing a secure electronic data-

1 base developed or operated by another entity.
2 The owner of such database shall establish the
3 requirements and processes to respond to re-
4 quests and may provide for data access to other
5 members of the pharmaceutical distribution
6 supply chain, as appropriate. The development
7 and operation of such a database shall not re-
8 lieve a manufacturer of the requirement under
9 this paragraph to respond to a request for
10 verification submitted by means other than a
11 secure electronic database.

12 “(E) SALEABLE RETURNED PRODUCT.—
13 Beginning 4 years after the date of enactment
14 of the Drug Supply Chain Security Act (except
15 as provided pursuant to subsection (a)(5)),
16 upon receipt of a returned product that the
17 manufacturer intends to further distribute, be-
18 fore further distributing such product, the man-
19 ufacturer shall verify the product identifier, in-
20 cluding the standardized numerical identifier,
21 for each sealed homogeneous case of such prod-
22 uct or, if such product is not in a sealed homo-
23 geneous case, verify the product identifier, in-
24 cluding the standardized numerical identifier,
25 on each package.

1 “(F) NONSALEABLE RETURNED PROD-
2 UCT.—A manufacturer may return a nonsale-
3 able product to the manufacturer or repack-
4 ager, to the wholesale distributor from whom
5 such product was purchased, or to a person act-
6 ing on behalf of such a person, including a re-
7 turns processor, without providing the informa-
8 tion described in paragraph (1)(A)(i).

9 “(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

10 “(1) PRODUCT TRACING.—

11 “(A) IN GENERAL.—Beginning not later
12 than January 1, 2015, the following require-
13 ments shall apply to wholesale distributors:

14 “(i) A wholesale distributor shall not
15 accept ownership of a product unless the
16 previous owner prior to, or at the time of,
17 the transaction provides the transaction
18 history, transaction information, and a
19 transaction statement for the product, as
20 applicable under this subparagraph.

21 “(ii)(I)(aa) If the wholesale dis-
22 tributor purchased a product directly from
23 the manufacturer, the exclusive distributor
24 of the manufacturer, or a repackager that
25 purchased directly from the manufacturer,

1 then prior to, or at the time of, each trans-
2 action in which the wholesale distributor
3 transfers ownership of a product, the
4 wholesale distributor shall provide to the
5 subsequent purchaser—

6 “(AA) a transaction statement,
7 which shall state that such wholesale
8 distributor, or a member of the affil-
9 iate of such wholesale distributor, pur-
10 chased the product directly from the
11 manufacturer, exclusive distributor of
12 the manufacturer, or repackager that
13 purchased the product directly from
14 the manufacturer; and

15 “(BB) subject to subclause (II),
16 the transaction history and trans-
17 action information.

18 “(bb) The wholesale distributor shall
19 provide the transaction history, transaction
20 information, and transaction statement
21 under item (aa)—

22 “(AA) if provided to a dis-
23 penser, on a single document in a
24 paper or electronic format; and

1 “(BB) if provided to a
2 wholesale distributor, through
3 any combination of self-generated
4 paper, electronic data, or manu-
5 facturer-provided information on
6 the product package.

7 “(II) For purposes of transactions de-
8 scribed in subclause (I), transaction his-
9 tory and transaction information shall not
10 be required to include the lot number of
11 the product, the initial transaction date, or
12 the initial shipment date from the manu-
13 facturer (as defined in subparagraphs (F),
14 (G), and (H) of section 581(26)).

15 “(iii) If the wholesale distributor did
16 not purchase a product directly from the
17 manufacturer, the exclusive distributor of
18 the manufacturer, or a repackager that
19 purchased directly from the manufacturer,
20 as described in clause (ii), then prior to, or
21 at the time of, each transaction or subse-
22 quent transaction, the wholesale distributor
23 shall provide to the subsequent purchaser a
24 transaction statement, transaction history,
25 and transaction information, in a paper or

1 electronic format that complies with the
2 guidance document issued under sub-
3 section (a)(2).

4 “(iv) For the purposes of clause (iii),
5 the transaction history supplied shall begin
6 only with the wholesale distributor de-
7 scribed in clause (ii)(I), but the wholesale
8 distributor described in clause (iii) shall in-
9 form the subsequent purchaser that such
10 wholesale distributor received a direct pur-
11 chase statement from a wholesale dis-
12 tributor described in clause (ii)(I).

13 “(v) A wholesale distributor shall—

14 “(I) capture the transaction in-
15 formation (including lot level informa-
16 tion) consistent with the requirements
17 of this section, transaction history,
18 and transaction statement for each
19 transaction described in clauses (i),
20 (ii), and (iii) and maintain such infor-
21 mation, history, and statement for not
22 less than 6 years after the date of the
23 transaction; and

24 “(II) maintain the confidentiality
25 of the transaction information (includ-

1 ing any lot level information con-
2 sistent with the requirements of this
3 section), transaction history, and
4 transaction statement for a product in
5 a manner that prohibits disclosure to
6 any person other than the Secretary
7 or other appropriate Federal or State
8 official, except to comply with clauses
9 (ii) and (iii), and, as applicable, pur-
10 suant to an agreement under subpara-
11 graph (D).

12 “(B) RETURNS.—

13 “(i) SALEABLE RETURNS.—Notwith-
14 standing subparagraph (A)(i), the fol-
15 lowing shall apply:

16 “(I) REQUIREMENTS.—Until the
17 date that is 6 years after the date of
18 enactment of the Drug Supply Chain
19 Security Act (except as provided pur-
20 suant to subsection (a)(5)), a whole-
21 sale distributor may accept returned
22 product from a dispenser or repack-
23 ager pursuant to the terms and condi-
24 tions of any agreement between the
25 parties, and, notwithstanding sub-

1 paragraph (A)(ii), may distribute such
2 returned product without providing
3 the transaction history. For trans-
4 actions subsequent to the return, the
5 transaction history of such product
6 shall begin with the wholesale dis-
7 tributor that accepted the returned
8 product, consistent with the require-
9 ments of this subsection.

10 “(II) ENHANCED REQUIRE-
11 MENTS.—Beginning 6 years after the
12 date of enactment of the Drug Supply
13 Chain Security Act (except as pro-
14 vided pursuant to subsection (a)(5)),
15 a wholesale distributor may accept re-
16 turned product from a dispenser or
17 repackager only if the wholesale dis-
18 tributor can associate returned prod-
19 uct with the transaction information
20 and transaction statement associated
21 with that product. For all trans-
22 actions after such date, the trans-
23 action history, as applicable, of such
24 product shall begin with the wholesale
25 distributor that accepted and verified

1 the returned product. For purposes of
2 this subparagraph, the transaction in-
3 formation and transaction history, as
4 applicable, need not include trans-
5 action dates if it is not reasonably
6 practicable to obtain such dates.

7 “(ii) NONSALEABLE RETURNS.—A
8 wholesale distributor may return a non-
9 saleable product to the manufacturer or re-
10 packager, to the wholesale distributor from
11 whom such product was purchased, or to a
12 person acting on behalf of such a person,
13 including a returns processor, without pro-
14 viding the information required under sub-
15 paragraph (A)(i).

16 “(C) REQUESTS FOR INFORMATION.—
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 purpose of investigating a
20 suspect product or an illegitimate product, a
21 wholesale distributor shall, not later than 1
22 business day, and not to exceed 48 hours, after
23 receiving the request or in other such reason-
24 able time as determined by the Secretary, based
25 on the circumstances of the request, provide the

1 applicable transaction information, transaction
2 history, and transaction statement for the prod-
3 uct.

4 “(D) TRADING PARTNER AGREEMENTS.—
5 Beginning 6 years after the date of enactment
6 of the Drug Supply Chain Security Act, a
7 wholesale distributor may disclose the trans-
8 action information, including lot level informa-
9 tion, transaction history, or transaction state-
10 ment of a product to the subsequent purchaser
11 of the product, pursuant to a written agreement
12 between such wholesale distributor and such
13 subsequent purchaser. Nothing in this subpara-
14 graph shall be construed to limit the applica-
15 bility of subparagraphs (A) through (C).

16 “(2) PRODUCT IDENTIFIER.—Beginning 6
17 years after the date of enactment of the Drug Sup-
18 ply Chain Security Act, a wholesale distributor may
19 engage in transactions involving a product only if
20 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 not later than January 1, 2015, the trading
24 partners of a wholesale distributor may be only au-
25 thorized trading partners.

1 “(4) VERIFICATION.—Beginning not later than
2 January 1, 2015, a wholesale distributor shall have
3 systems in place to enable the wholesale distributor
4 to comply with the following requirements:

5 “(A) SUSPECT PRODUCT.—

6 “(i) IN GENERAL.—Upon making a
7 determination that a product in the posses-
8 sion or control of a wholesale distributor is
9 a suspect product, or upon receiving a re-
10 quest for verification from the Secretary
11 that has made a determination that a
12 product within the possession or control of
13 a wholesale distributor is a suspect prod-
14 uct, a wholesale distributor shall—

15 “(I) quarantine such product
16 within the possession or control of the
17 wholesale distributor from product in-
18 tended for distribution until such
19 product is cleared or dispositioned;
20 and

21 “(II) promptly conduct an inves-
22 tigation in coordination with trading
23 partners, as applicable, to determine
24 whether the product is an illegitimate
25 product, which shall include validating

1 any applicable transaction history and
2 transaction information in the posses-
3 sion of the wholesale distributor and
4 otherwise investigating to determine
5 whether the product is an illegitimate
6 product, and, beginning 6 years after
7 the date of enactment of the Drug
8 Supply Chain Security Act (except as
9 provided pursuant to subsection
10 (a)(5)), verifying the product at the
11 package level, including the standard-
12 ized numerical identifier.

13 “(ii) CLEARED PRODUCT.—If the
14 wholesale distributor determines that a
15 suspect product is not an illegitimate prod-
16 uct, the wholesale distributor shall prompt-
17 ly notify the Secretary, if applicable, of
18 such determination and such product may
19 be further distributed.

20 “(iii) RECORDS.—A wholesale dis-
21 tributor shall keep records of the investiga-
22 tion of a suspect product for not less than
23 6 years after the conclusion of the inves-
24 tigation.

25 “(B) ILLEGITIMATE PRODUCT.—

1 “(i) IN GENERAL.—Upon deter-
2 mining, in coordination with the manufac-
3 turer, that a product in the possession or
4 control of a wholesale distributor is an ille-
5 gitimate product, the wholesale distributor
6 shall, in a manner that is consistent with
7 the systems and processes of such whole-
8 sale distributor—

9 “(I) quarantine such product
10 within the possession or control of the
11 wholesale distributor from product in-
12 tended for distribution until such
13 product is dispositioned;

14 “(II) disposition the illegitimate
15 product within the possession or con-
16 trol of the wholesale distributor;

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

22 “(IV) retain a sample of the
23 product for further physical examina-
24 tion or laboratory analysis of the
25 product by the manufacturer or Sec-

1 retary (or other appropriate Federal
2 or State official) upon request by the
3 manufacturer or Secretary (or other
4 appropriate Federal or State official),
5 as necessary and appropriate.

6 “(ii) MAKING A NOTIFICATION.—
7 Upon determining that a product in the
8 possession or control of the wholesale dis-
9 tributor is an illegitimate product, the
10 wholesale distributor shall notify the Sec-
11 retary and all immediate trading partners
12 that the wholesale distributor has reason
13 to believe may have received such illegit-
14 imate product of such determination not
15 later than 24 hours after making such de-
16 termination.

17 “(iii) RESPONDING TO A NOTIFICA-
18 TION.—Upon the receipt of a notification
19 from the Secretary or a trading partner
20 that a determination has been made that a
21 product is an illegitimate product, a whole-
22 sale distributor shall identify all illegit-
23 imate product subject to such notification
24 that is in the possession or control of the
25 wholesale distributor, including any prod-

1 uct that is subsequently received, and shall
2 perform the activities described in subpara-
3 graph (A).

4 “(iv) TERMINATING A NOTIFICA-
5 TION.—Upon making a determination, in
6 consultation with the Secretary, that a no-
7 tification is no longer necessary, a whole-
8 sale distributor shall promptly notify im-
9 mediate trading partners that the whole-
10 sale distributor notified pursuant to clause
11 (ii) that such notification has been termi-
12 nated.

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

18 “(C) ELECTRONIC DATABASE.—A whole-
19 sale distributor may satisfy the requirements of
20 this paragraph by developing a secure electronic
21 database or utilizing a secure electronic data-
22 base developed or operated by another entity.
23 The owner of such database shall establish the
24 requirements and processes to respond to re-
25 quests and may provide for data access to other

1 members of the pharmaceutical distribution
2 supply chain, as appropriate. The development
3 and operation of such a database shall not re-
4 lieve a wholesale distributor of the requirement
5 under this paragraph to respond to a
6 verification request submitted by means other
7 than a secure electronic database.

8 “(D) VERIFICATION OF SALEABLE RE-
9 TURNED PRODUCT.—Beginning 6 years after
10 the date of enactment of the Drug Supply
11 Chain Security Act, upon receipt of a returned
12 product that the wholesale distributor intends
13 to further distribute, before further distributing
14 such product, the wholesale distributor shall
15 verify the product identifier, including the
16 standardized numerical identifier, for each
17 sealed homogeneous case of such product or, if
18 such product is not in a sealed homogeneous
19 case, verify the product identifier, including the
20 standardized numerical identifier, on each pack-
21 age.

22 “(d) DISPENSER REQUIREMENTS.—

23 “(1) PRODUCT TRACING.—

24 “(A) IN GENERAL.—Beginning July 1,
25 2015, a dispenser—

1 “(i) shall not accept ownership of a
2 product, unless the previous owner prior
3 to, or at the time of, the transaction, pro-
4 vides transaction history, transaction infor-
5 mation, and a transaction statement;

6 “(ii) prior to, or at the time of, each
7 transaction in which the dispenser trans-
8 fers ownership of a product (but not in-
9 cluding dispensing to a patient or returns)
10 shall provide the subsequent owner with
11 transaction history, transaction informa-
12 tion, and a transaction statement for the
13 product, except that the requirements of
14 this clause shall not apply to sales by a
15 dispenser to another dispenser to fulfill a
16 specific patient need; and

17 “(iii) shall capture transaction infor-
18 mation (including lot level information, if
19 provided), transaction history, and trans-
20 action statements, as necessary to inves-
21 tigate a suspect product, and maintain
22 such information, history, and statements
23 for not less than 6 years after the trans-
24 action.

1 “(B) AGREEMENTS WITH THIRD PAR-
2 TIES.—A dispenser may enter into a written
3 agreement with a third party, including an au-
4 thorized wholesale distributor, under which the
5 third party confidentially maintains the trans-
6 action information, transaction history, and
7 transaction statements required to be main-
8 tained under this subsection on behalf of the
9 dispenser. If a dispenser enters into such an
10 agreement, the dispenser shall maintain a copy
11 of the written agreement and shall not be re-
12 lieved of the obligations of the dispenser under
13 this subsection.

14 “(C) RETURNS.—

15 “(i) SALEABLE RETURNS.—A dis-
16 penser may return product to the trading
17 partner from which the dispenser obtained
18 the product without providing the informa-
19 tion required under subparagraph (A).

20 “(ii) NONSALEABLE RETURNS.—A
21 dispenser may return a nonsaleable prod-
22 uct to the manufacturer or repackager, to
23 the wholesale distributor from whom such
24 product was purchased, to a returns proc-
25 essor, or to a person acting on behalf of

1 such a person without providing the infor-
2 mation required under subparagraph (A).

3 “(D) REQUESTS FOR INFORMATION.—

4 Upon a request by the Secretary or other ap-
5 propriate Federal or State official, in the event
6 of a recall or for the purpose of investigating a
7 suspect or an illegitimate product, a dispenser
8 shall, not later than 2 business days after re-
9 ceiving the request or in another such reason-
10 able time as determined by the Secretary, based
11 on the circumstances of the request, provide the
12 applicable transaction information, transaction
13 statement, and transaction history which the
14 dispenser received from the previous owner,
15 which shall not include the lot number of the
16 product, the initial transaction date, or the ini-
17 tial shipment date from the manufacturer un-
18 less such information was included in the trans-
19 action information, transaction statement, and
20 transaction history provided by the manufac-
21 turer or wholesale distributor to the dispenser.
22 The dispenser may respond to the request by
23 providing the applicable information in either
24 paper or electronic format. Until the date that
25 is 4 years after the date of enactment of the

1 Drug Supply Chain Security Act, the Secretary
2 or other appropriate Federal or State official
3 shall grant a dispenser additional time, as nec-
4 essary, only with respect to a request to provide
5 lot level information described in subparagraph
6 (F) of section 581(26) that was provided to the
7 dispenser in paper format, limit the request
8 time period to the 6 months preceding the re-
9 quest or other relevant date, and, in the event
10 of a recall, the Secretary, or other appropriate
11 Federal or State official may request informa-
12 tion only if such recall involves a serious ad-
13 verse health consequence or death to humans.

14 “(2) PRODUCT IDENTIFIER.—Beginning not
15 later than 7 years after the date of enactment of the
16 Drug Supply Chain Security Act, a dispenser may
17 engage in transactions involving a product only if
18 such product is encoded with a product identifier
19 (except as provided pursuant to subsection (a)(5)).

20 “(3) AUTHORIZED TRADING PARTNERS.—Be-
21 ginning not later than January 1, 2015, the trading
22 partners of a dispenser may be only authorized trad-
23 ing partners.

24 “(4) VERIFICATION.—Beginning not later than
25 January 1, 2015, a dispenser shall have systems in

1 place to enable the dispenser to comply with the fol-
2 lowing requirements:

3 “(A) SUSPECT PRODUCT.—

4 “(i) IN GENERAL.—Upon making a
5 determination that a product in the posses-
6 sion or control of the dispenser is a suspect
7 product, or upon receiving a request for
8 verification from the Secretary that has
9 made a determination that a product with-
10 in the possession or control of a dispenser
11 is a suspect product, a dispenser shall—

12 “(I) quarantine such product
13 within the possession or control of the
14 dispenser from product intended for
15 distribution until such product is
16 cleared or dispositioned; and

17 “(II) promptly conduct an inves-
18 tigation in coordination with trading
19 partners, as applicable, to determine
20 whether the product is an illegitimate
21 product.

22 “(ii) INVESTIGATION.—An investiga-
23 tion conducted under clause (i)(II) shall in-
24 clude—

1 “(I) beginning 7 years after the
2 date of enactment of the Drug Supply
3 Chain Security Act, verifying whether
4 the lot number of a suspect product
5 corresponds with the lot number for
6 such product;

7 “(II) beginning 7 years after the
8 date of enactment of such Act,
9 verifying that the product identifier,
10 including the standardized numerical
11 identifier, of at least 3 packages or 10
12 percent of such suspect product,
13 whichever is greater, or all packages,
14 if there are fewer than 3, corresponds
15 with the product identifier for such
16 product;

17 “(III) validating any applicable
18 transaction history and transaction in-
19 formation in the possession of the dis-
20 penser; and

21 “(IV) otherwise investigating to
22 determine whether the product is an
23 illegitimate product.

24 “(iii) CLEARED PRODUCT.—If the dis-
25 penser makes the determination that a sus-

1 pect product is not an illegitimate product,
2 the dispenser shall promptly notify the
3 Secretary, if applicable, of such determina-
4 tion and such product may be further dis-
5 tributed or dispensed.

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

10 “(B) ILLEGITIMATE PRODUCT.—

11 “(i) IN GENERAL.—Upon deter-
12 mining, in coordination with the manufac-
13 turer, that a product in the possession or
14 control of a dispenser is an illegitimate
15 product, the dispenser shall—

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

19 “(II) 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 dispenser; and

24 “(III) 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 dispenser is an
11 illegitimate product, the dispenser shall no-
12 tify the Secretary and all immediate trad-
13 ing partners that the dispenser has reason
14 to believe may have received such illegit-
15 imate product of such determination not
16 later than 24 hours after making such de-
17 termination.

18 “(iii) RESPONDING TO A NOTIFICA-

19 TION.—Upon the receipt of a notification
20 from the Secretary or a trading partner
21 that a determination has been made that a
22 product is an illegitimate product, a dis-
23 penser shall identify all illegitimate product
24 subject to such notification that is in the
25 possession or control of the dispenser, in-

1 cluding any product that is subsequently
2 received, and shall perform the activities
3 described in subparagraph (A).

4 “(iv) TERMINATING A NOTIFICA-
5 TION.—Upon making a determination, in
6 consultation with the Secretary, that a no-
7 tification is no longer necessary, a dis-
8 penser shall promptly notify immediate
9 trading partners that the dispenser notified
10 pursuant to clause (ii) that such notifica-
11 tion has been terminated.

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

16 “(C) ELECTRONIC DATABASE.—A dis-
17 penser may satisfy the requirements of this
18 paragraph by developing a secure electronic
19 database or utilizing a secure electronic data-
20 base developed or operated by another entity.

21 “(5) EXCEPTION.—Notwithstanding any other
22 provision of law, the requirements under paragraphs
23 (1) and (4) shall not apply to licensed health care
24 practitioners authorized to prescribe or administer
25 medication under State law or other licensed individ-

1 uals under the supervision or direction of such prac-
2 titioners who dispense or administer product in the
3 usual course of professional practice.

4 “(e) REPACKAGER REQUIREMENTS.—

5 “(1) PRODUCT TRACING.—

6 “(A) IN GENERAL.—Beginning not later
7 than January 1, 2015, a repackager described
8 in section 581(16)(A) shall—

9 “(i) not accept ownership of a product
10 unless the previous owner, prior to, or at
11 the time of, the transaction, provides
12 transaction history, transaction informa-
13 tion, and a transaction statement for the
14 product;

15 “(ii) prior to, or at the time of, each
16 transaction in which the repackager trans-
17 fers ownership of a product, provide the
18 subsequent owner with transaction history,
19 transaction information, and a transaction
20 statement for the product; and

21 “(iii) capture the transaction informa-
22 tion (including lot level information),
23 transaction history, and transaction state-
24 ment for each transaction described in
25 clauses (i) and (ii) and maintain such in-

1 formation, history, and statement for not
2 less than 6 years after the transaction.

3 “(B) RETURNS.—

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

14 “(ii) SALEABLE OR NONSALEABLE
15 PRODUCT.—A repackager described in sec-
16 tion 581(16)(B) may return a saleable or
17 nonsaleable product to the manufacturer,
18 repackager, or to the wholesale distributor
19 from whom such product was received
20 without providing the information required
21 under subparagraph (A)(ii) on behalf of
22 the hospital or other health care entity
23 that took ownership of such product pursu-
24 ant to the terms and conditions of any

1 agreement between such repackager and
2 the entity that owns the product.

3 “(C) REQUESTS FOR INFORMATION.—

4 Upon a request by the Secretary or other ap-
5 propriate Federal or State official, in the event
6 of a recall or for the purpose of investigating a
7 suspect product or an illegitimate product, a re-
8 packager described in section 581(16)(A) shall,
9 not later than 1 business day, and not to exceed
10 48 hours, after receiving the request or in other
11 such reasonable time as determined by the Sec-
12 retary, provide the applicable transaction infor-
13 mation, transaction history, and transaction
14 statement for the product.

15 “(2) PRODUCT IDENTIFIER.—

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

20 “(i) shall affix or imprint a product
21 identifier to each package and homogenous
22 case of product intended to be introduced
23 in a transaction in commerce;

24 “(ii) shall maintain the product iden-
25 tifier information for such product for not

1 less than 6 years after the date of the
2 transaction;

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

8 “(iv) shall maintain records for not
9 less than 6 years to allow the repackager
10 to associate the product identifier the re-
11 packager affixes or imprints with the prod-
12 uct identifier assigned by the original man-
13 ufacturer of the product.

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

18 “(3) AUTHORIZED TRADING PARTNERS.—Be-
19 ginning January 1, 2015, the trading partners of a
20 repackager described in section 581(16) may be only
21 authorized trading partners.

22 “(4) VERIFICATION.—Beginning not later than
23 January 1, 2015, a repackager described in section
24 581(16)(A) shall have systems in place to enable the

1 repackager to comply with the following require-
2 ments:

3 “(A) SUSPECT PRODUCT.—

4 “(i) IN GENERAL.—Upon making a
5 determination that a product in the posses-
6 sion or control of the repackager is a sus-
7 pect product, or upon receiving a request
8 for verification from the Secretary that has
9 made a determination that a product with-
10 in the possession or control of a repack-
11 ager is a suspect product, a repackager
12 shall—

13 “(I) quarantine such product
14 within the possession or control of the
15 repackager from product intended for
16 distribution until such product is
17 cleared or dispositioned; and

18 “(II) promptly conduct an inves-
19 tigation in coordination with trading
20 partners, as applicable, to determine
21 whether the product is an illegitimate
22 product, which shall include validating
23 any applicable transaction history and
24 transaction information in the posses-
25 sion of the repackager and otherwise

1 investigating to determine whether the
2 product is an illegitimate product,
3 and, beginning 5 years after the date
4 of enactment of the Drug Supply
5 Chain Security Act (except as pro-
6 vided pursuant to subsection (a)(5)),
7 verifying the product at the package
8 level, including the standardized nu-
9 merical identifier.

10 “(ii) CLEARED PRODUCT.—If the re-
11 packager makes the determination that a
12 suspect product is not an illegitimate prod-
13 uct, the repackager shall promptly notify
14 the Secretary, if applicable, of such deter-
15 mination and such product may be further
16 distributed.

17 “(iii) RECORDS.—A repackager 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
25 control of a repackager is an illegitimate

1 product, the repackager shall, in a manner
2 that is consistent with the systems and
3 processes of such repackager—

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

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

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 repackager; 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 manufacturer or Secretary (or other
24 appropriate Federal or State official),
25 as necessary and appropriate.

1 “(ii) MAKING A NOTIFICATION.—

2 Upon determining that a product in the
3 possession or control of the repackager is
4 an illegitimate product, the repackager
5 shall notify the Secretary and all imme-
6 diate trading partners that the repackager
7 has reason to believe may have received the
8 illegitimate product of such determination
9 not later than 24 hours after making such
10 determination.

11 “(iii) RESPONDING TO A NOTIFICA-

12 TION.—Upon the receipt of a notification
13 from the Secretary or a trading partner, a
14 repackager shall identify all illegitimate
15 product subject to such notification that is
16 in the possession or control of the repack-
17 ager, 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 repack-
24 ager shall promptly notify immediate trad-
25 ing partners that the repackager notified

1 pursuant to clause (ii) that such notifica-
2 tion has been terminated.

3 “(v) RECORDS.—A repackager 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 5 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 manufacturer, wholesale distributor, or
12 dispenser that is in possession or control of a
13 product they believe to be repackaged by such
14 repackager, a repackager shall, not later than
15 24 hours after receiving the verification request
16 or in other such reasonable time as determined
17 by the Secretary, based on the circumstances of
18 the request, notify the person making the re-
19 quest whether the product identifier, including
20 the standardized numerical identifier, that is
21 the subject of the request corresponds to the
22 product identifier affixed or imprinted by the
23 repackager. If a repackager responding to a
24 verification request identifies a product identi-
25 fier that does not correspond to that affixed or

1 imprinted by the repackager, the repackager
2 shall treat such product as suspect product and
3 conduct an investigation as described in sub-
4 paragraph (A). If the repackager has reason to
5 believe the product is an illegitimate product,
6 the repackager shall advise the person making
7 the request of such belief at the time such re-
8 packager responds to the verification request.

9 “(D) ELECTRONIC DATABASE.—A repack-
10 ager may satisfy the requirements of paragraph
11 (4) by developing a secure electronic database
12 or utilizing a secure electronic database devel-
13 oped or operated by another entity. The owner
14 of such database shall establish the require-
15 ments and processes to respond to requests and
16 may provide for data access to other members
17 of the pharmaceutical distribution supply chain,
18 as appropriate. The development and operation
19 of such a database shall not relieve a repack-
20 ager of the requirement under subparagraph
21 (C) to respond to a verification request sub-
22 mitted by means other than a secure electronic
23 database.

24 “(E) VERIFICATION OF SALEABLE RE-
25 TURNED PRODUCT.—Beginning 5 years after

1 the date of enactment of the Drug Supply
2 Chain Security Act, upon receipt of a returned
3 product that the repackager intends to further
4 distribute, before further distributing such
5 product, the repackager shall verify the product
6 identifier for each sealed homogeneous case of
7 such product or, if such product is not in a
8 sealed homogeneous case, verify the product
9 identifier on each package.

10 “(f) 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 a 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 “(g) 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 (h), 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 (h), 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 (h), the Secretary shall enter into a 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. Such assess-
23 ment shall be completed not later than 8½
24 years after the date of enactment of the Drug
25 Supply Chain Security Act.

1 “(B) CONDITION.—As a condition of the
2 award of the contract under subparagraph (A),
3 the private, independent consulting firm shall
4 agree to consult with dispensers with 25 or
5 fewer full-time employees when conducting the
6 assessment under such subparagraph.

7 “(C) CONTENT.—The assessment under
8 subparagraph (A) shall assess whether—

9 “(i) the necessary software and hard-
10 ware is readily accessible to such dis-
11 pensers;

12 “(ii) the necessary software and hard-
13 ware is prohibitively expensive to obtain,
14 install, and maintain for such dispensers;
15 and

16 “(iii) the necessary hardware and
17 software can be integrated into business
18 practices, such as interoperability with
19 wholesale distributors, for such dispensers.

20 “(D) PUBLICATION.—The Secretary
21 shall—

22 “(i) publish the statement of work for
23 the assessment under subparagraph (A)
24 for public comment prior to beginning the
25 assessment;

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

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

9 “(4) PROCEDURE.—Notwithstanding section
10 553 of title 5, United States Code, the Secretary, in
11 promulgating any regulation pursuant to this sec-
12 tion, shall—

13 “(A) provide appropriate flexibility by—

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

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

22 “(I) timelines for small busi-
23 nesses to comply with the require-
24 ments set forth in the regulations in
25 order to ensure that such require-

1 ments do not impose undue economic
2 hardship for small businesses (includ-
3 ing small business dispensers for
4 whom the criteria set forth in the as-
5 sessment under paragraph (3) is not
6 met), if the Secretary determines that
7 such requirements would result in
8 undue economic hardship; and

9 “(II) the establishment of a proc-
10 ess by which a dispenser may request
11 a waiver from any of the requirements
12 set forth in such regulations if the
13 Secretary determines that such re-
14 quirements would result in an undue
15 economic hardship; and

16 “(iii) taking into consideration—

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

22 “(II) the public meetings held
23 and related guidance documents
24 issued under this section;

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

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

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

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

19 “(C) provide a period of not less than 60
20 days for comments on the proposed regulation;
21 and

22 “(D) publish in the Federal Register the
23 final regulation not less than 2 years prior to
24 the effective date of the regulation.

25 “(h) GUIDANCE DOCUMENTS.—

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

8 “(2) SUSPECT AND ILLEGITIMATE PRODUCT.—

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

16 “(i) identify specific scenarios that
17 could significantly increase the risk of a
18 suspect product entering the pharma-
19 ceutical distribution supply chain;

20 “(ii) provide recommendation on how
21 trading partners may identify such product
22 and make a determination on whether the
23 product is a suspect product as soon as
24 practicable; and

1 “(iii) set forth the process by which
2 manufacturers, repackagers, wholesale dis-
3 tributors, and dispensers shall terminate
4 notifications in consultation with the Sec-
5 retary regarding illegitimate product pur-
6 suant to subsections (b)(4)(B), (c)(4)(B),
7 (d)(4)(B), and (e)(4)(B).

8 “(B) REVISED GUIDANCE.—If the Sec-
9 retary revises the guidance issued under sub-
10 paragraph (A), the Secretary shall follow the
11 procedure set forth in paragraph (5).

12 “(3) UNIT LEVEL TRACING.—

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

1 ments established under subsection (g). Such
2 guidance document shall—

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

15 “(ii) identify methods and processes
16 to enhance secure tracing of product at the
17 package level, such as secure processes to
18 facilitate the use of inference, enhanced
19 verification activities, the use of aggrega-
20 tion and inference, processes that utilize
21 the product identifiers to enhance tracing
22 of product at the package level, including
23 the standardized numerical identifier, or
24 package security features; and

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

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

8 “(4) STANDARDS FOR INTEROPERABLE DATA
9 EXCHANGE.—

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

20 “(i) identifies and makes rec-
21 ommendations with respect to the stand-
22 ards necessary for adoption in order to
23 support the secure, interoperable electronic
24 data exchange among the pharmaceutical
25 distribution supply chain that comply with

1 a form and format developed by a widely
2 recognized international standards develop-
3 ment organization;

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

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

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

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

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

21 “(A) publish a notice in the Federal Reg-
22 ister for a period not less than 30 days an-
23 nouncing that the draft or revised draft guid-
24 ance is available;

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

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

8 “(D) revise the draft guidance, as appro-
9 priate;

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

14 “(F) post the final guidance document on
15 the Internet Web site of the Food and Drug
16 Administration and make such final guidance
17 document available in hard copy; and

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

21 “(i) PUBLIC MEETINGS.—

22 “(1) IN GENERAL.—The Secretary shall hold
23 not less than 5 public meetings to enhance the safe-
24 ty and security of the pharmaceutical distribution
25 supply chain and provide for comment. The Sec-

1 retary may hold the first such public meeting not
2 earlier than 1 year after the date of enactment of
3 the Drug Supply Chain Security Act. In carrying
4 out the public meetings described in this paragraph,
5 the Secretary shall—

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

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

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

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

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

23 “(ii) the scalability of such require-
24 ments, including as it relates to product
25 lines; and

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

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

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

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

20 “(E) Whether electronic tracing require-
21 ments, including tracing of product at the pack-
22 age level, are feasible, cost effective, and needed
23 to protect the public health.

24 “(F) The systems and processes needed to
25 utilize the product identifiers to enhance tracing

1 of product at the package level, including allow-
2 ing for verification, aggregation, and inference,
3 as necessary.

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

8 “(H) The impact that such additional re-
9 quirements would have on patient safety, the
10 drug supply, cost and regulatory burden, and
11 timely patient access to prescription drugs.

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

14 “(j) PILOT PROJECTS.—

15 “(1) IN GENERAL.—The Secretary shall estab-
16 lish 1 or more pilot projects, in coordination with
17 authorized manufacturers, repackagers, wholesale
18 distributors, and dispensers, to explore and evaluate
19 methods to enhance the safety and security of the
20 pharmaceutical distribution supply chain. Such
21 projects shall build upon efforts, in existence as of
22 the date of enactment of the Drug Supply Chain Se-
23 curity Act, to enhance the safety and security of the
24 pharmaceutical distribution supply chain, take into
25 consideration any pilot projects conducted prior to

1 such date of enactment, including any pilot projects
2 that use aggregation and inference, and inform the
3 draft and final guidance under paragraphs (3) and
4 (4) of subsection (h).

5 “(2) CONTENT.—

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

13 “(B) PROJECT DESIGN.—The pilot
14 projects under paragraph (1) shall be designed
15 to—

16 “(i) utilize the product identifier for
17 tracing of a product, which may include
18 verification of the product identifier of a
19 product, including the use of aggregation
20 and inference;

21 “(ii) improve the technical capabilities
22 of each sector and subsector to comply
23 with systems and processes needed to uti-
24 lize the product identifiers to enhance trac-
25 ing of a product;

1 “(iii) identify system attributes that
2 are necessary to implement the require-
3 ments established under this section; and

4 “(iv) complete other activities as de-
5 termined by the Secretary.

6 “(k) SUNSET.—The following requirements shall
7 have no force or effect beginning on the date that is 10
8 years after the date of enactment of the Drug Supply
9 Chain Security Act:

10 “(1) The provision and receipt of transaction
11 history under this section.

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

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

18 “(l) RULE OF CONSTRUCTION.—The requirements
19 set forth in subsections (g)(4), (i), and (j) shall not be
20 construed as a condition, prohibition, or precedent for pre-
21 cluding or delaying the provisions becoming effective pur-
22 suant to subsection (g).

23 “(m) REQUESTS FOR INFORMATION.—On the date
24 that is 10 years after the date of enactment of the Drug
25 Supply Chain Security Act, the timeline for responses to

1 requests for information from the Secretary, or other ap-
2 propriate Federal or State official, as applicable, under
3 subsections (b)(1)(B), (c)(1)(C), and (e)(1)(C) shall be
4 not later than 24 hours after receiving the request from
5 the Secretary or other appropriate Federal or State offi-
6 cial, as applicable, or in such other reasonable time as de-
7 termined by the Secretary based on the circumstances of
8 the request.”.

9 **SEC. 204. NATIONAL STANDARDS FOR PRESCRIPTION DRUG**
10 **WHOLESALE DISTRIBUTORS.**

11 (a) AMENDMENTS.—

12 (1) REQUIREMENT.—Section 503(e) (21 U.S.C.
13 353(e)) is amended by striking paragraphs (1), (2),
14 and (3) and inserting the following:

15 “(1) REQUIREMENT.—Subject to section 583:

16 “(A) IN GENERAL.—No person may en-
17 gage in wholesale distribution of a drug subject
18 to subsection (b)(1) in any State unless such
19 person—

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

22 “(II) if the State from which the drug
23 is distributed has not established a licen-
24 sure requirement, is licensed by the Sec-
25 retary; and

1 “(ii) if the drug is distributed inter-
2 state, is licensed by the State into which
3 the drug is distributed if the State into
4 which the drug is distributed requires the
5 licensure of a person that distributes drugs
6 into the State.

7 “(B) STANDARDS.—Each Federal and
8 State license described in subparagraph (A)
9 shall meet the standards, terms, and conditions
10 established by the Secretary under section 583.

11 “(2) REPORTING AND DATABASE.—

12 “(A) REPORTING.—Beginning January 1,
13 2015, any person who owns or operates an es-
14 tablishment that engages in wholesale distribu-
15 tion shall—

16 “(i) report to the Secretary, on an an-
17 nual basis pursuant to a schedule deter-
18 mined by the Secretary—

19 “(I) each State by which the per-
20 son is licensed and the appropriate
21 identification number of each such li-
22 cense; and

23 “(II) the name, address, and con-
24 tact information of each facility at
25 which, and all trade names under

1 which, the person conducts business;
2 and

3 “(ii) report to the Secretary within a
4 reasonable period of time and in a reason-
5 able manner, as determined by the Sec-
6 retary, any significant disciplinary actions,
7 such as the revocation or suspension of a
8 wholesale distributor license, taken by a
9 State or the Federal Government during
10 the reporting period against the wholesale
11 distributor.

12 “(B) DATABASE.—Not later than January
13 1, 2015, the Secretary shall establish a data-
14 base of authorized wholesale distributors. Such
15 database shall—

16 “(i) identify each authorized wholesale
17 distributor by name, contact information,
18 and each State where such wholesale dis-
19 tributor is appropriately licensed to engage
20 in wholesale distribution;

21 “(ii) be available to the public on the
22 Internet Web site of the Food and Drug
23 Administration; and

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

1 “(C) COORDINATION.—The Secretary shall
2 establish a format and procedure for appro-
3 priate State officials to access the information
4 provided pursuant to subparagraph (A) in a
5 prompt and secure manner.

6 “(D) CONFIDENTIALITY.—Nothing in this
7 paragraph shall be construed as authorizing the
8 Secretary to disclose any information that is a
9 trade secret or confidential information subject
10 to section 552(b)(4) of title 5, United States
11 Code, or section 1905 of title 18, United States
12 Code.

13 “(3) COSTS.—

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

1 basis to generate only the amount of revenue
2 needed to perform this service. Fees authorized
3 under this paragraph shall be collected and
4 available for obligation only to the extent and in
5 the amount provided in advance in appropria-
6 tions Acts. Such fees are authorized to remain
7 available until expended. Such sums as may be
8 necessary may be transferred from the Food
9 and Drug Administration salaries and expenses
10 appropriation account without fiscal year limi-
11 tation to such appropriation account for sala-
12 ries and expenses with such fiscal year limita-
13 tion.

14 “(B) STATE LICENSING FEES.—Nothing in
15 this Act shall prohibit States from collecting
16 fees from wholesale distributors in connection
17 with State licensing of such distributors.”.

18 (2) WHOLESALE DISTRIBUTION.—Section
19 503(e) (21 U.S.C. 353(e)), as amended by para-
20 graph (1), is further amended by adding at the end
21 the following:

22 “(4) For the purposes of this subsection and
23 subsection (d), the term ‘wholesale distribution’
24 means the distribution of a drug subject to sub-
25 section (b) to a person other than a consumer or pa-

1 tient, or receipt of a drug subject to subsection (b)
2 by a person other than the consumer or patient, but
3 does not include—

4 “(A) intracompany distribution of any
5 drug between members of an affiliate or within
6 a manufacturer;

7 “(B) the distribution of a drug, or an offer
8 to distribute a drug among hospitals or other
9 health care entities which are under common
10 control;

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

19 “(D) the dispensing of a drug pursuant to
20 a prescription executed in accordance with sub-
21 section (b)(1);

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

1 “(F) the distribution of a drug or an offer
2 to distribute a drug by a charitable organization
3 to a nonprofit affiliate of the organization to
4 the extent otherwise permitted by law;

5 “(G) the purchase or other acquisition by
6 a dispenser, hospital, or other health care entity
7 of a drug for use by such dispenser, hospital, or
8 other health care entity;

9 “(H) the distribution of a drug by the
10 manufacturer of such drug;

11 “(I) the receipt or transfer of a drug by an
12 authorized third-party logistics provider pro-
13 vided that such third-party logistics provider
14 does not take ownership of the drug;

15 “(J) a common carrier that transports a
16 drug, provided that the common carrier does
17 not take ownership of the drug;

18 “(K) the distribution of a drug, or an offer
19 to distribute a drug by an authorized repack-
20 ager that has taken ownership or possession of
21 the drug and repacks it in accordance with sec-
22 tion 582(e);

23 “(L) salable drug returns when conducted
24 by a dispenser;

1 “(M) the distribution of a collection of fin-
2 ished medical devices, which may include a
3 product or biological product, assembled in kit
4 form strictly for the convenience of the pur-
5 chaser or user (referred to in this subparagraph
6 as a ‘medical convenience kit’) if—

7 “(i) the medical convenience kit is as-
8 sembled in an establishment that is reg-
9 istered with the Food and Drug Adminis-
10 tration as a device manufacturer in accord-
11 ance with section 510(b)(2);

12 “(ii) the medical convenience kit does
13 not contain a controlled substance that ap-
14 pears in a schedule contained in the Com-
15 prehensive Drug Abuse Prevention and
16 Control Act of 1970;

17 “(iii) in the case of a medical conven-
18 ience kit that includes a product, the per-
19 son that manufactures the kit—

20 “(I) purchased such product di-
21 rectly from the pharmaceutical manu-
22 facturer or from a wholesale dis-
23 tributor that purchased the product
24 directly from the pharmaceutical man-
25 ufacturer; and

1 “(II) does not alter the primary
2 container or label of the product as
3 purchased from the manufacturer or
4 wholesale distributor; and

5 “(iv) in the case of a medical conven-
6 ience kit that includes a product, the prod-
7 uct is—

8 “(I) an intravenous solution in-
9 tended for the replenishment of fluids
10 and electrolytes;

11 “(II) a product intended to main-
12 tain the equilibrium of water and min-
13 erals in the body;

14 “(III) a product intended for irri-
15 gation or reconstitution;

16 “(IV) an anesthetic;

17 “(V) an anticoagulant;

18 “(VI) a vasopressor; or

19 “(VII) a sympathomimetic;

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

1 “(O) the distribution of an intravenous
2 drug used to maintain the equilibrium of water
3 and minerals in the body, such as dialysis solu-
4 tions;

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

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

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

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

1 (3) THIRD-PARTY LOGISTICS PROVIDERS.—Sec-
2 tion 503(e) (21 U.S.C. 353(e)), as amended by para-
3 graph (2), is further amended by adding at the end
4 the following:

5 “(5) THIRD-PARTY LOGISTICS PROVIDERS.—
6 Notwithstanding paragraphs (1) through (4), each
7 entity that meets the definition of a third-party lo-
8 gistics provider under section 581(22) shall obtain a
9 license as a third-party logistics provider as de-
10 scribed in section 584(a) and is not required to ob-
11 tain a license as a wholesale distributor if the entity
12 never assumes an ownership interest in the product
13 it handles.”.

14 (4) AFFILIATE.—Section 503(e) (21 U.S.C.
15 353(e)), as amended by paragraph (3), is further
16 amended by adding at the end the following:

17 “(6) AFFILIATE.—For purposes of this sub-
18 section, the term ‘affiliate’ means a business entity
19 that has a relationship with a second business entity
20 if, directly or indirectly—

21 “(A) one business entity controls, or has
22 the power to control, the other business entity;
23 or

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

1 (5) STANDARDS.—Subchapter H of chapter V,
2 as added by section 202, is amended by adding at
3 the end the following:

4 **“SEC. 583. NATIONAL STANDARDS FOR PRESCRIPTION**
5 **DRUG WHOLESALE DISTRIBUTORS.**

6 “(a) IN GENERAL.—The Secretary shall, not later
7 than 2 years after the date of enactment of the Drug Sup-
8 ply Chain Security Act, establish by regulation standards
9 for the licensing of persons under section 503(e)(1) (as
10 amended by the Drug Supply Chain Security Act), includ-
11 ing the revocation, reissuance, and renewal of such license.

12 “(b) CONTENT.—For the purpose of ensuring uni-
13 formity with respect to standards set forth in this section,
14 the standards established under subsection (a) shall apply
15 to all State and Federal licenses described under section
16 503(e)(1) (as amended by the Drug Supply Chain Secu-
17 rity Act) and shall include standards for the following:

18 “(1) The storage and handling of prescription
19 drugs, including facility requirements.

20 “(2) The establishment and maintenance of
21 records of the distributions of such drugs.

22 “(3) The furnishing of a bond or other equiva-
23 lent means of security, as follows:

24 “(A)(i) For the issuance or renewal of a
25 wholesale distributor license, an applicant that

1 is not a government owned and operated whole-
2 sale distributor shall submit a surety bond of
3 \$100,000 or other equivalent means of security
4 acceptable to the State.

5 “(ii) For purposes of clause (i), the State
6 or other applicable authority may accept a sur-
7 ety bond in the amount of \$25,000 if the an-
8 nual gross receipts of the previous tax year for
9 the wholesaler is \$10,000,000 or less.

10 “(B) If a wholesale distributor can provide
11 evidence that it possesses the required bond in
12 a State, the requirement for a bond in another
13 State shall be waived.

14 “(4) Mandatory background checks and
15 fingerprinting of facility managers or designated
16 representatives.

17 “(5) The establishment and implementation of
18 qualifications for key personnel.

19 “(6) The mandatory physical inspection of any
20 facility to be used in wholesale distribution within a
21 reasonable time frame from the initial application of
22 the facility and to be conducted by the licensing au-
23 thority or by the State, consistent with subsection
24 (c).

1 “(7) In accordance with subsection (d), the pro-
2 hibition of certain persons from receiving or main-
3 taining licensure for wholesale distribution.

4 “(c) INSPECTIONS.—To satisfy the inspection re-
5 quirement under subsection (b)(6), the Federal or State
6 licensing authority may conduct the inspection or may ac-
7 cept an inspection by the State in which the facility is lo-
8 cated, or by a third-party accreditation or inspection serv-
9 ice approved by the Secretary or the State licensing such
10 wholesale distributor.

11 “(d) PROHIBITED PERSONS.—The standards estab-
12 lished under subsection (a) shall include requirements to
13 prohibit a person from receiving or maintaining licensure
14 for wholesale distribution if the person—

15 “(1) has been convicted of any felony for con-
16 duct relating to wholesale distribution, any felony
17 violation of subsection (i) or (k) of section 301, or
18 any felony violation of section 1365 of title 18,
19 United States Code, relating to product tampering;
20 or

21 “(2) has engaged in a pattern of violating the
22 requirements of this section, or State requirements
23 for licensure, that presents a threat of serious ad-
24 verse health consequences or death to humans.

1 “(e) REQUIREMENTS.—The Secretary, in promul-
2 gating any regulation pursuant to this section, shall, not-
3 withstanding section 553 of title 5, United States Code—

4 “(1) issue a notice of proposed rulemaking that
5 includes a copy of the proposed regulation;

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

8 “(3) provide that the final regulation take effect
9 on the date that is 2 years after the date such final
10 regulation is published.”.

11 (b) AUTHORIZED DISTRIBUTORS OF RECORD.—Sec-
12 tion 503(d) (21 U.S.C. 353(d)) is amended by adding at
13 the end the following:

14 “(4) In this subsection, the term ‘authorized
15 distributors of record’ means those distributors with
16 whom a manufacturer has established an ongoing re-
17 lationship to distribute such manufacturer’s prod-
18 ucts.”.

19 (c) EFFECTIVE DATE.—The amendments made by
20 subsections (a) and (b) shall take effect on January 1,
21 2015.

1 **SEC. 205. NATIONAL STANDARDS FOR THIRD-PARTY LOGIS-**
2 **TICS PROVIDERS; UNIFORM NATIONAL POL-**
3 **ICY.**

4 Subchapter H of chapter V, as amended by section
5 204, is further amended by adding at the end the fol-
6 lowing:

7 **“SEC. 584. NATIONAL STANDARDS FOR THIRD-PARTY LO-**
8 **GISTICS PROVIDERS.**

9 “(a) REQUIREMENTS.—No third-party logistics pro-
10 vider in any State may conduct activities in any State un-
11 less each facility of such third-party logistics provider—

12 “(1)(A) is licensed by the State from which the
13 drug is distributed by the third-party logistics pro-
14 vider, in accordance with the regulations promul-
15 gated under subsection (d); or

16 “(B) if the State from which the drug distrib-
17 uted by the third-party logistics provider has not es-
18 tablished a licensure requirement, is licensed by the
19 Secretary, in accordance with the regulations pro-
20 mulgated under subsection (d); and

21 “(2) if the drug is distributed interstate, is li-
22 censed by the State into which the drug is distrib-
23 uted by the third-party logistics provider if such
24 State licenses third-party logistics providers that dis-
25 tribute drugs into the State and the third-party lo-

1 logistics provider is not licensed by the Secretary as
2 described in paragraph (1)(B).

3 “(b) REPORTING.—Beginning 1 year after the date
4 of enactment of the Drug Supply Chain Security Act, a
5 facility of a third-party logistics provider shall report to
6 the Secretary, on an annual basis pursuant to a schedule
7 determined by the Secretary—

8 “(1) the State by which the facility is licensed
9 and the appropriate identification number of such li-
10 cense; and

11 “(2) the name and address of the facility and
12 all trade names under which such facility conducts
13 business.

14 “(c) COSTS.—

15 “(1) AUTHORIZED FEES OF SECRETARY.—If a
16 State does not establish a licensing program for a
17 third-party logistics provider, the Secretary shall li-
18 cense the third-party logistics provider located in
19 such State and may collect a reasonable fee in such
20 amount necessary to reimburse the Secretary for
21 costs associated with establishing and administering
22 the licensure program and conducting periodic in-
23 spections under this section. The Secretary shall ad-
24 just fee rates as needed on an annual basis to gen-
25 erate only the amount of revenue needed to perform

1 this service. Fees authorized under this paragraph
2 shall be collected and available for obligation only to
3 the extent and in the amount provided in advance in
4 appropriations Acts. Such fees are authorized to re-
5 main available until expended. Such sums as may be
6 necessary may be transferred from the Food and
7 Drug Administration salaries and expenses appro-
8 priation account without fiscal year limitation to
9 such appropriation account for salaries and expenses
10 with such fiscal year limitation.

11 “(2) STATE LICENSING FEES.—

12 “(A) STATE ESTABLISHED PROGRAM.—

13 Nothing in this Act shall prohibit a State that
14 has established a program to license a third-
15 party logistics provider from collecting fees
16 from a third-party logistics provider for such a
17 license.

18 “(B) NO STATE ESTABLISHED PRO-

19 GRAM.—A State that does not establish a pro-
20 gram to license a third-party logistics provider
21 in accordance with this section shall be prohib-
22 ited from collecting a State licensing fee from
23 a third-party logistics provider.

24 “(d) REGULATIONS.—

1 “(1) IN GENERAL.—Not later than 2 years
2 after the date of enactment of the Drug Supply
3 Chain Security Act, the Secretary shall issue regula-
4 tions regarding the standards for licensing under
5 subsection (a), including the revocation and
6 reissuance of such license, to third-party logistics
7 providers under this section.

8 “(2) CONTENT.—Such regulations shall—

9 “(A) establish a process by which a third-
10 party accreditation program approved by the
11 Secretary shall, upon request by a third-party
12 logistics provider, issue a license to each third-
13 party logistics provider that meets the require-
14 ments set forth in this section;

15 “(B) establish a process by which the Sec-
16 retary shall issue a license to each third-party
17 logistics provider that meets the requirements
18 set forth in this section if the Secretary is not
19 able to approve a third-party accreditation pro-
20 gram because no such program meets the Sec-
21 retary’s requirements necessary for approval of
22 such a third-party accreditation program;

23 “(C) require that the entity complies with
24 storage practices, as determined by the Sec-
25 retary for such facility, including—

1 “(i) maintaining access to warehouse
2 space of suitable size to facilitate safe op-
3 erations, including a suitable area to quar-
4 antine suspect product;

5 “(ii) maintaining adequate security;
6 and

7 “(iii) having written policies and pro-
8 cedures to—

9 “(I) address receipt, security,
10 storage, inventory, shipment, and dis-
11 tribution of a product;

12 “(II) identify, record, and report
13 confirmed losses or thefts in the
14 United States;

15 “(III) correct errors and inac-
16 curacies in inventories;

17 “(IV) provide support for manu-
18 facturer recalls;

19 “(V) prepare for, protect against,
20 and address any reasonably foresee-
21 able crisis that affects security or op-
22 eration at the facility, such as a
23 strike, fire, or flood;

24 “(VI) ensure that any expired
25 product is segregated from other

1 products and returned to the manu-
2 facturer or repackager or destroyed;

3 “(VII) maintain the capability to
4 trace the receipt and outbound dis-
5 tribution of a product, and supplies
6 and records of inventory; and

7 “(VIII) quarantine or destroy a
8 suspect product if directed to do so by
9 the respective manufacturer, wholesale
10 distributor, dispenser, or an author-
11 ized government agency;

12 “(D) provide for periodic inspection by the
13 licensing authority, as determined by the Sec-
14 retary, of such facility warehouse space to en-
15 sure compliance with this section;

16 “(E) prohibit a facility from having as a
17 manager or designated representative anyone
18 convicted of any felony violation of subsection
19 (i) or (k) of section 301 or any violation of sec-
20 tion 1365 of title 18, United States Code relat-
21 ing to product tampering;

22 “(F) provide for mandatory background
23 checks of a facility manager or a designated
24 representative of such manager;

1 “(G) require a third-party logistics pro-
2 vider to provide the applicable licensing author-
3 ity, upon a request by such authority, a list of
4 all product manufacturers, wholesale distribu-
5 tors, and dispensers for whom the third-party
6 logistics provider provides services at such facil-
7 ity; and

8 “(H) include procedures under which any
9 third-party logistics provider license—

10 “(i) expires on the date that is 3
11 years after issuance of the license; and

12 “(ii) may be renewed for additional 3-
13 year periods.

14 “(3) PROCEDURE.—In promulgating the regula-
15 tions under this subsection, the Secretary shall, not-
16 withstanding section 553 of title 5, United States
17 Code—

18 “(A) issue a notice of proposed rulemaking
19 that includes a copy of the proposed regulation;

20 “(B) provide a period of not less than 60
21 days for comments on the proposed regulation;
22 and

23 “(C) provide that the final regulation takes
24 effect upon the expiration of 1 year after the
25 date that such final regulation is issued.

1 “(e) VALIDITY.—A license issued under this section
2 shall remain valid as long as such third-party logistics pro-
3 vider remains licensed consistent with this section. If the
4 Secretary finds that the third-party accreditation program
5 demonstrates that all applicable requirements for licensure
6 under this section are met, the Secretary shall issue a li-
7 cense under this section to a third-party logistics provider
8 receiving accreditation, pursuant to subsection (d)(2)(A).

9 **“SEC. 585. UNIFORM NATIONAL POLICY.**

10 “(a) PRODUCT TRACING AND OTHER REQUIRE-
11 MENTS.—Beginning on the date of enactment of the Drug
12 Supply Chain Security Act, no State or political subdivi-
13 sion of a State may establish or continue in effect any
14 requirements for tracing products through the distribution
15 system (including any requirements with respect to state-
16 ments of distribution history, transaction history, trans-
17 action information, or transaction statement of a product
18 as such product changes ownership in the supply chain,
19 or verification, investigation, disposition, notification, or
20 recordkeeping relating to such systems, including paper or
21 electronic pedigree systems or for tracking and tracing
22 drugs throughout the distribution system) which are in-
23 consistent with, more stringent than, or in addition to, any
24 requirements applicable under section 503(e) (as amended

1 by such Act) or this subchapter (or regulations issued
2 thereunder), or which are inconsistent with—

3 “(1) any waiver, exception, or exemption pursu-
4 ant to section 581 or 582; or

5 “(2) any restrictions specified in section 582.

6 “(b) WHOLESALE DISTRIBUTOR AND THIRD-PARTY
7 LOGISTICS PROVIDER STANDARDS.—

8 “(1) IN GENERAL.—Beginning on the date of
9 enactment of the Drug Supply Chain Security Act,
10 no State or political subdivision of a State may es-
11 tablish or continue any standards, requirements, or
12 regulations with respect to wholesale prescription
13 drug distributor or third-party logistics provider li-
14 censure that are inconsistent with, less stringent
15 than, directly related to, or covered by the standards
16 and requirements applicable under section 503(e)
17 (as amended by such Act), in the case of a wholesale
18 distributor, or section 584, in the case of a third-
19 party logistics provider.

20 “(2) STATE REGULATION OF THIRD-PARTY LO-
21 GISTICS PROVIDERS.—No State shall regulate third-
22 party logistics providers as wholesale distributors.

23 “(3) ADMINISTRATION FEES.—Notwithstanding
24 paragraph (1), a State may administer fee collec-
25 tions for effectuating the wholesale drug distributor

1 and third-party logistics provider licensure require-
2 ments under sections 503(e) (as amended by the
3 Drug Supply Chain Security Act), 583, and 584.

4 “(4) ENFORCEMENT, SUSPENSION, AND REV-
5 OCATION.—Notwithstanding paragraph (1), a
6 State—

7 “(A) may take administrative action, in-
8 cluding fines, to enforce a requirement promul-
9 gated by the State in accordance with section
10 503(e) (as amended by the Drug Supply Chain
11 Security Act) or this subchapter;

12 “(B) may provide for the suspension or
13 revocation of licenses issued by the State for
14 violations of the laws of such State;

15 “(C) upon conviction of violations of Fed-
16 eral, State, or local drug laws or regulations,
17 may provide for fines, imprisonment, or civil
18 penalties; and

19 “(D) may regulate activities of licensed en-
20 tities in a manner that is consistent with prod-
21 uct tracing requirements under section 582.

22 “(c) EXCEPTION.—Nothing in this section shall be
23 construed to preempt State requirements related to the
24 distribution of prescription drugs if such requirements are
25 not related to product tracing as described in subsection

1 (a) or wholesale distributor and third-party logistics pro-
2 vider licensure as described in subsection (b) applicable
3 under section 503(e) (as amended by the Drug Supply
4 Chain Security Act) or this subchapter (or regulations
5 issued thereunder).”.

6 **SEC. 206. PENALTIES.**

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

9 (1) by striking “or” after “the requirements of
10 section 503(d),”; and

11 (2) by inserting “, failure to comply with the
12 requirements under section 582, the failure to com-
13 ply with the requirements under section 584, as ap-
14 plicable,” after “in violation of section 503(e)”.

15 (b) MISBRANDING.—Section 502 (21 U.S.C. 352), as
16 amended by section 103, is further amended by adding
17 at the end the following:

18 “(cc) If it is a drug and it fails to bear the product
19 identifier as required by section 582.”.

20 **SEC. 207. CONFORMING AMENDMENT.**

21 (a) IN GENERAL.—Section 303(b)(1)(D) (21 U.S.C.
22 333(b)(1)(D)) is amended by striking “503(e)(2)(A)” and
23 inserting “503(e)(1)”.

24 (b) EFFECTIVE DATE.—The amendment made by
25 subsection (a) shall take effect on January 1, 2015.

1 **SEC. 208. SAVINGS CLAUSE.**

2 Except as provided in the amendments made by para-
3 graphs (1), (2), and (3) of section 204(a) and by section
4 206(a), nothing in this title (including the amendments
5 made by this title) shall be construed as altering any au-
6 thority of the Secretary of Health and Human Services
7 with respect to a drug subject to section 503(b)(1) of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 353(b)(1)) under any other provision of such Act or the
10 Public Health Service Act (42 U.S.C. 201 et seq.).

 Passed the House of Representatives September 28,
2013.

Attest:

KAREN L. HAAS,

Clerk.

Calendar No. 236

113TH CONGRESS
1ST Session

H. R. 3204

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes.

NOVEMBER 5, 2013

Read the second time and placed on the calendar