

113TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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

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IN THE SENATE OF THE UNITED STATES

\_\_\_\_\_ introduced the following bill; which was read twice  
and referred to the Committee on \_\_\_\_\_

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**A BILL**

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”.

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

7       (a) REFERENCES IN ACT.—Except as otherwise spec-  
8       ified, amendments made by this Act to a section or other  
9       provision of law are amendments to such section or other

1 provision of the Federal Food, Drug, and Cosmetic Act  
 2 (21 U.S.C. 301 et seq.).

3 (b) TABLE OF CONTENTS.—The table of contents of  
 4 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. 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 national policy.  
 Sec. 206. Penalties.  
 Sec. 207. Conforming amendment.  
 Sec. 208. Savings clause.

## 5 **TITLE I—DRUG COMPOUNDING**

### 6 **SEC. 101. SHORT TITLE.**

7 This Act may be cited as the “Compounding Quality  
 8 Act”.

### 9 **SEC. 102. OUTSOURCING FACILITIES.**

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

12 (1) by redesignating section 503B as section  
 13 503C; and

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

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

4           “(a) IN GENERAL.—Sections 502(f)(1), 505, and 582  
5   shall not apply to a drug compounded by or under the  
6   direct supervision of a licensed pharmacist in an outsource-  
7   ing facility if each of the following conditions is met:

8           “(1) REGISTRATION AND REPORTING.—The  
9   drug is compounded in an outsourcing facility that  
10   is in compliance with the registration and reporting  
11   requirements of subsection (b).

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

17           “(A)(i) the bulk drug substance appears on  
18   a list established by the Secretary identifying  
19   bulk substances for which there is a clinical  
20   need, by—

21           “(I) publishing a notice in the Federal  
22   Register proposing bulk substances to be  
23   included on the list, including the rationale  
24   for such proposal;

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

4 “(III) publishing a notice in the Fed-  
5 eral Register designating bulk substances  
6 for inclusion on the list; or

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

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

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

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

24 “(3) INGREDIENTS (OTHER THAN BULK DRUG  
25 SUBSTANCES).—If any ingredients (other than bulk

1 drug substances) are used in compounding the drug,  
2 such ingredients comply with the standards of the  
3 applicable United States Pharmacopoeia or National  
4 Formulary monograph, if such monograph exists, or  
5 of another compendium or pharmacopeia recognized  
6 by the Secretary for purposes of this paragraph.

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

14 “(5) ESSENTIALLY A COPY OF A MARKETED  
15 AND APPROVED DRUG.—The drug is not essentially  
16 a copy of one or more marketed and approved drugs.

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

19 “(A) is not identified (directly or as part  
20 of a category of drugs) on a list published by  
21 the Secretary of drugs or categories of drugs  
22 that present demonstrable difficulties for  
23 compounding that are reasonably likely to lead  
24 to an adverse effect on the safety or effective-  
25 ness of the drug or category of drugs, taking

1           into account the risks and benefits to patients;  
2           or

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

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

20                 “(8) PROHIBITION ON WHOLESALING.—The  
21          drug will not be sold or transferred by an entity  
22          other than the outsourcing facility that compounded  
23          such drug. This paragraph does not prohibit admin-  
24          istration of a drug in a health care setting or dis-

1       pensing a drug pursuant to a prescription executed  
2       in accordance with section 503(b)(1).

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

6               “(10) LABELING OF DRUGS.—

7                       “(A) LABEL.—The label of the drug shall  
8       include—

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

14                              “(ii) the name, address, and phone  
15       number of the applicable outsourcing facil-  
16       ity; and

17                              “(iii) with respect to the drug—

18                                       “(I) the lot or batch number;

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

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

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

1 “(V) the date that the drug was  
2 compounded;

3 “(VI) the expiration date;

4 “(VII) storage and handling in-  
5 structions;

6 “(VIII) the National Drug Code  
7 number, if available;

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

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

19 “(B) CONTAINER.—The container from  
20 which the individual units of the drug are re-  
21 moved for dispensing or for administration  
22 (such as a plastic bag containing individual  
23 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](http://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 “(b) REGISTRATION OF OUTSOURCING FACILITIES  
17 AND REPORTING OF DRUGS.—

18 “(1) REGISTRATION OF OUTSOURCING FACILI-  
19 TIES.—

20 “(A) ANNUAL REGISTRATION.—Upon  
21 electing to become an outsourcing facility, and  
22 during the period beginning on October 1 and  
23 ending on December 31 of each year thereafter,  
24 each outsourcing facility—

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

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

12 “(B) AVAILABILITY OF REGISTRATION FOR  
13 INSPECTION; LIST.—

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

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

1           any such compounding from bulk drug  
2           substances is for sterile or nonsterile  
3           drugs.

4           “(2) DRUG REPORTING BY OUTSOURCING FA-  
5           CILITIES.—

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

13               “(i) identifying the drugs compounded  
14               by such outsourcing facility during the pre-  
15               vious 6-month period; and

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

1 produced, and the National Drug Code  
2 number of the final product, if assigned.

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

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

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

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

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

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

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

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

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

14 “(i) The compliance history of the  
15 outsourcing facility.

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

18 “(iii) The inherent risk of the drugs  
19 compounded at the outsourcing facility.

20 “(iv) The inspection frequency and  
21 history of the outsourcing facility, includ-  
22 ing whether the outsourcing facility has  
23 been inspected pursuant to section 704  
24 within the last 4 years.

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

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

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

16                  “(c) DEFINITIONS.—In this section:

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

22                  “(2) The term ‘essentially a copy of a marketed  
23                  and approved drug’ means—

24                  “(A) a drug that is identical or nearly  
25                  identical to a marketed and approved drug, or

1 a marketed drug not subject to section 503(b)  
2 and not subject to approval in an application  
3 submitted under section 505, unless, in the case  
4 of a marketed and approved drug, the drug ap-  
5 pears on the drug shortage list in effect under  
6 section 506E at the time of compounding, dis-  
7 tribution, and dispensing; or

8 “(B) a drug, a component of which is a  
9 bulk drug substance that is a component of a  
10 marketed and approved drug or a marketed  
11 drug that is not subject to section 503(b) and  
12 not subject to approval in an application sub-  
13 mitted under section 505, unless there is a  
14 change, made for an identified individual pa-  
15 tient, which produces for that patient a clinical  
16 difference, as determined by the prescribing  
17 practitioner, between the compounded drug and  
18 the comparable marketed and approved drug.

19 “(3) The term ‘marketed and approved drug’  
20 means a drug that is approved under section 505  
21 and is currently marketed by the person that holds  
22 the approved application.

23 “(4) The term ‘outsourcing facility’ means a fa-  
24 cility at one geographic location or address—

25 “(A) that—

1 “(i) is engaged in the compounding of  
2 sterile drug; and

3 “(ii) complies with all of the require-  
4 ments of this section;

5 “(B) that may or may not be a licensed  
6 pharmacy and may or may not obtain prescrip-  
7 tions for identified individual patients; and

8 “(C) in which all drugs compounded in  
9 such facility are compounded in compliance  
10 with this section.

11 “(5) The term ‘sterile drug’ means a drug that  
12 is intended for parenteral administration, an oph-  
13 thalmic or oral inhalation drug in aqueous format,  
14 or required to be sterile under Federal or State  
15 law.”.

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

21 (b) FEES.—Subchapter C of chapter VII (21 U.S.C.  
22 379f et seq.) is amended by adding at the end the fol-  
23 lowing:



1       **“PART 9—FEES RELATING TO OUTSOURCING**  
2                       **FACILITIES**

3   **“SEC. 744J. DEFINITIONS.**

4 “In this part:

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

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

11 “(3) The term ‘outsourcing facility’ has the  
12 meaning given to such term in section 503B(c)(5).

“(4) The term ‘reinspection’ means, with respect to an outsourcing facility, 1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified noncompliance materially related to an applicable requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary’s satisfaction.

21 “SEC. 744K. AUTHORITY TO ASSESS AND USE OUTSOURC-  
22                   ING FACILITY FEES.

23 “(a) ESTABLISHMENT AND REINSPECTION FEES.—

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

1           “(A) an annual establishment fee from  
2           each outsourcing facility; and

3           “(B) a reinspection fee from each out-  
4           sourcing facility subject to a reinspection in  
5           such fiscal year.

6           “(2) MULTIPLE REINSPECTIONS.—An outsource-  
7           ing facility subject to multiple reinspections in a fis-  
8           cal year shall be subject to a reinspection fee for  
9           each reinspection.

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

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

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

19          “(c) AMOUNT OF ESTABLISHMENT FEE AND REIN-  
20          SPECTION FEE.—

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

23           “(A) except as provided in paragraph (4),  
24           the amount of the annual establishment fee

1 under subsection (b) shall be equal to the sum  
2 of—

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

6 “(ii) the small business adjustment  
7 factor described in paragraph (3); and

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

12 “(2) INFLATION ADJUSTMENT FACTOR.—

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

19 “(i) 1;

20 “(ii) the average annual percent  
21 change in the cost, per full-time equivalent  
22 position of the Food and Drug Administra-  
23 tion, of all personnel compensation and  
24 benefits paid with respect to such positions  
25 for the first 3 years of the preceding 4 fis-

1 cal years, multiplied by the proportion of  
2 personnel compensation and benefits costs  
3 to total costs of an average full-time equiv-  
4 alent position of the Food and Drug Ad-  
5 ministration for the first 3 years of the  
6 preceding 4 fiscal years; plus

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

19 “(B) COMPOUNDED BASIS.—The adjust-  
20 ment made each fiscal year under subparagraph  
21 (A) shall be added on a compounded basis to  
22 the sum of all adjustments made each fiscal  
23 year after fiscal year 2014 under subparagraph  
24 (A).

1           “(3) SMALL BUSINESS ADJUSTMENT FACTOR.—

2           The small business adjustment factor described in  
3           this paragraph shall be an amount established by  
4           the Secretary for each fiscal year based on the Sec-  
5           retary’s estimate of—

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

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

14           “(4) EXCEPTION FOR SMALL BUSINESSES.—

15                   “(A) IN GENERAL.—In the case of an out-  
16                   sourcing facility with gross annual sales of  
17                   \$1,000,000 or less in the 12 months ending  
18                   April 1 of the fiscal year immediately preceding  
19                   the fiscal year in which the fees under this sec-  
20                   tion are assessed, the amount of the establish-  
21                   ment fee under subsection (b) for a fiscal year  
22                   shall be equal to  $\frac{1}{3}$  of the amount calculated  
23                   under paragraph (1)(A)(i) for such fiscal year.

24                   “(B) APPLICATION.—To qualify for the ex-  
25                   ception under this paragraph, a small business

1           shall submit to the Secretary a written request  
2           for such exception, in a format specified by the  
3           Secretary in guidance, certifying its gross an-  
4           nual sales for the 12 months ending April 1 of  
5           the fiscal year immediately preceding the fiscal  
6           year in which fees under this subsection are as-  
7           sessed. Any such application shall be submitted  
8           to the Secretary not later than April 30 of such  
9           immediately preceding fiscal year.

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

13                   “(A) provide for the crediting of fees from  
14                   the previous year to the next year if the Sec-  
15                   retary overestimated the amount of the small  
16                   business adjustment factor for such previous  
17                   fiscal year; and

18                   “(B) consider the need to account for any  
19                   adjustment of fees and such other factors as  
20                   the Secretary determines appropriate.

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

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

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

18       “(g) COLLECTION OF FEES.—

19               “(1) ESTABLISHMENT FEE.—An outsourcing  
20 facility shall remit the establishment fee due under  
21 this section in a fiscal year when submitting a reg-  
22 istration pursuant to section 503B(b) for such fiscal  
23 year.

24               “(2) REINSPECTION FEE.—The Secretary shall  
25 specify in the Federal Register notice described in

1 subsection (b)(2) the manner in which reinspection  
2 fees assessed under this section shall be collected  
3 and the timeline for payment of such fees. Such a  
4 fee shall be collected after the Secretary has con-  
5 ducted a reinspection of the outsourcing facility in-  
6 volved.

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

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

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

22 “(4) COLLECTION OF UNPAID FEES.—In any  
23 case where the Secretary does not receive payment  
24 of a fee assessed under this section within 30 cal-  
25 endar days after it is due, such fee shall be treated



1 as a claim of the United States Government subject  
2 to provisions of subchapter II of chapter 37 of title  
3 31, United States Code.

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

17 “(i) AUTHORIZATION OF APPROPRIATIONS.—For fis-  
18 cal year 2015 and each subsequent fiscal year, there is  
19 authorized to be appropriated for fees under this section  
20 an amount equivalent to the total amount of fees assessed  
21 for such fiscal year under this section.”.

22 **SEC. 103. PENALTIES.**

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

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

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

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

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

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

13       **SEC. 104. REGULATIONS.**

14       (a) REGULATIONS.—In promulgating any regulations  
15       to implement this title (and the amendments made by this  
16       title), the Secretary of Health and Human Services  
17       shall—

18               (1) issue a notice of proposed rulemaking that  
19       includes the proposed regulation;

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

23               (3) publish the final regulation not more than  
24       18 months following publication of the proposed rule

1       and not less than 30 calendar days before the effec-  
2       tive date of such final regulation.

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

4       (a) SUBMISSIONS FROM STATE BOARDS OF PHAR-  
5   MACY.—In a manner specified by the Secretary of Health  
6   and Human Services (referred to in this section as the  
7   “Secretary”), the Secretary shall receive submissions from  
8   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 one or more re-  
14    quirements of 503A of the Federal Food, Drug, and  
15    Cosmetic Act (21 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 one or more require-  
16 ments of section 503A of the Federal Food, Drug,  
17 and Cosmetic Act.

18 **SEC. 106. SEVERABILITY.**

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

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

23 (2) by striking subsection (c);

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

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

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 dispositions 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 affiliated  
17 group or 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 manufacturers  
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 sympathicomimetic;

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 the date that is 1 year after the  
12 date of enactment of the Drug Supply Chain  
13 Security Act—

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

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

22 “(iii) the owners of such product on  
23 such date shall be exempt from asserting  
24 receipt of transaction information and

1 transaction statement from the prior owner  
2 as required under this section.

3 “(6) WHOLESALE DISTRIBUTOR LICENSES.—  
4 Notwithstanding section 581(9)(A), until the effective date of the wholesale distributor licensing regulations under section 583, the term ‘licensed’ or ‘authorized’, as it relates to a wholesale distributor with respect to prescription drugs, shall mean a wholesale distributor with a valid license under State law.

10 “(7) THIRD-PARTY LOGISTICS PROVIDER LICENSES.—Until the effective date of the third-party logistics provider licensing regulations under section 584, a third-party logistics provider shall be considered ‘licensed’ under section 581(9)(B) unless the Secretary has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof.

18 “(8) LABEL CHANGES.—Changes made to package labels solely to incorporate the product identifier may be submitted to the Secretary in the annual report of an establishment, in accordance with section 314.70(d) of chapter 21, Code of Federal Regulations (or any successor regulation).

1           “(9) PRODUCT IDENTIFIERS.—With respect to  
2           any requirement relating to product identifiers under  
3           this subchapter—

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

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

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

16                   “(B) verification of the product identifier  
17                   may occur by using human-readable or ma-  
18                   chine-readable methods.

19           “(b) MANUFACTURER REQUIREMENTS.—

20                   “(1) PRODUCT TRACING.—

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

23                                   “(i) prior to, or at the time of, each  
24                                   transaction in which such manufacturer  
25                                   transfers ownership of a product, provide

1 the subsequent owner with transaction his-  
2 tory, transaction information, and a trans-  
3 action statement, in a single document in  
4 an paper or electronic format; and

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

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

24 “(C) ELECTRONIC FORMAT.—



1           “(i) IN GENERAL.—Beginning not  
2 later than 4 years after the date of enact-  
3 ment of the Drug Supply Chain Security  
4 Act, except as provided under clause (ii), a  
5 manufacturer shall provide the transaction  
6 information, transaction history, and  
7 transaction statement required under sub-  
8 paragraph (A)(i) in electronic format.

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

20           “(2) PRODUCT IDENTIFIER.—

21           “(A) IN GENERAL.—Beginning not later  
22 than 4 years after the date of enactment of the  
23 Drug Supply Chain Security Act, a manufac-  
24 turer shall affix or imprint a product identifier  
25 to each package and homogenous case of a

1 product intended to be introduced in a trans-  
2 action into commerce. Such manufacturer shall  
3 maintain the product identifier information for  
4 such product for not less than 6 years after the  
5 date of the transaction.

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

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

14 “(4) VERIFICATION.—Beginning not later than  
15 January 1, 2015, a manufacturer shall have systems  
16 in place to enable the manufacturer to comply with  
17 the following requirements:

18 “(A) SUSPECT PRODUCT.—

19 “(i) IN GENERAL.—Upon making a  
20 determination that a product in the posses-  
21 sion or control of the manufacturer is a  
22 suspect product, or upon receiving a re-  
23 quest for verification from the Secretary  
24 that has made a determination that a  
25 product within the possession or control of

1 a manufacturer is a suspect product, a  
2 manufacturer shall—

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

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

23 “(ii) CLEARED PRODUCT.—If the  
24 manufacturer makes the determination  
25 that a suspect product is not an illegit-

1           imate product, the manufacturer shall  
2           promptly notify the Secretary, if applica-  
3           ble, of such determination and such prod-  
4           uct may be further distributed.

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

9           “(B) ILLEGITIMATE PRODUCT.—

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

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

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

24           “(III) take reasonable and appro-  
25           priate steps to assist a trading part-

1 ner to disposition an illegitimate prod-  
2 uct not in the possession or control of  
3 the manufacturer; and

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

13 “(ii) MAKING A NOTIFICATION.—

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

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

22                  “(iii) RESPONDING TO A NOTIFICA-  
23                  TION.—Upon the receipt of a notification  
24                  from the Secretary or a trading partner  
25                  that a determination has been made that a

1 product is an illegitimate product, a manu-  
2 facturer shall identify all illegitimate prod-  
3 uct subject to such notification that is in  
4 the possession or control of the manufac-  
5 turer, including any product that is subse-  
6 quently received, and shall perform the ac-  
7 tivities described in subparagraph (A).

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

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

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

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

24 “(D) ELECTRONIC DATABASE.—A manu-  
25 facturer may satisfy the requirements of this



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

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

1 including the standardized numerical identifier,  
2 on each package.

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

11 “(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

12 “(1) PRODUCT TRACING.—

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

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

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

1 of the manufacturer, or a repackager that  
2 purchased directly from the manufacturer,  
3 then prior to, or at the time of, each trans-  
4 action in which the wholesale distributor  
5 transfers ownership of a product, the  
6 wholesale distributor shall provide to the  
7 subsequent purchaser—

8 “(AA) a transaction statement,  
9 which shall state that such wholesale  
10 distributor, or a member of the affili-  
11 ated group of such wholesale dis-  
12 tributor, purchased the product di-  
13 rectly from the manufacturer, exclu-  
14 sive distributor of the manufacturer,  
15 or repackager that purchased the  
16 product directly from the manufac-  
17 turer; and

18 “(BB) subject to subclause (II),  
19 the transaction history and trans-  
20 action information.

21 “(bb) The wholesale distributor shall  
22 provide the transaction history, transaction  
23 information, and transaction statement  
24 under item (aa)—

1                   “(AA) if provided to a dis-  
2                   penser, on a single document in a  
3                   paper or electronic format; and

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

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

18                  “(iii) If the wholesale distributor did  
19                  not purchase a product directly from the  
20                  manufacturer, the exclusive distributor of  
21                  the manufacturer, or a repackager that  
22                  purchased directly from the manufacturer,  
23                  as described in clause (ii), then prior to, or  
24                  at the time of, each transaction or subse-  
25                  quent transaction, the wholesale distributor

1 shall provide to the subsequent purchaser a  
2 transaction statement, transaction history,  
3 and transaction information, in a paper or  
4 electronic format that complies with the  
5 guidance document issued under sub-  
6 section (a)(2).

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

16 “(v) A wholesale distributor shall—

17 “(I) capture the transaction in-  
18 formation (including lot level informa-  
19 tion), transaction history, and trans-  
20 action statement for each transaction  
21 described in clauses (i), (ii), and (iii)  
22 and maintain such information, his-  
23 tory, and statement for not less than  
24 6 years after the date of the trans-  
25 action; and

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

14 “(B) RETURNS.—

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

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

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

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

1 product shall begin with the wholesale  
2 distributor that accepted and verified  
3 the returned product. For purposes of  
4 this subparagraph, the transaction in-  
5 formation and transaction history, as  
6 applicable, need not include trans-  
7 action dates if it is not reasonably  
8 practicable to obtain such dates.

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

18 “(C) REQUESTS FOR INFORMATION.—  
19 Upon a request by the Secretary or other ap-  
20 propriate Federal or State official, in the event  
21 of a recall or for the purpose of investigating a  
22 suspect product or an illegitimate product, a  
23 wholesale distributor shall, not later than 1  
24 business day, and not to exceed 48 hours, after  
25 receiving the request or in other such reason-



1           able time as determined by the Secretary, based  
2           on the circumstances of the request, provide the  
3           applicable transaction information, transaction  
4           history, and transaction statement for the prod-  
5           uct.

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

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

24          “(3) AUTHORIZED TRADING PARTNERS.—Be-  
25          ginning not later than January 1, 2015, the trading

1 partners of a wholesale distributor may be only au-  
2 thorized trading partners.

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

7 “(A) SUSPECT PRODUCT.—

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

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

23 “(II) promptly conduct an inves-  
24 tigation in coordination with trading  
25 partners, as applicable, to determine

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

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

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

1 6 years after the conclusion of the inves-  
2 tigation.

3 “(B) ILLEGITIMATE PRODUCT.—

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

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

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

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

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

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

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

1 sale distributor shall identify all illegit-  
2 imate product subject to such notification  
3 that is in the possession or control of the  
4 wholesale distributor, including any prod-  
5 uct that is subsequently received, and shall  
6 perform the activities described in subpara-  
7 graph (A).

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

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

22 “(C) ELECTRONIC DATABASE.—A whole-  
23 sale distributor may satisfy the requirements of  
24 this 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 wholesale distributor of the requirement  
9 under this paragraph to respond to a  
10 verification request submitted by means other  
11 than a secure electronic database.

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

1 “(d) DISPENSER REQUIREMENTS.—

2 “(1) PRODUCT TRACING.—

3 “(A) IN GENERAL.—Beginning July 1,  
4 2015, a dispenser—

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

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

21 “(iii) shall capture transaction infor-  
22 mation (including lot level information),  
23 transaction history, and transaction state-  
24 ments, as necessary to investigate a sus-  
25 pect product, and maintain such informa-



tion, history, and statements for not less than 6 years after the transaction.

“(B) AGREEMENTS WITH THIRD PARTIES.—A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements required to be maintained under this subsection on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection.

16 “(C) RETURNS.—

“(i) SALEABLE RETURNS.—A dispenser may return product to the trading partner from which the dispenser obtained the product without providing the information required under subparagraph (A).

“(ii) NONSALEABLE RETURNS.—A dispenser may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such

1 product was purchased, to a returns proc-  
2 essor, or to a person acting on behalf of  
3 such a person without providing the infor-  
4 mation required under subparagraph (A).

5 “(D) REQUESTS FOR INFORMATION.—

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

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

16 “(2) PRODUCT IDENTIFIER.—Beginning not  
17 later than 7 years after the date of enactment of the  
18 Drug Supply Chain Security Act, a dispenser 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 dispenser may be only authorized trad-  
25 ing partners.

1           “(4) VERIFICATION.—Beginning not later than  
2           January 1, 2015, a dispenser shall have systems in  
3           place to enable the dispenser to comply with the fol-  
4           lowing 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 the dispenser is a suspect  
9                           product, or upon receiving a request for  
10                          verification from the Secretary that has  
11                          made a determination that a product with-  
12                          in the possession or control of a dispenser  
13                          is a suspect product, a dispenser shall—

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

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

1 “(ii) INVESTIGATION.—An investiga-  
2 tion conducted under clause (i)(II) shall in-  
3 clude—

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

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

20 “(III) validating any applicable  
21 transaction history and transaction in-  
22 formation in the possession of the dis-  
23 penser; and

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

“(iii) CLEARED PRODUCT.—If the dispenser makes the determination that a suspect product is not an illegitimate product, the dispenser shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed or dispensed.

“(iv) RECORDS.—A dispenser shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

15 “(B) ILLEGITIMATE PRODUCT.—

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

21 “(I) disposition the illegitimate  
22 product within the possession or con-  
23 trol of the dispenser;

24 “(II) take reasonable and appro-  
25 priate steps to assist a trading part-

1                   ner to disposition an illegitimate prod-  
2                   uct not in the possession or control of  
3                   the dispenser; and

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

13               “(ii) MAKING A NOTIFICATION.—  
14               Upon determining that a product in the  
15               possession or control of the dispenser is an  
16               illegitimate product, the dispenser shall no-  
17               tify the Secretary and all immediate trad-  
18               ing partners that the dispenser has reason  
19               to believe may have received such illegit-  
20               imate product of such determination not  
21               later than 24 hours after making such de-  
22               termination.

23               “(iii) RESPONDING TO A NOTIFICA-  
24               TION.—Upon the receipt of a notification  
25               from the Secretary or a trading partner

1           that a determination has been made that a  
2           product is an illegitimate product, a dis-  
3           penser shall identify all illegitimate product  
4           subject to such notification that is in the  
5           possession or control of the dispenser, in-  
6           cluding any product that is subsequently  
7           received, and shall perform the activities  
8           described in subparagraph (A).

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

17          “(v) RECORDS.—A dispenser shall  
18          keep records of the disposition of an illegit-  
19          imate product for not less than 6 years  
20          after the conclusion of the disposition.

21          “(C) ELECTRONIC DATABASE.—A dis-  
22          penser may satisfy the requirements of this  
23          paragraph by developing a secure electronic  
24          database or utilizing a secure electronic data-  
25          base developed or operated by another entity.



1           “(5) EXCEPTION.—Notwithstanding any other  
2           provision of law, the requirements under paragraphs  
3           (1) and (4) shall not apply to licensed health care  
4           practitioners authorized to prescribe medication  
5           under State law or other licensed individuals under  
6           the supervision or direction of such practitioners  
7           who dispense product in the usual course of profes-  
8           sional practice.

9           “(e) REPACKAGER REQUIREMENTS.—

10           “(1) PRODUCT TRACING.—

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

14                           “(i) not accept ownership of a product  
15                           unless the previous owner, prior to, or at  
16                           the time of, the transaction, provides  
17                           transaction history, transaction informa-  
18                           tion, and a transaction statement for the  
19                           product;

20                           “(ii) prior to, or at the time of, each  
21                           transaction in which the repackager trans-  
22                           fers ownership of a product, provide the  
23                           subsequent owner with transaction history,  
24                           transaction information, and a transaction  
25                           statement for the product; and

1 “(iii) capture the transaction informa-  
2 tion (including lot level information),  
3 transaction history, and transaction state-  
4 ment for each transaction described in  
5 clauses (i) and (ii) and maintain such in-  
6 formation, history, and statement for not  
7 less than 6 years after the transaction.

8 “(B) RETURNS.—

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

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

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

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

19 “(2) PRODUCT IDENTIFIER.—

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

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

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

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

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

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

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

22 “(3) AUTHORIZED TRADING PARTNERS.—Be-  
23 ginning January 1, 2015, the trading partners of a  
24 repackager described in section 581(16) may be only  
25 authorized trading partners.

“(4) VERIFICATION.—Beginning not later than January 1, 2015, a repackager described in section 581(16)(A) shall have systems in place to enable the repackager to comply with the following requirements:

6 “(A) SUSPECT PRODUCT.—

“(i) IN GENERAL.—Upon making a determination that a product in the possession or control of the repackager is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a repackager is a suspect product, a repackager shall—

16 “(I) quarantine such product  
17 within the possession or control of the  
18 repackager from product intended for  
19 distribution until such product is  
20 cleared or dispositioned; 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 repackager and otherwise  
4 investigating to determine whether the  
5 product is an illegitimate product,  
6 and, beginning 5 years after the date  
7 of enactment of the Drug Supply  
8 Chain Security Act (except as pro-  
9 vided pursuant to subsection (a)(5)),  
10 verifying the product at the package  
11 level, including the standardized nu-  
12 merical identifier.

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

20 “(iii) RECORDS.—A repackager shall  
21 keep records of the investigation of a sus-  
22 pect product for not less than 6 years after  
23 the conclusion of the investigation.

24 “(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 repackager is an illegitimate  
5                   product, the repackager shall, in a manner  
6                   that is consistent with the systems and  
7                   processes of such repackager—

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

13                  “(II) disposition the illegitimate  
14                  product within the possession or con-  
15                  trol of the repackager;

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

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

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

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

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

24 “(iv) TERMINATING A NOTIFICA-  
25 TION.—Upon making a determination, in



1           consultation with the Secretary, that a no-  
2           tification is no longer necessary, a repack-  
3           ager shall promptly notify immediate trad-  
4           ing partners that the repackager notified  
5           pursuant to clause (ii) that such notifica-  
6           tion has been terminated.

7           “(v) RECORDS.—A repackager shall  
8           keep records of the disposition of an illegit-  
9           imate product for not less than 6 years  
10          after the conclusion of the disposition.

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

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

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

1           mitted by means other than a secure electronic  
2           database.

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

14          “(f) DROP SHIPMENTS.—

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

1 and provides the transaction information, trans-  
2 action history, and transaction statement directly to  
3 the dispenser.

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

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

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

12 “(g) ENHANCED DRUG DISTRIBUTION SECURITY.—

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

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

1 guidance issued in accordance with paragraph  
2 (5) of such subsection.

3 “(B) The transaction information required  
4 under this section shall include the product  
5 identifier at the package level for each package  
6 included in the transaction.

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

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

1           “(E) The systems and processes necessary  
2           to promptly facilitate gathering the information  
3           necessary to produce the transaction informa-  
4           tion for each transaction going back to the  
5           manufacturer, as applicable, shall be required—

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

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

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

1 “(2) COMPLIANCE.—

2 “(A) INFORMATION MAINTENANCE AGREE-  
3 MENT.—A dispenser may enter into a written  
4 agreement with a third party, including an au-  
5 thorized wholesale distributor, under which the  
6 third party shall confidentially maintain any in-  
7 formation and statements required to be main-  
8 tained under this section. If a dispenser enters  
9 into such an agreement, the dispenser shall  
10 maintain a copy of the written agreement and  
11 shall not be relieved of the obligations of the  
12 dispenser under this subsection.

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

19 “(i) establishing timelines for compli-  
20 ance by small businesses (including small  
21 business dispensers with 25 or fewer full-  
22 time employees) with such requirements, in  
23 order to ensure that such requirements do  
24 not impose undue economic hardship for  
25 small businesses, including small business

1 dispensers for whom the criteria set forth  
2 in the assessment under paragraph (3) is  
3 not met, if the Secretary determines that  
4 such requirements under paragraph (1)  
5 would result in undue economic hardship;  
6 and

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

15 “(3) ASSESSMENT.—

16 “(A) IN GENERAL.—Not later than the  
17 date that is 18 months after the Secretary  
18 issues the final guidance required under sub-  
19 section (h), the Secretary shall enter into a con-  
20 tract with a private, independent consulting  
21 firm with expertise to conduct a technology and  
22 software assessment that looks at the feasibility  
23 of dispensers with 25 or fewer full-time employ-  
24 ees conducting interoperable, electronic tracing  
25 of products at the package level. Such assess-



1           ment shall be completed not later than 8½  
2           years after the date of enactment of the Drug  
3           Supply Chain Security Act.

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

10          “(C) CONTENT.—The assessment under  
11          subparagraph (A) shall assess whether—

12               “(i) the necessary software and hard-  
13               ware is readily accessible to such dis-  
14               pensers;

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

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

23          “(D) PUBLICATION.—The Secretary  
24          shall—

1 “(i) publish the statement of work for  
2 the assessment under subparagraph (A)  
3 for public comment prior to beginning the  
4 assessment;

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

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

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

17 “(A) provide appropriate flexibility by—

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

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

1                   “(I) timelines for small busi-  
2                   nesses to comply with the require-  
3                   ments set forth in the regulations in  
4                   order to ensure that such require-  
5                   ments do not impose undue economic  
6                   hardship for small businesses (includ-  
7                   ing small business dispensers for  
8                   whom the criteria set forth in the as-  
9                   sessment under paragraph (3) is not  
10                  met), if the Secretary determines that  
11                  such requirements would result in  
12                  undue economic hardship; and

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

20                  “(iii) taking into consideration—

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

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

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

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

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

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

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

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

4           “(h) GUIDANCE DOCUMENTS.—

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

12          “(2) SUSPECT AND ILLEGITIMATE PRODUCT.—

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

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

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

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

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

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

15 “(3) UNIT LEVEL TRACING.—

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 “(i) PUBLIC MEETINGS.—

24 “(1) IN GENERAL.—The Secretary shall hold  
25 not less than 5 public meetings to enhance the safe-

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 “(j) PILOT PROJECTS.—

19 “(1) IN GENERAL.—The Secretary shall estab-  
20 lish 1 or more pilot projects, in coordination with  
21 authorized manufacturers, repackagers, wholesale  
22 distributors, and dispensers, to explore and evaluate  
23 methods to enhance the safety and security of the  
24 pharmaceutical distribution supply chain. Such  
25 projects shall build upon efforts, in existence as of

1 the date of enactment of the Drug Supply Chain Se-  
2 curity Act, to enhance the safety and security of the  
3 pharmaceutical distribution supply chain, take into  
4 consideration any pilot projects conducted prior to  
5 such date of enactment, including any pilot projects  
6 that use aggregation and inference, and inform the  
7 draft and final guidance under paragraphs (3) and  
8 (4) of subsection (h).

9 “(2) CONTENT.—

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

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

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

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

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

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

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

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

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

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

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

cluding or delaying the provisions becoming effective pursuant to subsection (g).

“(m) REQUESTS FOR INFORMATION.—On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the timeline for responses to requests for information from the Secretary, or other appropriate Federal or State official, as applicable, under subsections (b)(1)(B), (c)(1)(C), and (e)(1)(C) shall be not later than 24 hours after receiving the request from the Secretary or other appropriate Federal or State official, as applicable, or in such other reasonable time as determined by the Secretary based on the circumstances of the request.”.

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

(a) AMENDMENTS.—

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

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

“(A) IN GENERAL.—No person may engage in wholesale distribution of a drug subject to subsection (b)(1) in any State unless such person—



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

3 “(II) if the State from which the drug  
4 is distributed has not established a licen-  
5 sure requirement, is licensed by the Sec-  
6 retary; and

7 “(ii) if the drug is distributed inter-  
8 state, is licensed by the State into which  
9 the drug is distributed if the State into  
10 which the drug is distributed requires the  
11 licensure of a person that distributes drugs  
12 into the State.

13 “(B) STANDARDS.—Each Federal and  
14 State license described in subparagraph (A)  
15 shall meet the standards, terms, and conditions  
16 established by the Secretary under section 583.

17 “(2) REPORTING AND DATABASE.—

18 “(A) REPORTING.—Beginning January 1,  
19 2015, any person who owns or operates an es-  
20 tablishment that engages in wholesale distribu-  
21 tion shall—

22 “(i) report to the Secretary, on an an-  
23 nual basis pursuant to a schedule deter-  
24 mined by the Secretary—

1 “(I) each State by which the per-  
2 son is licensed and the appropriate  
3 identification number of each such li-  
4 cense; and

“(II) the name, address, and contact information of each facility at which, and all trade names under which, the person conducts business; and

“(ii) report to the Secretary within a reasonable period of time and in a reasonable manner, as determined by the Secretary, any significant disciplinary actions, such as the revocation or suspension of a wholesale distributor license, taken by a State or the Federal Government during the reporting period against the wholesale distributor.

19 “(B) DATABASE.—Not later than January  
20 1, 2015, the Secretary shall establish a data-  
21 base of authorized wholesale distributors. Such  
22 database shall—

“(i) identify each authorized wholesale distributor by name, contact information, and each State where such wholesale dis-

1           tributor is appropriately licensed to engage  
2           in wholesale distribution;

3           “(ii) be available to the public on the  
4           Internet Web site of the Food and Drug  
5           Administration; and

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

8           “(C) COORDINATION.—The Secretary shall  
9           establish a format and procedure for appro-  
10          prium State officials to access the information  
11          provided pursuant to subparagraph (A) in a  
12          prompt and secure manner.

13          “(D) CONFIDENTIALITY.—Nothing in this  
14          paragraph shall be construed as authorizing the  
15          Secretary to disclose any information that is a  
16          trade secret or confidential information subject  
17          to section 552(b)(4) of title 5, United States  
18          Code, or section 1905 of title 18, United States  
19          Code.

20          “(3) COSTS.—

21          “(A) AUTHORIZED FEES OF SECRETARY.—  
22          If a State does not establish a licensing pro-  
23          gram for persons engaged in the wholesale dis-  
24          tribution of a drug subject to subsection (b),  
25          the Secretary shall license a person engaged in

1           wholesale distribution located in such State and  
2           may collect a reasonable fee in such amount  
3           necessary to reimburse the Secretary for costs  
4           associated with establishing and administering  
5           the licensure program and conducting periodic  
6           inspections under this section. The Secretary  
7           shall adjust fee rates as needed on an annual  
8           basis to generate only the amount of revenue  
9           needed to perform this service. Fees authorized  
10          under this paragraph shall be collected and  
11          available for obligation only to the extent and in  
12          the amount provided in advance in appropria-  
13          tions Acts. Such fees are authorized to remain  
14          available until expended. Such sums as may be  
15          necessary may be transferred from the Food  
16          and Drug Administration salaries and expenses  
17          appropriation account without fiscal year limi-  
18          tation to such appropriation account for sala-  
19          ries and expenses with such fiscal year limita-  
20          tion.

21               “(B) STATE LICENSING FEES.—Nothing in  
22          this Act shall prohibit States from collecting  
23          fees from wholesale distributors in connection  
24          with State licensing of such distributors.”.

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

5           “(4) For the purposes of this subsection and  
6     subsection (d), the term ‘wholesale distribution’  
7     means the distribution of a drug subject to sub-  
8     section (b) to a person other than a consumer or pa-  
9     tient, or receipt of a drug subject to subsection (b)  
10    by a person other than the consumer or patient, but  
11    does not include—

12           “(A) intracompany distribution of any  
13     drug between members of an affiliated group or  
14     within a manufacturer;

15           “(B) the distribution of a drug, or an offer  
16     to distribute a drug among hospitals or other  
17     health care entities which are under common  
18     control;

19           “(C) the distribution of a drug or an offer  
20     to distribute a drug for emergency medical rea-  
21     sons, including a public health emergency dec-  
22     laration pursuant to section 319 of the Public  
23     Health Service Act, except that, for purposes of  
24     this paragraph, a drug shortage not caused by

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

3 “(D) the dispensing of a drug pursuant to  
4 a prescription executed in accordance with sub-  
5 section (b)(1);

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

9 “(F) the distribution of a drug or an offer  
10 to distribute a drug by a charitable organization  
11 to a nonprofit affiliate of the organization to  
12 the extent otherwise permitted by law;

13 “(G) the purchase or other acquisition by  
14 a dispenser, hospital, or other health care entity  
15 of a drug for use by such dispenser, hospital, or  
16 other health care entity;

17 “(H) the distribution of a drug by the  
18 manufacturer of such drug;

19 “(I) the receipt or transfer of a drug by an  
20 authorized third-party logistics provider pro-  
21 vided that such third-party logistics provider  
22 does not take ownership of the drug;

23 “(J) a common carrier that transports a  
24 drug, provided that the common carrier does  
25 not take ownership of the drug;

1           “(K) the distribution of a drug, or an offer  
2           to distribute a drug by an authorized repack-  
3           ager that has taken ownership or possession of  
4           the drug and repacks it in accordance with sec-  
5           tion 582(e);

6           “(L) salable drug returns when conducted  
7           by a dispenser;

8           “(M) the distribution of a collection of fin-  
9           ished medical devices, which may include a  
10          product or biological product, assembled in kit  
11          form strictly for the convenience of the pur-  
12          chaser or user (referred to in this subparagraph  
13          as a ‘medical convenience kit’) if—

14               “(i) the medical convenience kit is as-  
15               sembled in an establishment that is reg-  
16               istered with the Food and Drug Adminis-  
17               tration as a device manufacturer in accord-  
18               ance with section 510(b)(2);

19               “(ii) the medical convenience kit does  
20               not contain a controlled substance that ap-  
21               pears in a schedule contained in the Com-  
22               prehensive Drug Abuse Prevention and  
23               Control Act of 1970;

1 “(iii) in the case of a medical conven-  
2 ience kit that includes a product, the per-  
3 son that manufacturers the kit—

4 “(I) purchased such product di-  
5 rectly from the pharmaceutical manu-  
6 facturer or from a wholesale dis-  
7 tributor that purchased the product  
8 directly from the pharmaceutical man-  
9 ufacturer; and

10 “(II) does not alter the primary  
11 container or label of the product as  
12 purchased from the manufacturer or  
13 wholesale distributor; and

14 “(iv) in the case of a medical conven-  
15 ience kit that includes a product, the prod-  
16 uct is—

17 “(I) an intravenous solution in-  
18 tended for the replenishment of fluids  
19 and electrolytes;

20 “(II) a product intended to main-  
21 tain the equilibrium of water and min-  
22 erals in the body;

23 “(III) a product intended for irri-  
24 gation or reconstitution;

25 “(IV) an anesthetic;



1 “(V) an anticoagulant;

2 “(VI) a vasopressor; or

3 “(VII) a sympathicomimetic;

4 “(N) the distribution of an intravenous  
5 drug that, by its formulation, is intended for  
6 the replenishment of fluids and electrolytes  
7 (such as sodium, chloride, and potassium) or  
8 calories (such as dextrose and amino acids);

9 “(O) the distribution of an intravenous  
10 drug used to maintain the equilibrium of water  
11 and minerals in the body, such as dialysis solu-  
12 tions;

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

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

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

21 “(S) the transfer of a product by a hos-  
22 pital or other health care entity, or by a whole-  
23 sale distributor or manufacturer operating at  
24 the direction of the hospital or other health care  
25 entity, to a repackager described in section

1           581(16)(B) and registered under section 510  
2           for the purpose of repackaging the drug for use  
3           by that hospital, or other health care entity and  
4           other health care entities that are under com-  
5           mon control, if ownership of the drug remains  
6           with the hospital or other health care entity at  
7           all times.”.

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

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

21           (4) AFFILIATE.—Section 503(e) (21 U.S.C.  
22          353(e)), as amended by paragraph (3), is further  
23          amended by adding at the end the following:

24           “(6) AFFILIATE.—For purposes of this sub-  
25          section, the term ‘affiliate’ means a business entity

1       that has a relationship with a second business entity  
2       if, directly or indirectly—

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

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

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

11   **“SEC. 583. NATIONAL STANDARDS FOR PRESCRIPTION**  
12               **DRUG WHOLESALE DISTRIBUTORS.**

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

19       “(b) CONTENT.—For the purpose of ensuring uni-  
20      formity with respect to standards set forth in this section,  
21      the standards established under subsection (a) shall apply  
22      to all State and Federal licenses described under section  
23      503(e)(1) (as amended by the Drug Supply Chain Secu-  
24      rity Act) and shall include standards for the following:

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

3           “(2) The establishment and maintenance of  
4           records of the distributions of such drugs.

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

7                   “(A)(i) For the issuance or renewal of a  
8                   wholesale distributor license, an applicant that  
9                   is not a government owned and operated whole-  
10                  sale distributor shall submit a surety bond of  
11                  \$100,000 or other equivalent means of security  
12                  acceptable to the State.

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

18                  “(B) If a wholesale distributor can provide  
19                  evidence that it possesses the required bond in  
20                  a State, the requirement for a bond in another  
21                  State shall be waived.

22           “(4) Mandatory background checks and  
23           fingerprinting of facility managers or designated  
24           representatives.

1           “(5) The establishment and implementation of  
2           qualifications for key personnel.

3           “(6) The mandatory physical inspection of any  
4           facility to be used in wholesale distribution within a  
5           reasonable time frame from the initial application of  
6           the facility and to be conducted by the licensing au-  
7           thority or by the State, consistent with subsection  
8           (c).

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

12          “(c) INSPECTIONS.—To satisfy the inspection re-  
13          quirement under subsection (b)(6), the Federal or State  
14          licensing authority may conduct the inspection or may ac-  
15          cept an inspection by the State in which the facility is lo-  
16          cated, or by a third-party accreditation or inspection serv-  
17          ice approved by the Secretary or the State licensing such  
18          wholesale distributor.

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

23                 “(1) has been convicted of any felony for con-  
24                 duct relating to wholesale distribution, any felony  
25                 violation of subsection (i) or (k) of section 301, or

1 any felony violation of section 1365 of title 18,  
2 United States Code, relating to product tampering;  
3 or

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

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

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

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

15 “(3) provide that the final regulation take effect  
16 on the date that is 2 years after the date such final  
17 regulation is published.”.

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

21 “(4) In this subsection, the term ‘authorized  
22 distributors of record’ means those distributors with  
23 whom a manufacturer has established an ongoing re-  
24 lationship to distribute such manufacturer’s prod-  
25 ucts.”.

1 (c) EFFECTIVE DATE.—The amendments made by  
2 subsections (a) and (b) shall take effect on January 1,  
3 2015.

4 **SEC. 205. NATIONAL STANDARDS FOR THIRD-PARTY LOGIS-**  
5 **TICS PROVIDERS; UNIFORM NATIONAL POL-**  
6 **ICY.**

7 Subchapter H of chapter V, as amended by section  
8 204, is further amended by adding at the end the fol-  
9 lowing:

10 **“SEC. 584. NATIONAL STANDARDS FOR THIRD-PARTY LO-**  
11 **GISTICS PROVIDERS.**

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

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

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

24 “(2) if the drug is distributed interstate, is li-  
25 censed by the State into which the drug is distrib-

1       uted by the third-party logistics provider if such  
2       State licenses third-party logistics providers that dis-  
3       tribute drugs into the State and the third-party lo-  
4       gistcs provider is not licensed by the Secretary as  
5       described in paragraph (1)(B).

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

11           “(1) the State by which the facility is licensed  
12           and the appropriate identification number of such li-  
13           cense; and

14           “(2) the name and address of the facility and  
15           all trade names under which such facility conducts  
16           business.

17      “(c) COSTS.—

18           “(1) AUTHORIZED FEES OF SECRETARY.—If a  
19           State does not establish a licensing program for a  
20           third-party logistics provider, the Secretary shall li-  
21           cense the third-party logistics provider located in  
22           such State and may collect a reasonable fee in such  
23           amount necessary to reimburse the Secretary for  
24           costs associated with establishing and administering  
25           the licensure program and conducting periodic in-



1       spections under this section. The Secretary shall ad-  
2       just fee rates as needed on an annual basis to gen-  
3       erate only the amount of revenue needed to perform  
4       this service. Fees authorized under this paragraph  
5       shall be collected and available for obligation only to  
6       the extent and in the amount provided in advance in  
7       appropriations Acts. Such fees are authorized to re-  
8       main available until expended. Such sums as may be  
9       necessary may be transferred from the Food and  
10      Drug Administration salaries and expenses appro-  
11      priation account without fiscal year limitation to  
12      such appropriation account for salaries and expenses  
13      with such fiscal year limitation.

14           “(2) STATE LICENSING FEES.—

15           “(A) STATE ESTABLISHED PROGRAM.—  
16           Nothing in this Act shall prohibit a State that  
17           has established a program to license a third-  
18           party logistics provider from collecting fees  
19           from a third-party logistics provider for such a  
20           license.

21           “(B) NO STATE ESTABLISHED PRO-  
22           GRAM.—A State that does not establish a pro-  
23           gram to license a third-party logistics provider  
24           in accordance with this section shall be prohib-

1           ited from collecting a State licensing fee from  
2           a third-party logistics provider.

3           “(d) REGULATIONS.—

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

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

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

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

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

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

8           “(ii) maintaining adequate security;  
9 and

10           “(iii) having written policies and pro-  
11 cedures to—

12           “(I) address receipt, security,  
13 storage, inventory, shipment, and dis-  
14 tribution of a product;

15           “(II) identify, record, and report  
16 confirmed losses or thefts in the  
17 United States;

18           “(III) correct errors and inac-  
19 curacies in inventories;

20           “(IV) provide support for manu-  
21 facturer recalls;

22           “(V) prepare for, protect against,  
23 and address any reasonably foresee-  
24 able crisis that affects security or op-

1                   eration at the facility, such as a  
2                   strike, fire, or flood;

3                   “(VI) ensure that any expired  
4                   product is segregated from other  
5                   products and returned to the manu-  
6                   facturer or repackager or destroyed;

7                   “(VII) maintain the capability to  
8                   trace the receipt and outbound dis-  
9                   tribution of a product, and supplies  
10                  and records of inventory; and

11                  “(VIII) quarantine or destroy a  
12                  suspect product if directed to do so by  
13                  the respective manufacturer, wholesale  
14                  distributor, dispenser, or an author-  
15                  ized government agency;

16                  “(D) provide for periodic inspection by the  
17                  licensing authority, as determined by the Sec-  
18                  retary, of such facility warehouse space to en-  
19                  sure compliance with this section;

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

1           “(F) provide for mandatory background  
2 checks of a facility manager or a designated  
3 representative of such manager;

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

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

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

15           “(ii) may be renewed for additional 3-  
16 year periods.

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

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

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

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

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

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

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

1 consistent with, more stringent than, or in addition to, any  
2 requirements applicable under section 503(e) (as amended  
3 by such Act) or this subchapter (or regulations issued  
4 thereunder), or which are inconsistent with—

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

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

8 “(b) WHOLESALE DISTRIBUTOR AND THIRD-PARTY  
9 LOGISTICS PROVIDER STANDARDS.—

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

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

1           “(3) ADMINISTRATION FEES.—Notwithstanding  
2       paragraph (1), a State may administer fee collec-  
3       tions for effectuating the wholesale drug distributor  
4       and third-party logistics provider licensure require-  
5       ments under sections 503(e) (as amended by the  
6       Drug Supply Chain Security Act), 583, and 584.

7           “(4) ENFORCEMENT, SUSPENSION, AND REV-  
8       OCATION.—Notwithstanding paragraph (1), a  
9       State—

10           “(A) may take administrative action, in-  
11       cluding fines, to enforce a requirement promul-  
12       gated by the State in accordance with section  
13       503(e) (as amended by the Drug Supply Chain  
14       Security Act) or this subchapter;

15           “(B) may provide for the suspension or  
16       revocation of licenses issued by the State for  
17       violations of the laws of such State;

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

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



1       “(c) EXCEPTION.—Nothing in this section shall be  
2 construed to preempt State requirements related to the  
3 distribution of prescription drugs if such requirements are  
4 not related to product tracing as described in subsection  
5 (a) or wholesale distributor and third-party logistics pro-  
6 vider licensure as described in subsection (b) applicable  
7 under section 503(e) (as amended by the Drug Supply  
8 Chain Security Act) or this subchapter (or regulations  
9 issued thereunder).”.

10 **SEC. 206. PENALTIES.**

11       (a) PROHIBITED ACT.—Section 301(t) (21 U.S.C.  
12 331(t)), is amended—

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

15           (2) by inserting “, failure to comply with the  
16 requirements under section 582, the failure to com-  
17 ply with the requirements under section 584, as ap-  
18 plicable,” after “in violation of section 503(e)”.

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

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

1   **SEC. 207. CONFORMING AMENDMENT.**

2           (a) IN GENERAL.—Section 303(b)(1)(D) (21 U.S.C.  
3   333(b)(1)(D)) is amended by striking “503(e)(2)(A)” and  
4   inserting “503(e)(1)”.

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

8   **SEC. 208. SAVINGS CLAUSE.**

9           Except as provided in the amendments made by para-  
10   graphs (1), (2), and (3) of section 204(a) and by section  
11   206(a), nothing in this title (including the amendments  
12   made by this title) shall be construed as altering any au-  
13   thority of the Secretary of Health and Human Services  
14   with respect to a drug subject to section 503(b)(1) of the  
15   Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
16   353(b)(1)) under any other provision of such Act or the  
17   Public Health Service Act (42 U.S.C. 201 et seq.).