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.

IN THE SENATE OF THE UNITED STATES

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

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Drug Quality and Security Act''.

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

(a) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other

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

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

TITLE I—DRUG COMPOUNDING

SEC. 101. SHORT TITLE.

This Act may be cited as the ''Compounding Quality Act''.

SEC. 102. OUTSOURCING FACILITIES.

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

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

(2) by inserting after section 503A the following new section:

"SEC. 503B. OUTSOURCING FACILITIES.

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

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

"(2) BULK DRUG SUBSTANCES.—The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)) unless —

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

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

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

"(III) publishing a notice in the Federal Register designating bulk substances for inclusion on the list; or

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

"(B) if an applicable monograph exists under the United States Pharmacopoeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

"(C) the bulk drug substances are each manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

"(D) the bulk drug substances are each accompanied by a valid certificate of analysis.

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

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

''(4) DRUGS WITHDRAWN OR REMOVED BECAUSE UNSAFE OR NOT EFFECTIVE.—The drug does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

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

''(6) DRUGS PRESENTING DEMONSTRABLE DIFFICULTIES FOR COMPOUNDING.—The drug—

''(A) is not identified (directly or as part of a category of drugs) on a list published by the Secretary of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking

into account the risks and benefits to patients; or

"(B) is compounded in accordance with all applicable conditions identified on the list described in subparagraph (A) as conditions that are necessary to prevent the drug or category of drugs from presenting the demonstrable difficulties described in subparagraph (A).

"(7) ELEMENTS TO ASSURE SAFE USE.—In the case of a drug that is compounded from a drug that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 505–1, or from a bulk drug substance that is a component of such drug, the outsourcing facility demonstrates to the Secretary prior to beginning compounding that such pharmacist or physician will utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy.

"(8) PROHIBITION ON WHOLESALING.—The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph does not prohibit administration of a drug in a health care setting or dis-

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

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

''(10) LABELING OF DRUGS.—

''(A) LABEL.—The label of the drug shall include—

''(i) the statement 'This is a compounded drug.' or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

''(ii) the name, address, and phone number of the applicable outsourcing facility; and

''(iii) with respect to the drug—

''(I) the lot or batch number;

''(II) the established name of the drug;

''(III) the dosage form and strength;

''(IV) the statement of quantity or volume, as appropriate;

"(V) the date that the drug was compounded;

"(VI) the expiration date;

"(VII) storage and handling instructions;

"(VIII) the National Drug Code number, if available;

"(IX) the statement 'Not for resale', and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement 'Office Use Only'; and

"(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

"(B) CONTAINER.—The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include—

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

"(ii) the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088 (or any successor Internet Web site or phone number); and

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

"(C) ADDITIONAL INFORMATION.—The label and labeling of the drug shall include any other information as determined necessary and specified in regulations promulgated by the Secretary.

"(b) REGISTRATION OF OUTSOURCING FACILITIES AND REPORTING OF DRUGS.—

"(1) REGISTRATION OF OUTSOURCING FACILITIES.—

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

"(i) shall register with the Secretary its name, place of business, and unique facility identifier (which shall conform to the requirements for the unique facility identifier established under section 510), and a point of contact email address; and

"(ii) shall indicate whether the outsourcing facility intends to compound a drug that appears on the list in effect under section 506E during the subsequent calendar year.

"(B) AVAILABILITY OF REGISTRATION FOR INSPECTION; LIST.—

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

"(ii) LIST.—The Secretary shall make available on the public Internet Web site of the Food and Drug Administration a list of the name of each facility registered under this subsection as an outsourcing facility, the State in which each such facility is located, whether the facility compounds from bulk drug substances, and whether

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

''(2) DRUG REPORTING BY OUTSOURCING FACILITIES.—

''(A) IN GENERAL.—Upon initially registering as an outsourcing facility, once during the month of June of each year, and once during the month of December of each year, each outsourcing facility that registers with the Secretary under paragraph (1) shall submit to the Secretary a report—

''(i) identifying the drugs compounded by such outsourcing facility during the previous 6-month period; and

''(ii) with respect to each drug identified under clause (i), providing the active ingredient, the source of such active ingredient, the National Drug Code number of the source drug or bulk active ingredient, if available, the strength of the active ingredient per unit, the dosage form and route of administration, the package description, the number of individual units

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

''(B) FORM.—Each report under subparagraph (A) shall be prepared in such form and manner as the Secretary may prescribe by regulation or guidance.

''(C) CONFIDENTIALITY.—Reports submitted under this paragraph shall be exempt from inspection under paragraph (1)(B)(i), unless the Secretary finds that such an exemption would be inconsistent with the protection of the public health.

''(3) ELECTRONIC REGISTRATION AND REPORTING.—Registrations and drug reporting under this subsection (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting waiver.

''(4) RISK-BASED INSPECTION FREQUENCY.—

''(A) IN GENERAL.—Outsourcing facilities—

''(i) shall be subject to inspection pursuant to section 704; and

"(ii) shall not be eligible for the exemption under section 704(a)(2)(A).

"(B) RISK-BASED SCHEDULE.—The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect outsourcing facilities in accordance with a risk-based schedule established by the Secretary.

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

"(i) The compliance history of the outsourcing facility.

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

"(iii) The inherent risk of the drugs compounded at the outsourcing facility.

"(iv) The inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected pursuant to section 704 within the last 4 years.

''(v) Whether the outsourcing facility has registered under this paragraph as an entity that intends to compound a drug that appears on the list in effect under section 506E.

''(vi) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

''(5) ADVERSE EVENT REPORTING.—Outsourcing facilities shall submit adverse event reports to the Secretary in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).

''(c) DEFINITIONS.—In this section:

''(1) The term 'compounding' includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a marketed and approved drug or bulk drugs substance to create a drug.

''(2) The term 'essentially a copy of a marketed and approved drug' means—

''(A) a drug that is identical or nearly identical to a marketed and approved drug, or

a marketed drug not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless, in the case of a marketed and approved drug, the drug appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or

''(B) a drug, a component of which is a bulk drug substance that is a component of a marketed and approved drug or a marketed drug that is not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless there is a change, made for an identified individual patient, which produces for that patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable marketed and approved drug.

''(3) The term 'marketed and approved drug' means a drug that is approved under section 505 and is currently marketed by the person that holds the approved application.

''(4) The term 'outsourcing facility' means a facility at one geographic location or address—

''(A) that—

"(i) is engaged in the compounding of sterile drug; and

"(ii) complies with all of the requirements of this section;

"(B) that may or may not be a licensed pharmacy and may or may not obtain prescriptions for identified individual patients; and

"(C) in which all drugs compounded in such facility are compounded in compliance with this section.

"(5) The term 'sterile drug' means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or required to be sterile under Federal or State law.".

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

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

"PART 9—FEES RELATING TO OUTSOURCING FACILITIES

"SEC. 744J. DEFINITIONS.

''In this part:

''(1) The term 'affiliate' has the meaning given such term in section 735(11).

''(2) The term 'gross annual sales' means the total worldwide gross annual sales, in United States dollars, for an outsourcing facility, including the sales of all the affiliates of the outsourcing facility.

''(3) The term 'outsourcing facility' has the 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.

"SEC. 744K. AUTHORITY TO ASSESS AND USE OUTSOURCING FACILITY FEES.

''(a) ESTABLISHMENT AND REINSPECTION FEES.—

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

''(A) an annual establishment fee from each outsourcing facility; and

''(B) a reinspection fee from each outsourcing facility subject to a reinspection in such fiscal year.

''(2) MULTIPLE REINSPECTIONS.—An outsourcing facility subject to multiple reinspections in a fiscal year shall be subject to a reinspection fee for each reinspection.

''(b) ESTABLISHMENT AND REINSPECTION FEE SETTING.—The Secretary shall—

''(1) establish the amount of the establishment fee and reinspection fee to be collected under this section for each fiscal year based on the methodology described in subsection (c); and

''(2) publish such fee amounts in a Federal Register notice not later than 60 calendar days before the start of each such year.

''(c) AMOUNT OF ESTABLISHMENT FEE AND REINSPECTION FEE.—

''(1) IN GENERAL.—For each outsourcing facility in a fiscal year—

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

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

"(i) $15,000, multiplied by the inflation adjustment factor described in paragraph (2); plus

"(ii) the small business adjustment factor described in paragraph (3); and

"(B) the amount of any reinspection fee (if applicable) under subsection (b) shall be equal to $15,000, multiplied by the inflation adjustment factor described in paragraph (2).

"(2) INFLATION ADJUSTMENT FACTOR.—

"(A) IN GENERAL.—For fiscal year 2015 and subsequent fiscal years, the fee amounts established in paragraph (1) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

"(i) 1;

"(ii) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fis-

cal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years; plus

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

''(B) COMPOUNDED BASIS.—The adjustment made each fiscal year under subparagraph (A) shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under subparagraph (A).

''(3) SMALL BUSINESS ADJUSTMENT FACTOR.—The small business adjustment factor described in this paragraph shall be an amount established by the Secretary for each fiscal year based on the Secretary's estimate of—

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

''(B) the adjustment to the establishment fee necessary to achieve total fees equaling the total fees that the Secretary would have collected if no entity qualified for the small business exception in paragraph (4).

''(4) EXCEPTION FOR SMALL BUSINESSES.—

''(A) IN GENERAL.—In the case of an outsourcing facility with gross annual sales of $1,000,000 or less in the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which the fees under this section are assessed, the amount of the establishment fee under subsection (b) for a fiscal year shall be equal to \1/3\ of the amount calculated under paragraph (1)(A)(i) for such fiscal year.

''(B) APPLICATION.—To qualify for the exception under this paragraph, a small business

shall submit to the Secretary a written request for such exception, in a format specified by the Secretary in guidance, certifying its gross annual sales for the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which fees under this subsection are assessed. Any such application shall be submitted to the Secretary not later than April 30 of such immediately preceding fiscal year.

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

''(A) provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of the small business adjustment factor for such previous fiscal year; and

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

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

''(e) SUPPLEMENT NOT SUPPLANT.—Funds received by the Secretary pursuant to this section shall be used to supplement and not supplant any other Federal funds available to carry out the activities described in this section.

''(f) CREDITING AND AVAILABILITY OF FEES.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the purpose of paying the costs of oversight of outsourcing facilities.

''(g) COLLECTION OF FEES.—

''(1) ESTABLISHMENT FEE.—An outsourcing facility shall remit the establishment fee due under this section in a fiscal year when submitting a registration pursuant to section 503B(b) for such fiscal year.

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

subsection (b)(2) the manner in which reinspection fees assessed under this section shall be collected and the timeline for payment of such fees. Such a fee shall be collected after the Secretary has conducted a reinspection of the outsourcing facility involved.

''(3) EFFECT OF FAILURE TO PAY FEES.—

''(A) REGISTRATION.—An outsourcing facility shall not be considered registered under section 503B(b) in a fiscal year until the date that the outsourcing facility remits the establishment fee under this subsection for such fiscal year.

''(B) MISBRANDING.—All drugs manufactured, prepared, propagated, compounded, or processed by an outsourcing facility for which any establishment fee or reinspection fee has not been paid, as required by this section, shall be deemed misbranded under section 502 until the fees owed for such outsourcing facility under this section have been paid.

''(4) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under this section within 30 calendar days after it is due, such fee shall be treated

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

''(h) ANNUAL REPORT TO CONGRESS.—Not later than 120 calendar days after each fiscal year in which fees are assessed and collected under this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to include a description of fees assessed and collected for such year, a summary description of entities paying the fees, a description of the hiring and placement of new staff, a description of the use of fee resources to support inspecting outsourcing facilities, and the number of inspections and reinspections of such facilities performed each year.

''(i) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year 2015 and each subsequent fiscal year, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.''.

SEC. 103. PENALTIES.

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

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

''(2) With respect to a drug to be compounded pursuant to section 503A or 503B, the intentional falsification of a prescription, as applicable.

''(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 503B.''.

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

''(bb) If the advertising or promotion of a compounded drug is false or misleading in any particular.''.

SEC. 104. REGULATIONS.

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

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

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

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

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

SEC. 105. ENHANCED COMMUNICATION.

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

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

(2) expressing concerns that a compounding pharmacy may be acting contrary to one or more requirements of 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a).

(b) CONTENT OF SUBMISSIONS FROM STATE BOARDS OF PHARMACY.—An action referred to in subsection (a)(1) is, with respect to a pharmacy that compounds drugs, any of the following:

(1) The issuance of a warning letter, or the imposition of sanctions or penalties, by a State for violations of a State's pharmacy regulations pertaining to compounding.

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

of a State's pharmacy regulations pertaining to compounding.

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

(c) CONSULTATION.—The Secretary shall implement subsection (a) in consultation with the National Association of Boards of Pharmacy.

(d) NOTIFYING STATE BOARDS OF PHARMACY.—The Secretary shall immediately notify State boards of pharmacy when—

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

(2) the Secretary makes a determination that a pharmacy is acting contrary to one or more requirements of section 503A of the Federal Food, Drug, and Cosmetic Act.

SEC. 106. SEVERABILITY.

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

(1) in subsection (a), in the matter preceding paragraph (1), by striking ''unsolicited'';

(2) by striking subsection (c);

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

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

(b) SEVERABILITY.—If any provision of this Act (including the amendments made by this Act) is declared unconstitutional, or the applicability of this Act (including the amendments made by this Act) to any person or circumstance is held invalid, the constitutionality of the remainder of this Act (including the amendments made by this Act) and the applicability thereof to other persons and circumstances shall not be affected.

SEC. 107. GAO STUDY.

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

(b) CONTENTS.—The report required under this section shall include—

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

(2) a review of the State laws and policies governing pharmacy compounding, including enforcement of State laws and policies;

(3) an assessment of the available tools to permit purchasers of compounded drugs to determine the safety and quality of such drugs;

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

(5) an evaluation of the Food and Drug Administration's implementation of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.

TITLE II—DRUG SUPPLY CHAIN SECURITY

SEC. 201. SHORT TITLE.

This title may be cited as the ''Drug Supply Chain Security Act''.

SEC. 202. PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

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

''Subchapter H—Pharmaceutical Distribution Supply Chain

''SEC. 581. DEFINITIONS.

''In this subchapter:

''(1) AFFILIATE.—The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

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

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

''(2) AUTHORIZED.—The term 'authorized' means—

''(A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 510;

''(B) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6), and complying with the licensure reporting requirements under section 503(e), as amended by the Drug Supply Chain Security Act;

''(C) in the case of a third-party logistics provider, having a valid license under State law or section 584(a)(1), in accordance with section 582(a)(7), and complying with the licensure reporting requirements under section 584(b); and

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

"(3) DISPENSER.—The term 'dispenser'—

"(A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and

"(B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).

"(4) DISPOSITION.—The term 'disposition', with respect to a product within the possession or control of an entity, means the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

"(5) DISTRIBUTE OR DISTRIBUTION.—The term 'distribute' or 'distribution' means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) or the dispensing of a product approved under section 512(b).

"(6) EXCLUSIVE DISTRIBUTOR.—The term 'exclusive distributor' means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

"(7) HOMOGENEOUS CASE.—The term 'homogeneous case' means a sealed case containing only product that has a single National Drug Code number belonging to a single lot.

"(8) ILLEGITIMATE PRODUCT.—The term 'illegitimate product' means a product for which credible evidence shows that the product—

"(A) is counterfeit, diverted, or stolen;

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

"(C) is the subject of a fraudulent transaction; or

"(D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

"(9) LICENSED.—The term 'licensed' means—

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

"(B) in the case of a third-party logistics provider, having a valid license in accordance with section 584(a) or section 582(a)(7), as applicable; and

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

"(10) MANUFACTURER.—The term 'manufacturer' means, with respect to a product—

"(A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;

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

"(C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

"(11) PACKAGE.—

"(A) IN GENERAL.—The term 'package' means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product.

"(B) INDIVIDUAL SALEABLE UNIT.—For purposes of this paragraph, an 'individual saleable unit' is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.

"(12) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug for human use subject to section 503(b)(1).

''(13) PRODUCT.—The term 'product' means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 582, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in clause xiv, xv, or xvi of paragraph (24)(B), any medical gas (as defined in section 575), homeopathic drugs marketed in accordance with applicable guidance under this Act, or a drug compounded in compliance with section 503A or 503B.

''(14) PRODUCT IDENTIFIER.—The term 'product identifier' means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the

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

''(15) QUARANTINE.—The term 'quarantine' means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

''(16) REPACKAGER.—The term 'repackager' means a person who owns or operates an establishment that repacks and relabels a product or package for—

''(A) further sale; or

''(B) distribution without a further transaction.

''(17) RETURN.—The term 'return' means providing product to the authorized immediate trading partner from which such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.

''(18) RETURNS PROCESSOR OR REVERSE LOGISTICS PROVIDER.—The term 'returns processor' or 'reverse logistics provider' means a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such

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

''(19) SPECIFIC PATIENT NEED.—The term 'specific patient need' refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

''(20) STANDARDIZED NUMERICAL IDENTIFIER.—The term 'standardized numerical identifier' means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

''(21) SUSPECT PRODUCT.—The term 'suspect product' means a product for which there is reason to believe that such product—

''(A) is potentially counterfeit, diverted, or stolen;

"(B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

"(C) is potentially the subject of a fraudulent transaction; or

"(D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

"(22) THIRD-PARTY LOGISTICS PROVIDER.—The term 'third-party logistics provider' means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

"(23) TRADING PARTNER.—The term 'trading partner' means—

"(A) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, re-

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

''(B) a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

''(24) TRANSACTION.—

''(A) IN GENERAL.—The term 'transaction' means the transfer of product between persons in which a change of ownership occurs.

''(B) EXEMPTIONS.—The term 'transaction' does not include—

''(i) intracompany distribution of any product between members of an affiliated group or within a manufacturer;

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

''(iii) the distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that a drug shortage

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

''(iv) the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1);

''(v) the distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with section 503(d);

''(vi) the distribution of blood or blood components intended for transfusion;

''(vii) the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

''(viii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

''(ix) the distribution of a product pursuant to the sale or merger of a phar-

macy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;

''(x) the dispensing of a product approved under section 512(c);

''(xi) products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021);

''(xii) a combination product that is not subject to approval under section 505 or licensure under section 351 of the Public Health Service Act, and that is—

''(I) a product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or oth-

erwise combined or mixed and produced as a single entity;

''(II) 2 or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or

''(III) 2 or more finished medical devices plus one or more drug or biological products that are packaged together in what is referred to as a 'medical convenience kit' as described in clause (xiii);

''(xiii) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this clause as a 'medical convenience kit') if—

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

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

"(II) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

"(III) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

"(aa) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

"(bb) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

"(IV) in the case of a medical convenience kit that includes a product, the product is—

"(aa) an intravenous solution intended for the replenishment of fluids and electrolytes;

"(bb) a product intended to maintain the equilibrium of water and minerals in the body;

"(cc) a product intended for irrigation or reconstitution;

"(dd) an anesthetic;

"(ee) an anticoagulant;

"(ff) a vasopressor; or

"(gg) a sympathicomimetic;

"(xiv) the distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

"(xv) the distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

"(xvi) the distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

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

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

"(25) TRANSACTION HISTORY.—The term 'transaction history' means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

"(26) TRANSACTION INFORMATION.—The term 'transaction information' means—

"(A) the proprietary or established name or names of the product;

"(B) the strength and dosage form of the product;

"(C) the National Drug Code number of the product;

"(D) the container size;

"(E) the number of containers;

"(F) the lot number of the product;

"(G) the date of the transaction;

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

"(I) the business name and address of the person from whom ownership is being transferred; and

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

"(27) TRANSACTION STATEMENT.—The 'transaction statement' is a statement, in paper or electronic form, that the entity transferring ownership in a transaction—

"(A) is authorized as required under the Drug Supply Chain Security Act;

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

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

"(D) did not knowingly ship a suspect or illegitimate product;

"(E) had systems and processes in place to comply with verification requirements under section 582;

"(F) did not knowingly provide false transaction information; and

"(G) did not knowingly alter the transaction history.

"(28) VERIFICATION OR VERIFY.—The term 'verification' or 'verify' means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582.

"(29) WHOLESALE DISTRIBUTOR.—The term 'wholesale distributor' means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4), as amended by the Drug Supply Chain Security Act).

"SEC. 582. REQUIREMENTS.

"(a) IN GENERAL.—

''(1) OTHER ACTIVITIES.—Each manufacturer, repackager, wholesale distributor, and dispenser shall comply with the requirements set forth in this section with respect to the role of such manufacturer, repackager, wholesale distributor, or dispenser in a transaction involving product. If an entity meets the definition of more than one of the entities listed in the preceding sentence, such entity shall comply with all applicable requirements in this section, but shall not be required to duplicate requirements.

''(2) INITIAL STANDARDS.—

''(A) IN GENERAL.—The Secretary shall, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale distributors, dispensers, and other pharmaceutical distribution supply chain stakeholders, issue a draft guidance document that establishes standards for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, for compliance with this subsection and subsections (b), (c), (d), and (e). In establishing such standards, the Secretary shall consider the feasibility of establishing standardized documentation to be used by members of

the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data. The standards established under this paragraph shall take into consideration the standards established under section 505D and shall comply with a form and format developed by a widely recognized international standards development organization.

''(B) PUBLIC INPUT.—Prior to issuing the draft guidance under subparagraph (A), the Secretary shall gather comments and information from stakeholders and maintain such comments and information in a public docket for at least 60 days prior to issuing such guidance.

''(C) PUBLICATION.—The Secretary shall publish the standards established under subparagraph (A) not later than 1 year after the date of enactment of the Drug Supply Chain Security Act.

''(3) WAIVERS, EXCEPTIONS, AND EXEMPTIONS.—

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

Chain Security Act, the Secretary shall, by guidance—

''(i) establish a process by which an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a waiver from any of the requirements set forth in this section, which the Secretary may grant if the Secretary determines that such requirements would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act;

''(ii) establish a process by which the Secretary determines exceptions, and a process through which a manufacturer or repackager may request such an exception, to the requirements relating to product identifiers if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with this section; and

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

"(B) CONTENT.—The guidance issued under subparagraph (A) shall include a process for the biennial review and renewal of such waivers, exceptions, and exemptions, as applicable.

"(C) PROCESS.—In issuing the guidance under this paragraph, the Secretary shall provide an effective date that is not later than 180 days prior to the date on which manufacturers are required to affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce consistent with this section.

"(4) SELF-EXECUTING REQUIREMENTS.—Except where otherwise specified, the requirements of this section may be enforced without further regulations or guidance from the Secretary.

"(5) GRANDFATHERING PRODUCT.—

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

Drug Supply Chain Security Act, the Secretary shall finalize guidance specifying whether and under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of this section shall be exempted from the requirements of this section.

"(B) TRACING.—For a product that entered the pharmaceutical distribution supply chain prior to the date that is 1 year after the date of enactment of the Drug Supply Chain Security Act—

"(i) authorized trading partners shall be exempt from providing transaction information as required under subsections (b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii), and (e)(1)(A)(ii);

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

"(iii) the owners of such product on such date shall be exempt from asserting receipt of transaction information and

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

''(6) WHOLESALE DISTRIBUTOR LICENSES.—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.

''(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.

''(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).

''(9) PRODUCT IDENTIFIERS.—With respect to any requirement relating to product identifiers under this subchapter—

''(A) unless the Secretary allows, through guidance, the use of other technologies for data instead of or in addition to the technologies described in clauses (i) and (ii), the applicable data—

''(i) shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package; and

''(ii) shall be included in a linear or 2-dimensional data matrix barcode when affixed to, or imprinted upon, a homogeneous case; and

''(B) verification of the product identifier may occur by using human-readable or machine-readable methods.

''(b) MANUFACTURER REQUIREMENTS.—

''(1) PRODUCT TRACING.—

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

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

the subsequent owner with transaction history, transaction information, and a transaction statement, in a single document in an paper or electronic format; and

"(ii) capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction and maintain such information, history, and statement for not less than 6 years after the date of the transaction.

"(B) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a manufacturer shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

"(C) ELECTRONIC FORMAT.—

"(i) IN GENERAL.—Beginning not later than 4 years after the date of enactment of the Drug Supply Chain Security Act, except as provided under clause (ii), a manufacturer shall provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) in electronic format.

"(ii) EXCEPTION.—A manufacturer may continue to provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) in a paper format to a licensed health care practitioner authorized to prescribe medication under State law or other licensed individual under the supervision or direction of such a practitioner who dispenses product in the usual course of professional practice.

"(2) PRODUCT IDENTIFIER.—

"(A) IN GENERAL.—Beginning not later than 4 years after the date of enactment of the Drug Supply Chain Security Act, a manufacturer shall affix or imprint a product identifier to each package and homogenous case of a

product intended to be introduced in a transaction into commerce. Such manufacturer shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction.

''(B) EXCEPTION.—A package that is required to have a standardized numerical identifier is not required to have a unique device identifier.

''(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, the trading partners of a manufacturer may be only authorized trading partners.

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

''(A) SUSPECT PRODUCT.—

''(i) IN GENERAL.—Upon making a determination that a product in the possession or control of the manufacturer 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 manufacturer is a suspect product, a manufacturer shall—

"(I) quarantine such product within the possession or control of the manufacturer from product intended for distribution until such product is cleared or dispositioned; and

"(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the possession of the manufacturer and otherwise investigating to determine whether the product is an illegitimate product, and, beginning 4 years after the date of enactment of the Drug Supply Chain Security Act, verifying the product at the package level, including the standardized numerical identifier.

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

imate product, the manufacturer shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed.

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

"(B) ILLEGITIMATE PRODUCT.—

"(i) IN GENERAL.—Upon determining that a product in the possession or control of a manufacturer is an illegitimate product, the manufacturer shall, in a manner consistent with the systems and processes of such manufacturer—

"(I) quarantine such product within the possession or control of the manufacturer from product intended for distribution until such product is dispositioned;

"(II) disposition the illegitimate product within the possession or control of the manufacturer;

"(III) take reasonable and appropriate steps to assist a trading part-

ner to disposition an illegitimate product not in the possession or control of the manufacturer; and

''(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the Secretary (or other appropriate Federal or State official), as necessary and appropriate.

''(ii) MAKING A NOTIFICATION.—

''(I) ILLEGITIMATE PRODUCT.—Upon determining that a product in the possession or control of the manufacturer is an illegitimate product, the manufacturer shall notify the Secretary and all immediate trading partners that the manufacturer has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making such determination.

"(II) HIGH RISK OF ILLEGITIMACY.—A manufacturer shall notify the Secretary and immediate trading partners that the manufacturer has reason to believe may have in the trading partner's possession a product manufactured by, or purported to be a product manufactured by, the manufacturer not later than 24 hours after determining or being notified by the Secretary or a trading partner that there is a high risk that such product is an illegitimate product. For purposes of this subclause, a 'high risk' may include a specific high risk that could increase the likelihood that illegitimate product will enter the pharmaceutical distribution supply chain and other high risks as determined by the Secretary in guidance pursuant to subsection (h).

"(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a

product is an illegitimate product, a manufacturer shall identify all illegitimate product subject to such notification that is in the possession or control of the manufacturer, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

''(iv) TERMINATING A NOTIFICATION.—Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a manufacturer shall promptly notify immediate trading partners that the manufacturer notified pursuant to clause (ii) that such notification has been terminated.

''(v) RECORDS.—A manufacturer shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

''(C) REQUESTS FOR VERIFICATION.—Beginning 4 years after the date of enactment of the Drug Supply Chain Security Act, upon receiving a request for verification from an authorized repackager, wholesale distributor, or dispenser that is in possession or control of a

product such person believes to be manufactured by such manufacturer, a manufacturer shall, not later than 24 hours after receiving the request for verification or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the person making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by the manufacturer. If a manufacturer responding to a request for verification identifies a product identifier that does not correspond to that affixed or imprinted by the manufacturer, the manufacturer shall treat such product as suspect product and conduct an investigation as described in subparagraph (A). If the manufacturer has reason to believe the product is an illegitimate product, the manufacturer shall advise the person making the request of such belief at the time such manufacturer responds to the request for verification.

''(D) ELECTRONIC DATABASE.—A manufacturer may satisfy the requirements of this

paragraph by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a manufacturer of the requirement under this paragraph to respond to a request for verification submitted by means other than a secure electronic database.

''(E) SALEABLE RETURNED PRODUCT.—Beginning 4 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), upon receipt of a returned product that the manufacturer intends to further distribute, before further distributing such product, the manufacturer shall verify the product identifier, including the standardized numerical identifier, for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier, in-

cluding the standardized numerical identifier, on each package.

''(F) NONSALEABLE RETURNED PRODUCT.—A manufacturer may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information described in paragraph (1)(A)(i).

''(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

''(1) PRODUCT TRACING.—

''(A) IN GENERAL.—Beginning not later than January 1, 2015, the following requirements shall apply to wholesale distributors:

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

''(ii)(I)(aa) If the wholesale distributor purchased a product directly from the manufacturer, the exclusive distributor

of the manufacturer, or a repackager that purchased directly from the manufacturer, then prior to, or at the time of, each transaction in which the wholesale distributor transfers ownership of a product, the wholesale distributor shall provide to the subsequent purchaser—

''(AA) a transaction statement, which shall state that such wholesale distributor, or a member of the affiliated group of such wholesale distributor, purchased the product directly from the manufacturer, exclusive distributor of the manufacturer, or repackager that purchased the product directly from the manufacturer; and

''(BB) subject to subclause (II), the transaction history and transaction information.

''(bb) The wholesale distributor shall provide the transaction history, transaction information, and transaction statement under item (aa)—

"(AA) if provided to a dispenser, on a single document in a paper or electronic format; and

"(BB) if provided to a wholesale distributor, through any combination of self-generated paper, electronic data, or manufacturer-provided information on the product package.

"(II) For purposes of transactions described in subclause (I), transaction history and transaction information shall not be required to include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer (as defined in subparagraphs (F), (G), and (H) of section 581(26)).

"(iii) If the wholesale distributor did not purchase a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, as described in clause (ii), then prior to, or at the time of, each transaction or subsequent transaction, the wholesale distributor

shall provide to the subsequent purchaser a transaction statement, transaction history, and transaction information, in a paper or electronic format that complies with the guidance document issued under subsection (a)(2).

''(iv) For the purposes of clause (iii), the transaction history supplied shall begin only with the wholesale distributor described in clause (ii)(I), but the wholesale distributor described in clause (iii) shall inform the subsequent purchaser that such wholesale distributor received a direct purchase statement from a wholesale distributor described in clause (ii)(I).

''(v) A wholesale distributor shall—

''(I) capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction described in clauses (i), (ii), and (iii) and maintain such information, history, and statement for not less than 6 years after the date of the transaction; and

"(II) maintain the confidentiality of the transaction information (including any lot level information consistent with the requirements of this section), transaction history, and transaction statement for a product in a manner that prohibits disclosure to any person other than the Secretary or other appropriate Federal or State official, except to comply with clauses (ii) and (iii), and, as applicable, pursuant to an agreement under subparagraph (D).

"(B) RETURNS.—

"(i) SALEABLE RETURNS.—Notwithstanding subparagraph (A)(i), the following shall apply:

"(I) REQUIREMENTS.—Until the date that is 6 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager pursuant to the terms and condi-

tions of any agreement between the parties, and, notwithstanding subparagraph (A)(ii), may distribute such returned product without providing the transaction history. For transactions subsequent to the return, the transaction history of such product shall begin with the wholesale distributor that accepted the returned product, consistent with the requirements of this subsection.

''(II) ENHANCED REQUIREMENTS.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate returned product with the transaction information and transaction statement associated with that product. For all transactions after such date, the transaction history, as applicable, of such

product shall begin with the wholesale distributor that accepted and verified the returned product. For purposes of this subparagraph, the transaction information and transaction history, as applicable, need not include transaction dates if it is not reasonably practicable to obtain such dates.

''(ii) NONSALEABLE RETURNS.—A wholesale distributor may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information required under subparagraph (A)(i).

''(C) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a wholesale distributor shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request or in other such reason-

able time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

''(D) TRADING PARTNER AGREEMENTS.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, a wholesale distributor may disclose the transaction information, including lot level information, transaction history, or transaction statement of a product to the subsequent purchaser of the product, pursuant to a written agreement between such wholesale distributor and such subsequent purchaser. Nothing in this subparagraph shall be construed to limit the applicability of subparagraphs (A) through (C).

''(2) PRODUCT IDENTIFIER.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, a wholesale distributor may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)).

''(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, the trading

partners of a wholesale distributor may be only authorized trading partners.

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

''(A) SUSPECT PRODUCT.—

''(i) IN GENERAL.—Upon making a determination that a product in the possession or control of a wholesale distributor 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 wholesale distributor is a suspect product, a wholesale distributor shall—

''(I) quarantine such product within the possession or control of the wholesale distributor from product intended for distribution until such product is cleared or dispositioned; and

''(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine

whether the product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the possession of the wholesale distributor and otherwise investigating to determine whether the product is an illegitimate product, and, beginning 6 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), verifying the product at the package level, including the standardized numerical identifier.

''(ii) CLEARED PRODUCT.—If the wholesale distributor determines that a suspect product is not an illegitimate product, the wholesale distributor shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed.

''(iii) RECORDS.—A wholesale distributor shall keep records of the investigation of a suspect product for not less than

6 years after the conclusion of the investigation.

''(B) ILLEGITIMATE PRODUCT.—

''(i) IN GENERAL.—Upon determining, in coordination with the manufacturer, that a product in the possession or control of a wholesale distributor is an illegitimate product, the wholesale distributor shall, in a manner that is consistent with the systems and processes of such wholesale distributor—

''(I) quarantine such product within the possession or control of the wholesale distributor from product intended for distribution until such product is dispositioned;

''(II) disposition the illegitimate product within the possession or control of the wholesale distributor;

''(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the wholesale distributor; and

"(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

"(ii) MAKING A NOTIFICATION.—Upon determining that a product in the possession or control of the wholesale distributor is an illegitimate product, the wholesale distributor shall notify the Secretary and all immediate trading partners that the wholesale distributor has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making such determination.

"(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a whole-

sale distributor shall identify all illegitimate product subject to such notification that is in the possession or control of the wholesale distributor, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

''(iv) TERMINATING A NOTIFICATION.—Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a wholesale distributor shall promptly notify immediate trading partners that the wholesale distributor notified pursuant to clause (ii) that such notification has been terminated.

''(v) RECORDS.—A wholesale distributor shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

''(C) ELECTRONIC DATABASE.—A wholesale distributor may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure electronic data-

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

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

"(d) DISPENSER REQUIREMENTS.—

"(1) PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning July 1, 2015, a dispenser—

"(i) shall not accept ownership of a product, unless the previous owner prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement;

"(ii) prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient or returns) shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; and

"(iii) shall capture transaction information (including lot level information), transaction history, and transaction statements, as necessary to investigate a suspect 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.

''(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

product was purchased, to a returns processor, or to a person acting on behalf of such a person without providing the information required under subparagraph (A).

''(D) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect or an illegitimate product, a dispenser shall, not later than 2 business days after receiving the request or in another such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction statement, and transaction history which the dispenser received from the previous owner, which shall not include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer unless such information was included in the transaction information, transaction statement, and transaction history provided by the manufacturer or wholesale distributor to the dispenser. The dispenser may respond to the request by providing the applicable information in either

paper or electronic format. Until the date that is 4 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary or other appropriate Federal or State official shall grant a dispenser additional time, as necessary, only with respect to a request to provide lot level information described in subparagraph (F) of section 581(26) that was provided to the dispenser in paper format, limit the request time period to the 6 months preceding the request or other relevant date, and, in the event of a recall, the Secretary, or other appropriate Federal or State official may request information only if such recall involves a serious adverse health consequence or death to humans.

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

''(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, the trading partners of a dispenser may be only authorized trading partners.

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

"(A) SUSPECT PRODUCT.—

"(i) IN GENERAL.—Upon making a determination that a product in the possession or control of the dispenser 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 dispenser is a suspect product, a dispenser shall—

"(I) quarantine such product within the possession or control of the dispenser from product intended for distribution until such product is cleared or dispositioned; and

"(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product.

"(ii) INVESTIGATION.—An investigation conducted under clause (i)(II) shall include—

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

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

"(III) validating any applicable transaction history and transaction information in the possession of the dispenser; 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.

"(B) ILLEGITIMATE PRODUCT.—

"(i) IN GENERAL.—Upon determining, in coordination with the manufacturer, that a product in the possession or control of a dispenser is an illegitimate product, the dispenser shall—

"(I) disposition the illegitimate product within the possession or control of the dispenser;

"(II) take reasonable and appropriate steps to assist a trading part-

ner to disposition an illegitimate product not in the possession or control of the dispenser; and

"(III) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

"(ii) MAKING A NOTIFICATION.—Upon determining that a product in the possession or control of the dispenser is an illegitimate product, the dispenser shall notify the Secretary and all immediate trading partners that the dispenser has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making such determination.

"(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary or a trading partner

that a determination has been made that a product is an illegitimate product, a dispenser shall identify all illegitimate product subject to such notification that is in the possession or control of the dispenser, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

''(iv) TERMINATING A NOTIFICATION.—Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a dispenser shall promptly notify immediate trading partners that the dispenser notified pursuant to clause (ii) that such notification has been terminated.

''(v) RECORDS.—A dispenser shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

''(C) ELECTRONIC DATABASE.—A dispenser may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity.

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

''(e) REPACKAGER REQUIREMENTS.—

''(1) PRODUCT TRACING.—

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

''(i) not accept ownership of a product unless the previous owner, prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement for the product;

''(ii) prior to, or at the time of, each transaction in which the repackager transfers ownership of a product, provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product; and

"(iii) capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction described in clauses (i) and (ii) and maintain such information, history, and statement for not less than 6 years after the transaction.

"(B) RETURNS.—

"(i) NONSALEABLE PRODUCT.—A repackager described in section 581(16)(A) may return a nonsaleable product to the manufacturer or repackager, or to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information required under subparagraph (A)(ii).

"(ii) SALEABLE OR NONSALEABLE PRODUCT.—A repackager described in section 581(16)(B) may return a saleable or nonsaleable product to the manufacturer, repackager, or to the wholesale distributor from whom such product was received without providing the information required

under subparagraph (A)(ii) on behalf of the hospital or other health care entity that took ownership of such product pursuant to the terms and conditions of any agreement between such repackager and the entity that owns the product.

''(C) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a repackager described in section 581(16)(A) shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request or in other such reasonable time as determined by the Secretary, provide the applicable transaction information, transaction history, and transaction statement for the product.

''(2) PRODUCT IDENTIFIER.—

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

''(i) shall affix or imprint a product identifier to each package and homogenous

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

''(ii) shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction;

''(iii) may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)); and

''(iv) shall maintain records for not less than 6 years to allow the repackager to associate the product identifier the repackager affixes or imprints with the product identifier assigned by the original manufacturer of the product.

''(B) EXCEPTION.—A package that is required to have a standardized numerical identifier is not required to have a unique device identifier.

''(3) AUTHORIZED TRADING PARTNERS.—Beginning January 1, 2015, the trading partners of a repackager described in section 581(16) may be only 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:

"(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—

"(I) quarantine such product within the possession or control of the repackager from product intended for distribution until such product is cleared or dispositioned; and

"(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating

any applicable transaction history and transaction information in the possession of the repackager and otherwise investigating to determine whether the product is an illegitimate product, and, beginning 5 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), verifying the product at the package level, including the standardized numerical identifier.

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

''(iii) RECORDS.—A repackager shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

''(B) ILLEGITIMATE PRODUCT.—

"(i) IN GENERAL.—Upon determining, in coordination with the manufacturer, that a product in the possession or control of a repackager is an illegitimate product, the repackager shall, in a manner that is consistent with the systems and processes of such repackager—

"(I) quarantine such product within the possession or control of the repackager from product intended for distribution until such product is dispositioned;

"(II) disposition the illegitimate product within the possession or control of the repackager;

"(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the repackager; and

"(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal

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

"(ii) MAKING A NOTIFICATION.—Upon determining that a product in the possession or control of the repackager is an illegitimate product, the repackager shall notify the Secretary and all immediate trading partners that the repackager has reason to believe may have received the illegitimate product of such determination not later than 24 hours after making such determination.

"(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary or a trading partner, a repackager shall identify all illegitimate product subject to such notification that is in the possession or control of the repackager, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

"(iv) TERMINATING A NOTIFICATION.—Upon making a determination, in

consultation with the Secretary, that a notification is no longer necessary, a repackager shall promptly notify immediate trading partners that the repackager notified pursuant to clause (ii) that such notification has been terminated.

''(v) RECORDS.—A repackager shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

''(C) REQUESTS FOR VERIFICATION.—Beginning 5 years after the date of enactment of the Drug Supply Chain Security Act, upon receiving a request for verification from an authorized manufacturer, wholesale distributor, or dispenser that is in possession or control of a product they believe to be repackaged by such repackager, a repackager shall, not later than 24 hours after receiving the verification request or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the person making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the

product identifier affixed or imprinted by the repackager. If a repackager responding to a verification request identifies a product identifier that does not correspond to that affixed or imprinted by the repackager, the repackager shall treat such product as suspect product and conduct an investigation as described in subparagraph (A). If the repackager has reason to believe the product is an illegitimate product, the repackager shall advise the person making the request of such belief at the time such repackager responds to the verification request.

''(D) ELECTRONIC DATABASE.—A repackager may satisfy the requirements of paragraph (4) by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a repackager of the requirement under subparagraph (C) to respond to a verification request sub-

mitted by means other than a secure electronic database.

''(E) VERIFICATION OF SALEABLE RETURNED PRODUCT.—Beginning 5 years after the date of enactment of the Drug Supply Chain Security Act, upon receipt of a returned product that the repackager intends to further distribute, before further distributing such product, the repackager shall verify the product identifier for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier on each package.

''(f) DROP SHIPMENTS.—

''(1) IN GENERAL.—A wholesale distributor that does not physically handle or store product shall be exempt from the provisions of this section, except the notification requirements under clauses (ii), (iii), and (iv) of subsection (c)(4)(B), provided that the manufacturer, repackager, or other wholesale distributor that distributes the product to the dispenser by means of a drop shipment for such wholesale distributor includes on the transaction information and transaction history to the dispenser the contact information of such wholesale distributor

and provides the transaction information, transaction history, and transaction statement directly to the dispenser.

''(2) CLARIFICATION.—For purposes of this subsection, providing administrative services, including processing of orders and payments, shall not by itself, be construed as being involved in the handling, distribution, or storage of a product.''.

SEC. 203. ENHANCED DRUG DISTRIBUTION SECURITY.

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

''(g) ENHANCED DRUG DISTRIBUTION SECURITY.—

''(1) IN GENERAL.—On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:

''(A) The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of such

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

''(B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.

''(C) Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h), including any revision of such guidances issued in accordance with paragraph (5) of such subsection, which may include the use of aggregation and inference as necessary.

''(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

''(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required—

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

''(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

''(F) Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.

"(2) COMPLIANCE.—

"(A) INFORMATION MAINTENANCE AGREEMENT.—A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party shall confidentially maintain any information and statements required to be maintained under this section. 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.

"(B) ALTERNATIVE METHODS.—The Secretary, taking into consideration the assessment conducted under paragraph (3), shall provide for alternative methods of compliance with any of the requirements set forth in paragraph (1), including—

"(i) establishing timelines for compliance by small businesses (including small business dispensers with 25 or fewer full-time employees) with such requirements, in order to ensure that such requirements do not impose undue economic hardship for small businesses, including small business

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

''(ii) establishing a process by which a dispenser may request a waiver from any of the requirements set forth in paragraph (1) if the Secretary determines that such requirements would result in an undue economic hardship, which shall include a process for the biennial review and renewal of any such waiver.

''(3) ASSESSMENT.—

''(A) IN GENERAL.—Not later than the date that is 18 months after the Secretary issues the final guidance required under subsection (h), the Secretary shall enter into a contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level. Such assess-

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

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

"(C) CONTENT.—The assessment under subparagraph (A) shall assess whether—

"(i) the necessary software and hardware is readily accessible to such dispensers;

"(ii) the necessary software and hardware is prohibitively expensive to obtain, install, and maintain for such dispensers; and

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

"(D) PUBLICATION.—The Secretary shall—

''(i) publish the statement of work for the assessment under subparagraph (A) for public comment prior to beginning the assessment;

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

''(iii) hold a public meeting not later than 180 calendar days after receiving the final assessment at which public stakeholders may present their views on the assessment.

''(4) PROCEDURE.—Notwithstanding section 553 of title 5, United States Code, the Secretary, in promulgating any regulation pursuant to this section, shall—

''(A) provide appropriate flexibility by—

''(i) not requiring the adoption of specific business systems for the maintenance and transmission of data;

''(ii) prescribing alternative methods of compliance for any of the requirements set forth in paragraph (1) or set forth in regulations implementing such requirements, including—

"(I) timelines for small businesses to comply with the requirements set forth in the regulations in order to ensure that such requirements do not impose undue economic hardship for small businesses (including small business dispensers for whom the criteria set forth in the assessment under paragraph (3) is not met), if the Secretary determines that such requirements would result in undue economic hardship; and

"(II) the establishment of a process by which a dispenser may request a waiver from any of the requirements set forth in such regulations if the Secretary determines that such requirements would result in an undue economic hardship; and

"(iii) taking into consideration—

"(I) the results of pilot projects, including pilot projects pursuant to this section and private sector pilot projects, including those involving the use of aggregation and inference;

"(II) the public meetings held and related guidance documents issued under this section;

"(III) the public health benefits of any additional regulations in comparison to the cost of compliance with such requirements, including on entities of varying sizes and capabilities;

"(IV) the diversity of the pharmaceutical distribution supply chain by providing appropriate flexibility for each sector, including both large and small businesses; and

"(V) the assessment pursuant to paragraph (3) with respect to small business dispensers, including related public comment and the public meeting, and requirements under this section;

"(B) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

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

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

"(h) GUIDANCE DOCUMENTS.—

"(1) IN GENERAL.—For the purposes of facilitating the successful and efficient adoption of secure, interoperable product tracing at the package level in order to enhance drug distribution security and further protect the public health, the Secretary shall issue the guidance documents as provided for in this subsection.

"(2) SUSPECT AND ILLEGITIMATE PRODUCT.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall issue a guidance document to aid trading partners in the identification of a suspect product and notification termination. Such guidance document shall—

"(i) identify specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain;

"(ii) provide recommendation on how trading partners may identify such product

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

"(iii) set forth the process by which manufacturers, repackagers, wholesale distributors, and dispensers shall terminate notifications in consultation with the Secretary regarding illegitimate product pursuant to subsections (b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B).

"(B) REVISED GUIDANCE.—If the Secretary revises the guidance issued under subparagraph (A), the Secretary shall follow the procedure set forth in paragraph (5).

"(3) UNIT LEVEL TRACING.—

"(A) IN GENERAL.—In order to enhance drug distribution security at the package level, not later than 18 months after conducting a public meeting on the system attributes necessary to enable secure tracing of product at the package level, including allowing for the use of verification, inference, and aggregation, as necessary, the Secretary shall issue a final guidance document that outlines and makes recommendations with respect to the system at-

tributes necessary to enable secure tracing at the package level as required under the requirements established under subsection (g). Such guidance document shall—

"(i) define the circumstances under which the sectors within the pharmaceutical distribution supply chain may, in the most efficient manner practicable, infer the contents of a case, pallet, tote, or other aggregate of individual packages or containers of product, from a product identifier associated with the case, pallet, tote, or other aggregate, without opening each case, pallet, tote, or other aggregate or otherwise individually scanning each package;

"(ii) identify methods and processes to enhance secure tracing of product at the package level, such as secure processes to facilitate the use of inference, enhanced verification activities, the use of aggregation and inference, processes that utilize the product identifiers to enhance tracing of product at the package level, including

the standardized numerical identifier, or package security features; and

"(iii) ensure the protection of confidential commercial information and trade secrets.

"(B) PROCEDURE.—In issuing the guidance under subparagraph (A), and in revising such guidance, if applicable, the Secretary shall follow the procedure set forth in paragraph (5).

"(4) STANDARDS FOR INTEROPERABLE DATA EXCHANGE.—

"(A) IN GENERAL.—In order to enhance secure tracing of a product at the package level, the Secretary, not later than 18 months after conducting a public meeting on the interoperable standards necessary to enhance the security of the pharmaceutical distribution supply chain, shall update the guidance issued pursuant to subsection (a)(2), as necessary and appropriate, and finalize such guidance document so that the guidance document—

"(i) identifies and makes recommendations with respect to the standards necessary for adoption in order to support the secure, interoperable electronic

data exchange among the pharmaceutical distribution supply chain that comply with a form and format developed by a widely recognized international standards development organization;

"(ii) takes into consideration standards established pursuant to subsection (a)(2) and section 505D;

"(iii) facilitates the creation of a uniform process or methodology for product tracing; and

"(iv) ensures the protection of confidential commercial information and trade secrets.

"(B) PROCEDURE.—In issuing the guidance under subparagraph (A), and in revising such guidance, if applicable, the Secretary shall follow the procedure set forth in paragraph (5).

"(5) PROCEDURE.—In issuing or revising any guidance issued pursuant to this subsection or subsection (g), except the initial guidance issued under paragraph (2)(A), the Secretary shall—

"(A) publish a notice in the Federal Register for a period not less than 30 days an-

nouncing that the draft or revised draft guidance is available;

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

"(C) provide an opportunity for comment and review and take into consideration any comments received;

"(D) revise the draft guidance, as appropriate;

"(E) publish a notice in the Federal Register for a period not less than 30 days announcing that the final guidance or final revised guidance is available;

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

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

"(i) PUBLIC MEETINGS.—

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

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

''(A) prioritize topics necessary to inform the issuance of the guidance described in paragraphs (3) and (4) of subsection (h); and

''(B) take all measures reasonable and practicable to ensure the protection of confidential commercial information and trade secrets.

''(2) CONTENT.—Each of the following topics shall be addressed in at least one of the public meetings described in paragraph (1):

''(A) An assessment of the steps taken under subsections (b) through (e) to build capacity for a unit-level system, including the impact of the requirements of such subsections on—

''(i) the ability of the health care system collectively to maintain patient access to medicines;

''(ii) the scalability of such requirements, including as it relates to product lines; and

''(iii) the capability of different sectors and subsectors, including both large and small businesses, to affix and utilize the product identifier.

''(B) The system attributes necessary to support the requirements set forth under subsection (g), including the standards necessary for adoption in order to support the secure, interoperable electronic data exchange among sectors within the pharmaceutical distribution supply chain.

''(C) Best practices in each of the different sectors within the pharmaceutical distribution supply chain to implement the requirements of this section.

''(D) The costs and benefits of the implementation of this section, including the impact on each pharmaceutical distribution supply chain sector and on public health.

''(E) Whether electronic tracing requirements, including tracing of product at the pack-

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

"(F) The systems and processes needed to utilize the product identifiers to enhance tracing of product at the package level, including allowing for verification, aggregation, and inference, as necessary.

"(G) The technical capabilities and legal authorities, if any, needed to establish an interoperable, electronic system that provides for tracing of product at the package level.

"(H) The impact that such additional requirements would have on patient safety, the drug supply, cost and regulatory burden, and timely patient access to prescription drugs.

"(I) Other topics, as determined appropriate by the Secretary.

"(j) PILOT PROJECTS.—

"(1) IN GENERAL.—The Secretary shall establish 1 or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. Such projects shall build upon efforts, in existence as of

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

''(2) CONTENT.—

''(A) IN GENERAL.—The Secretary shall ensure that the pilot projects under paragraph (1) reflect the diversity of the pharmaceutical distribution supply chain and that the pilot projects, when taken as a whole, include participants representative of every sector, including both large and small businesses.

''(B) PROJECT DESIGN.—The pilot projects under paragraph (1) shall be designed to—

''(i) utilize the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference;

"(ii) improve the technical capabilities of each sector and subsector to comply with systems and processes needed to utilize the product identifiers to enhance tracing of a product;

"(iii) identify system attributes that are necessary to implement the requirements established under this section; and

"(iv) complete other activities as determined by the Secretary.

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

"(1) The provision and receipt of transaction history under this section.

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

"(3) The requirements set forth under subparagraphs (A)(v)(II) and (D) of subsection (c)(1), as applied to lot level information only.

"(l) RULE OF CONSTRUCTION.—The requirements set forth in subsections (g)(4), (i), and (j) shall not be 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—

"(i)(I) is licensed by the State from which the drug is distributed; or

"(II) if the State from which the drug is distributed has not established a licensure requirement, is licensed by the Secretary; and

"(ii) if the drug is distributed interstate, is licensed by the State into which the drug is distributed if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State.

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

"(2) REPORTING AND DATABASE.—

"(A) REPORTING.—Beginning January 1, 2015, any person who owns or operates an establishment that engages in wholesale distribution shall—

"(i) report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary—

''(I) each State by which the person is licensed and the appropriate identification number of each such license; 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.

''(B) DATABASE.—Not later than January 1, 2015, the Secretary shall establish a database of authorized wholesale distributors. Such database shall—

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

tributor is appropriately licensed to engage in wholesale distribution;

''(ii) be available to the public on the Internet Web site of the Food and Drug Administration; and

''(iii) be regularly updated on a schedule determined by the Secretary.

''(C) COORDINATION.—The Secretary shall establish a format and procedure for appropriate State officials to access the information provided pursuant to subparagraph (A) in a prompt and secure manner.

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

''(3) COSTS.—

''(A) AUTHORIZED FEES OF SECRETARY.—If a State does not establish a licensing program for persons engaged in the wholesale distribution of a drug subject to subsection (b), the Secretary shall license a person engaged in

wholesale distribution located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

''(B) STATE LICENSING FEES.—Nothing in this Act shall prohibit States from collecting fees from wholesale distributors in connection with State licensing of such distributors.''.

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

''(4) For the purposes of this subsection and subsection (d), the term 'wholesale distribution' means the distribution of a drug subject to subsection (b) to a person other than a consumer or patient, or receipt of a drug subject to subsection (b) by a person other than the consumer or patient, but does not include—

''(A) intracompany distribution of any drug between members of an affiliated group or within a manufacturer;

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

''(C) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that, for purposes of this paragraph, a drug shortage not caused by

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

"(D) the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b)(1);

"(E) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

"(F) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

"(G) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

"(H) the distribution of a drug by the manufacturer of such drug;

"(I) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

"(J) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

"(K) the distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 582(e);

"(L) salable drug returns when conducted by a dispenser;

"(M) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a 'medical convenience kit') if—

"(i) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2);

"(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

"(iii) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

"(I) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

"(II) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

"(iv) in the case of a medical convenience kit that includes a product, the product is—

"(I) an intravenous solution intended for the replenishment of fluids and electrolytes;

"(II) a product intended to maintain the equilibrium of water and minerals in the body;

"(III) a product intended for irrigation or reconstitution;

"(IV) an anesthetic;

"(V) an anticoagulant;

"(VI) a vasopressor; or

"(VII) a sympathicomimetic;

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

"(O) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

"(P) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

"(Q) the distribution of medical gas, as defined in section 575;

"(R) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

"(S) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section

581(16)(B) and registered under section 510 for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.''.

(3) THIRD-PARTY LOGISTICS PROVIDERS.—Section 503(e) (21 U.S.C. 353(e)), as amended by paragraph (2), is further amended by adding at the end the following:

''(5) THIRD-PARTY LOGISTICS PROVIDERS.—Notwithstanding paragraphs (1) through (4), each entity that meets the definition of a third-party logistics provider under section 581(22) shall obtain a license as a third-party logistics provider as described in section 584(a) and is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles.''.

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

''(6) AFFILIATE.—For purposes of this subsection, the term 'affiliate' means a business entity

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

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

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

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

''SEC. 583. NATIONAL STANDARDS FOR PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS.

''(a) IN GENERAL.—The Secretary shall, not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, establish by regulation standards for the licensing of persons under section 503(e)(1) (as amended by the Drug Supply Chain Security Act), including the revocation, reissuance, and renewal of such license.

''(b) CONTENT.—For the purpose of ensuring uniformity with respect to standards set forth in this section, the standards established under subsection (a) shall apply to all State and Federal licenses described under section 503(e)(1) (as amended by the Drug Supply Chain Security Act) and shall include standards for the following:

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

''(2) The establishment and maintenance of records of the distributions of such drugs.

''(3) The furnishing of a bond or other equivalent means of security, as follows:

''(A)(i) For the issuance or renewal of a wholesale distributor license, an applicant that is not a government owned and operated wholesale distributor shall submit a surety bond of $100,000 or other equivalent means of security acceptable to the State.

''(ii) For purposes of clause (i), the State or other applicable authority may accept a surety bond in the amount of $25,000 if the annual gross receipts of the previous tax year for the wholesaler is $10,000,000 or less.

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

''(4) Mandatory background checks and fingerprinting of facility managers or designated representatives.

''(5) The establishment and implementation of qualifications for key personnel.

''(6) The mandatory physical inspection of any facility to be used in wholesale distribution within a reasonable time frame from the initial application of the facility and to be conducted by the licensing authority or by the State, consistent with subsection (c).

''(7) In accordance with subsection (d), the prohibition of certain persons from receiving or maintaining licensure for wholesale distribution.

''(c) INSPECTIONS.—To satisfy the inspection requirement under subsection (b)(6), the Federal or State licensing authority may conduct the inspection or may accept an inspection by the State in which the facility is located, or by a third-party accreditation or inspection service approved by the Secretary or the State licensing such wholesale distributor.

''(d) PROHIBITED PERSONS.—The standards established under subsection (a) shall include requirements to prohibit a person from receiving or maintaining licensure for wholesale distribution if the person—

''(1) has been convicted of any felony for conduct relating to wholesale distribution, any felony violation of subsection (i) or (k) of section 301, or

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

''(2) has engaged in a pattern of violating the requirements of this section, or State requirements for licensure, that presents a threat of serious adverse health consequences or death to humans.

''(e) REQUIREMENTS.—The Secretary, in promulgating any regulation pursuant to this section, shall, notwithstanding section 553 of title 5, United States Code—

''(1) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

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

''(3) provide that the final regulation take effect on the date that is 2 years after the date such final regulation is published.''.

(b) AUTHORIZED DISTRIBUTORS OF RECORD.—Section 503(d) (21 U.S.C. 353(d)) is amended by adding at the end the following:

''(4) In this subsection, the term 'authorized distributors of record' means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.''.

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

SEC. 205. NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS; UNIFORM NATIONAL POLICY.

Subchapter H of chapter V, as amended by section 204, is further amended by adding at the end the following:

"SEC. 584. NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS.

''(a) REQUIREMENTS.—No third-party logistics provider in any State may conduct activities in any State unless each facility of such third-party logistics provider—

''(1)(A) is licensed by the State from which the drug is distributed by the third-party logistics provider, in accordance with the regulations promulgated under subsection (d); or

''(B) if the State from which the drug distributed by the third-party logistics provider has not established a licensure requirement, is licensed by the Secretary, in accordance with the regulations promulgated under subsection (d); and

''(2) if the drug is distributed interstate, is licensed by the State into which the drug is distrib-

uted by the third-party logistics provider if such State licenses third-party logistics providers that distribute drugs into the State and the third-party logistics provider is not licensed by the Secretary as described in paragraph (1)(B).

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

''(1) the State by which the facility is licensed and the appropriate identification number of such license; and

''(2) the name and address of the facility and all trade names under which such facility conducts business.

''(c) COSTS.—

''(1) AUTHORIZED FEES OF SECRETARY.—If a State does not establish a licensing program for a third-party logistics provider, the Secretary shall license the third-party logistics provider located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic in-

spections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

''(2) STATE LICENSING FEES.—

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

''(B) NO STATE ESTABLISHED PROGRAM.—A State that does not establish a program to license a third-party logistics provider in accordance with this section shall be prohib-

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

''(d) REGULATIONS.—

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

''(2) CONTENT.—Such regulations shall—

''(A) establish a process by which a third-party accreditation program approved by the Secretary shall, upon request by a third-party logistics provider, issue a license to each third-party logistics provider that meets the requirements set forth in this section;

''(B) establish a process by which the Secretary shall issue a license to each third-party logistics provider that meets the requirements set forth in this section if the Secretary is not able to approve a third-party accreditation program because no such program meets the Secretary's requirements necessary for approval of such a third-party accreditation program;

"(C) require that the entity complies with storage practices, as determined by the Secretary for such facility, including—

"(i) maintaining access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;

"(ii) maintaining adequate security; and

"(iii) having written policies and procedures to—

"(I) address receipt, security, storage, inventory, shipment, and distribution of a product;

"(II) identify, record, and report confirmed losses or thefts in the United States;

"(III) correct errors and inaccuracies in inventories;

"(IV) provide support for manufacturer recalls;

"(V) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or op-

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

''(VI) ensure that any expired product is segregated from other products and returned to the manufacturer or repackager or destroyed;

''(VII) maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and

''(VIII) quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency;

''(D) provide for periodic inspection by the licensing authority, as determined by the Secretary, of such facility warehouse space to ensure compliance with this section;

''(E) prohibit a facility from having as a manager or designated representative anyone convicted of any felony violation of subsection (i) or (k) of section 301 or any violation of section 1365 of title 18, United States Code relating to product tampering;

''(F) provide for mandatory background checks of a facility manager or a designated representative of such manager;

''(G) require a third-party logistics provider to provide the applicable licensing authority, upon a request by such authority, a list of all product manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at such facility; and

''(H) include procedures under which any third-party logistics provider license—

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

''(ii) may be renewed for additional 3-year periods.

''(3) PROCEDURE.—In promulgating the regulations under this subsection, the Secretary shall, notwithstanding section 553 of title 5, United States Code—

''(A) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

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

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

''(e) VALIDITY.—A license issued under this section shall remain valid as long as such third-party logistics provider remains licensed consistent with this section. If the Secretary finds that the third-party accreditation program demonstrates that all applicable requirements for licensure under this section are met, the Secretary shall issue a license under this section to a third-party logistics provider receiving accreditation, pursuant to subsection (d)(2)(A).

''SEC. 585. UNIFORM NATIONAL POLICY.

''(a) PRODUCT TRACING AND OTHER REQUIREMENTS.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are in-

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

''(1) any waiver, exception, or exemption pursuant to section 581 or 582; or

''(2) any restrictions specified in section 582.

''(b) WHOLESALE DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER STANDARDS.—

''(1) IN GENERAL.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

''(2) STATE REGULATION OF THIRD-PARTY LOGISTICS PROVIDERS.—No State shall regulate third-party logistics providers as wholesale distributors.

"(3) ADMINISTRATION FEES.—Notwithstanding paragraph (1), a State may administer fee collections for effectuating the wholesale drug distributor and third-party logistics provider licensure requirements under sections 503(e) (as amended by the Drug Supply Chain Security Act), 583, and 584.

"(4) ENFORCEMENT, SUSPENSION, AND REVOCATION.—Notwithstanding paragraph (1), a State—

"(A) may take administrative action, including fines, to enforce a requirement promulgated by the State in accordance with section 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter;

"(B) may provide for the suspension or revocation of licenses issued by the State for violations of the laws of such State;

"(C) upon conviction of violations of Federal, State, or local drug laws or regulations, may provide for fines, imprisonment, or civil penalties; and

"(D) may regulate activities of licensed entities in a manner that is consistent with product tracing requirements under section 582.

''(c) EXCEPTION.—Nothing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if such requirements are not related to product tracing as described in subsection (a) or wholesale distributor and third-party logistics provider licensure as described in subsection (b) applicable under section 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter (or regulations issued thereunder).''.

SEC. 206. PENALTIES.

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

(1) by striking ''or'' after ''the requirements of section 503(d),''; and

(2) by inserting '', failure to comply with the requirements under section 582, the failure to comply with the requirements under section 584, as applicable,'' after ''in violation of section 503(e)''.

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

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

SEC. 207. CONFORMING AMENDMENT.

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

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

SEC. 208. SAVINGS CLAUSE.

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