II

113TH CONGRESS
1ST SESSION

S. 957

To amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain.

IN THE SENATE OF THE UNITED STATES

MAY 15, 2013

Mr. BENNET (for himself, Mr. BURR, Mr. HARKIN, Mr. ALEXANDER, and Mr. ISAKSON) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain.

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 Supply Chain Security Act''.

SEC. 2. PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

Chapter V of the Federal Food, Drug, and Cosmetic Act (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) 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.

''(2) COMPRESSED MEDICAL GAS.—The term 'compressed medical gas' means any substance in its gaseous or cryogenic liquid form that meets medical

purity standards and has application in a medical or homecare environment, including oxygen and nitrous oxide.

''(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 only dispenses 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.

''(6) EXCLUSIVE DISTRIBUTOR.—The term 'exclusive distributor' means the wholesale distributor that directly purchased product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent 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 could result in serious adverse health consequence or death to humans.

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

"(A) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6);

"(B) 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

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

"(10) MANUFACTURER.—

"(A) IN GENERAL.—The term 'manufacturer' means, with respect to a product—

"(i) 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;

"(ii) a co-licensed partner of the person described in clause (i) that obtains the product directly from the person described in clause (i) or (ii); or

"(iii) an affiliate of a person described in clause (i) or (iii) that receives the product directly from a person described in clause (i), (ii), or (iii).

"(B) AFFILIATE.—For purposes of this paragraph, the term 'affiliate' means a member of an affiliated group, as that term is defined in section 1504(a) of the Internal Revenue Code.

"(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 manufac-

turer 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 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), or any compressed medical gas.

''(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 such as automated designation.

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

''(17) RETURN.—The term 'return' means providing product to the authorized immediate trading partner from which such product was purchased, 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 OR SNI.—The term 'standardized numerical identifier' or 'SNI' 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, repackager, 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 (as defined in section 1504(a) of the Internal Revenue Code of 1986);

''(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 valid 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 1954 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 pharmacy or pharmacies or a wholesale dis-

tributor 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(b);

''(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—

''(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 otherwise 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 products or device and biological product; or

''(III) 2 or more finished medical devices plus one or more drug or biological products which 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 or a collection of finished drug or biological products assembled in kit form strictly for the convenience of the purchaser or user (to be known 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 person who manufactures a medical convenience kit purchased the product contained in the medical convenience kit directly from the pharmaceutical manufacturer or

from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer;

''(III) the person who manufactures a medical convenience kit does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor;

''(IV) 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; and

''(V) the products contained in the medical convenience kit are—

''(aa) intravenous solutions intended for the replenishment of fluids and electrolytes;

''(bb) products intended to maintain the equilibrium of water and minerals in the body;

''(cc) products intended for irrigation or reconstitution;

"(dd) anesthetics;

"(ee) anticoagulants;

"(ff) vasopressors; or

"(gg) sympathicomimetics;

"(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 reconstitution, or sterile water, whether intended for such purposes or for injection;

"(xvii) the distribution of compressed medical gas; 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 different from 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, third-party logistics provider, and dispenser shall comply with the requirements set forth in this section with respect to the role of such manufacturer, repackager, wholesale distributor, third-party logistics provider, 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, third-party logistics providers, dispensers, and other pharmaceutical distribution supply chain stakeholders, issue a draft guidance document that establishes standards for the interoperable exchange of transaction information for compliance with subsections (a), (b), (c), (d), (e), and (f). 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 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 section, 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) of this section;

"(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; or

''(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 1 year after the date of enactment of the

Drug Supply Chain Security Act, a manufacturer shall—

"(i) prior to, or at the time of, each transaction in which such manufacturer transfers—

"(I) ownership of a product, provide the subsequent recipient with transaction history, transaction information, and a transaction statement; or

"(II) possession of a product to a third-party logistics provider for the purpose of transferring ownership as part of a transaction to a subsequent recipient, provide to the third-party logistics provider the transaction history, transaction information, and a transaction statement for such transaction to a subsequent recipient; and

"(ii) maintain the transaction information, transaction history, and transaction statement for each transaction 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 24 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.

''(2) PRODUCT IDENTIFIER.—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.

''(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than 1 year after the date of enactment of the Drug Supply Chain Security Act, the

trading partners of a manufacturer may be only authorized trading partners.

''(4) VERIFICATION.—Beginning not later than 1 year after the date of enactment of the Drug Supply Chain Security Act, 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.

''(ii) CLEARED PRODUCT.—If the manufacturer makes the determination that a suspect product is not an illegitimate 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 partner 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 Fed-

eral 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 (i).

''(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 manu-

facturer 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 they believe to be manufactured by such manufacturer, a manufacturer 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 standard numeric 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 verification request 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 verification request.

''(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 verification re-

quest 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 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) 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 required under paragraph (1)(A)(i).

''(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

''(1) PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning not later than 1 year after the date of enactment of the Drug Supply Chain Security Act, 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 affili-

ated group of such wholesale distributor, purchased the product directly from the manufacturer, exclusive distributor of the manufacturer, or repackager that purchased 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 an electronic or paper 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—

''(I) shall provide to the subsequent purchaser a transaction statement, transaction history, and transaction information; and

''(II) may provide the information described in subclause (I) to a subsequent purchaser on a single document in an electronic or paper format or through any combination of self-generated paper, electronic data, or manufacturer provided information on the product package.

"(iv) For the purposes of clause (iii)(I), 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 the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, and shall identify the manufacturer, exclusive distributor of the manufacturer, or repackager that purchased directly from the manufacturer from which the direct purchase statement was received.

"(v) A wholesale distributor shall maintain the transaction information, transaction history, and transaction statement for each transaction described in clauses (i), (ii), and (iii) for not less than 6 years after the date of the transaction.

"(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 pursuant to the terms and conditions 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 pro-

vided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser 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 prescription drug to the manufacturer or repackager, to the wholesale distributor from whom such prescription drug was purchased, or to a person acting on behalf of such a person, including a re-

turns 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 24 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.

''(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 1 year after the date of enactment of the Drug Supply Chain Security Act, the

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

''(4) VERIFICATION.—Beginning not later than 1 year after the date of enactment of the Drug Supply Chain Security Act, 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 the 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.

''(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 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 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 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 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.

''(d) DISPENSER REQUIREMENTS.—

''(1) PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning 1 year after the date of enactment of the Drug Supply Chain Security Act, 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 maintain transaction information, transaction history, and transaction statements, as necessary to investigate a suspect product, 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 (B).

"(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 persons without providing the information required under subparagraph (A)(i).

"(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.

"(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 1 year after the date of enactment of the Drug Supply Chain Security Act, the trading partners of a dispenser may be only authorized trading partners.

''(4) VERIFICATION.—Beginning not later than 1 year after the date of enactment of the Drug Supply Chain Security Act, 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 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 partner 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.

"(e) REPACKAGER REQUIREMENTS.—

"(1) PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning not later than 1 year after the date of enactment of the Drug Supply Chain Security Act, a repackager 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, or transfers possession of a product to a third-party logistics provider, provide the subsequent owner with transaction history, transaction information, and a transaction statement; and

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

"(B) NONSALEABLE RETURNS.—A repackager 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).

"(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 shall, not later than 24 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.

''(2) PRODUCT IDENTIFIER.—Beginning not later than 5 years after enactment of the Drug Supply Chain Security Act, a repackager—

''(A) shall a fix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction in commerce;

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

''(C) 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

''(D) 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.

''(3) AUTHORIZED TRADING PARTNERS.—Beginning 1 year after the date of enactment of the Drug Supply Chain Security Act, the trading partners of a repackager may be only authorized trading partners.

''(4) VERIFICATION.—Beginning not later than 1 year after the date of enactment of the Drug Supply Chain Security Act, a repackager 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.

''(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 manufac-

turer, 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 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 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 standard numeric 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 manufacturer 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 paragraph (4) to respond to a verification request submitted 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) THIRD-PARTY LOGISTICS PROVIDER REQUIREMENTS.—

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

''(A) not accept possession of a product unless the owner of the product provides the transaction history, transaction information, and a transaction statement for the product;

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

''(C) 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, not later than 24 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.

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

''(3) AUTHORIZED TRADING PARTNERS.—Beginning 1 year after the date of enactment of the Drug Supply Chain Security Act, the trading partners of a third-party logistics provider may be only authorized trading partners.

''(4) VERIFICATION.—Beginning not later than 1 year after the date of enactment of the Drug Supply Chain Security Act, a third-party logistics provider shall have systems in place to enable the third-

party logistics provider 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 third-party logistics provider is a suspect product, a third-party logistics provider shall—

"(I) quarantine such product within the possession or control of the third-party logistics provider from product intended for distribution until such product is cleared or transferred to the owner of such product for disposition of the product; and

"(II) promptly notify the owner of such product of the need to conduct an investigation to determine whether the product is an illegitimate product.

"(ii) CLEARED PRODUCT.—If the owner of the product notifies the third-party logistics provider of the determination that a suspect product is not an illegitimate product, such product may be further distributed.

''(iii) RECORDS.—A third-party logistics provider shall keep records of the activities described in subclauses (I) and (II) of clause (i), as such subclauses relate to 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 third-party logistics provider is an illegitimate product, the third-party logistics provider shall—

''(I) promptly notify the owner of such product of the need to disposition such product; and

''(II) promptly transfer possession of the product to the owner of such product to disposition the product.

''(ii) MAKING A NOTIFICATION.—Upon determining that a product in the possession or control of the third-party logistics provider is an illegitimate product,

the third-party logistics provider shall notify the Secretary not later than 24 hours after making such determination.

''(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary, a third-party logistics provider shall identify all illegitimate product subject to such notification that is in the possession or control of the third-party logistics provider, 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 and the owner of such product, that a notification is no longer necessary, a third-party logistics provider shall promptly terminate such notification.

''(v) RECORDS.—A third-party logistics provider shall keep records of the activities described in subclauses (I) and (II) of clause (i) as such subclauses relate to an illegitimate product for not less than 6

years after the conclusion of the disposition.

''(g) DROP SHIPMENTS.—This section shall not apply to any entity that does not physically handle, distribute, or store product. For purposes of this section, providing various 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. For purposes of this section, the term 'entity' means a wholesale distributor, relabeler, repackager, or any other status.''.

SEC. 3. ENHANCED DRUG DISTRIBUTION SECURITY.

(a) IN GENERAL.—Section 582 of the Federal Food, Drug, and Cosmetic Act, as added by section 2, is amended by adding at the end the following:

''(h) 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 (i), 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 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 (i), 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 shall be permitted to 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 (i), the Secretary shall enter into 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 employ-

ees conducting interoperable, electronic tracing of products at the package level. In no case may such assessment commence later than 7.5 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 conducted 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 not 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 conducted 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 timelines—

"(I) 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) which shall include establishing 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;

"(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 the final regulation not less than 2 years prior to the effective date of the regulation.

"(i) 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 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 if the product is a suspect product as soon as practicable; and

"(iii) set forth the process by which manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers shall terminate notifications in consultation with the Secretary regarding illegitimate product pursuant to subsections (b)(4)(B), (c)(4)(B), (d)(4)(B), (e)(4)(B), and (f)(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, the Secretary shall issue a final guidance document that outlines and makes recommendations with respect to the system attributes necessary to enable secure trac-

ing at the package level as required under the requirements established under subsection (h). 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 enhanced verification activities, the use of aggregation and inference, processes that utilize the product identifiers to enhance tracing of product at the package level, 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 recommendation 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 (h), 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 announcing 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.

"(j) PUBLIC MEETINGS.—

"(1) IN GENERAL.—The Secretary shall hold not less than 3 public meetings to enhance the safety and security of the pharmaceutical distribution supply chain and provide for comment. The Sec-

retary 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 (i); 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 (f) 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 (h), 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 package level are feasible, cost-effective and needed to protect public health.

''(F) The systems and processes needed to utilize the product identifiers to enhance tracing of product at the package level.

''(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.

''(k) PILOT PROJECTS.—

''(1) IN GENERAL.—The Secretary shall establish 1 or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, third-party logistics providers, 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, and inform the draft and final guidance under paragraphs (3) and (4) of subsection (i).

''(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.

''(l) 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 subsection (c)(1)(B)(i).

''(m) RULE OF CONSTRUCTION.—The requirements set forth in subsections (h)(4), (j), and (k) shall not be construed as a condition, prohibition, or precedent for precluding or delaying the provisions becoming effective pursuant to subsection (h).''.

SEC. 4. NATIONAL LICENSURE STANDARDS FOR WHOLESALE DISTRIBUTORS.

(a) AMENDMENTS.—

(1) LICENSE REQUIREMENT.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended by striking paragraphs (1), (2), and (3) and inserting the following:

"(1) LICENSE 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 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) LICENSE 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) LICENSURE REPORTING AND DATABASE.—

"(A) LICENSURE REPORTING.—Beginning 1 year after the date of enactment of the Drug

Supply Chain Security Act, any person who owns or operates an establishment that engages in wholesale distribution shall 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 and address of each facility at which, and all trade names under which, the person conducts business.

''(B) DATABASE.—Not later than 1 year after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall establish a database of licensed wholesale distributors. Such database shall—

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

"(3) COSTS.—

"(A) AUTHORIZED LICENSURE 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.

"(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) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)), as amended by subsection (a), 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 (as defined in section 1504(a) of the Internal Revenue Code of 1986);

''(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 dec-

laration 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;

''(D) the dispensing of a drug pursuant to a valid prescription executed in accordance with section 503(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) saleable drug returns when conducted by a dispenser;

"(M) the distribution of a medical convenience kit which is a collection of finished drug or biologic products assembled in kit form strictly for the convenience of the purchaser or user 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 person who manufactures the medical convenience kit purchased the finished drug or biologic product contained in the medical convenience kit directly from the pharmaceutical manufacturer or from

a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer;

''(iii) the person who manufactures a medical convenience kit does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor;

''(iv) 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 (21 U.S.C. 801, et seq.); and

''(v) the products contained in the medical convenience kit are—

''(I) intravenous solutions intended for the replenishment of fluids and electrolytes;

''(II) drugs intended to maintain the equilibrium of water and minerals in the body;

''(III) drugs intended for irrigation or reconstitution;

''(IV) anesthetics;

''(V) anticoagulants;

''(VI) vasopressors; or

''(VII) sympathicomimetics;

''(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 reconstitution, or sterile water, whether intended for such purposes or for injection;

''(Q) the distribution of compressed medical gas, defined as any substance in its gaseous or cryogenic liquid form that meets medical purity standards and has application in a medical or homecare environment, including oxygen and nitrous oxide;

''(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 to a repackager 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) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)), as amended by subsection (a), 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) LICENSURE STANDARDS.—Subchapter H of chapter V of the Federal Food, Drug, and Cosmetic

Act, as added by section 2, is amended by adding at the end the following:

"SEC. 583. NATIONAL LICENSURE STANDARDS FOR 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, by regulation establish minimum standards, terms, and conditions 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.—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 prescribe minimum requirements for—

"(1) the storage and handling of such 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 if—

"(A) an applicant that is not a government owned and operated wholesale distributor, for the issuance or renewal of a wholesale dis-

tributor license shall submit a surety bond of one hundred thousand dollars or other equivalent means of security acceptable to the State;

''(B) for purposes of subparagraph (A), the State or other applicable authority may accept a surety bond less than $100,000 if the annual gross receipts of the previous tax year for the wholesaler is $10,000,000 or less, in which case the surety bond shall be $25,000; and

''(C) if a wholesale distributor can provide evidence that it possesses the required bond in a State, the requirement for a bond in another State is 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); and

''(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 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) CONFORMING AMENDMENTS.—Section 503(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(d)) is amended—

(1) by striking ''authorized distributor of record'' each place such term appears and inserting ''wholesale distributor''; and

(2) by striking ''authorized distributors of record'' each place such term appears and inserting ''wholesale distributors''.

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

SEC. 5. NATIONAL LICENSURE STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS; UNIFORM NATIONAL POLICY.

Subchapter H of chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 4, is further amended by adding at the end the following:

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

''(a) LICENSE 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 distributed by the third-party logistics provider if such State licenses third-party logistics providers that distribute drugs into the State and the third-party lo-

gistics provider is not licensed by the Secretary as described in subparagraph (A)(ii).

''(b) LICENSURE 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 LICENSURE 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 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.

''(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 prohibited from collecting a State licensing fee from a third-party logistics provider.

''(d) LICENSE 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 minimum issuance and eligibility requirements for licensing under subsection (a), including the revocation and reissuance of such li-

cense, 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 minimum 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 minimum 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 operation 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 re-packager or destroyed;

"(VII) maintain the capability to electronically 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; and

''(G) require a third-party logistics provider to provide the Secretary, upon a request by the Secretary, a list of all product manufacturers, wholesale distributors, and dispensers

for whom the third-party logistics provider provides services at such facility.

''(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) RENEWAL OF LICENSES.—The Secretary shall develop procedures for license renewal. Licenses issued under this section shall expire on the date that is 3 years after issuance of the license. Such an expired license may be renewed for additional 3-year periods according to procedures developed by the Secretary.

''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 drugs through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a pharmaceutical product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or record-keeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent 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 issued by the Secretary under section 581 or 582; or

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

''(b) DISTRIBUTION AND LICENSING 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 drug distributor or third-party logistics provider licensure that are less stringent than the standards and re-

quirements 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 OF LICENSES.—Notwithstanding paragraph (1), a State—

''(A) may take administrative action, including fines, to enforce a licensure 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 subsection (a) or (b) 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), including any requirements applicable under section 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter (or regulations issued thereunder).''.

SEC. 6. PENALTIES.

(a) PROHIBITED ACT.—Section 301(t) of the Federal Food, Drug, and Cosmetic Act (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 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), is amended by adding at the end the following:

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

SEC. 7. CONFORMING AMENDMENTS.

Section 303(b)(1)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(b)(1)(D)) is amended by striking ''503(e)(2)(A)'' and inserting ''503(e)(1)''.

SEC. 8. SAVINGS CLAUSE.

Except as provided in the amendments made by paragraphs (1), (2), and (3) of section 4(a) and by section 6(a), nothing in this Act (including the amendments made by this Act) 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.).

○