AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

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

S. 959

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

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

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pharmaceutical Quality, Security, and Accountability Act''.

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

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

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

TITLE I—HUMAN DRUG COMPOUNDING

SEC. 101. SHORT TITLE.

This title may be cited as the ''Pharmaceutical Compounding Quality and Accountability Act''.

SEC. 102. REGULATION OF HUMAN DRUG COMPOUNDING.

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

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

"SEC. 503A. HUMAN DRUG COMPOUNDING.

"(a) SCOPE.—

"(1) COMPOUNDING.—In this section, the terms 'compounding' and 'compound'—

"(A) include—

"(i) the combining, admixing, mixing, diluting, reconstituting, or otherwise altering of a marketed drug;

"(ii) compounding a drug from a bulk drug substance; and

"(iii) repackaging; and

"(B) exclude mixing, reconstituting, or other such acts with respect to a marketed drug that are limited to and performed in accordance with specific directions for such acts contained in approved labeling provided by a drug's manufacturer, when performed based upon a prescription for an identified individual patient or when such mixing, reconstituting, or other such acts with respect to a marketed drug are performed within a health care entity by a practitioner, or other licensed individual under the

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

''(2) ADMINISTRATION AND DISPENSING NOT A SALE.—In this section, the terms 'sale', 'sell', and 'resale' do not include—

''(A) circumstances in which drug is administered to a patient or provided to a patient who has been instructed to self-administer the drug;

''(B) the dispensing of a drug by—

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

''(ii) a hospital or health system, as defined in subsection (b)(11)(B), to a patient of such hospital or health system; or

''(C) any fee associated with such administration, provision, or dispensing of the drug.

''(3) EXCLUSIONS.—For purposes of this section, the activities described in paragraph (1) shall not be considered 'compounding' if such activities are conducted in whole or in part with respect to—

''(A) blood or blood components for transfusion;

"(B) medical gases, as defined in section 575; or

"(C) human cells, tissues, or cellular or tissue-based products.

"(4) ANIMAL DRUGS FOR HUMAN USE.—Nothing in this section shall be construed to permit the use of animal drugs in compounding a drug for human use.

"(b) DEFINITIONS.—In this section:

"(1) COMPOUNDING MANUFACTURER.—

"(A) IN GENERAL.—The term 'compounding manufacturer' means a facility at one geographic location or address—

"(i) that compounds any sterile drug without receiving a prescription for an identified individual patient for such sterile drug prior to beginning compounding, and distributes or offers to sell such compounded sterile drug in interstate commerce; or

"(ii) that repackages any preservative-free sterile drug or engages in sterile pooling.

"(B) EXCLUSIONS.—

"(i) EXCLUDED ACTIVITIES.—Notwithstanding subparagraph (A)(ii), a facility shall not be considered a compounding manufacturer if such facility—

"(I) repackages drugs in accordance with section 506F or the final guidance described in section 506F(d) once the final guidance is published; and

"(II) does not otherwise meet the definition of compounding manufacturer under subparagraph (A).

"(ii) COMPOUNDING NUCLEAR PHARMACY.—The term 'compounding manufacturer' shall not include a compounding nuclear pharmacy.

"(iii) INFUSION PHARMACY.—The term 'compounding manufacturer' shall not include an infusion pharmacy, unless the infusion pharmacy compounds as described in subparagraph (A)(i).

"(C) EFFECT.—Nothing in this paragraph requires a compounding manufacturer to receive a prescription before or after compounding or pooling a drug. Compounding

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

''(2) COMPOUNDING NUCLEAR PHARMACY.—The term 'compounding nuclear pharmacy' means an entity that—

''(A) is a State-licensed pharmacy or a Federal facility;

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

''(C) does not compound non-radioactive drugs that would cause the entity to be a compounding manufacturer described in paragraph (1)(A); and

''(D) meets the requirements of this section applicable to drugs compounded by traditional compounders with respect to any non-radioactive drug compounding conducted at such pharmacy or facility.

''(3) COPY.—The term 'copy' means an identical or nearly identical version of a drug.

''(4) INFUSION PHARMACY.—The term 'infusion pharmacy' means an entity that—

''(A) is a State-licensed pharmacy or a Federal facility;

''(B) is accredited to provide infusion pharmacy services by a national accreditation body approved by the Secretary for purposes of this section;

''(C) provides infusion therapy, pursuant to a prescription for an identified individual patient received prior to beginning compounding and pooling, for administration in the patient's home, or in a health care entity wherein infusion products are administered directly to patients; and

''(D) does not compound drugs, other than as provided for in subparagraph (C), that would cause the entity to be a compounding manufacturer described in paragraph (1)(A).

''(5) PRACTITIONER.—The term 'practitioner' includes a physician or any other person that is authorized to prescribe medication under State law.

''(6) PRACTITIONER ORDER.—

"(A) IN GENERAL.—The term 'practitioner order' means an order for a compounded prescription drug—

"(i) issued by an identified practitioner—

"(I) who has determined that a compounded drug is necessary to meet the clinical need of the patients of such practitioner; and

"(II) for use by such practitioner in administering the drug to such practitioner's patients in a health care setting (referred to in this section as 'office use'); and

"(ii) that includes a statement specifying that such drug may be compounded.

"(B) EXCLUSIONS.—The term 'practitioner order' does not include—

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

"(ii) any other type of order pursuant to which a drug is dispensed to a patient for use or administration by the patient in the patient's home.

"(7) RADIOACTIVE DRUG.—The term 'radioactive drug'—

"(A) means any substance defined as a drug in section 201(g)(1) that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide regenerator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides; and

"(B) includes a 'radioactive biological product,' which means a biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"(8) REPACKAGE OR REPACKAGING.—The term 'repackage' or 'repackaging'—

"(A) means taking a drug approved under section 505 or licensed under section 351 of the Public Health Service Act from the container in which it is distributed by the original manufacturer and placing it in a different container of the same or smaller size without further manip-

ulating the drug (such as by diluting it or mixing it with another, different drug or drugs); and

"(B) does not include removing the drug from its original container for immediate administration to an identified individual patient, such as withdrawing a drug into a syringe for immediate injection or removing the drug from its original container within a health care entity by a practitioner, or other licensed individual under the supervision or direction of such practitioner, for administration within the same day within such health care entity.

"(9) STERILE DRUG.—The term 'sterile drug' means a drug that is—

"(A) intended for parenteral administration;

"(B) an ophthalmic or oral inhalation drug in aqueous format; or

"(C) required to be sterile under Federal or State law.

"(10) STERILE POOLING.—The term 'sterile pooling'—

"(A) means taking a single sterile drug approved under section 505 from the container in

which it is distributed by the original manufacturer and combining it with the same sterile drug from one or more other containers without or before further manipulating the product (such as by diluting it or mixing it with another, different drug or drugs);

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

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

''(11) TRADITIONAL COMPOUNDER.—

''(A) IN GENERAL.—The term 'traditional compounder' means a facility that does not meet the definition of a compounding manufacturer under paragraph (1) and wherein each drug compounded in that facility is compounded—

''(i) by—

"(I) a licensed pharmacist, or a pharmacy technician working under the supervision of such pharmacist, where permitted by State law, in a State-licensed pharmacy or a licensed Federal facility; or

"(II) a licensed physician or other individual working under the supervision or direction of such physician, where permitted by State law; and

"(ii)(I) upon receipt of a prescription for an identified individual patient;

"(II) before receipt of a prescription for an identified individual patient, only in limited quantities based on a history of the licensed pharmacist or licensed physician receiving a prescription for the compounding of the drug, which orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and—

"(aa) such individual patient for whom the prescription will be provided; or

"(bb) the licensed physician or other licensed practitioner who will write such prescription; or

"(III) for administration within the health care entity where the drug was compounded within the same day, if the drug is compounded by an individual as described in clause (i)(II).

"(B) EXCEPTION REGARDING HOSPITALS AND HEALTH SYSTEMS.—

"(i) HOSPITALS AND HEALTH SYSTEMS.—A pharmacy within a hospital or health system shall be considered a traditional compounder and shall be subject to the requirements of traditional compounders under this section if such pharmacy meets the definition under subparagraph (A)(i) (without regard to clause (ii)) and if, with respect to a drug compounded or pooled by such pharmacy, the only activity conducted by the pharmacy is to dispense or administer such drug (which may include interstate shipment) solely to a patient of such hospital or health system.

"(ii) HEALTH SYSTEM DEFINED.—In this subparagraph, the term 'health system'—

"(I) means an entity that owns and operates—

"(aa) one hospital; or

"(bb) two or more hospitals that have common access to databases with drug order information for patients; and

"(II) includes only the inpatient, outpatient, and ambulatory facilities wholly owned and operated by such entity, and accredited by a national accreditation body approved by the Secretary for purposes of this section.

"(C) EXCEPTION REGARDING OFFICE USE.—

"(i) IN GENERAL.—A pharmacy that compounds a drug for office use (other than a pharmacy that is considered a traditional compounder pursuant to subparagraph (B)) and that otherwise meets the definition in subparagraph (A), is a traditional compounder if—

"(I) in lieu of the prescription for an identified individual patient as described in subparagraph (A)(ii), the pharmacy receives a practitioner order; and

"(II) the pharmacy complies with the requirements described in subsection (g).

"(ii) LIMITATION.—Notwithstanding clause (i), a pharmacy that compounds a sterile drug for office use is not a traditional compounder if the pharmacy does not receive a prescription for an identified individual patient for such sterile drug prior to beginning compounding, and distributes or offers to sell such a compounded sterile drug in interstate commerce.

"(D) EXCEPTION REGARDING INFUSION PHARMACIES.—An infusion pharmacy shall be considered a traditional compounder if such pharmacy meets the definition under paragraph (4) and drugs compounded or pooled by such pharmacy, other than as described in subparagraph (C) of such paragraph, shall be subject

to the requirements of traditional compounders under this section.

''(c) EXEMPTIONS FROM CERTAIN REQUIREMENTS.—

''(1) IN GENERAL.—Except as otherwise provided in paragraphs (2), (3), and (4), a compounded drug shall be subject to all the requirements of this Act applicable to new drugs.

''(2) DRUGS COMPOUNDED BY TRADITIONAL COMPOUNDERS.—Sections 501(a)(2)(B), 502(f)(1), 505, and 582 of this Act and section 351 of the Public Health Service Act shall not apply to a compounded drug if such drug—

''(A) is compounded by a traditional compounder that is in compliance with this section with respect to all drugs compounded at the facility; and

''(B) meets the requirements of this section applicable to drugs compounded by traditional compounders.

''(3) DRUGS COMPOUNDED BY COMPOUNDING MANUFACTURERS.—Sections 502(f)(1), 505, and 582 of this Act and section 351 of the Public Health Service Act shall not apply to a compounded prescription drug, if such prescription drug—

"(A) is compounded by a compounding manufacturer—

"(i) that is not licensed as a pharmacy in any State; and

"(ii) that is in compliance with this section; and

"(B) meets the requirements of this section applicable to drugs compounded by compounding manufacturers.

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

"(A) each radioactive drug is compounded—

"(i) by a licensed pharmacist;

"(ii) solely using one or more radioactive drugs approved under section 505 or licensed under section 351 of the Public Health Service Act, or solely using such drugs and one or more ingredients in compliance with subsection (e)(1)(B); and

"(iii) in compliance with the United States Pharmacopoeia chapters on pharmacy compounding; and

"(B) each nonradioactive drug—

"(i) is compounded in compliance with the requirements of this section that apply to a traditional compounder with respect to all nonradioactive drugs compounded at the facility; and

"(ii) meets the requirements of this section applicable to drugs compounded by traditional compounders.

"(d) DRUGS THAT MAY NOT BE COMPOUNDED.—

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

"(A) DRUGS THAT ARE DEMONSTRABLY DIFFICULT TO COMPOUND.—A drug or category of drugs that presents demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of that drug or category of drugs taking into account the risks and benefits to patients, which may include a complex dosage

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

''(B) MARKETED DRUGS.—A drug (other than a biological product) compounded from bulk drug substances that is a copy of a marketed drug approved under section 505 or a variation of such drug, except as provided in paragraph (3).

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

''(D) DRUGS SUBJECT TO RISK EVALUATION AND MITIGATION STRATEGY.—A copy or variation of a drug approved under section 505 or licensed under section 351 of the Public Health Service Act that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 505–1, except provided in paragraph (5).

''(E) DRUGS REMOVED FOR SAFETY AND EFFICACY.—A drug that appears on a list published by the Secretary in the Federal Register of drugs that have been withdrawn or removed from the market because such drug or compo-

nents of such drug have been found to be unsafe or not effective.

"(2) DRUGS THAT ARE DEMONSTRABLY DIFFICULT TO COMPOUND.—

"(A) IN GENERAL.—The Secretary may promulgate a regulation that designates drugs or categories of drugs described in subparagraph (C).

"(B) INTERIM LIST.—

"(i) IN GENERAL.—Before the effective date of the regulation promulgated under subparagraph (A), the Secretary may designate drugs or categories of drugs described in subparagraph (C), by—

"(I) publishing a notice of such drugs or categories of drugs proposed for designation, including the rationale for such designation, in the Federal Register;

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

"(III) publishing a notice in the Federal Register designating such drugs or categories of drugs that can-

not be compounded, including the rationale for such designation.

''(ii) SUNSET.—Any notice provided under clause (i) shall cease to have force or effect on the date that is 5 years after the date of enactment of the Pharmaceutical Compounding Quality and Accountability Act or on the effective date of the final regulation under subparagraph (A), whichever is earlier.

''(C) DRUGS OR CATEGORIES OF DRUGS.—A drug or category of drugs described in this subparagraph is a drug or category of drugs that may not be compounded, or that may be compounded only under conditions specified by the Secretary, because such drug or category of drugs presents demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of that drug or category of drugs taking into account the risks and benefits to patients. Drugs or categories of drugs that may be so designated include drugs that are complex dosage forms or biological products, such as extended release products (as defined by the

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

''(D) CONSULTATION WITH STAKEHOLDERS.—Prior to making a designation under subparagraph (A) or (B), the Secretary shall consult with relevant stakeholders including pharmacists, professional associations, patient and public health advocacy groups, manufacturers and physicians about the need for the compounded drugs to be included or excluded from the lists of drugs so designated.

''(E) UPDATES TO LIST.—Five years after the effective date of the regulation described in subparagraph (A), and every 5 years thereafter, the Secretary shall publish a Federal Register notice seeking public input about the need for the compounded drugs to be included or excluded from the list of drugs designated under subparagraph (A). Nothing in the previous sentence prohibits notifications or submissions before or during any 5-year period described under such sentence regarding the need for the compounded drugs to be included or excluded from such list.

''(3) EXCEPTIONS REGARDING MARKETED DRUGS.—

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

''(i) such compounding is conducted by a traditional compounder;

''(ii) the compounded variation produces for the identified individual patient a clinical difference between the compounded drug and such marketed drug, as determined by the prescribing practitioner; and

''(iii) prior to compounding such variation, the traditional compounder receives a prescription order for an identified individual patient specifying that the variation may be compounded.

''(B) COPYING MARKETED DRUGS FROM BULK DRUG SUBSTANCES.—

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

505 may be compounded from one or more bulk drug substances only if—

"(I) such marketed drug, at the time of compounding a copy of such drug and at the time of distribution of the compounded drug, is on the drug shortage list under section 506E or has otherwise been identified by the Secretary, in the Secretary's sole discretion, as in shortage, such as in a specific region or on a drug shortage list maintained by a private party;

"(II) the facility compounding the drug submits notice to the Secretary not later than 3 calendar days after beginning the compounding of such drug, identifying the entity compounding the drug and the drug to be compounded under this subparagraph, in a manner (which may include electronic means) that the Secretary determines does not place an undue burden on the compounder;

"(III) in the case of a compounding manufacturer, the

compounding manufacturer has registered under subsection (h)(3) as an entity that intends to compound pursuant to this subparagraph; and

''(IV) at the time of compounding and at the time of distribution of the compounded drug, the drug does not appear on a list of resolved drug shortages established and made publicly available by the Secretary.

''(ii) SINGLE NOTICE.—A single notice submitted under clause (i)(II) shall fulfill such notice requirement until the drug appears on the list described in clause (i)(IV) or for one year after the notice, whichever is sooner. If a drug for which a notice was submitted under clause (i)(II) still fulfills the requirements of clause (i)(I) one year after the notice was submitted, an entity wishing to continue compounding the drug shall submit a new notice in accordance with clause (i)(II).

''(C) NOTICE WAIVER.—The Secretary may waive the notice required under subparagraph (B)(i)(II).''

''(D) LIMITATION REGARDING OFFICE USE.—Notwithstanding subsections (b)(11)(C) and (g), if compounding a variation from bulk drug substances of a marketed drug as described in subparagraph (A), a traditional compounder shall require a prescription for an identified individual patient.

''(E) EXCLUSION.—For purposes of this subsection, repackaging a marketed drug approved under section 505 does not make the repackaged drug a copy of such marketed drug, unless the repackaged drug is also a copy of a marketed approved drug.

''(4) EXCEPTIONS REGARDING BIOLOGICAL PRODUCTS.—

''(A) IN GENERAL.—A drug that is a biological product may be compounded only if—

''(i)(I) such compounded drug is compounded solely using a licensed biological product, or solely using a licensed biological product and one or more ingredients in compliance with subsection (e)(1)(B), in-

tended to dilute the licensed biological product; or

''(II) in the case of a licensed allergenic product, such drug is compounded solely using one or more licensed allergenic products, or solely using one or more licensed allergenic products and one or more ingredients in compliance with subsection (e)(1)(B);

''(ii)(I) such compounded drug produces for the patient a clinical difference between such compounded drug and the licensed biological product, as determined by—

''(aa) the prescribing practitioner (in the case of a drug compounded by a traditional compounder); or

''(bb) a licensed practitioner responsible for the patient's care in a health care entity that provides medical services through licensed practitioners directly to patients (in the case of a drug compounded by a compounding manufacturer); or

"(II) such compounded drug is repackaged from a licensed biological product by a compounding manufacturer;

"(iii) prior to beginning compounding—

"(I) except as provided in subparagraph (B), the traditional compounder receives a prescription for an identified individual patient specifying that the biological product may be compounded for an identified individual patient; or

"(II) the compounding manufacturer receives a practitioner order from a health care entity that provides medical services through licensed practitioners directly to patients, specifying that the biological product may be compounded; and

"(iv) in the case of a radioactive biological product, the compounded drug is compounded by a compounding nuclear pharmacy in accordance with subsection (b)(2).

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

"(i) such compounded drug is a diluted or repackaged variation of the licensed biological product for emergent use in pediatric patients; and

"(ii) such compounded drug produces for the patient a clinical difference between such compounded variation and the licensed biological product, as determined by a licensed practitioner responsible for the patient's care in the hospital or health system.

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

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

"(5) REQUIREMENT FOR DRUGS THAT HAVE RISK EVALUATION AND MITIGATION STRATEGIES.—

"(A) IN GENERAL.—A copy or variation of a drug approved under section 505 or biological product licensed under section 351 of the Public Health Service Act that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 505–1, may be compounded only if—

"(i) the entity compounding the copy or variation receives a prescription for an identified individual patient specifying that the drug or biological product may be compounded; and

"(ii) the entity compounding the copy or variation demonstrates to the Secretary, prior to beginning compounding, that the entity will utilize controls that are comparable to the controls applicable under the relevant risk evaluation and mitigation strategy for the approved drug or licensed biological product.

"(B) EFFECT.—Nothing in this paragraph shall be construed to permit compounding a copy or variation of a drug other than as permitted in paragraphs (3) and (4).

''(e) QUALITY OF DRUG INGREDIENTS.—

''(1) HUMAN DRUGS.—A traditional compounder or a compounding manufacturer shall—

''(A) if compounding a drug from bulk drug substances (as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulations)), use only bulk drug substances—

''(i) that—

''(I) comply with the standards of the applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists and has not been identified under paragraph (2);

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

''(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary that appears on a list developed by the Secretary

through regulations issued by the Secretary;

''(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

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

''(B) use ingredients (other than bulk drug substances) that comply with the standards of the applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists and has not been identified under paragraph (2).

''(2) IDENTIFICATION BY SECRETARY.—

''(A) IN GENERAL.—Notwithstanding the existence of an applicable monograph under subparagraph (A)(i)(I) or (B) of paragraph (1), the Secretary may identify bulk drug substances and ingredients (other than bulk drug substances) that the Secretary determines, based on public health concerns taking into account historical use, reports in peer-reviewed

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

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

"(i) publish a notice of the bulk drug substances and ingredients (other than bulk drug substances) proposed for identification in the Federal Register, including the rationale for such proposal;

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

"(iii) publish a notice in the Federal Register identifying the bulk drug substances and ingredients (other than bulk drug substances) that may not be used in compounding a drug.

"(f) REQUIREMENTS REGARDING WHOLESALING AND LABELING APPLICABLE TO TRADITIONAL COMPOUNDERS AND COMPOUNDING MANUFACTURERS.—A compounded drug—

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

"(2) compounded by a compounding manufacturer may not be sold or transferred to an entity other than a health care entity that provides medical services through licensed practitioners directly to patients, or a network of such providers, except that a compounding manufacturer may transfer without profit a compounded sterile drug to a licensed pharmacy if—

"(A) as of the date of enactment of the Pharmaceutical Compounding Quality and Accountability Act, and at the time of such transfer, the licensed pharmacy falls under the same corporate ownership as the compounding manufacturer;

"(B) the transfer of such compounded sterile drug is solely for the purpose of dispensing the compounded sterile drug to the end user, who has been instructed by the prescribing physician to self-administer such compounded sterile drug;

"(C) as of the date of enactment of the Pharmaceutical Compounding Quality and Ac-

countability Act, and at the time of such transfer, the compounding manufacturer is an entity wholly owned by an entity that provides pharmacy benefits management services on behalf of a health benefits plan;

''(D) the compounding manufacturer identifies itself to the Secretary upon registering under subsection (h)(3) as an entity that qualifies for the exception under this paragraph, and provides documentation of the compounding of such drugs as of the date of enactment of the Pharmaceutical Compounding Quality and Accountability Act, in a manner described by the Secretary; and

''(E) the compounding manufacturer receives confirmation from the Secretary that the compounding manufacturer qualifies for the exception under this paragraph and the sterile drug or drugs for which the exemption applies; and

''(3) offered for sale shall be labeled 'not for resale'.

''(g) OFFICE USE REQUIREMENTS APPLICABLE TO CERTAIN TRADITIONAL COMPOUNDERS.—

"(1) IN GENERAL.—Pursuant to subsection (b)(11)(C), a traditional compounder may not dispense a compounded drug to a health care entity for office use unless such traditional compounder meets the following requirements:

"(A) In any 30 day period, of the total drugs dispensed pursuant to practitioner orders and prescriptions for identified individual patients, no more than 10 percent may be dispensed pursuant to practitioner orders.

"(B) The traditional compounder shall receive the names of each patient who received a drug dispensed to a provider pursuant to a practitioner order, or, if not all of the drug was administered, confirmation that the remaining drug was not administered, not later than 14 days after such drug was dispensed to such provider.

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

"(D) The label of a drug compounded pursuant to a practitioner order shall include—

"(i) the statement 'Office Use Only' and the statement 'Not for Resale' (as required under subsection (f)(3)); and

"(ii) the statement 'Use within 14 days of _____' with the date of dispensing filled in the blank, unless a shorter beyond use or expiration date applies, in which case such shorter period shall be included on the label.

"(2) SAFE HARBOR.—

"(A) TOTAL DRUGS DISPENSED.—For purposes of paragraph (1)(A), the total drugs dispensed and the amount of drugs dispensed via practitioner orders shall be determined based on the number of identified individual patient prescriptions and a reasonable estimate of the number of patients to whom each drug dispensed pursuant to a practitioner order would be administered.

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

compounder fails to receive names or confirmation described in paragraph (1)(B) for practitioner orders that were filled for the same practitioner on multiple occasions.

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

''(4) PUBLIC HEALTH EMERGENCY.—The Secretary may waive the requirements under paragraph (1)(B) for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act.

''(h) OTHER REQUIREMENTS APPLICABLE TO COMPOUNDING MANUFACTURERS.—

''(1) LICENSED PHARMACIST OVERSIGHT.—A compounding manufacturer shall ensure that a pharmacist licensed in the State where the compounding manufacturer is located exercises direct supervision over the operations of the compounding manufacturer.

''(2) COMPOUNDING OF NON-STERILE DRUGS.—

"(A) IN GENERAL.—A compounding manufacturer may not compound a non-sterile drug, except as provided in this paragraph.

"(B) LIST BY SECRETARY.—The Secretary shall establish a list of non-sterile drugs that may be compounded by a compounding manufacturer.

"(C) CONSIDERATIONS.—In establishing and updating the list under this paragraph, the Secretary shall—

"(i) reference the drugs and other information identified under subclauses (I) and (II) of paragraph (3)(B)(i) and submitted in an initial registration report under such paragraph; and

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

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

"(i) publish a notice of such non-sterile drugs proposed for identification in the

Federal Register, including the rationale for such proposal;

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

"(iii) publish a notice in the Federal Register identifying the non-sterile drugs that may be compounded by a compounding manufacturer.

"(E) TRANSITION RULE.—Until the date the Secretary publishes the first notice described under subparagraph (D)(iii), a compounding manufacturer may compound a non-sterile drug.

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

need for non-sterile drugs to be included or excluded from the list.

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

''(3) REGISTRATION OF COMPOUNDING MANUFACTURERS AND REPORTING OF DRUGS.—

''(A) REGISTRATION OF COMPOUNDING MANUFACTURERS.—

''(i) ANNUAL REGISTRATION.—During the period beginning on October 1 and ending on December 31 each year, each compounding manufacturer shall register with the Secretary its name, place of business, and unique facility identifier (which shall conform to the requirements for the unique facility identifier established under section 510), and a point of contact e-mail address, and shall indicate whether the compounding manufacturer intends to compound a drug in shortage pursuant to subsection (d)(3)(A)(ii).

"(ii) NEW COMPOUNDING MANUFACTURERS.—Each compounding manufacturer, upon first engaging in the operations described in subsection (b)(1), shall immediately register with the Secretary and provide the information described under clause (i). The Secretary shall establish a timeline for registration for the first year following the effective date of the Pharmaceutical Compounding Quality and Accountability Act. In no case may registration be required until at least 60 calendar days following publication of the timeline in the Federal Register.

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

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

"(II) LIST.—The Secretary shall make available on the Internet Web site of the Food and Drug Administration a list of the name of each fa-

cility registered under this subsection as a compounding manufacturer, the State in which each such compounding manufacturer is located, whether the compounding manufacturer compounds from bulk drug substances as described in subsection (e)(1)(A), and whether any such compounding from bulk drug substances is for sterile or non-sterile drugs.

''(B) DRUG REPORTING BY COMPOUNDING MANUFACTURERS.—

''(i) IN GENERAL.—Each compounding manufacturer who registers with the Secretary under subparagraph (A) shall submit to the Secretary, upon initially registering as a compounding manufacturer under subparagraph (A)(ii) and once during the month of June of each year and once during the month of December of each year, a report—

''(I) identifying the drugs compounded by such compounding manu-

facturer during the previous 6-month period; and

"(II) with respect to each drug identified under subclause (I), providing the active ingredient, the source of such active ingredient, the National Drug Code number, if available, of the source drug or bulk active ingredient, the strength of the active ingredient per unit, the dosage form and route of administration, the package description, the number of individual units produced, and the National Drug Code number of the final product, if assigned.

"(ii) FORM.—Each report under clause (i) shall be prepared in such form and manner as the Secretary may prescribe by regulation or guidance.

"(iii) CONFIDENTIALITY.—Reports submitted pursuant to this subparagraph shall be exempt from inspection under subparagraph (A)(iii), unless the Secretary finds that such an exemption would be in-

consistent with the protection of the public health.

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

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

''(i) IN GENERAL.—Compounding manufacturers shall be subject to inspection pursuant to section 704.

''(ii) RISK-BASED SCHEDULE.—The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect compounding manufacturers described in clause (i) in accordance with a risk-based schedule established by the Secretary.

''(iii) RISK FACTORS.—In establishing the risk-based schedule under clause (ii), the Secretary shall inspect compounding

manufacturers according to the known safety risks of such compounding manufacturers, which shall be based on the following factors:

''(I) The compliance history of the compounding manufacturer.

''(II) The record, history, and nature of recalls linked to the compounding manufacturer.

''(III) The inherent risk of the drug compounded at the compounding manufacturer.

''(IV) The inspection frequency and history of the compounding manufacturer, including whether the compounding manufacturer has been inspected pursuant to section 704 within the last 4 years.

''(V) Whether the compounding manufacturer has registered under this paragraph as an entity that intends to compound pursuant to subsection (d)(3)(A)(ii).

''(VI) Any other criteria deemed necessary and appropriate by the Sec-

retary for purposes of allocating inspection resources.

"(4) ADVERSE EVENT REPORTING.—

"(A) DEFINITIONS.—In this paragraph:

"(i) ADVERSE EVENT.—The term 'adverse event' means any health-related event associated with the use of a compounded drug that is adverse, including—

"(I) an event occurring in the course of the use of the drug in professional practice;

"(II) an event occurring from an overdose of the drug, whether accidental or intentional;

"(III) an event occurring from abuse of the drug;

"(IV) an event occurring from withdrawal of the drug; and

"(V) any failure of expected pharmacological action of the drug.

"(ii) SERIOUS ADVERSE EVENT.—The term 'serious adverse event' means an adverse event that—

"(I) results in—

"(aa) death;

"(bb) an adverse drug event that places the patient at immediate risk of death from the adverse drug event as it occurred (not including an adverse drug event that might have caused death had it occurred in a more severe form);

"(cc) inpatient hospitalization or prolongation of existing hospitalization;

"(dd) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or

"(ee) a congenital anomaly or birth defect; or

"(II) based on appropriate medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent an outcome described in subclause (I).

"(B) REPORTS.—

"(i) SERIOUS ADVERSE EVENT REPORTING REQUIREMENT.—

"(I) 15-DAY REPORT.—If a compounding manufacturer becomes aware of any serious adverse event, such manufacturer shall submit reports of each instance to the Secretary as soon as practicable, but in no case later than 15 calendar days after the initial receipt of the applicable information. Such manufacturer shall investigate and submit to the Secretary followup reports for each such instance not later than 15 calendar days after receipt of new information or as requested by the Secretary. Unless and until the Secretary establishes the content and format of adverse event reports by guidance or regulation, reports shall be submitted in accordance with the content and format requirements under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations) or section 600.80 of title 21, Code of Federal Regulations (or any successor regulations).

"(II) ANNUAL REPORT.—Compounding manufacturers that report serious adverse events shall submit in December of each year a narrative summary of any analysis of each report submitted under subclause (I), including a history of actions taken during the year because of each report, using the content, format, and manner established by the Secretary by guidance or regulation. Until such time as the Secretary publishes such guidance or regulation, each compounding manufacturer shall retain such summaries as part of the records to be maintained in accordance with subparagraph (C).

"(ii) PRODUCT QUALITY REPORTING REQUIREMENT.—Not later than 3 calendar days after the compounding manufacturer becomes aware of information pertaining to sterility, stability, or other product quality concerns that could result in serious adverse events, the compounding manufacturer shall submit to the Secretary a prod-

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

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

''(5) LABELING OF DRUGS.—

''(A) LABEL.—The label of a drug compounded by a compounding manufacturer shall include—

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

''(ii) the name, address, and phone number of the applicable compounding manufacturer; and

''(iii) with respect to the compounded drug—

"(I) the lot or batch number;

"(II) the established name of the medication;

"(III) the dosage form and strength;

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

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

"(VI) the expiration date;

"(VII) storage and handling instructions;

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

"(IX) the 'not for resale' statement as required by subsection (f)(3); and

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

"(B) CONTAINER.—The container from which the individual units of a drug compounded by a compounding manufacturer are

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

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

"(ii) the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088; and

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

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

"(i) COMPOUNDING MANUFACTURER ESTABLISHMENT AND REINSPECTION FEES.—

"(1) DEFINITIONS.—In this subsection—

"(A) the term 'affiliate' has the meaning given such term in section 735(11);

"(B) the term 'gross annual sales' means the total worldwide gross annual sales, in

United States dollars, for a compounding manufacturer, including the sales of all the affiliates of the compounding manufacturer; and

"(C) the term 'reinspection' means, with respect to a compounding manufacturer, 1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified noncompliance materially related to an applicable requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.

"(2) ESTABLISHMENT AND REINSPECTION FEES.—

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

"(i) an annual establishment fee from each compounding manufacturer; and

"(ii) a reinspection fee from each compounding manufacturer subject to a reinspection in such fiscal year.

"(B) MULTIPLE REINSPECTIONS.—A compounding manufacturer subject to multiple

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

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

"(4) AMOUNT OF ESTABLISHMENT FEE AND REINSPECTION FEE.—

"(A) IN GENERAL.—For each compounding manufacturer in a fiscal year—

"(i) except as provided in subparagraph (D), the amount of the annual establishment fee under paragraph (2) shall be equal to the sum of—

"(I) $15,000, multiplied by the inflation adjustment factor described in subparagraph (B); plus

"(II) the small business adjustment factor described in subparagraph (C); and

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

"(B) INFLATION ADJUSTMENT FACTOR.—

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

"(I) one;

"(II) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food

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

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

"(ii) COMPOUNDED BASIS.—The adjustment made each fiscal year under clause (i) shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under clause (i).

"(C) SMALL BUSINESS ADJUSTMENT FACTOR.—The small business adjustment factor re-

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

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

"(ii) the adjustment to the establishment fee necessary to achieve total fees equaling the total fees that the Secretary would have collected if no entity qualified for the small business exception in subparagraph (D).

"(D) EXCEPTION FOR SMALL BUSINESSES.—

"(i) IN GENERAL.—In the case of a compounding manufacturer with gross annual sales of $1,000,000 or less in the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which the fees under this subsection are assessed, the amount of the establishment fee under paragraph (2) for a fiscal year shall be equal to ⅓ of the amount cal-

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

''(ii) APPLICATION.—To qualify for the exception under this subparagraph, a small business shall submit to the Secretary a written request for such exception, in a format specified by the Secretary in guidance, certifying its gross annual sales for the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which fees under this subsection are assessed. Any such application must be submitted to the Secretary not later than April 30 for the following fiscal year. Any statement or representation made to the Secretary shall be subject to section 1001 of title 18, United States Code.

''(E) CREDITING OF FEES.—In establishing the small business adjustment factor under subparagraph (C) for a fiscal year, the Secretary shall provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of the small business adjustment factor for such previous fiscal year, and consider the need to ac-

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

''(5) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to clauses (i) and (ii) of paragraph (2)(A) available solely to pay for the costs of oversight of compounding manufacturers.

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

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

''(8) COLLECTION OF FEES.—

''(A) ESTABLISHMENT FEE.—A compounding manufacturer shall remit the establishment fee due under this subsection in a fiscal year when submitting a registration pursuant to subsection (h) for such fiscal year.

''(B) REINSPECTION FEE.—The Secretary shall specify in the Federal Register notice described in paragraph (3) the manner in which reinspection fees assessed under this subsection shall be collected and the timeline for payment of such fees. Such a fee shall be collected after the Secretary has conducted a reinspection of the compounding manufacturer involved.

''(C) EFFECT OF FAILURE TO PAY FEES.—

''(i) REGISTRATION.—A compounding manufacturer shall not be considered registered under subsection (h) in a fiscal year until the date that the compounding manufacturer remits the establishment fee under this subsection for such fiscal year.

''(ii) MISBRANDING.—All drugs manufactured, prepared, propagated, compounded, or processed by a compounding manufacturer for which any establishment

fee or reinspection fee has not been paid as required by this subsection shall be deemed misbranded under section 502(cc) until the fees owed for such compounding manufacturer under this subsection have been paid.

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

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

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

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

''(j) ACTION BY SECRETARY REGARDING COMPLAINTS FROM STATE BOARDS OF PHARMACY.—

''(1) IDENTIFICATION OF COMPOUNDING MANUFACTURERS.—The Secretary shall encourage States to identify to the Secretary any facility that is licensed by a State as a pharmacy that appears to be an entity that is required to be registered with the Secretary as a compounding manufacturer.

''(2) DESIGNATION.—The Secretary shall designate a point of contact and establish a format and procedure for a State Board of Pharmacy to notify the Secretary if it appears to a State Board of Pharmacy that an entity licensed by a State as a pharmacy is required to be registered with the Secretary as a compounding manufacturer.

''(3) DETERMINATION.—If the Secretary determines that such an entity described in paragraph (2)

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

''(4) EFFECT.—The Secretary shall encourage direct communications between States regarding traditional compounders. Nothing in this subsection shall expand the Secretary's authority over or responsibility for traditional compounders.''.

(c) REPORTS BY GAO.—

(1) REPORT ON HEALTH SYSTEM COMPOUNDING.—

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

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

(i) What types of drugs are compounded in high volumes inside hospitals and health systems? And of those drugs, which are sterile?

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

(iii) How often are hospital and health system pharmacies being inspected by Federal or State authorities, or the applicable designees of those authorities? How does this compare to the inspection frequency of other traditional pharmacies?

(iv) How do hospital and health systems monitor the quality and effectiveness of their internally compounded drugs?

(v) How many adverse events, violations, or citations were issued associated with drugs compounded under section 503A(b)(11)(B) of the Federal Food, Drug, and Cosmetic Act (as added by this Act).

(vi) Are hospitals or health systems taking ownership of stand-alone sterile compounding operations, which would otherwise be compounding manufacturers, that compound drugs for the use in such hospital or health system?

(C) CONSULTATION WITH STAKEHOLDERS.—In conducting the study under this paragraph, the Comptroller General shall consult with relevant stakeholders, including physicians, compounding manufacturers, pharmacists, hospitals, patients, public health groups, professional associations, and other health providers.

(D) REPORT.—Not later than July 31, 2016, the Comptroller General shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the results of the study under this paragraph, including a summary of any trends in the quantity and sources of compounded drugs used in hospitals (including the number of hospitals that contract with external pharmacies).

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

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

(1) in subsection (e), by striking ''417, 416, 504'' and inserting ''417, 416, 503A(h), 504''; and

(2) by adding at the end the following:

''(ccc)(1) The resale of a compounded drug that is labeled 'not for resale' as required by section 503A.

''(2) The failure to register in accordance with subsection (h) of section 503A or the failure to submit a report as required by subsection (h)(3)(B) or (h)(4) of such section.

''(3) With respect to a drug to be compounded under section 503A, the intentional falsification of a prescription, a practitioner order (as defined in subsection (b)(6) of such section), or name required under subsection (g)(1)(B) of such section 503A.

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

the dispensing of such compounded drug in a manner inconsistent with subsection (g)(1) of such section.''.

SEC. 103. OTHER REQUIREMENTS.

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

''(bb) If it is a compounded drug and the labeling does not include the information as required by subsections (f)(3), (g)(1), and (h)(5) of section 503A, as applicable.

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

''(dd) If it is a drug, and it was manufactured, prepared, propagated, compounded, or processed by a compounding manufacturer for which fees have not been paid as required by section 503A(h).''.

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

''The exemption in subparagraph (A) does not apply with respect to compounding manufacturers (as such term is defined in section 503A).''.

SEC. 104. IMPLEMENTATION.

(a) CONSULTATION WITH STAKEHOLDERS.—In implementing this title (and the amendments made by this

title), the Secretary of Health and Human Services shall consult with relevant stakeholders including pharmacists, professional associations, patient and public health advocacy groups, manufacturers and physicians.

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

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

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

(3) publish the final regulation not more than 18 months following publication of the proposed rule and not less than 30 calendar days before the effective date of such final regulation.

SEC. 105. EFFECTIVE DATE.

This title (and the amendments made by this title) shall take effect on the date that is 1 year after the date of enactment of this Act.

TITLE II—DRUG SUPPLY CHAIN SECURITY

SEC. 201. SHORT TITLE.

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

SEC. 202. PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

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

''Subchapter H—Pharmaceutical Distribution Supply Chain

''SEC. 581. DEFINITIONS.

''In this subchapter:

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

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

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

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

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

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

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

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

''(3) DISPENSER.—The term 'dispenser'—

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

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

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

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

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

"(6) EXCLUSIVE DISTRIBUTOR.—The term 'exclusive distributor' means the wholesale distributor

that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

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

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

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

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

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

''(D) appears otherwise unfit for distribution such that the product 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 in accordance with section 503(e) or section 582(a)(6), as applicable;

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

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

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

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

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

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

"(11) PACKAGE.—

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

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

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

"(13) PRODUCT.—The term 'product' means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 582, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Fed-

eral 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), an intravenous product described in clause xiv, xv, or xvi of paragraph (23), any medical gas (as defined in section 575),), homeopathic drugs marketed in accordance with applicable guidance under this Act, or a drug compounded in compliance with section 503A.

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

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

''(16) REPACKAGER.—The term 'repackager' means a person who owns or operates an establish-

ment that repacks and relabels a product or package for—

"(A) further sale; or

"(B) distribution without a further transaction.

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

"(18) RETURNS PROCESSOR OR REVERSE LOGISTICS PROVIDER.—The term 'returns processor' or 'reverse logistics provider' means a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

"(19) SPECIFIC PATIENT NEED.—The term 'specific patient need' refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one phar-

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

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

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

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

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

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

''(D) appears otherwise unfit for distribution such that the product would result in seri-

ous 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 or within a manufacturer;

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

''(iii) the distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

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

''(v) the distribution of product samples by a manufacturer or a licensed

wholesale distributor in accordance with section 503(d);

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

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

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

''(ix) the distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;

"(x) the dispensing of a product approved under section 512(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 not subject to approval under section 505 or licensure under section 351 of the Public Health Service Act, and that is—

"(I) a product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or 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 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, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this clause as a 'medical convenience kit') if—

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

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

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

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

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

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

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

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

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

"(dd) an anesthetic;

"(ee) an anticoagulant;

"(ff) a vasopressor; or

"(gg) a sympathicomimetic;

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

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

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

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

"(xviii) the distribution or sale of any licensed product under section 351 of the

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

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

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

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

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

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

''(D) the container size;

''(E) the number of containers;

''(F) the lot number of the product;

''(G) the date of the transaction;

''(H) the date of the shipment, if 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, transaction history, and transaction statements, in paper or electronic format, for compliance with subsections (a), (b), (c), (d), (e), and (f). In establishing such standards, the Secretary shall consider the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data. The standards established under this paragraph shall take into consideration the standards established under section 505D and shall comply

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

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

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

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

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

"(i) establish a process by which an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a waiver from any of the requirements set forth in this section if the Sec-

retary determines that such requirements would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act;

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

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

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

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

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

''(5) GRANDFATHERING PRODUCT.—

''(A) PRODUCT IDENTIFIER.—Not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall finalize guidance specifying whether and under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of this section shall be exempted from the requirements of this section.

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

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

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

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

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

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

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

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

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

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

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

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

''(b) MANUFACTURER REQUIREMENTS.—

''(1) PRODUCT TRACING.—

''(A) IN GENERAL.—Beginning not later than 1 year after the date of enactment of the Drug Supply Chain Security Act, a manufacturer shall—

''(i)(I) prior to, or at the time of, each transaction in which such manufacturer transfers ownership of a product, provide the subsequent recipient with transaction history, transaction information, and a transaction statement, in a single document in an electronic or paper format; and

''(II) prior to, or at the time of, each transaction in which such manufacturer transfers 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.

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

ment of the Drug Supply Chain Security Act, a manufacturer shall provide the transaction information, transaction history, and transaction statement required under subclauses (I) and (II) of subparagraph (A)(i) in electronic form.

''(2) PRODUCT IDENTIFIER.—

''(A) IN GENERAL.—Beginning not later than 4 years after the date of enactment of the Drug Supply Chain Security Act, a manufacturer shall affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce. Such manufacturer shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction.

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

''(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than 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, including the standardized numerical identifier.

''(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 prod-

uct, 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 Federal or State official), as necessary and appropriate.

"(ii) MAKING A NOTIFICATION.—

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

"(II) HIGH RISK OF ILLEGITIMACY.—A manufacturer shall notify the Secretary and immediate trading partners that the manufacturer has reason to believe may have in the trading partner's possession a product manufactured by, or purported to be a product manufactured by, the manufacturer not later than 24 hours after determining or being notified by the Secretary or a trading partner that there is a high risk that such product is an illegitimate product. For pur-

poses 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 manufacturer shall promptly notify immediate trading partners that the manufacturer no-

tified pursuant to clause (ii) that such notification has been terminated.

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

''(C) REQUESTS FOR VERIFICATION.—Beginning 4 years after the date of enactment of the Drug Supply Chain Security Act, upon receiving a request for verification from an authorized repackager, wholesale distributor, or dispenser that is in possession or control of a product such person believes to be manufactured by such manufacturer, a manufacturer shall, not later than 24 hours after receiving the verification request or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the person making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by the 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 request submitted by means other than a secure electronic database.

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

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

"(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

"(1) PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning not later than 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 his-

tory and transaction information shall not be required to include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer (as defined in subparagraphs (F), (G), and (H) of section 581(26)).

''(iii) If the wholesale distributor did not purchase a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, as described in clause (ii), then prior to, or at the time of, each transaction or subsequent transaction, the wholesale distributor shall provide to the subsequent purchaser a transaction statement, transaction history, and transaction information, in a paper or electronic format that complies with the guidance document issued under subsection (a)(2).

''(iv) For the purposes of clause (iii), the transaction history supplied shall begin only with the wholesale distributor described in clause (ii)(I), but the wholesale distributor described in clause (iii) shall in-

form the subsequent purchaser that such wholesale distributor received a direct purchase statement from a wholesale distributor described in clause (ii)(I).

"(v) A wholesale distributor shall—

"(I) 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; and

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

"(B) RETURNS.—

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

"(I) REQUIREMENTS.—Until the date that is 6 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager pursuant to the terms and 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 provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate returned product with the transaction information and transaction statement associated with that product. For all transactions after such date, the transaction history, as applicable, of such product shall begin with the wholesale distributor that accepted and verified the returned product. For purposes of this subparagraph, the transaction information and transaction history, as applicable, need not include transaction dates if it is not reasonably practicable to obtain such dates.

''(ii) NONSALEABLE RETURNS.—A wholesale distributor may return a nonsaleable 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 returns processor, without providing the information required under subparagraph (A)(i).

''(C) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product a wholesale distributor shall, not later than 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.

''(D) TRADING PARTNER AGREEMENTS.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, a wholesale distributor may disclose the transaction information, including lot level information, transaction history, or transaction statement of a product to the subsequent purchaser of the product, pursuant to a written agreement

between such wholesale distributor and such subsequent purchaser.

''(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, including the standardized numerical identifier.

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

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

''(B) ILLEGITIMATE PRODUCT.—

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

''(I) quarantine such product within the possession or control of the

wholesale distributor from product intended for distribution until such product is dispositioned;

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

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

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

''(ii) MAKING A NOTIFICATION.—Upon determining that a product in the possession or control of the wholesale distributor is an illegitimate product, the wholesale distributor shall notify the Sec-

retary 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 wholesale 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 dis-

tributor 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, including the standardized numerical identifier, for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier, including the standardized numerical identifier, on each package.

''(d) DISPENSER REQUIREMENTS.—

''(1) PRODUCT TRACING.—

''(A) IN GENERAL.—Beginning 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 (A).

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

"(D) REQUESTS FOR INFORMATION.—

"(i) IN GENERAL.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect or an illegitimate product, a dispenser shall, not later than 2 business days after receiving the request or in another such reasonable time as determined by the Secretary, based on the circumstances of the

request, provide the applicable transaction information, transaction statement, and transaction history which the dispenser received from the previous owner, which shall not include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer unless such information was included in the transaction information, transaction statement, and transaction history provided by the manufacturer or wholesale distributor to the dispenser. The dispenser may respond to the request by providing the applicable information in either paper or electronic format.

''(ii) EXCEPTION.—Until the date that is 4 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall grant a dispenser additional time, as necessary, only with respect to a request described in clause (i) to provide lot level information that was provided to the dispenser in paper format.

''(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, including the standardized numerical identifier, of at least 3 packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than 3, corresponds

with the product identifier for such product;

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

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

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

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

"(B) ILLEGITIMATE PRODUCT.—

"(i) IN GENERAL.—Upon determining, in coordination with the manufacturer, that a product in the possession or

control of a dispenser is an illegitimate product, the dispenser shall—

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

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

imate 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 described in section 581(16)(A) shall—

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

''(ii) prior to, or at the time of, each transaction in which the repackager transfers ownership of a product, 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) RETURNS.—

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

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

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

''(C) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a repackager described in section 581(16)(A) shall, not later than 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.—

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

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

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

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

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

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

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

''(3) AUTHORIZED TRADING PARTNERS.—Beginning 1 year after the date of enactment of the Drug Supply Chain Security Act, the trading part-

ners of a repackager described in section 581(16) 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 described in section 581(16)(A) shall have systems in place to enable the repackager to comply with the following requirements:

''(A) SUSPECT PRODUCT.—

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

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

''(II) promptly conduct an investigation in coordination with trading

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

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

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

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

''(B) ILLEGITIMATE PRODUCT.—

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

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

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

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

''(IV) retain a sample of the product for further physical examina-

tion 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 subse-

quently 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 the date of enactment of the Drug Supply Chain Security Act, upon receiving a request for verification from an authorized manufacturer, wholesale distributor, or dispenser that is in possession or control of a product they believe to be repackaged by such repackager, a repackager shall, not later than 24 hours after receiving the verification request or in other such reasonable time as determined by the Secretary, based on the circumstances of

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

''(D) ELECTRONIC DATABASE.—A repackager may satisfy the requirements of paragraph (4) by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain,

as appropriate. The development and operation of such a database shall not relieve a repackager of the requirement under subparagraph (C) to respond to a verification request 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 part-

ners 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 logis-

tics 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.—

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

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

SEC. 203. ENHANCED DRUG DISTRIBUTION SECURITY.

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

''(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, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (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 informa-

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

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

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

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

"(2) COMPLIANCE.—

"(A) INFORMATION MAINTENANCE AGREEMENT.—A dispenser may enter into a written

agreement with a third party, including an authorized wholesale distributor, under which the third party shall confidentially maintain any information and statements required to be maintained under this section. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection.

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

''(i) establishing timelines for compliance by small businesses (including small business dispensers with 25 or fewer full time employees) with such requirements, in order to ensure that such requirements do not impose undue economic hardship for small businesses, including small business dispensers for whom the criteria set forth in the assessment under paragraph (3) is not met, if the Secretary determines that

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

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

"(3) ASSESSMENT.—

"(A) IN GENERAL.—Not later than the date that is 18 months after the Secretary issues the final guidance required under subsection (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 employees conducting interoperable, electronic tracing of products at the package level. In no case may such assessment commence later than 7½ 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 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 subpara-

graph (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 and private sector pilot projects, including those involving the use of aggregation and inference;

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

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

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

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

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

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

"(D) publish 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 the date of enactment of the Drug Supply Chain Security Act, the Secretary shall issue a guidance document to aid trading partners in the identification of a suspect product and notification termination. Such guidance document shall—

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

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

and make a determination 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)(4)(B).

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

"(3) UNIT LEVEL TRACING.—

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

ommendations with respect to the system attributes necessary to enable secure tracing 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 secure processes to facilitate the use of inference, enhanced verification activities, the use of aggregation and inference, processes that utilize the product identifiers to enhance tracing of product at the package level, including

the standardized numerical identifier, or package security features; and

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

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

"(4) STANDARDS FOR INTEROPERABLE DATA EXCHANGE.—

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

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

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

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

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

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

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

"(5) PROCEDURE.—In issuing or revising any guidance issued pursuant to this subsection or subsection (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 an-

nouncing that the draft or revised draft guidance is available;

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

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

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

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

"(F) post the final guidance document on the Internet Website 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 safe-

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

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

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

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

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

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

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

''(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, including any pilot projects that use aggregation and inference, 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 subsections (b)(4)(E), (c)(1)(B)(i), (d)(1)(C)(i), and (e)(4)(E).

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

''(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 pre-

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

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

(a) AMENDMENTS.—

(1) LICENSE REQUIREMENT.—Section 503(e) (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, address, and contact information 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 estab-

lish 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) (21 U.S.C. 353(e)), as amended by paragraph (1), is further amended by adding at the end the following:

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

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

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

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

"(D) the dispensing of a drug pursuant to a prescription executed in accordance with 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) salable drug returns when conducted by a dispenser;

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

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

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

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

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

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

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

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

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

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

"(IV) an anesthetic;

"(V) an anticoagulant;

"(VI) a vasopressor; or

"(VII) a sympathicomimetic;

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

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

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

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

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

"(S) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section 581(16)(B) and registered under section 510 for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.".

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

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

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

''(6) AFFILIATE.—For purposes of this subsection, the term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

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

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

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

"SEC. 583. NATIONAL LICENSURE STANDARDS FOR PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS.

''(a) IN GENERAL.—The Secretary shall, not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, establish by regulation 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 the following:

''(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, as follows:

''(A)(i) For the issuance or renewal of a wholesale distributor license, an applicant that is not a government owned and operated wholesale distributor shall submit a surety bond of

$100,000 or other equivalent means of security acceptable to the State.

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

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

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

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

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

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

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

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

''(1) has been convicted of any felony for conduct relating to wholesale distribution, any felony violation of subsection (i) or (k) of section 301, or any felony violation of section 1365 of title 18, United States Code, relating to product tampering; or

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

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

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

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

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

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

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

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

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

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

"SEC. 584. NATIONAL 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 logistics provider is not licensed by the Secretary as described in paragraph (1)(B).

''(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 license, to third-party logistics providers under this section.

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

''(A) establish a process by which a third-party accreditation program approved by the

Secretary shall, upon request by a third-party logistics provider, issue a license to each third-party logistics provider that meets the 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 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, not-

withstanding 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 products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product

as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or 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 pursuant to 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 prescription drug distributor or third-party logistics provider licensure that are less stringent than the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

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

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

''(4) ENFORCEMENT, SUSPENSION, AND REVOCATION 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. 206. PENALTIES.

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

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

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

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

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

SEC. 207. CONFORMING AMENDMENT.

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

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

SEC. 208. SAVINGS CLAUSE.

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