

113TH CONGRESS
1ST SESSION

S. 957

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

IN THE SENATE OF THE UNITED STATES

MAY 15, 2013

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

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Drug Supply Chain
5 Security Act”.

6 **SEC. 2. PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.**

7 Chapter V of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 351 et seq.) is amended by adding at the
9 end the following:

1 **“Subchapter H—Pharmaceutical Distribution**
2 **Supply Chain**

3 **“SEC. 581. DEFINITIONS.**

4 “In this subchapter:

5 “(1) AUTHORIZED.—The term ‘authorized’
6 means—

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

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

16 “(C) in the case of a third-party logistics
17 provider, having a valid license under State law
18 or section 584(a)(1), in accordance with section
19 582(a)(7) and complying with the licensure re-
20 porting requirements under section 584(b); and

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

23 “(2) COMPRESSED MEDICAL GAS.—The term
24 ‘compressed medical gas’ means any substance in its
25 gaseous or cryogenic liquid form that meets medical

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

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

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

14 “(B) does not include a person who only
15 dispenses products to be used in animals in ac-
16 cordance with section 512(a)(5).

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

1 or laboratory analysis of the product by a manufac-
2 turer or regulatory or law enforcement agency.

3 “(5) DISTRIBUTE OR DISTRIBUTION.—The
4 term ‘distribute’ or ‘distribution’ means the sale,
5 purchase, trade, delivery, handling, storage, or re-
6 ceipt of a product.

7 “(6) EXCLUSIVE DISTRIBUTOR.—The term ‘ex-
8 clusive distributor’ means the wholesale distributor
9 that directly purchased product from the manufac-
10 turer and is the sole distributor of that manufactur-
11 er’s product to a subsequent wholesale distributor or
12 dispenser.

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

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

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

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

24 “(C) is the subject of a fraudulent trans-
25 action; or

1 “(D) appears otherwise unfit for distribu-
2 tion such that the product could result in seri-
3 ous adverse health consequence or death to hu-
4 mans.

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

6 “(A) in the case of a wholesale distributor,
7 having a valid license under State law or sec-
8 tion 583, in accordance with section 582(a)(6);

9 “(B) in the case of a third-party logistics
10 provider, having a valid license under State law
11 or section 584(a)(1), in accordance with section
12 582(a)(7); and

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

15 “(10) MANUFACTURER.—

16 “(A) IN GENERAL.—The term ‘manufac-
17 turer’ means, with respect to a product—

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

1 “(ii) a co-licensed partner of the per-
2 son described in clause (i) that obtains the
3 product directly from the person described
4 in clause (i) or (ii); or

5 “(iii) an affiliate of a person described
6 in clause (i) or (iii) that receives the prod-
7 uct directly from a person described in
8 clause (i), (ii), or (iii).

9 “(B) AFFILIATE.—For purposes of this
10 paragraph, the term ‘affiliate’ means a member
11 of an affiliated group, as that term is defined
12 in section 1504(a) of the Internal Revenue
13 Code.

14 “(11) PACKAGE.—

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

21 “(B) INDIVIDUAL SALEABLE UNIT.—For
22 purposes of this paragraph, an ‘individual sale-
23 able unit’ is the smallest container of product
24 introduced into commerce by the manufacturer
25 or repackager that is intended by the manufac-

1 turer or repackager for individual sale to a dis-
2 penser.

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

6 “(13) PRODUCT.—The term ‘product’ means a
7 prescription drug in a finished dosage form for ad-
8 ministration to a patient without substantial further
9 manufacturing (such as capsules, tablets, and
10 lyophilized products before reconstitution), but does
11 not include blood or blood components intended for
12 transfusion, radioactive drugs or radioactive biologi-
13 cal products (as defined in section 600.3(ee) of title
14 21, Code of Federal Regulations) that are regulated
15 by the Nuclear Regulatory Commission or by a State
16 pursuant to an agreement with such Commission
17 under section 274 of the Atomic Energy Act of 1954
18 (42 U.S.C. 2021), or any compressed medical gas.

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

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

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

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

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

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

1 purchaser, manufacturer, or seller or disposed of for
2 no further distribution.

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

10 “(20) STANDARDIZED NUMERICAL IDENTIFIER
11 OR SNI.—The term ‘standardized numerical identi-
12 fier’ or ‘SNI’ means a set of numbers or characters
13 used to uniquely identify each package or homoge-
14 nous case that is composed of the National Drug
15 Code that corresponds to the specific product (in-
16 cluding the particular package configuration) com-
17 bined with a unique alphanumeric serial number of
18 up to 20 characters.

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

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

24 “(B) is potentially intentionally adulterated
25 such that the product would result in serious

1 adverse health consequences or death to hu-
2 mans;

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

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

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

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

17 “(23) TRADING PARTNER.—The term ‘trading
18 partner’ means—

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

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

7 “(24) TRANSACTION.—

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

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

13 “(i) intracompany distribution of any
14 product between members of an affiliated
15 group (as defined in section 1504(a) of the
16 Internal Revenue Code of 1986);

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

20 “(iii) the distribution of a product for
21 emergency medical reasons including a
22 public health emergency declaration pursu-
23 ant to section 319 of the Public Health
24 Service Act, except that a drug shortage
25 not caused by a public health emergency

1 shall not constitute an emergency medical
2 reason;

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

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

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

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

16 “(viii) the sale, purchase, or trade of
17 a drug or an offer to sell, purchase, or
18 trade a drug by a charitable organization
19 described in section 501(c)(3) of the Inter-
20 nal Revenue Code of 1954 to a nonprofit
21 affiliate of the organization to the extent
22 otherwise permitted by law;

23 “(ix) the distribution of a product
24 pursuant to the sale or merger of a phar-
25 macy or pharmacies or a wholesale dis-

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

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

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

15 “(xii) a combination product that is—

16 “(I) a product comprised of a de-
17 vice and 1 or more other regulated
18 components (such as a drug/device,
19 biologic/device, or drug/device/biologic)
20 that are physically, chemically, or oth-
21 erwise combined or mixed and pro-
22 duced as a single entity;

23 “(II) 2 or more separate prod-
24 ucts packaged together in a single
25 package or as a unit and comprised of

1 a drug and device products or device
2 and biological product; or

3 “(III) 2 or more finished medical
4 devices plus one or more drug or bio-
5 logical products which are packaged
6 together in what is referred to as a
7 ‘medical convenience kit’ as described
8 in clause (xiii);

9 “(xiii) the distribution of a collection
10 of finished medical devices or a collection
11 of finished drug or biological products as-
12 sembled in kit form strictly for the conven-
13 ience of the purchaser or user (to be
14 known as a ‘medical convenience kit’) if—

15 “(I) the medical convenience kit
16 is assembled in an establishment that
17 is registered with the Food and Drug
18 Administration as a device manufac-
19 turer in accordance with section
20 510(b)(2);

21 “(II) the person who manufac-
22 tures a medical convenience kit pur-
23 chased the product contained in the
24 medical convenience kit directly from
25 the pharmaceutical manufacturer or

1 from a wholesale distributor that pur-
2 chased the product directly from the
3 pharmaceutical manufacturer;

4 “(III) the person who manufac-
5 tures a medical convenience kit does
6 not alter the primary container or
7 label of the product as purchased
8 from the manufacturer or wholesale
9 distributor;

10 “(IV) the medical convenience kit
11 does not contain a controlled sub-
12 stance that appears in a schedule con-
13 tained in the Comprehensive Drug
14 Abuse Prevention and Control Act of
15 1970; and

16 “(V) the products contained in
17 the medical convenience kit are—

18 “(aa) intravenous solutions
19 intended for the replenishment of
20 fluids and electrolytes;

21 “(bb) products intended to
22 maintain the equilibrium of water
23 and minerals in the body;

24 “(cc) products intended for
25 irrigation or reconstitution;

1 “(dd) anesthetics;

2 “(ee) anticoagulants;

3 “(ff) vasopressors; or

4 “(gg) sympathicomimetics;

5 “(xiv) the distribution of an intra-
6 venous product that, by its formulation, is
7 intended for the replenishment of fluids
8 and electrolytes (such as sodium, chloride,
9 and potassium) or calories (such as dex-
10 trose and amino acids);

11 “(xv) the distribution of an intra-
12 venous product used to maintain the equi-
13 librium of water and minerals in the body,
14 such as dialysis solutions;

15 “(xvi) the distribution of a product
16 that is intended for irrigation or recon-
17 stitution, or sterile water, whether intended
18 for such purposes or for injection;

19 “(xvii) the distribution of compressed
20 medical gas; or

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

1 “(25) TRANSACTION HISTORY.—The term
2 ‘transaction history’ means a statement in paper or
3 electronic form, including the transaction informa-
4 tion for each prior transaction going back to the
5 manufacturer of the product.

6 “(26) TRANSACTION INFORMATION.—The term
7 ‘transaction information’ means—

8 “(A) the proprietary or established name
9 or names of the product;

10 “(B) the strength and dosage form of the
11 product;

12 “(C) the National Drug Code number of
13 the product;

14 “(D) the container size;

15 “(E) the number of containers;

16 “(F) the lot number of the product;

17 “(G) the date of the transaction;

18 “(H) the date of the shipment, if different
19 from the date of the transaction;

20 “(I) the business name and address of the
21 person from whom ownership is being trans-
22 ferred; and

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

1 “(27) TRANSACTION STATEMENT.—The ‘trans-
2 action statement’ is a statement, in paper or elec-
3 tronic form, that the entity transferring ownership
4 in a transaction—

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

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

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

13 “(D) did not knowingly ship a suspect or
14 illegitimate product;

15 “(E) had systems and processes in place to
16 comply with verification requirements under
17 section 582;

18 “(F) did not knowingly provide false trans-
19 action information; and

20 “(G) did not knowingly alter the trans-
21 action history.

22 “(28) VERIFICATION OR VERIFY.—The term
23 ‘verification’ or ‘verify’ means determining whether
24 the product identifier affixed to, or imprinted upon,
25 a package or homogeneous case corresponds to the

1 standardized numerical identifier or lot number, and
2 expiration date assigned to the product by the man-
3 ufacturer or the repackager, as applicable in accord-
4 ance with section 582.

5 “(29) WHOLESALE DISTRIBUTOR.—The term
6 ‘wholesale distributor’ means a person (other than a
7 manufacturer, a manufacturer’s co-licensed partner,
8 a third-party logistics provider, or repackager) en-
9 gaged in wholesale distribution (as defined in section
10 503(e)(4), as amended by the Drug Supply Chain
11 Security Act).

12 **“SEC. 582. REQUIREMENTS.**

13 “(a) IN GENERAL.—

14 “(1) OTHER ACTIVITIES.—Each manufacturer,
15 repackager, wholesale distributor, third-party logis-
16 tics provider, and dispenser shall comply with the re-
17 quirements set forth in this section with respect to
18 the role of such manufacturer, repackager, wholesale
19 distributor, third-party logistics provider, or dis-
20 penser in a transaction involving product. If an enti-
21 ty meets the definition of more than one of the enti-
22 ties listed in the preceding sentence, such entity
23 shall comply with all applicable requirements in this
24 section, but shall not be required to duplicate re-
25 quirements.

1 “(2) INITIAL STANDARDS.—

2 “(A) IN GENERAL.—The Secretary shall,
3 in consultation with other appropriate Federal
4 officials, manufacturers, repackagers, wholesale
5 distributors, third-party logistics providers, dis-
6 pensers, and other pharmaceutical distribution
7 supply chain stakeholders, issue a draft guid-
8 ance document that establishes standards for
9 the interoperable exchange of transaction infor-
10 mation for compliance with subsections (a), (b),
11 (c), (d), (e), and (f). The standards established
12 under this paragraph shall take into consider-
13 ation the standards established under section
14 505D and shall comply with a form and format
15 developed by a widely recognized international
16 standards development organization.

17 “(B) PUBLIC INPUT.—Prior to issuing the
18 draft guidance under subparagraph (A), the
19 Secretary shall gather comments and informa-
20 tion from stakeholders and maintain such com-
21 ments and information in a public docket for at
22 least 60 days prior to issuing such guidance.

23 “(C) PUBLICATION.—The Secretary shall
24 publish the standards established under sub-
25 paragraph (A) not later than 1 year after the

1 date of enactment of the Drug Supply Chain
2 Security Act.

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

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

9 “(i) establish a process by which an
10 authorized manufacturer, repackager,
11 wholesale distributor, or dispenser may re-
12 quest a waiver from any of the require-
13 ments set forth in this section if the Sec-
14 retary determines that such requirements
15 would result in an undue economic hard-
16 ship or for emergency medical reasons, in-
17 cluding a public health emergency declara-
18 tion pursuant to section 319 of the Public
19 Health Service Act;

20 “(ii) establish a process by which the
21 Secretary determines exceptions, and a
22 process through which a manufacturer or
23 repackager may request such an exception,
24 to the requirements relating to product
25 identifiers if a product is packaged in a

1 container too small or otherwise unable to
2 accommodate a label with sufficient space
3 to bear the information required for com-
4 pliance with this section; and

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

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

14 “(C) PROCESS.—In issuing the guidance
15 under this section, the Secretary shall provide
16 an effective date that is not later than 180 days
17 prior to the date on which manufacturers are
18 required to affix or imprint a product identifier
19 to each package and homogenous case of prod-
20 uct intended to be introduced in a transaction
21 into commerce consistent with this section.

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

1 “(5) GRANDFATHERING PRODUCT.—

2 “(A) PRODUCT IDENTIFIER.—Not later
3 than 2 years after the date of enactment of the
4 Drug Supply Chain Security Act, the Secretary
5 shall finalize guidance specifying whether and
6 under what circumstances product that is not
7 labeled with a product identifier and that is in
8 the pharmaceutical distribution supply chain at
9 the time of the effective date of the require-
10 ments of this section shall be exempted from
11 the requirements of this section.

12 “(B) TRACING.—For a product that en-
13 tered the pharmaceutical distribution supply
14 chain prior to the date that is 1 year after the
15 date of enactment of the Drug Supply Chain
16 Security Act—

17 “(i) authorized trading partners shall
18 be exempt from providing transaction in-
19 formation as required under subsections
20 (b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii),
21 and (e)(1)(A)(ii) of this section;

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

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

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

13 “(7) THIRD-PARTY LOGISTICS PROVIDER LI-
14 CENSES.—Until the effective date of the third-party
15 logistics provider licensing regulations under section
16 584, a third-party logistics provider shall be consid-
17 ered ‘licensed’ under section 581(9)(B) unless the
18 Secretary has made a finding that the third-party lo-
19 gistics provider does not utilize good handling and
20 distribution practices and publishes notice thereof.

21 “(8) LABEL CHANGES.—Changes made to pack-
22 age labels solely to incorporate the product identifier
23 may be submitted to the Secretary in the annual re-
24 port of an establishment, in accordance with section

1 314.70(d) of chapter 21, Code of Federal Regula-
2 tions (or any successor regulation).

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

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

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

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

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

21 “(b) MANUFACTURER REQUIREMENTS.—

22 “(1) PRODUCT TRACING.—

23 “(A) IN GENERAL.—Beginning not later
24 than 1 year after the date of enactment of the

1 Drug Supply Chain Security Act, a manufac-
2 turer shall—

3 “(i) prior to, or at the time of, each
4 transaction in which such manufacturer
5 transfers—

6 “(I) ownership of a product, pro-
7 vide the subsequent recipient with
8 transaction history, transaction infor-
9 mation, and a transaction statement;
10 or

11 “(II) possession of a product to a
12 third-party logistics provider for the
13 purpose of transferring ownership as
14 part of a transaction to a subsequent
15 recipient, provide to the third-party
16 logistics provider the transaction his-
17 tory, transaction information, and a
18 transaction statement for such trans-
19 action to a subsequent recipient; and

20 “(ii) maintain the transaction infor-
21 mation, transaction history, and trans-
22 action statement for each transaction for
23 not less than 6 years after the date of the
24 transaction.

1 “(B) REQUESTS FOR INFORMATION.—

2 Upon a request by the Secretary or other ap-
3 propriate Federal or State official, in the event
4 of a recall or for the purpose of investigating a
5 suspect product or an illegitimate product, a
6 manufacturer shall, not later than 24 hours
7 after receiving the request or in other such rea-
8 sonable time as determined by the Secretary,
9 based on the circumstances of the request, pro-
10 vide the applicable transaction information,
11 transaction history, and transaction statement
12 for the product.

13 “(2) PRODUCT IDENTIFIER.—Beginning not
14 later than 4 years after the date of enactment of the
15 Drug Supply Chain Security Act, a manufacturer
16 shall affix or imprint a product identifier to each
17 package and homogenous case of a product intended
18 to be introduced in a transaction into commerce.
19 Such manufacturer shall maintain the product iden-
20 tifier information for such product for not less than
21 6 years after the date of the transaction.

22 “(3) AUTHORIZED TRADING PARTNERS.—Be-
23 ginning not later than 1 year after the date of enact-
24 ment of the Drug Supply Chain Security Act, the

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

3 “(4) VERIFICATION.—Beginning not later than
4 1 year after the date of enactment of the Drug Sup-
5 ply Chain Security Act, a manufacturer shall have
6 systems in place to enable the manufacturer to com-
7 ply with the following requirements:

8 “(A) SUSPECT PRODUCT.—

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

18 “(I) quarantine such product
19 within the possession or control of the
20 manufacturer from product intended
21 for distribution until such product is
22 cleared or dispositioned; and

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

1 whether the product is an illegitimate
2 product, which shall include validating
3 any applicable transaction history and
4 transaction information in the posses-
5 sion of the manufacturer and other-
6 wise investigating to determine wheth-
7 er the product is an illegitimate prod-
8 uct, and, beginning 4 years after the
9 date of enactment of the Drug Supply
10 Chain Security Act, verifying the
11 product at the package level.

12 “(ii) CLEARED PRODUCT.—If the
13 manufacturer makes the determination
14 that a suspect product is not an illegit-
15 imate product, the manufacturer shall
16 promptly notify the Secretary, if applica-
17 ble, of such determination and such prod-
18 uct may be further distributed.

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

23 “(B) ILLEGITIMATE PRODUCT.—

24 “(i) IN GENERAL.—Upon determining
25 that a product in the possession or control

1 of a manufacturer is an illegitimate prod-
2 uct, the manufacturer shall, in a manner
3 consistent with the systems and processes
4 of such manufacturer—

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

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

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

18 “(IV) retain a sample of the
19 product for further physical examina-
20 tion or laboratory analysis of the
21 product by the manufacturer or Sec-
22 retary (or other appropriate Federal
23 or State official) upon request by the
24 Secretary (or other appropriate Fed-

1 eral or State official), as necessary
2 and appropriate.

3 “(ii) MAKING A NOTIFICATION.—

4 “(I) ILLEGITIMATE PRODUCT.—

5 Upon determining that a product in
6 the possession or control of the manu-
7 facturer is an illegitimate product, the
8 manufacturer shall notify the Sec-
9 retary and all immediate trading part-
10 ners that the manufacturer has reason
11 to believe may have received such ille-
12 gitimate product of such determina-
13 tion not later than 24 hours after
14 making such determination.

15 “(II) HIGH RISK OF ILLEGIT-

16 IMACY.—A manufacturer shall notify
17 the Secretary and immediate trading
18 partners that the manufacturer has
19 reason to believe may have in the
20 trading partner’s possession a product
21 manufactured by, or purported to be a
22 product manufactured by, the manu-
23 facturer not later than 24 hours after
24 determining or being notified by the
25 Secretary or a trading partner that

1 there is a high risk that such product
2 is an illegitimate product. For pur-
3 poses of this subclause, a ‘high risk’
4 may include a specific high-risk that
5 could increase the likelihood that ille-
6 gitimate product will enter the phar-
7 maceutical distribution supply chain
8 and other high risks as determined by
9 the Secretary in guidance pursuant to
10 subsection (i).

11 “(iii) RESPONDING TO A NOTIFICA-
12 TION.—Upon the receipt of a notification
13 from the Secretary or a trading partner
14 that a determination has been made that a
15 product is an illegitimate product, a manu-
16 facturer shall identify all illegitimate prod-
17 uct subject to such notification that is in
18 the possession or control of the manufac-
19 turer, including any product that is subse-
20 quently received, and shall perform the ac-
21 tivities described in subparagraph (A).

22 “(iv) TERMINATING A NOTIFICA-
23 TION.—Upon making a determination, in
24 consultation with the Secretary, that a no-
25 tification is no longer necessary, a manu-

1 facturer shall promptly notify immediate
2 trading partners that the manufacturer no-
3 tified pursuant to clause (ii) that such no-
4 tification has been terminated.

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

9 “(C) REQUESTS FOR VERIFICATION.—Be-
10 ginning 4 years after the date of enactment of
11 the Drug Supply Chain Security Act, upon re-
12 ceiving a request for verification from an au-
13 thorized repackager, wholesale distributor, or
14 dispenser that is in possession or control of a
15 product they believe to be manufactured by
16 such manufacturer, a manufacturer shall, not
17 later than 24 hours after receiving the
18 verification request or in other such reasonable
19 time as determined by the Secretary, based on
20 the circumstances of the request, notify the per-
21 son making the request whether the product
22 identifier, including the standard numeric iden-
23 tifier, that is the subject of the request cor-
24 responds to the product identifier affixed or im-
25 printed by the manufacturer. If a manufacturer

1 responding to a verification request identifies a
2 product identifier that does not correspond to
3 that affixed or imprinted by the manufacturer,
4 the manufacturer shall treat such product as
5 suspect product and conduct an investigation as
6 described in subparagraph (A). If the manufac-
7 turer has reason to believe the product is an il-
8 legitimate product, the manufacturer shall ad-
9 vise the person making the request of such be-
10 lief at the time such manufacturer responds to
11 the verification request.

12 “(D) ELECTRONIC DATABASE.—A manu-
13 facturer may satisfy the requirements of this
14 paragraph by developing a secure electronic
15 database or utilizing a secure electronic data-
16 base developed or operated by another entity.
17 The owner of such database shall establish the
18 requirements and processes to respond to re-
19 quests and may provide for data access to other
20 members of the pharmaceutical distribution
21 supply chain, as appropriate. The development
22 and operation of such a database shall not re-
23 lieve a manufacturer of the requirement under
24 this paragraph to respond to a verification re-

1 quest submitted by means other than a secure
2 electronic database.

3 “(E) SALEABLE RETURNED PRODUCT.—
4 Beginning 4 years after the date of enactment
5 of the Drug Supply Chain Security Act (except
6 as provided pursuant to subsection (a)(5)),
7 upon receipt of a returned product that the
8 manufacturer intends to further distribute, be-
9 fore further distributing such product, the man-
10 ufacturer shall verify the product identifier for
11 each sealed homogeneous case of such product
12 or, if such product is not in a sealed homo-
13 geneous case, verify the product identifier on
14 each package.

15 “(F) NONSALEABLE RETURNED PROD-
16 UCT.—A manufacturer may return a nonsale-
17 able product to the manufacturer or repack-
18 ager, to the wholesale distributor from whom
19 such product was purchased, or to a person act-
20 ing on behalf of such a person, including a re-
21 turns processor, without providing the informa-
22 tion required under paragraph (1)(A)(i).

23 “(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

24 “(1) PRODUCT TRACING.—

1 “(A) IN GENERAL.—Beginning not later
2 than 1 year after the date of enactment of the
3 Drug Supply Chain Security Act, the following
4 requirements shall apply to wholesale distribu-
5 tors:

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

13 “(ii)(I)(aa) If the wholesale dis-
14 tributor purchased a product directly from
15 the manufacturer, the exclusive distributor
16 of the manufacturer, or a repackager that
17 purchased directly from the manufacturer,
18 then prior to, or at the time of, each trans-
19 action in which the wholesale distributor
20 transfers ownership of a product, the
21 wholesale distributor shall provide to the
22 subsequent purchaser—

23 “(AA) a transaction statement,
24 which shall state that such wholesale
25 distributor, or a member of the affili-

1 ated group of such wholesale dis-
2 tributor, purchased the product di-
3 rectly from the manufacturer, exclu-
4 sive distributor of the manufacturer,
5 or repackager that purchased directly
6 from the manufacturer; and

7 “(BB) subject to subclause (II),
8 the transaction history and trans-
9 action information.

10 “(bb) The wholesale distributor shall
11 provide the transaction history, transaction
12 information, and transaction statement
13 under item (aa)—

14 “(AA) if provided to a dispenser,
15 on a single document in an electronic
16 or paper format; and

17 “(BB) if provided to a wholesale
18 distributor, through any combination
19 of self-generated paper, electronic
20 data, or manufacturer-provided infor-
21 mation on the product package.

22 “(II) For purposes of transactions de-
23 scribed in subclause (I), transaction his-
24 tory and transaction information shall not
25 be required to include the lot number of

1 the product, the initial transaction date, or
2 the initial shipment date from the manu-
3 facturer (as defined in subparagraphs (F),
4 (G), and (H) of section 581(26)).

5 “(iii) If the wholesale distributor did
6 not purchase a product directly from the
7 manufacturer, the exclusive distributor of
8 the manufacturer, or a repackager that
9 purchased directly from the manufacturer,
10 as described in clause (ii), then prior to, or
11 at the time of, each transaction or subse-
12 quent transaction, the wholesale dis-
13 tributor—

14 “(I) shall provide to the subse-
15 quent purchaser a transaction state-
16 ment, transaction history, and trans-
17 action information; and

18 “(II) may provide the informa-
19 tion described in subclause (I) to a
20 subsequent purchaser on a single doc-
21 ument in an electronic or paper for-
22 mat or through any combination of
23 self-generated paper, electronic data,
24 or manufacturer provided information
25 on the product package.

1 “(iv) For the purposes of clause
2 (iii)(I), the transaction history supplied
3 shall begin only with the wholesale dis-
4 tributor described in clause (ii)(I), but the
5 wholesale distributor described in clause
6 (iii) shall inform the subsequent purchaser
7 that such wholesale distributor received a
8 direct purchase statement from the manu-
9 facturer, the exclusive distributor of the
10 manufacturer, or a repackager that pur-
11 chased directly from the manufacturer,
12 and shall identify the manufacturer, exclu-
13 sive distributor of the manufacturer, or re-
14 packager that purchased directly from the
15 manufacturer from which the direct pur-
16 chase statement was received.

17 “(v) A wholesale distributor shall
18 maintain the transaction information,
19 transaction history, and transaction state-
20 ment for each transaction described in
21 clauses (i), (ii), and (iii) for not less than
22 6 years after the date of the transaction.

23 “(B) RETURNS.—

1 “(i) SALEABLE RETURNS.—Notwith-
2 standing subparagraph (A)(i), the fol-
3 lowing shall apply:

4 “(I) REQUIREMENTS.—Until the
5 date that is 6 years after the date of
6 enactment of the Drug Supply Chain
7 Security Act (except as provided pur-
8 suant to subsection (a)(5)), a whole-
9 sale distributor may accept returned
10 product from a dispenser pursuant to
11 the terms and conditions of any agree-
12 ment between the parties, and, not-
13 withstanding subparagraph (A)(ii),
14 may distribute such returned product
15 without providing the transaction his-
16 tory. For transactions subsequent to
17 the return, the transaction history of
18 such product shall begin with the
19 wholesale distributor that accepted the
20 returned product, consistent with the
21 requirements of this subsection.

22 “(II) ENHANCED REQUIRE-
23 MENTS.—Beginning 6 years after the
24 date of enactment of the Drug Supply
25 Chain Security Act (except as pro-

1 vided pursuant to subsection (a)(5)),
2 a wholesale distributor may accept re-
3 turned product from a dispenser only
4 if the wholesale distributor can asso-
5 ciate returned product with the trans-
6 action information and transaction
7 statement associated with that prod-
8 uct. For all transactions after such
9 date, the transaction history, as appli-
10 cable, of such product shall begin with
11 the wholesale distributor that accepted
12 and verified the returned product. For
13 purposes of this subparagraph, the
14 transaction information and trans-
15 action history, as applicable, need not
16 include transaction dates if it is not
17 reasonably practicable to obtain such
18 dates.

19 “(ii) NONSALEABLE RETURNS.—A
20 wholesale distributor may return a non-
21 saleable prescription drug to the manufac-
22 turer or repackager, to the wholesale dis-
23 tributor from whom such prescription drug
24 was purchased, or to a person acting on
25 behalf of such a person, including a re-

1 turns processor, without providing the in-
2 formation required under subparagraph
3 (A)(i).

4 “(C) REQUESTS FOR INFORMATION.—
5 Upon a request by the Secretary or other ap-
6 propriate Federal or State official, in the event
7 of a recall or for the purpose of investigating a
8 suspect product or an illegitimate product a
9 wholesale distributor shall, not later than 24
10 hours after receiving the request or in other
11 such reasonable time as determined by the Sec-
12 retary, based on the circumstances of the re-
13 quest, provide the applicable transaction infor-
14 mation, transaction history, and transaction
15 statement for the product.

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

22 “(3) AUTHORIZED TRADING PARTNERS.—Be-
23 ginning not later than 1 year after the date of enact-
24 ment of the Drug Supply Chain Security Act, the

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

3 “(4) VERIFICATION.—Beginning not later than
4 1 year after the date of enactment of the Drug Sup-
5 ply Chain Security Act, a wholesale distributor shall
6 have systems in place to enable the wholesale dis-
7 tributor to comply with the following requirements:

8 “(A) SUSPECT PRODUCT.—

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

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

24 “(II) promptly conduct an inves-
25 tigation in coordination with trading

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

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

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

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

3 “(B) ILLEGITIMATE PRODUCT.—

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

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

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

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

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

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

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

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

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

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

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

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

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

22 “(d) DISPENSER REQUIREMENTS.—

23 “(1) PRODUCT TRACING.—

1 “(A) IN GENERAL.—Beginning 1 year
2 after the date of enactment of the Drug Supply
3 Chain Security Act, a dispenser—

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

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

20 “(iii) shall maintain transaction infor-
21 mation, transaction history, and trans-
22 action statements, as necessary to inves-
23 tigate a suspect product, for not less than
24 6 years after the transaction.

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

14 “(C) RETURNS.—

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

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

1 such persons without providing the infor-
2 mation required under subparagraph
3 (A)(i).

4 “(D) REQUESTS FOR INFORMATION.—

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

23 “(2) PRODUCT IDENTIFIER.—Beginning not
24 later than 7 years after the date of enactment of the
25 Drug Supply Chain Security Act, a dispenser may

1 engage in transactions involving a product only if
2 such product is encoded with a product identifier
3 (except as provided pursuant to subsection (a)(5)).

4 “(3) AUTHORIZED TRADING PARTNERS.—Be-
5 ginning not later than 1 year after the date of enact-
6 ment of the Drug Supply Chain Security Act, the
7 trading partners of a dispenser may be only author-
8 ized trading partners.

9 “(4) VERIFICATION.—Beginning not later than
10 1 year after the date of enactment of the Drug Sup-
11 ply Chain Security Act, a dispenser shall have sys-
12 tems in place to enable the dispenser to comply with
13 the following requirements:

14 “(A) SUSPECT PRODUCT.—

15 “(i) IN GENERAL.—Upon making a
16 determination that a product in the posses-
17 sion or control of the dispenser is a suspect
18 product, or upon receiving a request for
19 verification from the Secretary that has
20 made a determination that a product with-
21 in the possession or control of a dispenser
22 is a suspect product, a dispenser shall—

23 “(I) quarantine such product
24 within the possession or control of the
25 dispenser from product intended for

1 distribution until such product is
2 cleared or dispositioned; and

3 “(II) promptly conduct an inves-
4 tigation in coordination with trading
5 partners, as applicable, to determine
6 whether the product is an illegitimate
7 product.

8 “(ii) INVESTIGATION.—An investiga-
9 tion conducted under clause (i)(II) shall in-
10 clude—

11 “(I) beginning 7 years after the
12 date of enactment of the Drug Supply
13 Chain Security Act, verifying whether
14 the lot number of a suspect product
15 corresponds with the lot number for
16 such product;

17 “(II) beginning 7 years after the
18 date of enactment of such Act,
19 verifying that the product identifier of
20 at least 3 packages or 10 percent of
21 such suspect product, whichever is
22 greater, or all packages, if there are
23 fewer than 3, corresponds with the
24 product identifier for such product;

1 “(III) validating any applicable
2 transaction history and transaction in-
3 formation in the possession of the dis-
4 penser; and

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

8 “(iii) CLEARED PRODUCT.—If the dis-
9 penser makes the determination that a sus-
10 pect product is not an illegitimate product,
11 the dispenser shall promptly notify the
12 Secretary, if applicable, of such determina-
13 tion and such product may be further dis-
14 tributed or dispensed.

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

19 “(B) ILLEGITIMATE PRODUCT.—

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

1 “(I) disposition the illegitimate
2 product within the possession or con-
3 trol of the dispenser;

4 “(II) take reasonable and appro-
5 priate steps to assist a trading part-
6 ner to disposition an illegitimate prod-
7 uct not in the possession or control of
8 the dispenser; and

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

18 “(ii) MAKING A NOTIFICATION.—
19 Upon determining that a product in the
20 possession or control of the dispenser is an
21 illegitimate product, the dispenser shall no-
22 tify the Secretary and all immediate trad-
23 ing partners that the dispenser has reason
24 to believe may have received such illegit-
25 imate product of such determination not

1 later than 24 hours after making such de-
2 termination.

3 “(iii) RESPONDING TO A NOTIFICA-
4 TION.—Upon the receipt of a notification
5 from the Secretary or a trading partner
6 that a determination has been made that a
7 product is an illegitimate product, a dis-
8 penser shall identify all illegitimate product
9 subject to such notification that is in the
10 possession or control of the dispenser, in-
11 cluding any product that is subsequently
12 received, and shall perform the activities
13 described in subparagraph (A).

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

22 “(v) RECORDS.—A dispenser shall
23 keep records of the disposition of an illegit-
24 imate product for not less than 6 years
25 after the conclusion of the disposition.

1 “(C) ELECTRONIC DATABASE.—A dis-
2 penser may satisfy the requirements of this
3 paragraph by developing a secure electronic
4 database or utilizing a secure electronic data-
5 base developed or operated by another entity.

6 “(e) REPACKAGER REQUIREMENTS.—

7 “(1) PRODUCT TRACING.—

8 “(A) IN GENERAL.—Beginning not later
9 than 1 year after the date of enactment of the
10 Drug Supply Chain Security Act, a repackager
11 shall—

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

18 “(ii) prior to, or at the time of, each
19 transaction in which the repackager trans-
20 fers ownership of a product, or transfers
21 possession of a product to a third-party lo-
22 gistcs provider, provide the subsequent
23 owner with transaction history, transaction
24 information, and a transaction statement;
25 and

1 “(iii) maintain the transaction infor-
2 mation, transaction history, and trans-
3 action statement for each transaction de-
4 scribed in clauses (i) and (ii) for not less
5 than 6 years after the transaction.

6 “(B) NONSALEABLE RETURNS.—A repack-
7 ager may return a nonsaleable product to the
8 manufacturer or repackager, or to the wholesale
9 distributor from whom such product was pur-
10 chased, or to a person acting on behalf of such
11 a person, including a returns processor, without
12 providing the information required under sub-
13 paragraph (A)(ii).

14 “(C) REQUESTS FOR INFORMATION.—
15 Upon a request by the Secretary or other ap-
16 propriate Federal or State official, in the event
17 of a recall or for the purpose of investigating a
18 suspect product or an illegitimate product, a re-
19 packager shall, not later than 24 hours after re-
20 ceiving the request or in other such reasonable
21 time as determined by the Secretary, based on
22 the circumstances of the request, provide the
23 applicable transaction information, transaction
24 history and transaction statement for the prod-
25 uct.

1 “(2) PRODUCT IDENTIFIER.—Beginning not
2 later than 5 years after enactment of the Drug Sup-
3 ply Chain Security Act, a repackager—

4 “(A) shall affix or imprint a product iden-
5 tifier to each package and homogenous case of
6 product intended to be introduced in a trans-
7 action in commerce;

8 “(B) shall maintain the product identifier
9 information for such product for not less than
10 6 years after the date of the transaction;

11 “(C) may engage in transactions involving
12 a product only if such product is encoded with
13 a product identifier (except as provided pursu-
14 ant to subsection (a)(5)); and

15 “(D) maintain records for not less than 6
16 years to allow the repackager to associate the
17 product identifier the repackager affixes or im-
18 prints with the product identifier assigned by
19 the original manufacturer of the product.

20 “(3) AUTHORIZED TRADING PARTNERS.—Be-
21 ginning 1 year after the date of enactment of the
22 Drug Supply Chain Security Act, the trading part-
23 ners of a repackager may be only authorized trading
24 partners.

1 “(4) VERIFICATION.—Beginning not later than
2 1 year after the date of enactment of the Drug Sup-
3 ply Chain Security Act, a repackager shall have sys-
4 tems in place to enable the repackager to comply
5 with the following requirements:

6 “(A) SUSPECT PRODUCT.—

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

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

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

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

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

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

23 “(B) ILLEGITIMATE PRODUCT.—

24 “(i) IN GENERAL.—Upon deter-
25 mining, in coordination with the manufac-

1 turer, that a product in the possession or
2 control of a repackager is an illegitimate
3 product, the repackager shall, in a manner
4 that is consistent with the systems and
5 processes of such repackager—

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

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

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

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

1 appropriate Federal or State official),
2 as necessary and appropriate.

3 “(ii) MAKING A NOTIFICATION.—

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

13 “(iii) RESPONDING TO A NOTIFICA-

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

22 “(iv) TERMINATING A NOTIFICA-

23 TION.—Upon a determination, in consulta-
24 tion with the Secretary, that a notification
25 is no longer necessary, a repackager shall

1 promptly notify immediate trading part-
2 ners that the repackager notified pursuant
3 to clause (ii) that such notification has
4 been terminated.

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

9 “(C) REQUESTS FOR VERIFICATION.—Be-
10 beginning 5 years after enactment of the Drug
11 Supply Chain Security Act, upon receiving a re-
12 quest for verification from an authorized manu-
13 facturer, wholesale distributor, or dispenser
14 that is in possession or control of a product
15 they believe to be repackaged by such repack-
16 ager, a repackager shall, not later than 24
17 hours after receiving the verification request or
18 in other such reasonable time as determined by
19 the Secretary, based on the circumstances of
20 the request, notify the person making the re-
21 quest whether the product identifier, including
22 the standard numeric identifier, that is the sub-
23 ject of the request corresponds to the product
24 identifier affixed or imprinted by the repack-
25 ager. If a repackager responding to a

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

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

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

12 “(f) THIRD-PARTY LOGISTICS PROVIDER REQUIRE-
13 MENTS.—

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

18 “(A) not accept possession of a product
19 unless the owner of the product provides the
20 transaction history, transaction information,
21 and a transaction statement for the product;

22 “(B) maintain a copy of the information
23 described in subparagraph (A) for not less than
24 6 years after the transfer of possession; and

1 “(C) upon a request by the Secretary or
2 other appropriate Federal or State official, in
3 the event of a recall or for the purpose of inves-
4 tigating a suspect product or an illegitimate
5 product, not later than 24 hours after receiving
6 the request or in other such reasonable time as
7 determined by the Secretary based on the cir-
8 cumstances of the request, provide the applica-
9 ble transaction information, transaction history,
10 and transaction statement for the product.

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

17 “(3) AUTHORIZED TRADING PARTNERS.—Be-
18 ginning 1 year after the date of enactment of the
19 Drug Supply Chain Security Act, the trading part-
20 ners of a third-party logistics provider may be only
21 authorized trading partners.

22 “(4) VERIFICATION.—Beginning not later than
23 1 year after the date of enactment of the Drug Sup-
24 ply Chain Security Act, a third-party logistics pro-
25 vider shall have systems in place to enable the third-

1 party logistics provider to comply with the following
2 requirements:

3 “(A) SUSPECT PRODUCT.—

4 “(i) IN GENERAL.—Upon making a
5 determination that a product in the posses-
6 sion or control of a third-party logistics
7 provider is a suspect product, a third-party
8 logistics provider shall—

9 “(I) quarantine such product
10 within the possession or control of the
11 third-party logistics provider from
12 product intended for distribution until
13 such product is cleared or transferred
14 to the owner of such product for dis-
15 position of the product; and

16 “(II) promptly notify the owner
17 of such product of the need to conduct
18 an investigation to determine whether
19 the product is an illegitimate product.

20 “(ii) CLEARED PRODUCT.—If the
21 owner of the product notifies the third-
22 party logistics provider of the determina-
23 tion that a suspect product is not an ille-
24 gitimate product, such product may be fur-
25 ther distributed.

1 “(iii) RECORDS.—A third-party logis-
2 tics provider shall keep records of the ac-
3 tivities described in subclauses (I) and (II)
4 of clause (i), as such subclauses relate to
5 a suspect product, for not less than 6
6 years after the conclusion of the investiga-
7 tion.

8 “(B) ILLEGITIMATE PRODUCT.—

9 “(i) IN GENERAL.—Upon deter-
10 mining, in coordination with the manufac-
11 turer, that a product in the possession or
12 control of a third-party logistics provider is
13 an illegitimate product, the third-party lo-
14 gistics provider shall—

15 “(I) promptly notify the owner of
16 such product of the need to dispo-
17 sition such product; and

18 “(II) promptly transfer posses-
19 sion of the product to the owner of
20 such product to disposition the prod-
21 uct.

22 “(ii) MAKING A NOTIFICATION.—
23 Upon determining that a product in the
24 possession or control of the third-party lo-
25 gistics provider is an illegitimate product,

1 the third-party logistics provider shall no-
2 tify the Secretary not later than 24 hours
3 after making such determination.

4 “(iii) RESPONDING TO A NOTIFICA-
5 TION.—Upon the receipt of a notification
6 from the Secretary, a third-party logistics
7 provider shall identify all illegitimate prod-
8 uct subject to such notification that is in
9 the possession or control of the third-party
10 logistics provider, including any product
11 that is subsequently received, and shall
12 perform the activities described in subpara-
13 graph (A).

14 “(iv) TERMINATING A NOTIFICA-
15 TION.—Upon making a determination, in
16 consultation with the Secretary and the
17 owner of such product, that a notification
18 is no longer necessary, a third-party logis-
19 tics provider shall promptly terminate such
20 notification.

21 “(v) RECORDS.—A third-party logis-
22 tics provider shall keep records of the ac-
23 tivities described in subclauses (I) and (II)
24 of clause (i) as such subclauses relate to
25 an illegitimate product for not less than 6

1 years after the conclusion of the dispo-
2 tion.

3 “(g) DROP SHIPMENTS.—This section shall not apply
4 to any entity that does not physically handle, distribute,
5 or store product. For purposes of this section, providing
6 various administrative services, including processing of or-
7 ders and payments, shall not by itself, be construed as
8 being involved in the handling, distribution, or storage of
9 a product. For purposes of this section, the term ‘entity’
10 means a wholesale distributor, relabeler, repackager, or
11 any other status.”.

12 **SEC. 3. ENHANCED DRUG DISTRIBUTION SECURITY.**

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

16 “(h) ENHANCED DRUG DISTRIBUTION SECURITY.—

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

22 “(A) The transaction information and the
23 transaction statements as required under this
24 section shall be exchanged in a secure, inter-
25 operable, electronic manner in accordance with

1 the standards established under the guidance
2 issued pursuant to paragraphs (3) and (4) of
3 subsection (i), including any revision of such
4 guidance issued in accordance with paragraph
5 (5) of such subsection.

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

10 “(C) Systems and processes for verification
11 of product at the package level shall be required
12 in accordance with the standards established
13 under the guidance issued pursuant to sub-
14 section (a)(2) and the guidances issued pursu-
15 ant to paragraphs (2), (3), and (4) of sub-
16 section (i), including any revision of such guid-
17 ances issued in accordance with paragraph (5)
18 of such subsection, which may include the use
19 of aggregation and inference as necessary.

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

1 a suspect product or an illegitimate product
2 shall be required.

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

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

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

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

1 transaction information and transaction state-
2 ment associated with that product.

3 “(2) COMPLIANCE.—

4 “(A) INFORMATION MAINTENANCE AGREE-
5 MENT.—A dispenser shall be permitted to enter
6 into a written agreement with a third party, in-
7 cluding an authorized wholesale distributor,
8 under which the third party shall confidentially
9 maintain any information and statements re-
10 quired to be maintained under this section. If
11 a dispenser enters into such an agreement, the
12 dispenser shall maintain a copy of the written
13 agreement and shall not be relieved of the obli-
14 gations of the dispenser under this subsection.

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

21 “(i) establishing timelines for compli-
22 ance by small businesses (including small
23 business dispensers with 25 or fewer full-
24 time employees) with such requirements, in
25 order to ensure that such requirements do

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

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

17 “(3) ASSESSMENT.—

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

1 ees conducting interoperable, electronic tracing
2 of products at the package level. In no case
3 may such assessment commence later than 7.5
4 years after the date of enactment of the Drug
5 Supply Chain Security Act.

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

12 “(C) CONTENT.—The assessment con-
13 ducted under subparagraph (A) shall assess
14 whether—

15 “(i) the necessary software and hard-
16 ware is readily accessible to such dis-
17 pensers;

18 “(ii) the necessary software and hard-
19 ware is not prohibitively expensive to ob-
20 tain, install, and maintain for such dis-
21 pensers; and

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

1 “(D) PUBLICATION.—The Secretary
2 shall—

3 “(i) publish the statement of work for
4 the assessment conducted under subpara-
5 graph (A) for public comment prior to be-
6 ginning the assessment;

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

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

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

19 “(A) provide appropriate flexibility by—

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

23 “(ii) prescribing alternative methods
24 of compliance for any of the requirements
25 set forth in paragraph (1) or set forth in

1 regulations implementing such require-
2 ments, including timelines—

3 “(I) for small businesses to com-
4 ply with the requirements set forth in
5 the regulations in order to ensure that
6 such requirements do not impose
7 undue economic hardship for small
8 businesses (including small business
9 dispensers for whom the criteria set
10 forth in the assessment under para-
11 graph (3) is not met), if the Secretary
12 determines that such requirements
13 would result in undue economic hard-
14 ship; and

15 “(II) which shall include estab-
16 lishing a process by which a dispenser
17 may request a waiver from any of the
18 requirements set forth in such regula-
19 tions if the Secretary determines that
20 such requirements would result in an
21 undue economic hardship; and

22 “(iii) taking into consideration—

23 “(I) the results of pilot projects,
24 including pilot projects pursuant to
25 this section;

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

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

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

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

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

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

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

4 “(i) GUIDANCE DOCUMENTS.—

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

12 “(2) SUSPECT AND ILLEGITIMATE PRODUCT.—

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

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

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

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

4 “(iii) set forth the process by which
5 manufacturers, repackagers, wholesale dis-
6 tributors, dispensers, and third-party logis-
7 tics providers shall terminate notifications
8 in consultation with the Secretary regard-
9 ing illegitimate product pursuant to sub-
10 sections (b)(4)(B), (c)(4)(B), (d)(4)(B),
11 (e)(4)(B), and (f)(B).

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

16 “(3) UNIT LEVEL TRACING.—

17 “(A) IN GENERAL.—In order to enhance
18 drug distribution security at the package level,
19 not later than 18 months after conducting a
20 public meeting on the system attributes nec-
21 essary to enable secure tracing of product at
22 the package level, the Secretary shall issue a
23 final guidance document that outlines and
24 makes recommendations with respect to the sys-
25 tem attributes necessary to enable secure trac-

1 ing at the package level as required under the
2 requirements established under subsection (h).

3 Such guidance document shall—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 “(j) PUBLIC MEETINGS.—

22 “(1) IN GENERAL.—The Secretary shall hold
23 not less than 3 public meetings to enhance the safe-
24 ty and security of the pharmaceutical distribution
25 supply chain and provide for comment. The Sec-

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 “(k) PILOT PROJECTS.—

15 “(1) IN GENERAL.—The Secretary shall estab-
16 lish 1 or more pilot projects, in coordination with
17 authorized manufacturers, repackagers, wholesale
18 distributors, third-party logistics providers, and dis-
19 pensers, to explore and evaluate methods to enhance
20 the safety and security of the pharmaceutical dis-
21 tribution supply chain. Such projects shall build
22 upon efforts, in existence as of the date of enact-
23 ment of the Drug Supply Chain Security Act, to en-
24 hance the safety and security of the pharmaceutical
25 distribution supply chain, take into consideration

1 any pilot projects conducted prior to such date of
2 enactment, and inform the draft and final guidance
3 under paragraphs (3) and (4) of subsection (i).

4 “(2) CONTENT.—

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

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

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

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

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

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

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

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

12 “(2) The requirements set forth for returns
13 under subsection (c)(1)(B)(i).

14 “(m) RULE OF CONSTRUCTION.—The requirements
15 set forth in subsections (h)(4), (j), and (k) shall not be
16 construed as a condition, prohibition, or precedent for pre-
17 cluding or delaying the provisions becoming effective pur-
18 suant to subsection (h).”.

19 **SEC. 4. NATIONAL LICENSURE STANDARDS FOR WHOLE-**
20 **SALE DISTRIBUTORS.**

21 (a) AMENDMENTS.—

22 (1) LICENSE REQUIREMENT.—Section 503(e) of
23 the Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 353(e)) is amended by striking paragraphs
25 (1), (2), and (3) and inserting the following:

1 “(1) LICENSE REQUIREMENT.—Subject to sec-
2 tion 583:

3 “(A) IN GENERAL.—No person may en-
4 gage in wholesale distribution of a drug subject
5 to subsection (b)(1) in any State unless such
6 person—

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

9 “(II) if the State from which the drug
10 distributed has not established a licensure
11 requirement, is licensed by the Secretary;
12 and

13 “(ii) if the drug is distributed inter-
14 state, is licensed by the State into which
15 the drug is distributed if the State into
16 which the drug is distributed requires the
17 licensure of a person that distributes drugs
18 into the State.

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

23 “(2) LICENSURE REPORTING AND DATABASE.—

24 “(A) LICENSURE REPORTING.—Beginning
25 1 year after the date of enactment of the Drug

1 Supply Chain Security Act, any person who
2 owns or operates an establishment that engages
3 in wholesale distribution shall report to the Sec-
4 retary, on an annual basis pursuant to a sched-
5 ule determined by the Secretary—

6 “(i) each State by which the person is
7 licensed and the appropriate identification
8 number of each such license; and

9 “(ii) the name and address of each fa-
10 cility at which, and all trade names under
11 which, the person conducts business.

12 “(B) DATABASE.—Not later than 1 year
13 after the date of enactment of the Drug Supply
14 Chain Security Act, the Secretary shall estab-
15 lish a database of licensed wholesale distribu-
16 tors. Such database shall—

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

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

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

3 “(3) COSTS.—

4 “(A) AUTHORIZED LICENSURE FEES OF
5 SECRETARY.—If a State does not establish a li-
6 censing program for persons engaged in the
7 wholesale distribution of a drug subject to sub-
8 section (b), the Secretary shall license a person
9 engaged in wholesale distribution located in
10 such State and may collect a reasonable fee in
11 such amount necessary to reimburse the Sec-
12 retary for costs associated with establishing and
13 administering the licensure program and con-
14 ducting periodic inspections under this section.
15 The Secretary shall adjust fee rates as needed
16 on an annual basis to generate only the amount
17 of revenue needed to perform this service. Fees
18 authorized under this paragraph shall be col-
19 lected and available for obligation only to the
20 extent and in the amount provided in advance
21 in appropriations Acts. Such fees are authorized
22 to remain available until expended.

23 “(B) STATE LICENSING FEES.—Nothing in
24 this Act shall prohibit States from collecting

1 fees from wholesale distributors in connection
2 with State licensing of such distributors.”.

3 (2) WHOLESALE DISTRIBUTION.—Section
4 503(e) of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 353(e)), as amended by subsection (a),
6 is further amended by adding at the end the fol-
7 lowing:

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

15 “(A) intracompany distribution of any
16 drug between members of an affiliated group
17 (as defined in section 1504(a) of the Internal
18 Revenue Code of 1986);

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

23 “(C) the distribution of a drug or an offer
24 to distribute a drug for emergency medical rea-
25 sons, including a public health emergency dec-

1 laration pursuant to section 319 of the Public
2 Health Service Act, except that a drug shortage
3 not caused by a public health emergency shall
4 not constitute an emergency medical reason;

5 “(D) the dispensing of a drug pursuant to
6 a valid prescription executed in accordance with
7 section 503(b)(1);

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

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

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

19 “(H) the distribution of a drug by the
20 manufacturer of such drug;

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

1 “(J) a common carrier that transports a
2 drug, provided that the common carrier does
3 not take ownership of the drug;

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

9 “(L) saleable drug returns when conducted
10 by a dispenser;

11 “(M) the distribution of a medical conven-
12 ience kit which is a collection of finished drug
13 or biologic products assembled in kit form
14 strictly for the convenience of the purchaser or
15 user if—

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

21 “(ii) the person who manufactures the
22 medical convenience kit purchased the fin-
23 ished drug or biologic product contained in
24 the medical convenience kit directly from
25 the pharmaceutical manufacturer or from

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

4 “(iii) the person who manufactures a
5 medical convenience kit does not alter the
6 primary container or label of the product
7 as purchased from the manufacturer or
8 wholesale distributor;

9 “(iv) the medical convenience kit does
10 not contain a controlled substance that ap-
11 pears in a schedule contained in the Com-
12 prehensive Drug Abuse Prevention and
13 Control Act of 1970 (21 U.S.C. 801, et
14 seq.); and

15 “(v) the products contained in the
16 medical convenience kit are—

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

20 “(II) drugs intended to maintain
21 the equilibrium of water and minerals
22 in the body;

23 “(III) drugs intended for irriga-
24 tion or reconstitution;

25 “(IV) anesthetics;

1 “(V) anticoagulants;

2 “(VI) vasopressors; or

3 “(VII) sympathicomimetics;

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

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

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

17 “(Q) the distribution of compressed med-
18 ical gas, defined as any substance in its gaseous
19 or cryogenic liquid form that meets medical pu-
20 rity standards and has application in a medical
21 or homecare environment, including oxygen and
22 nitrous oxide;

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

1 “(S) the transfer of a product by a hos-
2 pital or other health care entity to a repackager
3 registered under section 510 for the purpose of
4 repackaging the drug for use by that hospital,
5 or other health care entity and other health
6 care entities that are under common control, if
7 ownership of the drug remains with the hospital
8 or other health care entity at all times.”.

9 (3) THIRD-PARTY LOGISTICS PROVIDERS.—Sec-
10 tion 503(e) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 353(e)), as amended by sub-
12 section (a), is further amended by adding at the end
13 the following:

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

23 (4) LICENSURE STANDARDS.—Subchapter H of
24 chapter V of the Federal Food, Drug, and Cosmetic

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

3 **“SEC. 583. NATIONAL LICENSURE STANDARDS FOR WHOLE-**
4 **SALE DISTRIBUTORS.**

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

12 “(b) CONTENT.—The standards established under
13 subsection (a) shall apply to all State and Federal licenses
14 described under section 503(e)(1) (as amended by the
15 Drug Supply Chain Security Act) and shall prescribe min-
16 imum requirements for—

17 “(1) the storage and handling of such drugs,
18 including facility requirements;

19 “(2) the establishment and maintenance of
20 records of the distributions of such drugs;

21 “(3) the furnishing of a bond or other equiva-
22 lent means of security if—

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

1 tributor license shall submit a surety bond of
2 one hundred thousand dollars or other equiva-
3 lent means of security acceptable to the State;

4 “(B) for purposes of subparagraph (A),
5 the State or other applicable authority may ac-
6 cept a surety bond less than \$100,000 if the
7 annual gross receipts of the previous tax year
8 for the wholesaler is \$10,000,000 or less, in
9 which case the surety bond shall be \$25,000;
10 and

11 “(C) if a wholesale distributor can provide
12 evidence that it possesses the required bond in
13 a State, the requirement for a bond in another
14 State is waived;

15 “(4) mandatory background checks and
16 fingerprinting of facility managers or designated
17 representatives;

18 “(5) the establishment and implementation of
19 qualifications for key personnel;

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

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

4 “(c) INSPECTIONS.—To satisfy the inspection re-
5 quirement the Federal or State licensing authority may
6 conduct the inspection, or may accept an inspection by the
7 State in which the facility is located, or by a third-party
8 accreditation or inspection service approved by the Sec-
9 retary or the State licensing such wholesale distributor.

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

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

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

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

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

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

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

11 (b) CONFORMING AMENDMENTS.—Section 503(d) of
12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 353(d)) is amended—

14 (1) by striking “authorized distributor of
15 record” each place such term appears and inserting
16 “wholesale distributor”; and

17 (2) by striking “authorized distributors of
18 record” each place such term appears and inserting
19 “wholesale distributors”.

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

1 **SEC. 5. NATIONAL LICENSURE STANDARDS FOR THIRD-**
 2 **PARTY LOGISTICS PROVIDERS; UNIFORM NA-**
 3 **TIONAL POLICY.**

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

7 **“SEC. 584. NATIONAL LICENSURE STANDARDS FOR THIRD-**
 8 **PARTY LOGISTICS PROVIDERS.**

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

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

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

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

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

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

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

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

14 “(c) COSTS.—

15 “(1) AUTHORIZED LICENSURE FEES OF SEC-
16 RETARY.—If a State does not establish a licensing
17 program for a third-party logistics provider, the Sec-
18 retary shall license the third-party logistics provider
19 located in such State and may collect a reasonable
20 fee in such amount necessary to reimburse the Sec-
21 retary for costs associated with establishing and ad-
22 ministering the licensure program and conducting
23 periodic inspections under this section. The Sec-
24 retary shall adjust fee rates as needed on an annual
25 basis to generate only the amount of revenue needed

1 to perform this service. Fees authorized under this
2 paragraph shall be collected and available for obliga-
3 tion only to the extent and in the amount provided
4 in advance in appropriations Acts. Such fees are au-
5 thORIZED to remain available until expended.

6 “(2) STATE LICENSING FEES.—

7 “(A) STATE ESTABLISHED PROGRAM.—

8 Nothing in this Act shall prohibit a State that
9 has established a program to license a third-
10 party logistics provider from collecting fees
11 from a third-party logistics provider for such a
12 license.

13 “(B) NO STATE ESTABLISHED PRO-

14 GRAM.—A State that does not establish a pro-
15 gram to license a third-party logistics provider
16 in accordance with this section shall be prohib-
17 ited from collecting a State licensing fee from
18 a third-party logistics provider.

19 “(d) LICENSE REGULATIONS.—

20 “(1) IN GENERAL.—Not later than 2 years

21 after the date of enactment of the Drug Supply
22 Chain Security Act, the Secretary shall issue regula-
23 tions regarding the minimum issuance and eligibility
24 requirements for licensing under subsection (a), in-
25 cluding the revocation and reissuance of such li-

1 cense, to third-party logistics providers under this
2 section.

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

4 “(A) establish a process by which a third-
5 party accreditation program approved by the
6 Secretary shall, upon request by a third-party
7 logistics provider, issue a license to each third-
8 party logistics provider that meets the min-
9 imum requirements set forth in this section;

10 “(B) establish a process by which the Sec-
11 retary shall issue a license to each third-party
12 logistics provider that meets the minimum re-
13 quirements set forth in this section if the Sec-
14 retary is not able to approve a third-party ac-
15 creditation program because no such program
16 meets the Secretary’s requirements necessary
17 for approval of such a third-party accreditation
18 program;

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

22 “(i) maintaining access to warehouse
23 space of suitable size to facilitate safe op-
24 erations, including a suitable area to quar-
25 antine suspect product;

1 “(ii) maintaining adequate security;

2 and

3 “(iii) having written policies and pro-
4 cedures to—

5 “(I) address receipt, security,
6 storage, inventory, shipment, and dis-
7 tribution of a product;

8 “(II) identify, record, and report
9 confirmed losses or thefts in the
10 United States;

11 “(III) correct errors and inac-
12 curacies in inventories;

13 “(IV) provide support for manu-
14 facturer recalls;

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

20 “(VI) ensure that any expired
21 product is segregated from other
22 products and returned to the manu-
23 facturer or re-packager or destroyed;

24 “(VII) maintain the capability to
25 electronically trace the receipt and

1 outbound distribution of a product,
2 and supplies and records of inventory;
3 and

4 “(VIII) quarantine or destroy a
5 suspect product if directed to do so by
6 the respective manufacturer, wholesale
7 distributor, dispenser or an authorized
8 government agency;

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

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

19 “(F) provide for mandatory background
20 checks of a facility manager or a designated
21 representative of such manager; and

22 “(G) require a third-party logistics pro-
23 vider to provide the Secretary, upon a request
24 by the Secretary, a list of all product manufac-
25 turers, wholesale distributors, and dispensers

1 for whom the third-party logistics provider pro-
2 vides services at such facility.

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

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

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

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

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

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

22 “(a) PRODUCT TRACING AND OTHER REQUIRE-
23 MENTS.—Beginning on the date of enactment of the Drug
24 Supply Chain Security Act, no State or political subdivi-
25 sion of a State may establish or continue in effect any

1 requirements for tracing drugs through the distribution
2 system (including any requirements with respect to state-
3 ments of distribution history, transaction history, trans-
4 action information, or transaction statement of a pharma-
5 ceutical product as such product changes ownership in the
6 supply chain, or verification, investigation, disposition, no-
7 tification, or record-keeping relating to such systems, in-
8 cluding paper or electronic pedigree systems or for track-
9 ing and tracing drugs throughout the distribution system)
10 which are inconsistent with, more stringent than, or in ad-
11 dition to, any requirements applicable under section
12 503(e) (as amended by such Act) or this subchapter (or
13 regulations issued thereunder), or which are inconsistent
14 with—

15 “(1) any waiver, exception, or exemption issued
16 by the Secretary under section 581 or 582; or

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

18 “(b) DISTRIBUTION AND LICENSING STANDARDS.—

19 “(1) IN GENERAL.—Beginning on the date of
20 enactment of the Drug Supply Chain Security Act,
21 no State or political subdivision of a State may es-
22 tablish or continue any standards, requirements, or
23 regulations with respect to wholesale drug dis-
24 tributor or third-party logistics provider licensure
25 that are less stringent than the standards and re-

1 requirements applicable under section 503(e) (as
2 amended by such Act), in the case of a wholesale
3 distributor, or section 584, in the case of a third-
4 party logistics provider.

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

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

14 “(4) ENFORCEMENT, SUSPENSION, AND REV-
15 OCATION OF LICENSES.—Notwithstanding paragraph
16 (1), a State—

17 “(A) may take administrative action, in-
18 cluding fines, to enforce a licensure requirement
19 promulgated by the State in accordance with
20 section 503(e) (as amended by the Drug Supply
21 Chain Security Act) or this subchapter;

22 “(B) may provide for the suspension or
23 revocation of licenses issued by the State for
24 violations of the laws of such State;

1 “(C) upon conviction of violations of Fed-
2 eral, State, or local drug laws or regulations,
3 may provide for fines, imprisonment, or civil
4 penalties; and

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

8 “(c) EXCEPTION.—Nothing in subsection (a) or (b)
9 shall be construed to preempt State requirements related
10 to the distribution of prescription drugs if such require-
11 ments are not related to product tracing as described in
12 subsection (a), including any requirements applicable
13 under section 503(e) (as amended by the Drug Supply
14 Chain Security Act) or this subchapter (or regulations
15 issued thereunder).”.

16 **SEC. 6. PENALTIES.**

17 (a) PROHIBITED ACT.—Section 301(t) of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 331(t)), is
19 amended—

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

22 (2) by inserting “, failure to comply with the
23 requirements under section 582, the failure to com-
24 ply with the requirements under section 584, as ap-
25 plicable,” after “in violation of section 503(e)”.

1 (b) MISBRANDING.—Section 502 of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 352), is amend-
3 ed by adding at the end the following:

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

6 **SEC. 7. CONFORMING AMENDMENTS.**

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

10 **SEC. 8. SAVINGS CLAUSE.**

11 Except as provided in the amendments made by para-
12 graphs (1), (2), and (3) of section 4(a) and by section
13 6(a), nothing in this Act (including the amendments made
14 by this Act) shall be construed as altering any authority
15 of the Secretary of Health and Human Services with re-
16 spect to a drug subject to section 503(b)(1) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1))
18 under any other provision of such Act or the Public Health
19 Service Act (42 U.S.C. 201 et seq.).

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