

113TH CONGRESS  
1ST SESSION

# S. 957

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

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IN THE SENATE OF THE UNITED STATES

MAY 15, 2013

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

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## A BILL

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

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                   gistics 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.).

○