

[DISCUSSION DRAFT]

113TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

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

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Mr. LATTA (for himself, Mr. MATHESON, Mr. UPTON, and Mr. DINGELL) introduced the following bill; which was referred to the Committee on

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**A BILL**

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

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 (a) SHORT TITLE.—This Act may be cited as the  
5 “\_\_\_\_\_ Act of 2013”.

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

- Sec. 1. Short title.
- Sec. 2. Pharmaceutical distribution supply chain.
- Sec. 3. Enhanced drug distribution security.
- Sec. 4. National standards for wholesale distributors.
- Sec. 5. National licensure standards for third-party logistics providers.
- Sec. 6. Penalties.
- Sec. 7. Uniform national policy.
- Sec. 8. Electronic labeling requirement.

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

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

5 **“Subchapter H—Pharmaceutical Distribution**  
6 **Supply Chain**

7 **“SEC. 581. DEFINITIONS.**

8 “In this subchapter:

9 “(1) **AUTHORIZED.**—The term ‘authorized’  
10 means—

11 “(A) in the case of a manufacturer or re-  
12 packager, having a valid registration in accord-  
13 ance with section 510; and

14 “(B) in the case of a wholesale distributor,  
15 third-party logistics provider, or dispenser, li-  
16 censed (as defined in this section).

17 “(2) **DISPENSER.**—The term ‘dispenser’—

18 “(A) subject to subparagraph (B), means a  
19 retail pharmacy, hospital pharmacy, a group of  
20 chain pharmacies under common ownership and  
21 control that do not act as a wholesale dis-

1 tributor, or any other person authorized by law  
2 to dispense or administer prescription drugs  
3 and the affiliated warehouses or distribution  
4 centers of such persons under common owner-  
5 ship and control that do not act as a wholesale  
6 distributor; and

7 “(B) does not include a person who only  
8 dispenses prescription drug product to be used  
9 in animals in accordance with section  
10 512(a)(5).

11 “(3) DISPOSITION.—The term ‘disposition’,  
12 with respect to a prescription drug product within  
13 the possession and control of an entity—

14 “(A) means the removal of such prescrip-  
15 tion drug product, or taking measures to pre-  
16 vent the introduction of such prescription drug  
17 product, from the pharmaceutical distribution  
18 supply chain; and

19 “(B) may include disposal, return of the  
20 prescription drug product for disposal, or other  
21 appropriate handling and other actions such as  
22 retaining a sample of the prescription drug  
23 product for additional physical examination or  
24 laboratory analysis by a manufacturer or regu-  
25 latory or law enforcement agency.

1           “(4) DISTRIBUTE OR DISTRIBUTION.—The  
2 terms ‘distribute’ and ‘distribution’ mean the sale,  
3 purchase, trade, delivery, handling, or storage of a  
4 prescription drug product.

5           “(5) ILLEGITIMATE PRESCRIPTION DRUG PROD-  
6 UCT.—The term ‘illegitimate prescription drug prod-  
7 uct’ means a prescription drug product which a  
8 manufacturer has confirmed—

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

10           “(B) is intentionally adulterated such that  
11 the prescription drug product would result in  
12 serious adverse health consequences or death to  
13 humans; or

14           “(C) is otherwise unfit for distribution  
15 such that the prescription drug product is rea-  
16 sonably likely to cause serious adverse human  
17 health consequences or death.

18           “(6) LICENSED.—The term ‘licensed’ means—

19           “(A) in the case of a wholesale distributor,  
20 having a valid licence to make wholesale dis-  
21 tributions consistent with the standards under  
22 section 583;

23           “(B) in the case of a third-party logistics  
24 provider, having a valid license to engage in the

1 activities of a third-party logistics provider in  
2 accordance with section 584; and

3 “(C) in the case of a dispenser, having a  
4 valid license to dispense prescription drugs  
5 under State law.

6 “(7) MANUFACTURER.—The term ‘manufac-  
7 turer’ means, with respect to a prescription drug  
8 product—

9 “(A) a person that holds an application ap-  
10 proved under section 505 or a license issued  
11 under section 351 of the Public Health Service  
12 Act for such prescription drug product, or if  
13 such prescription drug product is not the sub-  
14 ject of an approved application or license, the  
15 person who manufactured the prescription drug  
16 product;

17 “(B) a co-licensed partner of the person  
18 described in subparagraph (A) that obtains the  
19 prescription drug product directly from the per-  
20 son described in such subparagraph; or

21 “(C) a person that—

22 “(i) is a member of an affiliated  
23 group (as defined in section 1504(a) of the  
24 Internal Revenue Code of 1986) to which

1 a person described in subparagraph (A) or  
2 (B) is also a member; and

3 “(ii) receives the prescription drug  
4 product directly from a person described in  
5 subparagraph (A) or (B).

6 “(8) PACKAGE.—The term ‘package’ means the  
7 smallest individual saleable unit of prescription drug  
8 product for distribution in interstate commerce by a  
9 manufacturer or repackager that is intended by the  
10 manufacturer for ultimate sale to the dispenser of  
11 such prescription drug product.

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

15 “(10) PRESCRIPTION DRUG PRODUCT.—The  
16 term ‘prescription drug product’ means a prescrip-  
17 tion drug in a finished dosage form for administra-  
18 tion to a patient without substantial further manu-  
19 facturing (such as capsules, tablets, and lyophilized  
20 prescription drug products before reconstitution).

21 “(11) PRESCRIPTION DRUG PRODUCT IDENTI-  
22 FIER.—The term ‘prescription drug product identi-  
23 fier’ means a standardized graphic that—

1           “(A) includes the standardized numerical  
2           identifier, lot number, and expiration date of a  
3           prescription drug product; and

4           “(B) is in both human-readable form and  
5           on a machine-readable data carrier that con-  
6           forms to the standards developed by a widely  
7           recognized international standards development  
8           organization.

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

13          “(13) RETURN.—The term ‘return’ means pro-  
14          viding prescription drug product to the authorized  
15          trading partner or trading partners from which such  
16          prescription drug product was purchased, or to a re-  
17          turns processor for handling of such prescription  
18          drug product.

19          “(14) RETURNS PROCESSOR.—The terms ‘re-  
20          turns processor’ mean a person who owns or oper-  
21          ates an establishment that provides for the disposi-  
22          tion of or otherwise processes saleable and nonsale-  
23          able prescription drug product received from an au-  
24          thorized trading partner such that the prescription  
25          drug product may be processed for credit to the pur-

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

3 “(15) SPECIFIC PATIENT NEED.—The term  
4 ‘specific patient need’—

5 “(A) means with respect to the transfer of  
6 a prescription drug product from one pharmacy  
7 to another, to fill a prescription for an identi-  
8 fied patient; and

9 “(B) does not include the transfer of a  
10 prescription drug product from one pharmacy  
11 to another for the purpose of increasing or re-  
12 plenishing stock in anticipation of a potential  
13 need.

14 “(16) STANDARDIZED NUMERICAL IDENTI-  
15 FIER.—The term ‘standardized numerical identifier’  
16 means a set of numbers or characters that—

17 “(A) is used to uniquely identify each  
18 package or homogenous case of the prescription  
19 drug product; and

20 “(B) is composed of the National Drug  
21 Code that corresponds to the specific prescrip-  
22 tion drug product (including the particular  
23 package configuration) combined with a unique  
24 alphanumeric serial number of up to 20 char-  
25 acters.

1           “(17) SUSPECT PRESCRIPTION DRUG PROD-  
2           UCT.—The term ‘suspect prescription drug product’  
3           means a prescription drug product for which there  
4           is reason to believe that such prescription drug prod-  
5           uct—

6                   “(A) is potentially counterfeit, diverted, or  
7                   stolen;

8                   “(B) is potentially intentionally adulterated  
9                   such that the prescription drug product would  
10                  result in serious adverse health consequences or  
11                  death to humans; or

12                  “(C) appears otherwise unfit for distribu-  
13                  tion such that the prescription drug product  
14                  would result in serious adverse health con-  
15                  sequences or death to humans.

16           “(18) THIRD-PARTY LOGISTICS PROVIDER.—  
17           The term ‘third-party logistics provider’ means an  
18           entity that provides or coordinates warehousing, dis-  
19           tribution, or other logistics services of a prescription  
20           drug product in interstate commerce on behalf of a  
21           manufacturer, wholesale distributor, or dispenser of  
22           a prescription drug product, but does not take own-  
23           ership of the prescription drug product, nor have re-  
24           sponsibility to direct the sale or disposition of, the  
25           prescription drug product.

1           “(19) TRADING PARTNER.—The term ‘trading  
2 partner’ means—

3           “(A) a manufacturer, repackager, whole-  
4 sale distributor, or dispenser from whom a  
5 manufacturer, repackager, wholesale dis-  
6 tributor, or dispenser accepts ownership of a  
7 prescription drug product or to whom a manu-  
8 facturer, repackager, wholesale distributor, or  
9 dispenser transfers ownership of a prescription  
10 drug product; or

11           “(B) a third-party logistics provider from  
12 whom a manufacturer, repackager, wholesale  
13 distributor, or dispenser accepts possession of a  
14 prescription drug product or to whom a manu-  
15 facturer, repackager, wholesale distributor, or  
16 dispenser transfers possession of a prescription  
17 drug product.

18           “(20) TRANSACTION.—

19           “(A) IN GENERAL.—The term ‘transaction’  
20 means the transfer in interstate commerce of  
21 prescription drug product between persons in  
22 which a change of ownership occurs.

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

1 “(i) intracompany distribution of any  
2 prescription drug product between mem-  
3 bers of an affiliated group (as defined in  
4 section 1504(a) of the Internal Revenue  
5 Code of 1986);

6 “(ii) the distribution of a prescription  
7 drug product among hospitals or other  
8 health care entities that are under common  
9 control;

10 “(iii) the distribution of a prescription  
11 drug product for emergency medical rea-  
12 sons including a public health emergency  
13 declaration pursuant to section 319 of the  
14 Public Health Service Act, except that a  
15 drug shortage not caused by a public  
16 health emergency shall not constitute an  
17 emergency medical reason;

18 “(iv) the dispensing of a prescription  
19 drug product pursuant to a valid prescrip-  
20 tion executed in accordance with section  
21 503(b)(1);

22 “(v) the distribution of prescription  
23 drug product samples by a manufacturer  
24 or a licensed wholesale distributor in ac-  
25 cordance with section 503(d);

1 “(vi) the distribution of blood or blood  
2 components intended for transfusion;

3 “(vii) the distribution of minimal  
4 quantities of prescription drug product by  
5 a licensed retail pharmacy to a licensed  
6 practitioner for office use;

7 “(viii) the distribution of a prescrip-  
8 tion drug product by a charitable organiza-  
9 tion to a nonprofit affiliate of the organiza-  
10 tion to the extent otherwise permitted by  
11 law;

12 “(ix) the distribution of a prescription  
13 drug product pursuant to the sale or merg-  
14 er of a pharmacy or pharmacies or a  
15 wholesale distributor or wholesale distribu-  
16 tors, except that any records required to be  
17 maintained for the prescription drug prod-  
18 uct shall be transferred to the new owner  
19 of the pharmacy or pharmacies or whole-  
20 sale distributor or wholesale distributors;

21 “(x) the dispensing of a prescription  
22 drug product approved under section  
23 512(b);

24 “(xi) the transfer of prescription drug  
25 products to or from any facility that is li-

1 censed by the Nuclear Regulatory Commis-  
2 sion or by a State pursuant to an agree-  
3 ment with such Commission under section  
4 274 of the Atomic Energy Act of 1954 (42  
5 U.S.C. 2021);

6 “(xii) the distribution of a combina-  
7 tion prescription drug product that con-  
8 sists of—

9 “(I) a prescription drug product  
10 comprised of two or more components  
11 that are each a drug, biological pre-  
12 scription drug product, or device and  
13 that are physically, chemically, or oth-  
14 erwise combined or mixed and pro-  
15 duced as a single entity;

16 “(II) two or more separate pre-  
17 scription drug products packaged to-  
18 gether in a single package or as a unit  
19 and comprised of a drug and device or  
20 a device and biological prescription  
21 drug product; or

22 “(III) two or more finished med-  
23 ical devices plus one or more drug or  
24 biological prescription drug products  
25 which are packaged together in a

1 medical convenience kit described in  
2 clause (xiv);

3 “(xiii) the distribution of a medical  
4 convenience kit which is a collection of fin-  
5 ished products (consisting of devices or  
6 drugs) assembled in kit form strictly for  
7 the convenience of the purchaser or user  
8 if—

9 “(I) the medical convenience kit  
10 is assembled in an establishment that  
11 is registered with the Food and Drug  
12 Administration as a medical device  
13 manufacturer;

14 “(II) the person who manufactur-  
15 ers the medical convenience kit pur-  
16 chased the prescription drug product  
17 directly from the manufacturer or  
18 from a wholesale distributor that pur-  
19 chased the prescription drug product  
20 directly from the manufacturer;

21 “(III) the person who manufac-  
22 turers the medical convenience kit  
23 does not alter the primary container  
24 or label of the prescription drug prod-

1           uct as purchased from the manufac-  
2           turer or wholesale distributor;

3                   “(IV) the medical convenience kit  
4           does not contain a controlled sub-  
5           stance (as defined in section 102 of  
6           the Controlled Substances Act); and

7                   “(V) the prescription drug prod-  
8           ucts contained in the medical conven-  
9           ience kit are—

10                   “(aa) intravenous solutions  
11           intended for the replenishment of  
12           fluids and electrolytes;

13                   “(bb) drugs intended to  
14           maintain the equilibrium of water  
15           and minerals in the body;

16                   “(cc) drugs intended for irri-  
17           gation or reconstitution;

18                   “(dd) anesthetics;

19                   “(ee) anticoagulants;

20                   “(ff) vasopressors; or

21                   “(gg) sympathicomimetics;

22                   “(xiv) the distribution of an intra-  
23           venous prescription drug product that, by  
24           its formulation, is intended for the replen-  
25           ishment of fluids and electrolytes (such as

1 sodium, chloride, and potassium) or cal-  
2 ories (such as dextrose and amino acids);

3 “(xv) the distribution of an intra-  
4 venous prescription drug product used to  
5 maintain the equilibrium of water and min-  
6 erals in the body, such as dialysis solu-  
7 tions;

8 “(xvi) the distribution of a prescrip-  
9 tion drug product that is intended for irri-  
10 gation or reconstitution, or sterile water,  
11 whether intended for such purposes or for  
12 injection; or

13 “(xvii) the distribution of compressed  
14 medical gas.

15 “(C) COMPRESSED MEDICAL GAS.—For  
16 purposes of subparagraph (B)(xviii), the term  
17 ‘compressed medical gas’ means any substance  
18 in its gaseous or cryogenic liquid form that  
19 meets medical purity standards and has appli-  
20 cation in a medical or homecare environment,  
21 including oxygen and nitrous oxide.

22 “(21) TRANSACTION HISTORY.—The term  
23 ‘transaction history’ means a statement that—

24 “(A) includes the transaction information  
25 for each transaction conducted with respect to

1 a prescription drug product beginning with the  
2 manufacturer or initial purchase distributor for  
3 each prior transaction going back to the manu-  
4 facturer of the prescription drug product or to  
5 the initial purchase distributor; and

6 “(B) is in paper or electronic form.

7 “(22) TRANSACTION INFORMATION.—The term  
8 ‘transaction information’ means—

9 “(A) the proprietary or established name  
10 or names of the prescription drug product;

11 “(B) the strength and dosage form of the  
12 prescription drug product;

13 “(C) the National Drug Code number of  
14 the prescription drug product;

15 “(D) the container size;

16 “(E) the number of containers;

17 “(F) the lot number of the prescription  
18 drug product;

19 “(G) the date of the transaction;

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

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

1           “(23) TRANSACTION STATEMENT.—The ‘trans-  
2           action statement’ is a statement, which states that  
3           the manufacturer, repackager, wholesale distributor,  
4           third-party logistics provider, or dispenser transfer-  
5           ring ownership in a transaction—

6                   “(A) is authorized;

7                   “(B) received transaction information and  
8                   a transaction statement as required under sec-  
9                   tion 582 from the prior owner of the prescrip-  
10                  tion drug product;

11                  “(C) did not knowingly and intentionally  
12                  ship an illegitimate prescription drug product;

13                  “(D) did not knowingly and intentionally  
14                  provide false transaction information; and

15                  “(E) did not knowingly and intentionally  
16                  alter the transaction history.

17           “(24) VERIFICATION AND VERIFY.—The terms  
18           ‘verification’ and ‘verify’—

19                   “(A) mean determining whether the pre-  
20                   scription drug product identifier affixed to, or  
21                   imprinted upon, a package or homogeneous case  
22                   of the prescription drug product corresponds to  
23                   the standardized numerical identifier or lot  
24                   number, and expiration date assigned to the

1 prescription drug product by the manufacturer  
2 or the repackager, as applicable; and

3 “(B) include making the determination  
4 under subparagraph (A) using human-readable  
5 or machine-readable methods.

6 “(25) WHOLESALE DISTRIBUTOR.—The term  
7 ‘wholesale distributor’—

8 “(A) means a person engaged in wholesale  
9 distribution (as defined in section 583); and

10 “(B) excludes—

11 “(i) a manufacturer, a co-licensed  
12 partner of a manufacturer, or a third-party  
13 logistics provider, or a dispenser who does  
14 not engage in such wholesale distribution;

15 “(ii) a repackager engaged in such  
16 wholesale distribution; or

17 “(iii) the distribution of prescription  
18 drug product or an offer to distribute pre-  
19 scription drug product by an authorized re-  
20 packager that has taken ownership or pos-  
21 session of the prescription drug product  
22 and repacked the prescription drug prod-  
23 uct in accordance with the requirements of  
24 section 582(e).

1 **“SEC. 582. REQUIREMENTS.**

2 “(a) IN GENERAL.—

3 “(1) COMPLIANCE REQUIRED.—An entity that  
4 is a manufacturer, repackager, wholesale distributor,  
5 third-party logistics provider, or dispenser shall com-  
6 ply with the requirements of this section. If an enti-  
7 ty meets the definition of more than one of the enti-  
8 ties referred to in the preceding sentence, such enti-  
9 ty shall comply with all applicable requirements of  
10 this section, but shall not be required to comply with  
11 duplicative requirements.

12 “(2) STANDARDS.—The Secretary shall, in con-  
13 sultation with other appropriate Federal officials,  
14 manufacturers, repackagers, wholesale distributors,  
15 third-party logistics providers, and dispensers, estab-  
16 lish, by regulation, standards for the exchange of  
17 transaction information for purposes of complying  
18 with this section. The standards established under  
19 this paragraph shall be in accordance with a form  
20 developed by a widely recognized international stand-  
21 ards development organization. In establishing such  
22 standards, the Secretary shall consider the feasibility  
23 of establishing standardized documentation to be  
24 used by all members of the pharmaceutical distribu-  
25 tion supply chain to convey the transaction history  
26 and transaction statement to the subsequent owner

1 of a prescription drug product. The Secretary shall  
2 publish such standards not later than 180 days after  
3 the date of the enactment of the [\_\_\_\_\_ Act of  
4 2013].

5 “(3) WAIVERS, EXCEPTIONS, AND EXEMP-  
6 TIONS.—Not later than one year after the date of  
7 the enactment of the [\_\_\_\_\_ Act of 2013], the  
8 Secretary shall promulgate a regulation to—

9 “(A) establish a process by which the Sec-  
10 retary may grant, at the request of an author-  
11 ized manufacturer, repackager, wholesale dis-  
12 tributor, or dispenser, a waiver from any of the  
13 requirements of this section—

14 “(i) if the Secretary determines that  
15 such requirements would result in an  
16 undue economic hardship; or

17 “(ii) for emergency medical reasons,  
18 including a public health emergency dec-  
19 laration pursuant to section 319 of the  
20 Public Health Service Act;

21 “(B) establish a process, with respect to  
22 the prescription drug product identifier require-  
23 ment under paragraph (2) of subsections (b),  
24 (c), (d), and (e) through which—

1 “(i) a manufacturer or repackager  
2 may request a waiver with respect to pre-  
3 scription drug products that are packaged  
4 in a container too small or otherwise un-  
5 able to accommodate a label with sufficient  
6 space to bear the information required for  
7 compliance with such requirement; and

8 “(ii) the Secretary determines whether  
9 to waive such requirement; and

10 “(C) establish a process by which the Sec-  
11 retary may add the prescription drug products  
12 or transactions that are exempt from the re-  
13 quirements of this section.

14 “(4) GRANDFATHERED PERSONS AND PRE-  
15 SCRIPTON DRUG PRODUCTS.—

16 “(A) IN GENERAL.—Not later than one  
17 year after the date of the enactment of the  
18 **[\_\_\_\_\_ Act of 2013]**, the Secretary shall  
19 specify, by regulation, whether and under what  
20 circumstances the prescription drug product  
21 identifier requirement under paragraph (2) of  
22 subsections (b), (c), (d), and (e) shall apply to  
23 a prescription drug product that is in the sup-  
24 ply chain on the date of the enactment of the  
25 **[\_\_\_\_\_ Act of 2013]**.

1           “(B) THIRD-PARTY LOGISTICS PROVIDER  
2           LICENSES.—Until the date that is 1 year after  
3           the effective date of the third-party logistics  
4           provider licensing requirements under section  
5           584, a third-party logistics provider shall be  
6           considered ‘licensed’ under section 581(6)(B)  
7           unless the Secretary has made a finding that  
8           the third-party logistics provider does not utilize  
9           good handling and distribution practices and  
10          publishes notice thereof.

11          “(C) LABEL CHANGES.—Changes made to  
12          package labels solely to incorporate the pre-  
13          scription drug product identifier may be sub-  
14          mitted to the Secretary in the annual report of  
15          an establishment, in accordance with section  
16          314.70(d) of chapter 21, Code of Federal Regu-  
17          lations (or any successor regulation).

18          “(b) MANUFACTURER REQUIREMENTS.—

19                 “(1) PRESCRIPTION DRUG PRODUCT TRAC-  
20                 ING.—

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

23                                 “(i) prior to each transaction in which  
24                                 such manufacturer transfers ownership of  
25                                 a prescription drug product, provide the

1 subsequent owner with the transaction his-  
2 tory and a transaction statement; and

3 “(ii) maintain the transaction infor-  
4 mation for each such transaction for not  
5 less than 3 years after the date of the  
6 transaction.

7 “(B) REQUESTS FOR INFORMATION.—  
8 Upon a request by the Secretary or other ap-  
9 propriate Federal or State official, in the event  
10 of a recall or for the purpose of investigating a  
11 suspect prescription drug product or an illegit-  
12 imate prescription drug product, a manufac-  
13 turer shall, not later than 2 business days after  
14 receiving the request or in such reasonable time  
15 as determined by the Secretary, provide to the  
16 Secretary or other official, the applicable trans-  
17 action history and transaction statement for the  
18 prescription drug product.

19 “(2) PRESCRIPTION DRUG PRODUCT IDENTI-  
20 FIER.—Beginning not later than 5 years after the  
21 date of the enactment of the [\_\_\_\_\_ Act of 2013],  
22 a manufacturer shall affix or imprint a prescription  
23 drug product identifier on each package and homog-  
24 enous case of a prescription drug product intended  
25 to be introduced in a transaction. Such manufac-

1 turer shall maintain a copy of the prescription drug  
2 product identifier for such prescription drug product  
3 for not less than 3 years after the date of the trans-  
4 action.

5 “(3) AUTHORIZED TRADING PARTNERS.—Be-  
6 ginning not later than January 1, 2015, a manufac-  
7 turer shall ensure that each of its trading partners  
8 is authorized.

9 “(4) LIST OF AUTHORIZED DISTRIBUTORS OF  
10 RECORD.—Beginning not later than January 1,  
11 2015, each manufacturer of a prescription drug  
12 shall—

13 “(A) maintain a list of the authorized dis-  
14 tributors of record of such drug at the cor-  
15 porate offices of such manufacturer;

16 “(B) make such list publicly available, in-  
17 cluding placement on the Internet website of  
18 such manufacturer; and

19 “(C) update such list not less than once  
20 per quarter.

21 “(5) VERIFICATION.—Beginning not later than  
22 January 1, 2015, a manufacturer shall implement  
23 systems and processes to enable the manufacturer to  
24 comply with the following requirements:

1                   “(A) SUSPECT PRESCRIPTION DRUG PROD-  
2                   UCT.—

3                   “(i) IN GENERAL.—Upon making a  
4                   determination that a prescription drug  
5                   product in the possession or control of the  
6                   manufacturer is a suspect prescription  
7                   drug product, or upon receiving a request  
8                   for verification from the Secretary that a  
9                   prescription drug product within the pos-  
10                  session or control of a manufacturer is a  
11                  suspect prescription drug product, a manu-  
12                  facturer shall promptly conduct an inves-  
13                  tigation in coordination with trading part-  
14                  ners, as applicable, to determine whether  
15                  the prescription drug product is an illegit-  
16                  imate prescription drug product. Beginning  
17                  not later than 5 years after the date of the  
18                  enactment of the \_\_\_\_\_ Act of 2013, such  
19                  investigation shall include—

20                               “(I) verifying the prescription  
21                               drug product at the package level;

22                               “(II) validating any applicable  
23                               transaction history in the possession  
24                               of the manufacturer; and

1                   “(III) otherwise investigating to  
2                   determine whether the prescription  
3                   drug product is an illegitimate pre-  
4                   scription drug product.

5                   “(ii) CLEARED PRESCRIPTION DRUG  
6                   PRODUCT.—If the manufacturer deter-  
7                   mines that a suspect prescription drug  
8                   product is not an illegitimate prescription  
9                   drug product, the manufacturer shall  
10                  promptly notify the Secretary of such de-  
11                  termination and such prescription drug  
12                  product may be further distributed.

13                  “(iii) RECORDS.—A manufacturer  
14                  shall keep records of its investigation of a  
15                  suspect prescription drug product for not  
16                  less than 3 years after the conclusion of  
17                  the investigation.

18                  “(B) ILLEGITIMATE PRESCRIPTION DRUG  
19                  PRODUCT.—

20                  “(i) IN GENERAL.—Upon determining  
21                  that a prescription drug product in the  
22                  possession or control of a manufacturer is  
23                  an illegitimate prescription drug product,  
24                  the manufacturer shall—

1                   “(I) quarantine such prescription  
2                   drug product from prescription drug  
3                   product intended for distribution; and

4                   “(II) provide for the disposition  
5                   of the illegitimate prescription drug  
6                   product.

7                   “(ii) TRADING PARTNER.—Upon de-  
8                   termining that a prescription drug product  
9                   in the possession or control of a trading  
10                  partner is an illegitimate prescription drug  
11                  product, the manufacturer shall take rea-  
12                  sonable steps to assist a trading partner to  
13                  provide for the disposition of the illegit-  
14                  imate prescription drug product.

15                  “(iii) MAKING A NOTIFICATION.—  
16                  Upon determining that a prescription drug  
17                  product in the possession or control of the  
18                  manufacturer is an illegitimate prescrip-  
19                  tion drug product, the manufacturer shall  
20                  notify the Secretary of such determination  
21                  not later than 24 hours after making such  
22                  determination. The Secretary shall deter-  
23                  mine whether additional trading partner  
24                  notification is appropriate.

1                   “(iv) RESPONDING TO A NOTIFICA-  
2                   TION.—Upon the receipt of a notification  
3                   from the Secretary that a determination  
4                   has been made that a prescription drug  
5                   product is an illegitimate prescription drug  
6                   product, a manufacturer shall—

7                   “(I) identify all illegitimate pre-  
8                   scription drug products that are sub-  
9                   ject to such notification and in the  
10                  possession or control of the manufac-  
11                  turer, including any prescription drug  
12                  product that is subsequently received;  
13                  and

14                  “(II) perform the activities de-  
15                  scribed in clause (i).

16                  “(v) RECORDS.—A manufacturer shall  
17                  keep records of the disposition of an illegit-  
18                  imate prescription drug product for not  
19                  less than 3 years after the conclusion of  
20                  the disposition.

21                  “(C) ELECTRONIC DATABASE.—A manu-  
22                  facturer may satisfy the requirements of this  
23                  paragraph through the use of a secure elec-  
24                  tronic database developed and operated by the  
25                  manufacturer or another entity. The owner of

1 such database shall establish the requirements  
2 and processes to respond to requests and may  
3 provide for data access to other members of the  
4 pharmaceutical distribution supply chain, as ap-  
5 propriate. The development and operation of  
6 such a database shall not relieve a manufac-  
7 turer of the requirement under this paragraph  
8 to respond to a verification request submitted  
9 by means other than a secure electronic data-  
10 base.

11 “(D) RETURNED PRESCRIPTION DRUG  
12 PRODUCT.—Beginning not later than 5 years  
13 after the date of the enactment of the \_\_\_\_\_  
14 Act of 2013, upon receipt of a returned pre-  
15 scription drug product that the manufacturer  
16 intends to further distribute, before further dis-  
17 tributing such prescription drug product, the  
18 manufacturer shall—

19 “(i) verify the prescription drug prod-  
20 uct identifier for each sealed homogeneous  
21 case of such prescription drug product; or

22 “(ii) if such prescription drug product  
23 is not in a sealed homogeneous case, verify  
24 the prescription drug product identifier on  
25 each package.

1 “(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

2 “(1) PRESCRIPTION DRUG PRODUCT TRAC-  
3 ING.—

4 “(A) IN GENERAL.—Beginning not later  
5 than April 1, 2015, a wholesale distributor  
6 shall—

7 “(i) not accept ownership of a pre-  
8 scription drug product unless the previous  
9 owner prior to the transaction provides the  
10 applicable transaction history and a trans-  
11 action statement for the prescription drug  
12 product;

13 “(ii) prior to each transaction in  
14 which the wholesale distributor transfers  
15 ownership of a prescription drug product—

16 “(I) in the case that the whole-  
17 sale distributor purchased the pre-  
18 scription drug product directly from  
19 the manufacturer, provide the subse-  
20 quent owner with transaction history  
21 and a transaction statement for the  
22 prescription drug product; or

23 “(II) in the case that the whole-  
24 sale distributor did not purchase the  
25 prescription drug product directly

1 from the manufacturer, the exclusive  
2 distributor of the manufacturer, or a  
3 repackager that purchased directly  
4 from the manufacturer, provide the  
5 subsequent owner with transaction  
6 history beginning with the wholesale  
7 distributor that did purchase the  
8 product directly from the manufac-  
9 turer, the exclusive distributor of the  
10 manufacturer, or a repackager that  
11 purchased directly from the manufac-  
12 turer;

13 “(iii) notwithstanding clause (ii), if  
14 the wholesale distributor purchased the  
15 prescription drug product directly from the  
16 manufacturer, its exclusive distributor, or  
17 a repackager that purchased directly from  
18 the manufacturer or its authorized dis-  
19 tributor of record—

20 “(I) provide an initial purchase  
21 transaction statement on the invoice  
22 to the customer, stating that the  
23 wholesale distributor purchased the  
24 prescription drug product package di-

1 rectly from the manufacturer, exclu-  
2 sive distributor, or repackager;

3 “(II) make available to the imme-  
4 diate subsequent recipient of such  
5 prescription drug product the infor-  
6 mation required under clause (ii)  
7 through any combination of self-gen-  
8 erated paper, electronic data, or man-  
9 ufacturer provided information on the  
10 prescription drug product package;  
11 and

12 “(III) for purposes of subclauses  
13 (I) and (II), need not include any  
14 transactions occurring before the  
15 transfer of the prescription drug prod-  
16 uct to the wholesale distributor; and

17 “(iv) maintain the transaction infor-  
18 mation for each transaction described in  
19 clauses (i) and (ii) for not less than 3  
20 years after the transaction.

21 “(B) RETURNS EXCEPTION.—

22 “(i) SALEABLE RETURNS.—Notwith-  
23 standing subparagraph (A), a wholesale  
24 distributor may—

1                   “(I) accept returned prescription  
2                   drug product without a transaction  
3                   history from a dispenser; and

4                   “(II) distribute such returned  
5                   prescription drug product with a  
6                   transaction history that begins with  
7                   the wholesale distributor that so ac-  
8                   cepted the returned product.

9                   “(ii) NONSALEABLE RETURNS.—A  
10                  wholesale distributor may return a non-  
11                  saleable prescription drug to the manufac-  
12                  turer or repackager, to the wholesale dis-  
13                  tributor from whom such prescription drug  
14                  was purchased, or to a person acting on  
15                  behalf of such a person, including a re-  
16                  turns processor, without providing the in-  
17                  formation required under subparagraph  
18                  (A).

19                  “(C) REQUESTS FOR INFORMATION.—  
20                  Upon a request by the Secretary or other ap-  
21                  propriate Federal or State official, in the event  
22                  of a recall or for the purpose of investigating a  
23                  suspect prescription drug product or an illegit-  
24                  imate prescription drug product a wholesale dis-  
25                  tributor shall, not later than 2 business days

1 after receiving the request or in such other rea-  
2 sonable time as determined by the Secretary,  
3 provide the applicable transaction history and  
4 transaction statements for the prescription drug  
5 product.

6 “(2) PRESCRIPTION DRUG PRODUCT IDENTIFI-  
7 FIER.—Beginning not later than 7 years after the  
8 date of the enactment of the [\_\_\_\_\_ Act of 2013],  
9 a wholesale distributor may engage in transactions  
10 involving a prescription drug product only if such  
11 prescription drug product is encoded with a prescrip-  
12 tion drug product identifier, except as provided in  
13 subsection (a)(4).

14 “(3) AUTHORIZED TRADING PARTNERS.—Be-  
15 ginning not later than January 1, 2015, a wholesale  
16 distributor shall ensure that each of its trading part-  
17 ners is authorized.

18 “(4) VERIFICATION.—Beginning not later than  
19 April 1, 2015, a wholesale distributor shall imple-  
20 ment systems to enable the wholesale distributor to  
21 comply with the following requirements:

22 “(A) SUSPECT PRESCRIPTION DRUG PROD-  
23 UCT.—

24 “(i) IN GENERAL.—Upon making a  
25 determination that a prescription drug

1 product in the possession or control of the  
2 wholesale distributor is a suspect prescrip-  
3 tion drug product, or upon receiving a re-  
4 quest for verification from the Secretary  
5 that a prescription drug product within the  
6 possession or control of a wholesale dis-  
7 tributor is a suspect prescription drug  
8 product, a wholesale distributor shall  
9 promptly conduct an investigation to deter-  
10 mine whether the prescription drug prod-  
11 uct is an illegitimate prescription drug  
12 product. Beginning not later than 7 years  
13 after the date of the enactment of the  
14 \_\_\_\_\_ Act of 2013, such investigation  
15 shall include—

16 “(I) verifying a package of the  
17 prescription drug product;

18 “(II) validating any applicable  
19 transaction history in the possession  
20 of the wholesale distributor; and

21 “(III) otherwise investigating to  
22 determine whether the prescription  
23 drug product is an illegitimate pre-  
24 scription drug product.

1 “(ii) CLEARED PRESCRIPTION DRUG  
2 PRODUCT.—If the wholesale distributor de-  
3 termines that a suspect prescription drug  
4 product is not an illegitimate prescription  
5 drug product, the wholesale distributor  
6 shall promptly notify the Secretary of such  
7 determination and such prescription drug  
8 product may be further distributed.

9 “(iii) RECORDS.—A wholesale dis-  
10 tributor shall keep records of its investiga-  
11 tion of a suspect prescription drug product  
12 for not less than 3 years after the conclu-  
13 sion of the investigation.

14 “(B) ILLEGITIMATE PRESCRIPTION DRUG  
15 PRODUCT.—

16 “(i) IN GENERAL.—Upon receiving  
17 notice that a manufacturer of a prescrip-  
18 tion drug product has determined that a  
19 prescription drug product in the possession  
20 or control of a wholesale distributor is an  
21 illegitimate prescription drug product, the  
22 wholesale distributor shall—

23 “(I) quarantine such prescription  
24 drug product within the possession or  
25 control of the manufacturer from pre-

1 prescription drug product intended for  
2 distribution; and

3 “(II) provide for the disposition  
4 of the illegitimate prescription drug  
5 product within the possession or con-  
6 trol of the wholesale distributor.

7 “(ii) TRADING PARTNER.—Upon de-  
8 termining that a prescription drug product  
9 in the possession or control of a trading  
10 partner is an illegitimate prescription drug  
11 product, the wholesale distributor shall  
12 take reasonable steps to assist a trading  
13 partner to provide for the disposition of  
14 the illegitimate prescription drug product.

15 “(iii) MAKING A NOTIFICATION.—  
16 Upon determining that a prescription drug  
17 product in the possession or control of the  
18 wholesale distributor is an illegitimate pre-  
19 scription drug product, the wholesale dis-  
20 tributor shall notify the Secretary of such  
21 determination not later than 24 hours  
22 after making such determination. The Sec-  
23 retary shall determine whether additional  
24 trading partner notification is appropriate.

1                   “(iv) RESPONDING TO A NOTIFICA-  
2                   TION.—Upon the receipt of a notification  
3                   from the Secretary that a determination  
4                   has been made that a prescription drug  
5                   product is an illegitimate prescription drug  
6                   product, a wholesale distributor shall—

7                   “(I) identify all illegitimate pre-  
8                   scription drug product subject to such  
9                   notification that is in the possession  
10                  or control of the wholesale distributor,  
11                  including any prescription drug prod-  
12                  uct that is subsequently received; and

13                  “(II) perform the activities de-  
14                  scribed in clause (i).

15                  “(v) RECORDS.—A wholesale dis-  
16                  tributor shall keep records of the dispo-  
17                  sition of an illegitimate prescription drug  
18                  product for not less than 3 years after the  
19                  conclusion of the disposition.

20                  “(C) ELECTRONIC DATABASE.—A whole-  
21                  sale distributor may satisfy the requirements of  
22                  this paragraph through the use of a secure elec-  
23                  tronic database developed and operated by the  
24                  manufacturer or another entity. The owner of  
25                  such database shall establish the requirements

1 and processes to respond to requests and may  
2 provide for data access to other members of the  
3 pharmaceutical distribution supply chain, as ap-  
4 propriate. The development and operation of  
5 such a database shall not relieve a wholesale  
6 distributor of the requirement under this para-  
7 graph to respond to a verification request sub-  
8 mitted by means other than a secure electronic  
9 database.

10 “(D) RETURNED PRESCRIPTION DRUG  
11 PRODUCT.—Beginning not later than 7 years  
12 after the date of the enactment of the \_\_\_\_\_  
13 Act of 2013, upon receipt of a returned pre-  
14 scription drug product that the wholesale dis-  
15 tributor intends to further distribute, before  
16 further distributing such prescription drug  
17 product, the wholesale distributor shall—

18 “(i) verify the prescription drug prod-  
19 uct identifier for each sealed homogeneous  
20 case of such prescription drug product; or

21 “(ii) if such prescription drug product  
22 is not in a sealed homogeneous case, verify  
23 the prescription drug product identifier on  
24 each package.

25 “(d) DISPENSER REQUIREMENTS.—

1           “(1) PRESCRIPTION DRUG PRODUCT TRAC-  
2           ING.—

3           “(A) IN GENERAL.—Beginning not later  
4           than July 1, 2015, a dispenser—

5           “(i) shall not accept ownership of a  
6           prescription drug product, unless the pre-  
7           vious owner prior to the transaction, pro-  
8           vides transaction history and a transaction  
9           statement;

10           “(ii) prior to each transaction in  
11           which the dispenser transfers ownership of  
12           a prescription drug product (but not in-  
13           cluding dispensing to a patient or returns)  
14           shall provide the subsequent owner with  
15           transaction history and a transaction state-  
16           ment for the prescription drug product, ex-  
17           cept that the requirements of this clause  
18           shall not apply to sales by a dispenser to  
19           another dispenser to fulfill a specific pa-  
20           tient need; and

21           “(iii) shall maintain transaction infor-  
22           mation for a period of not less than 3  
23           years after the date of the transaction.

24           “(B) AGREEMENTS WITH THIRD PAR-  
25           TIES.—A dispenser may enter into a written

1 agreement with a third party, including an au-  
2 thorized wholesale distributor, under which the  
3 third party confidentially maintains the trans-  
4 action information required to be maintained  
5 under this subsection on behalf of the dis-  
6 penser. If a dispenser enters into such an  
7 agreement, the dispenser shall maintain a copy  
8 of the written agreement.

9 “(C) RETURNS EXCEPTION.—

10 “(i) SALEABLE RETURNS.—Notwith-  
11 standing subparagraph (A)(ii), a dispenser  
12 may return prescription drug product to  
13 the trading partner from which the dis-  
14 penser obtained the prescription drug  
15 product without providing the information  
16 required under such subparagraph.

17 “(ii) NONSALEABLE RETURNS.—Not-  
18 withstanding subparagraph (A)(ii), a dis-  
19 penser may return a nonsaleable prescrip-  
20 tion drug to the manufacturer or repack-  
21 ager, to the wholesale distributor from  
22 whom such prescription drug was pur-  
23 chased, to a returns processor, or to a per-  
24 son acting on behalf of such persons with-

1 out providing the information required  
2 under such subparagraph.

3 “(D) REQUESTS FOR INFORMATION.—

4 Upon a request by the Secretary or other ap-  
5 propriate Federal or State official, in the event  
6 of a recall or for the purpose of investigating a  
7 suspect prescription drug product or an illegiti-  
8 mate prescription drug 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, pro-  
12 vide lot level transaction information.

13 “(2) PRESCRIPTION DRUG PRODUCT IDENTIFI-  
14 FIER.—Beginning not later than 8 years after the  
15 date of the enactment of the [\_\_\_\_\_ Act of 2013],  
16 a dispenser may engage in transactions involving a  
17 prescription drug product only if such prescription  
18 drug product is encoded with a prescription drug  
19 product identifier, except as provided in subsection  
20 (a)(4).

21 “(3) AUTHORIZED TRADING PARTNERS.—Be-  
22 ginning not later than January 1, 2015, a dispenser  
23 shall ensure that each of its trading partners is au-  
24 thorized.

1           “(4) VERIFICATION.—Beginning not later than  
2           January 1, 2015, a dispenser shall implement sys-  
3           tems to enable the dispenser to comply with the fol-  
4           lowing requirements:

5                   “(A) SUSPECT PRESCRIPTION DRUG PROD-  
6           UCT.—

7                           “(i) IN GENERAL.—Upon making a  
8                           determination that a prescription drug  
9                           product in the possession or control of the  
10                          dispenser is a suspect prescription drug  
11                          product, or upon receiving a request for  
12                          verification from the Secretary that a pre-  
13                          scription drug product within the posses-  
14                          sion or control of a dispenser is a suspect  
15                          prescription drug product, a dispenser  
16                          shall promptly conduct an investigation to  
17                          determine whether the prescription drug  
18                          product is an illegitimate prescription drug  
19                          product. Such investigation shall include—

20                                   “(I) verifying whether the lot  
21                                   number of a suspect prescription drug  
22                                   product corresponds with the lot num-  
23                                   ber for such prescription drug prod-  
24                                   uct;

1 “(II) beginning 8 years after the  
2 date of the enactment of the \_\_\_\_\_  
3 Act of 2013, verifying that the prod-  
4 uct identifier of at least 3 packages or  
5 10 percent of such suspect prescrip-  
6 tion drug product, whichever is great-  
7 er, or all packages, if there are fewer  
8 than 3, corresponds with the prescrip-  
9 tion drug product identifier for such  
10 product;

11 “(III) validating any applicable  
12 transaction history in the possession  
13 of the dispenser; and

14 “(IV) otherwise investigating to  
15 determine whether the prescription  
16 drug product is an illegitimate pre-  
17 scription drug product.

18 “(ii) CLEARED PRESCRIPTION DRUG  
19 PRODUCT.—If the dispenser makes the de-  
20 termination that a suspect prescription  
21 drug product is not an illegitimate pre-  
22 scription drug product, the dispenser shall  
23 promptly notify the Secretary of such de-  
24 termination and such prescription drug  
25 product may be further dispensed.

1 “(iii) RECORDS.—A dispenser shall  
2 keep records of its investigation of a sus-  
3 pect prescription drug product for not less  
4 than 3 years after the conclusion of the in-  
5 vestigation.

6 “(B) ILLEGITIMATE PRESCRIPTION DRUG  
7 PRODUCT.—

8 “(i) IN GENERAL.—Upon receiving  
9 notice that a manufacturer of a prescrip-  
10 tion drug product has determined that a  
11 prescription drug product in the possession  
12 or control of a dispenser is an illegitimate  
13 prescription drug product, the dispenser  
14 shall—

15 “(I) quarantine such prescription  
16 drug product within the possession or  
17 control of the dispenser from prescrip-  
18 tion drug product intended for dis-  
19 tribution; and

20 “(II) provide for the disposition  
21 of the illegitimate prescription drug  
22 product within the possession or con-  
23 trol of the dispenser.

24 “(ii) TRADING PARTNERS.—Upon de-  
25 termining that a prescription drug product

1 in the possession or control of a trading  
2 partner is an illegitimate prescription drug  
3 product, the dispenser shall take reason-  
4 able steps to assist a trading partner to  
5 provide for the disposition of the illegit-  
6 imate prescription drug product.

7 “(iii) MAKING A NOTIFICATION.—  
8 Upon determining that a prescription drug  
9 product in the possession or control of the  
10 dispenser is an illegitimate prescription  
11 drug product, the dispenser shall notify the  
12 Secretary of such determination not later  
13 than 24 hours after making such deter-  
14 mination. The Secretary shall determine  
15 whether additional trading partner notifi-  
16 cation is appropriate.

17 “(iv) RESPONDING TO A NOTIFICA-  
18 TION.—Upon the receipt of a notification  
19 from the Secretary that a determination  
20 has been made that a prescription drug  
21 product is an illegitimate prescription drug  
22 product, a dispenser shall—

23 “(I) identify all illegitimate pre-  
24 scription drug products that are sub-  
25 ject to such notification and in the

1 possession or control of the dispenser,  
2 including any prescription drug prod-  
3 uct that is subsequently received; and

4 “(II) perform the activities de-  
5 scribed in clause (i).

6 “(v) RECORDS.—A dispenser shall  
7 keep records of the disposition of an illegit-  
8 imate prescription drug product for not  
9 less than 3 years after the conclusion of  
10 the disposition.

11 “(C) ELECTRONIC DATABASE.—A dis-  
12 penser may satisfy the requirements of this  
13 paragraph through the use of a secure elec-  
14 tronic database developed and operated by the  
15 manufacturer or another entity. The owner of  
16 such database shall establish the requirements  
17 and processes to enable responding to requests  
18 and may provide for data access to other mem-  
19 bers of the pharmaceutical distribution supply  
20 chain, as appropriate. The development and op-  
21 eration of such a database shall not relieve a  
22 dispenser of the requirement under this para-  
23 graph to respond to a verification request sub-  
24 mitted by means other than a secure electronic  
25 database.

1 “(e) REPACKAGER REQUIREMENTS.—

2 “(1) PRESCRIPTION DRUG PRODUCT TRAC-  
3 ING.—

4 “(A) IN GENERAL.—Beginning not later  
5 than January 1, 2015, a repackager shall—

6 “(i) not accept ownership of a pre-  
7 scription drug product unless the previous  
8 owner, prior to the transaction, provides  
9 transaction history and a transaction state-  
10 ment for the prescription drug product;

11 “(ii) prior to each transaction in  
12 which the repackager transfers ownership  
13 of a prescription drug product, provide the  
14 subsequent owner with transaction history  
15 and a transaction statement;

16 “(iii) maintain the transaction infor-  
17 mation for each transaction described in  
18 clause (i) or (ii) for not less than 3 years  
19 after the transaction; and

20 “(iv) maintain records that allow the  
21 repackager to associate the prescription  
22 drug product identifier the repackager af-  
23 fixes or imprints with the prescription drug  
24 product identifier assigned by the original

1 manufacturer of the prescription drug  
2 product.

3 “(B) NONSALEABLE RETURNS.—A repack-  
4 ager may return a nonsaleable prescription  
5 drug product to the manufacturer or repack-  
6 ager, to the wholesale distributor from whom  
7 such prescription drug product was purchased,  
8 or to a person acting on behalf of such a per-  
9 son, including a returns processor, without pro-  
10 viding the information required under subpara-  
11 graph (A)(ii).

12 “(C) REQUESTS FOR INFORMATION.—  
13 Upon a request by the Secretary or other ap-  
14 propriate Federal or State official, in the event  
15 of a recall or for the purpose of investigating a  
16 suspect prescription drug product or an illegiti-  
17 mate prescription drug product, a repackager  
18 shall, not later than 2 business days after re-  
19 ceiving the request or in such other reasonable  
20 time as determined by the Secretary, provide  
21 the applicable transaction history and trans-  
22 action statement for the prescription drug prod-  
23 uct.

24 “(2) PRESCRIPTION DRUG PRODUCT IDENTI-  
25 FIER.—Beginning not later than 6 years after the

1 date of the enactment of the [\_\_\_\_\_ Act of 2013],  
2 a repackager—

3 “(A) shall affix or imprint a prescription  
4 drug product identifier to each package and ho-  
5 mogenous case of prescription drug product in-  
6 tended to be introduced in a transaction;

7 “(B) shall maintain the prescription drug  
8 product identifier for such prescription drug  
9 product for not less than 3 years after the date  
10 of the transaction; and

11 “(C) may engage in transactions involving  
12 a prescription drug product only if such pre-  
13 scription drug product is encoded with a pre-  
14 scription drug product identifier except as pro-  
15 vided in subsection (a)(4).

16 “(3) AUTHORIZED TRADING PARTNERS.—Be-  
17 ginning on January 1, 2015, a repackager shall en-  
18 sure that each of its trading partners is authorized.

19 “(4) VERIFICATION.—Beginning not later than  
20 January 1, 2015, a repackager shall implement sys-  
21 tems to enable the repackager to comply with the  
22 following requirements:

23 “(A) SUSPECT PRESCRIPTION DRUG PROD-  
24 UCT.—

1                   “(i) IN GENERAL.—Upon making a  
2                   determination that a prescription drug  
3                   product in the possession or control of the  
4                   repackager is a suspect prescription drug  
5                   product, or upon receiving a request for  
6                   verification from the Secretary that a pre-  
7                   scription drug product within the posses-  
8                   sion or control of a repackager is a suspect  
9                   prescription drug product, a repackager  
10                  shall promptly conduct an investigation to  
11                  determine whether the prescription drug  
12                  product is an illegitimate prescription drug  
13                  product, including—

14                               “(I) beginning not later than 6  
15                               years after the date of the enactment  
16                               of the \_\_\_\_\_ Act of 2013, verifying  
17                               the prescription drug product at the  
18                               package level;

19                               “(II) validating any applicable  
20                               transaction information in the posses-  
21                               sion of the repackager; and

22                               “(III) otherwise investigating to  
23                               determine whether the prescription  
24                               drug product is an illegitimate pre-  
25                               scription drug product.

1                   “(ii) CLEARED PRESCRIPTION DRUG  
2                   PRODUCT.—If the repackager determines  
3                   that a suspect prescription drug product is  
4                   not an illegitimate prescription drug prod-  
5                   uct, the repackager shall promptly notify  
6                   the Secretary of such determination and  
7                   such prescription drug product may be fur-  
8                   ther distributed.

9                   “(iii) RECORDS.—A repackager shall  
10                  keep records of its investigation of a sus-  
11                  pect prescription drug product for not less  
12                  than 3 years after the conclusion of the in-  
13                  vestigation.

14                  “(B) ILLEGITIMATE PRESCRIPTION DRUG  
15                  PRODUCT.—

16                  “(i) IN GENERAL.—Upon receiving  
17                  notice that a manufacturer of a prescrip-  
18                  tion drug product has determined that a  
19                  prescription drug product in the possession  
20                  or control of a repackager is an illegitimate  
21                  prescription drug product, the repackager  
22                  shall—

23                                  “(I) quarantine such prescription  
24                                  drug product within the possession or  
25                                  control of the repackager from pre-

1 prescription drug product intended for  
2 distribution; and

3 “(II) provide for the disposition  
4 of the illegitimate prescription drug  
5 product within the possession or con-  
6 trol of the repackager.

7 “(ii) TRADING PARTNER.—Upon de-  
8 termining that a prescription drug product  
9 in the possession or control of a trading  
10 partner is an illegitimate prescription drug  
11 product, the repackagers shall take reason-  
12 able steps to assist the trading partner to  
13 provide for the disposition of the illegit-  
14 imate prescription drug product.

15 “(iii) MAKING A NOTIFICATION.—  
16 Upon determining that a prescription drug  
17 product in the possession or control of the  
18 repackager is an illegitimate prescription  
19 drug product, the repackager shall notify  
20 the Secretary of such determination not  
21 later than 24 hours after making such de-  
22 termination. The Secretary shall determine  
23 whether additional trading partner notifi-  
24 cation is appropriate.

1                   “(iv) RESPONDING TO A NOTIFICA-  
2                   TION.—Upon the receipt of a notification  
3                   from the Secretary that a determination  
4                   has been made that a prescription drug  
5                   product is an illegitimate prescription drug  
6                   product, a repackager shall—

7                   “(I) identify all illegitimate pre-  
8                   scription drug products that are sub-  
9                   ject to such notification and in the  
10                  possession or control of the repack-  
11                  ager, including any prescription drug  
12                  product that is subsequently received;  
13                  and

14                  “(II) perform the activities de-  
15                  scribed in clause (i).

16                  “(v) RECORDS.—A repackager shall  
17                  keep records of the disposition of an illegit-  
18                  imate prescription drug product for not  
19                  less than 3 years after the conclusion of  
20                  the disposition.

21                  “(C) ELECTRONIC DATABASE.—A repack-  
22                  ager may satisfy the requirements of this para-  
23                  graph through the use of a secure electronic  
24                  database developed and operated by the manu-  
25                  facturer or another entity. The owner of such

1 database shall establish the requirements and  
2 processes to respond to requests and may pro-  
3 vide for data access to other members of the  
4 pharmaceutical distribution supply chain, as ap-  
5 propriate. The development and operation of  
6 such a database shall not relieve a repackager  
7 of the requirement under this paragraph to re-  
8 spond to a verification request submitted by  
9 means other than a secure electronic database.

10 “(D) RETURNED PRESCRIPTION DRUG  
11 PRODUCT.—Beginning not later than 6 years  
12 after the date of the enactment of the \_\_\_\_\_  
13 Act of 2013, upon receipt of a returned pre-  
14 scription drug product that the repackager in-  
15 tends to further distribute, before further dis-  
16 tributing such prescription drug product, the  
17 repackager shall—

18 “(i) verify the prescription drug prod-  
19 uct identifier for each sealed homogeneous  
20 case of such prescription drug product; or

21 “(ii) if such prescription drug product  
22 is not in a sealed homogeneous case, verify  
23 the prescription drug product identifier on  
24 each package.

1 “(f) THIRD-PARTY LOGISTICS PROVIDER REQUIRE-  
2 MENTS.—

3 “(1) AUTHORIZED TRADING PARTNERS.—Be-  
4 ginning on January 1, 2015, a third-party logistics  
5 provider shall ensure that each of its trading part-  
6 ners is authorized.

7 “(2) VERIFICATION.—Beginning not later than  
8 January 1, 2015, a third-party logistics provider  
9 shall implement systems to enable the third-party lo-  
10 gistics provider to comply with the following require-  
11 ments:

12 “(A) SUSPECT PRESCRIPTION DRUG PROD-  
13 UCT.—

14 “(i) IN GENERAL.—Upon making a  
15 determination that a prescription drug  
16 product in the possession or control of a  
17 third-party logistics provider is a suspect  
18 prescription drug product, a third-party lo-  
19 gistics provider shall promptly notify the  
20 owner of such prescription drug product of  
21 the need to conduct an investigation to de-  
22 termine whether the prescription drug  
23 product is an illegitimate prescription drug  
24 product.

1                   “(ii) CLEARED PRESCRIPTION DRUG  
2                   PRODUCT.—If the owner of the prescrip-  
3                   tion drug product notifies the third-party  
4                   logistics provider of the determination that  
5                   a suspect prescription drug product is not  
6                   an illegitimate prescription drug product,  
7                   such prescription drug product may be fur-  
8                   ther distributed.

9                   “(iii) RECORDS.—A third-party logis-  
10                   tics provider shall keep records of the ac-  
11                   tivities described in clauses (i) and (ii)  
12                   with respect to a suspect prescription drug  
13                   product for not less than 3 years after the  
14                   conclusion of the investigation.

15                   “(B) ILLEGITIMATE PRESCRIPTION DRUG  
16                   PRODUCT.—

17                   “(i) IN GENERAL.— Upon receiving  
18                   notice that a manufacturer of a prescrip-  
19                   tion drug product has determined that a  
20                   prescription drug product in the possession  
21                   or control of a third-party logistics pro-  
22                   vider is an illegitimate prescription drug  
23                   product, the third-party logistics provider  
24                   shall—

1                   “(I) quarantine such prescription  
2                   drug product within the possession or  
3                   control of the third-party logistics pro-  
4                   vider from prescription drug product  
5                   intended for distribution;

6                   “(II) promptly notify the owner  
7                   of such prescription drug product of  
8                   the need to provide for the disposition  
9                   of such prescription drug product; and

10                   “(III) promptly transfer posses-  
11                   sion of the prescription drug product  
12                   to the owner of such prescription drug  
13                   product to provide for the disposition  
14                   of the prescription drug product.

15                   “(ii) MAKING A NOTIFICATION.—  
16                   Upon determining that a prescription drug  
17                   product in the possession or control of the  
18                   third-party logistics provider is an illegit-  
19                   imate prescription drug product, the third-  
20                   party logistics provider shall notify the  
21                   Secretary not later than 24 hours after  
22                   making such determination. The Secretary  
23                   shall determine whether additional trading  
24                   partner notification is appropriate.

1                   “(iii) RESPONDING TO A NOTIFICA-  
2                   TION.—Upon the receipt of a notification  
3                   from the Secretary, a third-party logistics  
4                   provider shall—

5                   “(I) identify all illegitimate pre-  
6                   scription drug product subject to such  
7                   notification that is in the possession  
8                   or control of the third-party logistics  
9                   provider, including any prescription  
10                  drug product that is subsequently re-  
11                  ceived; and

12                  “(II) perform the activities de-  
13                  scribed in clause (i).

14                  “(iv) RECORDS.—A third-party logis-  
15                  tics provider shall keep records of the ac-  
16                  tivities described in clauses (i) and (ii)  
17                  with respect to an illegitimate prescription  
18                  drug product for not less than 3 years  
19                  after the conclusion of the disposition.

20                  “(g) DROP SHIPMENTS.—This section does not apply  
21                  to any entity, notwithstanding its status as a wholesale  
22                  distributor or repackager, or other status that is not in-  
23                  volved in the physical handling, distribution, or storage of  
24                  a prescription drug product. For purposes of this sub-  
25                  section, facilitating the distribution of a prescription drug

1 product by providing various administrative services, in-  
2 cluding processing of orders and payments, shall not, by  
3 itself, be construed as being involved in the handling, dis-  
4 tribution, or storage of a prescription drug product.”.

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

6 (a) PILOT PROJECTS.—

7 (1) IN GENERAL.—Not later than 2 years after  
8 the date of the enactment of this Act, the Secretary  
9 shall establish 1 or more pilot projects in coordina-  
10 tion with manufacturers, repackagers, wholesale dis-  
11 tributors, third-party logistics providers, and dis-  
12 pensers to explore and evaluate methods to enhance  
13 the safety and security of the pharmaceutical dis-  
14 tribution supply chain.

15 (2) CONTENT.—

16 (A) IN GENERAL.—The Secretary shall en-  
17 sure that the pilot projects under paragraph (1)  
18 collectively—

19 (i) reflect the diversity of the pharma-  
20 ceutical distribution supply chain; and

21 (ii) include participants representative  
22 of every sector within the pharmaceutical  
23 distribution supply chain, including partici-  
24 pants representative of small businesses.

1 (B) PROJECT DESIGN.—The pilot projects  
2 shall be designed to—

3 (i) utilize the prescription drug prod-  
4 uct identifier for tracing of a prescription  
5 drug product, which utilization may in-  
6 clude—

7 (I) verification of the prescription  
8 drug product identifier of a prescrip-  
9 tion drug product; and

10 (II) the use of aggregation and  
11 inference;

12 (ii) improve the technical capabilities  
13 of each sector within the pharmaceutical  
14 supply chain to comply with systems and  
15 processes needed to utilize the prescription  
16 drug product identifiers to enhance tracing  
17 of a prescription drug product; and

18 (iii) conduct such other activities as  
19 the Secretary determines appropriate to  
20 explore and evaluate methods to enhance  
21 the safety and security of the pharma-  
22 ceutical distribution supply chain.

23 (b) PUBLIC MEETINGS.—

24 (1) IN GENERAL.—Not later than 6 months  
25 after the date of the enactment of this Act, and at

1 least every 6 months thereafter until the submission  
2 of the report required by subsection (d)(2), the Sec-  
3 retary shall hold a public meeting to enhance the  
4 safety and security of the pharmaceutical distribu-  
5 tion supply chain. In conducting such meetings, the  
6 Secretary shall take all measures reasonable and  
7 practicable to ensure the protection of confidential  
8 commercial information and trade secrets.

9 (2) CONTENT.—In conducting meetings under  
10 this subsection, the Secretary shall seek to address,  
11 in at least one such meeting, each of the following  
12 topics:

13 (A) Best practices in each of the sectors  
14 within the pharmaceutical distribution supply  
15 chain to implement the requirements of section  
16 582 of the Federal Food, Drug, and Cosmetic  
17 Act, as added by section 2.

18 (B) The costs and benefits of implementa-  
19 tion of such section 582, including the impact  
20 on each pharmaceutical distribution supply  
21 chain sector and on public health.

22 (C) Whether additional electronic  
23 traceability requirements, including tracing of  
24 prescription drug product at the package level,  
25 are feasible, cost effective, overly burdensome

1 on small businesses, and needed to protect pub-  
2 lic health.

3 (D) The systems and processes needed to  
4 utilize the prescription drug product identifiers  
5 to enhance tracing of prescription drug product  
6 at the package level.

7 (E) The technical capabilities and legal au-  
8 thorities, if any, needed to establish an elec-  
9 tronic system that provides for enhanced trac-  
10 ing of prescription drug product at the package  
11 level.

12 (F) The impact that the requirements, sys-  
13 tems, processes, capabilities, and legal authori-  
14 ties referred to in subparagraphs (C), (D), and  
15 (E) would have on patient safety, the drug sup-  
16 ply, cost and regulatory burden, the timeliness  
17 of patient access to prescription drugs, and  
18 small businesses.

19 (c) STUDY OF THE PHARMACEUTICAL DISTRIBUTION  
20 SUPPLY CHAIN.—

21 (1) IN GENERAL.—The Comptroller General of  
22 the United States shall conduct a study to examine  
23 implementation of the requirements established  
24 under subchapter H of chapter V of the Federal  
25 Food, Drug, and Cosmetic Act, as added by section

1 2, in order to inform the regulations promulgated  
2 under this section.

3 (2) CONSIDERATION.—In conducting the study  
4 under this subsection, the Comptroller General shall  
5 provide for stakeholder input and shall consider the  
6 following:

7 (A) The implementation of the require-  
8 ments established under such subchapter H  
9 with respect to—

10 (i) the ability of the health care sys-  
11 tem collectively to maintain patient access  
12 to medicines;

13 (ii) the scalability of such require-  
14 ments, including with respect to prescrip-  
15 tion drug product lines; and

16 (iii) the capability of different sectors  
17 within the pharmaceutical distribution sup-  
18 ply chain, including small businesses, to  
19 affix and utilize the prescription drug  
20 product identifier.

21 (B) The need for additional legal authori-  
22 ties and activities to address additional gaps in  
23 the pharmaceutical distribution supply chain, if  
24 any, after the implementation of the require-

1           ments established under such subchapter H  
2           with respect to—

3                   (i) the systems and processes needed  
4                   to enhance tracing of prescription drug  
5                   product at the package level;

6                   (ii) the impact, feasibility, and cost ef-  
7                   fectiveness that additional requirements  
8                   pursuant to this section would have on  
9                   each pharmaceutical distribution supply  
10                  chain sector and the public health; and

11                  (iii) the systems and processes needed  
12                  to enhance interoperability among trading  
13                  partners.

14                  (C) Risks to the security and privacy of  
15                  data collected, maintained, or exchanged pursu-  
16                  ant to the requirements established under such  
17                  subchapter H.

18           (d) SMALL DISPENSERS.—

19                   (1) IN GENERAL.—Not later than 10 years  
20                   after the date of the enactment of this Act, the Sec-  
21                   retary shall enter into a contract with a private,  
22                   independent consulting firm with relevant expertise  
23                   to conduct a technology and software study on the  
24                   feasibility of dispensers that have 25 or fewer full-  
25                   time employees conducting interoperable, electronic

1 tracing of prescription drug products at the package  
2 level.

3 (2) CONDITION.—As a condition of the award  
4 of a contract under paragraph (1), the private inde-  
5 pendent consulting firm awarded such contract shall  
6 agree to consult with dispensers that have 25 or  
7 fewer full-time employees when conducting the study  
8 under such subparagraph.

9 (3) STUDY CONTENT.—The study conducted  
10 under paragraph (1) shall assess whether, with re-  
11 spect to conducting interoperable, electronic tracing  
12 of prescription drug products at the package level,  
13 the necessary hardware and software—

14 (A) is readily accessible to such dispensers;

15 (B) is not prohibitively expensive to obtain,  
16 install and maintain for such dispensers; and

17 (C) can be integrated into business prac-  
18 tices, such as interoperability with wholesale  
19 distributors, for such dispensers.

20 (4) PUBLICATION.—The Secretary shall pub-  
21 lish—

22 (A) the statement of work for the study  
23 conducted under paragraph (1) for public com-  
24 ment not later than 30 days before commencing  
25 the study; and

1 (B) the final version of such study for pub-  
2 lic comment not later than 30 days after such  
3 study is completed.

4 (5) REPORT TO CONGRESS.—Not later than 30  
5 days after the date on which the study conducted  
6 under paragraph (1) is completed, the Secretary  
7 shall submit to the Committee on Energy and Com-  
8 merce of the House of Representatives and the Com-  
9 mittee on Health, Education, Labor, and Pensions  
10 of the Senate, a report on the findings of the study  
11 and any recommendations to improve the technology  
12 and software available to small dispensers for pur-  
13 poses of conducting electronic, interoperable tracing  
14 of prescription drug products at the package level.

15 (6) PUBLIC MEETING.—Not later than 180  
16 days after the date on which the study conducted  
17 under paragraph (1) is completed, the Secretary  
18 shall hold a public meeting at which members of the  
19 public, including stakeholders, may present their  
20 views on the study.

21 (e) REPORTS.—

22 (1) GAO REPORT.—Not later than 12 years  
23 after the date of the enactment of this Act, the  
24 Comptroller General shall submit to the Committee  
25 on Energy and Commerce of the House of Rep-

1 representatives and the Committee on Health, Edu-  
2 cation, Labor, Pensions of the Senate a report on  
3 the results of the study conducted under subsection  
4 (c).

5 (2) FDA REPORT.—Not later than 12 years  
6 after the date of the enactment of this Act, the Sec-  
7 retary shall submit to the Committee on Energy and  
8 Commerce of the House of Representatives and the  
9 Committee on Health, Education, Labor, and Pen-  
10 sions of the Senate a report on the results of the  
11 pilot program conducted under subsection (a), tak-  
12 ing into consideration—

13 (A) the comments received during the pub-  
14 lic meetings conducted under subsection (b);  
15 and

16 (B) the results of the study conducted, and  
17 the public comments received during the public  
18 meeting held, under subsection (d).

19 (f) ESTABLISHMENT OF ADDITIONAL REQUIRE-  
20 MENTS.—

21 (1) IN GENERAL.—Notwithstanding any other  
22 provision of this Act, including the amendments  
23 made by this Act, not earlier than January 1, 2027,  
24 and not later than March 1, 2027, the Secretary  
25 shall issue proposed regulations that establish addi-

1 tional requirements to prevent a suspect product, il-  
2 legitimate product, or a product that is counterfeit,  
3 stolen, diverted, or otherwise unfit for distribution  
4 from entering into or being further distributed in  
5 the supply chain, including—

6 (A) requirements related to the use of  
7 interoperable electronic systems and tech-  
8 nologies for enhanced tracing of prescription  
9 drug product at the package level, which may  
10 include verification of the prescription drug  
11 product identifier of a package of prescription  
12 drug product and enhanced verification of sale-  
13 able returns;

14 (B) requirements related to the use of ad-  
15 ditional prescription drug product identifiers or  
16 prescription drug product identifier technology  
17 that meet the standards developed under sec-  
18 tion 582(a)(2) of the Federal Food, Drug, and  
19 Cosmetic Act, as added by section 2;

20 (C) requirements related to the use of ag-  
21 gregation, inference, and other methods, if de-  
22 termined to be necessary components of the  
23 systems and technologies referred to in sub-  
24 paragraph (A); and

1 (D) other data transmission and mainte-  
2 nance requirements and interoperability stand-  
3 ards.

4 (2) FLEXIBILITY.—The requirements described  
5 in paragraph (1) shall provide for flexibility for a  
6 member of the pharmaceutical supply chain, by—

7 (A) with respect to dispensers, allowing a  
8 dispenser to enter into a written agreement  
9 with a third party, including an authorized  
10 wholesale distributor, under which—

11 (i) the third party confidentially main-  
12 tains any information required to be main-  
13 tained under such requirements for the  
14 dispenser; and

15 (ii) the dispenser maintains a copy of  
16 the written agreement and is not relieved  
17 of the other obligations of the dispenser  
18 under such requirements;

19 (B) establishing a process by which an au-  
20 thorized manufacturer, repackager, wholesale  
21 distributor, or dispenser may request a waiver  
22 from any such requirements if the Secretary de-  
23 termines that such requirements would result in  
24 an undue economic hardship on the manufac-  
25 turer, wholesale distributor, or dispenser;

1 (C) not requiring the adoption of specific  
2 business systems by a member of the pharma-  
3 ceutical supply chain for the maintenance and  
4 transmission of prescription drug product trac-  
5 ing data; and

6 (D) prescribing alternative methods of  
7 compliance for small businesses, as specified in  
8 paragraph (4).

9 (3) CONSIDERATIONS.—In issuing proposed  
10 regulations under paragraph (1), the Secretary shall  
11 consider—

12 (A) the results of the pilot project con-  
13 ducted under subsection (a);

14 (B) the public meetings held under sub-  
15 section (b);

16 (C) the studies conducted under sub-  
17 sections (c) and (d);

18 (D) the reports submitted under subsection  
19 (e);

20 (E) the public health benefits of such regu-  
21 lations compared with the cost of compliance  
22 with the requirements contained in such regula-  
23 tions, including with respect to entities of vary-  
24 ing sizes and capabilities; and

1 (F) the diversity of the pharmaceutical dis-  
2 tribution supply chain by providing appropriate  
3 flexibility for each sector in the supply chain,  
4 including small businesses.

5 (4) SMALL BUSINESS PROTECTION.—The Sec-  
6 retary, taking into consideration the study conducted  
7 under paragraph (d), shall, if the Secretary deter-  
8 mines that the requirements established pursuant to  
9 paragraph (1) would result in an undue economic  
10 hardship on small businesses, provide for alternative  
11 methods of compliance with any such requirement by  
12 small businesses, including—

13 (A) establishing timelines for such compli-  
14 ance (including compliance by dispensers with  
15 25 or fewer full-time employees) that do not im-  
16 pose undue economic hardship for small busi-  
17 nesses, including dispensers with respect to  
18 which the study concluded has insufficient  
19 hardware and software to conduct interoper-  
20 able, electronic tracing of prescription drug  
21 products at the package level; and

22 (B) establishing a process by which a dis-  
23 penser may request a waiver from any such re-  
24 quirement.

1 (5) REGULATIONS.—In issuing regulations to  
2 carry out this subsection, the Secretary shall—

3 (A) issue a notice of proposed rulemaking  
4 that includes a copy of the proposed rule;

5 (B) provide for a period of not less than  
6 60 days for comments on the proposed rule;  
7 and

8 (C) provide for an effective date of the  
9 final rule that is 2 years after the date on  
10 which such final rule is published.

11 (6) SUNSET.—The requirements regarding the  
12 provision and receipt of transaction history and  
13 transaction statements under section 582 of the  
14 Federal Food, Drug, and Cosmetic Act, as added by  
15 section 2, shall cease to be effective on the date on  
16 which the regulations issued under this section are  
17 fully implemented.

18 (g) DEFINITIONS.—In this section:

19 (1) The terms defined in section 581 of the  
20 Federal Food, Drug, and Cosmetic Act, as added by  
21 section 2, shall have the same meanings in this sec-  
22 tion as such terms are given in such section 581.

23 (2) The term “Secretary” means the Secretary  
24 of Health and Human Services, acting through the  
25 Commissioner of Food and Drugs.

1 **SEC. 4. NATIONAL STANDARDS FOR WHOLESALE DISTRIBUTORS.**  
2

3 (a) STANDARDS.—Chapter V of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
5 ed—

6 (1) in section 503 of such Act (21 U.S.C. 353),  
7 by striking “(e)(1)(A)” and all that follows through  
8 “(3) For purposes of this subsection and subsection  
9 (d)—” and inserting the following:

10 “(e) For purposes of subsection (d)—”; and

11 (2) in subchapter H of chapter V of the Federal  
12 Food, Drug, and Cosmetic Act, as added by section  
13 2, by adding at the end the following:

14 **“SEC. 583. NATIONAL STANDARDS FOR WHOLESALE DIS-  
15 TRIBUTORS.**

16 “(a) STANDARDS.—

17 “(1) IN GENERAL.—The Secretary shall estab-  
18 lish, by regulation, standards for the licensing of  
19 persons that make wholesale distributions.

20 “(2) REQUIREMENTS.—The standards under  
21 paragraph (1) shall, with respect to wholesale dis-  
22 tributions, include requirements for—

23 “(A) the storage and handling of drugs  
24 subject to section 503(b)(1), including facility  
25 requirements;

1 “(B) the establishment and maintenance of  
2 records of the distributions of such drugs;

3 “(C) the furnishing of a bond or other  
4 equivalent means of security in accordance with  
5 paragraph (3);

6 “(D) mandatory background checks and  
7 fingerprinting of facility managers or des-  
8 ignated representatives;

9 “(E) the establishment and implementa-  
10 tion of qualifications for key personnel;

11 “(F) the mandatory physical inspection of  
12 any facility to be used in wholesale distribution  
13 within a reasonable timeframe from the initial  
14 application for licensure of the wholesale dis-  
15 tributor; and

16 “(G) in accordance with paragraph (5), the  
17 prohibition of certain persons from engaging in  
18 wholesale distribution.

19 “(3) BOND OR OTHER SECURITY.—The require-  
20 ments under paragraph (2)(C) shall provide for the  
21 following:

22 “(A) An applicant that is not a govern-  
23 ment-owned-and-operated wholesale distributor,  
24 for the issuance or renewal of a wholesale dis-  
25 tributor license, shall submit a surety bond of

1           \$100,000 or other equivalent means of security  
2           acceptable to the applicable licensing authority.

3           “(B) For purposes of subparagraph (A),  
4           the applicable licensing authority may accept a  
5           surety bond less than \$100,000 if the annual  
6           gross receipts of the previous tax year for the  
7           wholesale distributor is \$10,000,000 or less, in  
8           which case the surety bond may not be less  
9           than \$25,000.

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

14           “(4) INSPECTIONS.—To satisfy the inspection  
15           requirement under paragraph (2)(F), the Secretary  
16           may conduct the inspection, or may accept an in-  
17           spection by—

18           “(A) the government of the State in which  
19           the facility is located; or

20           “(B) a third-party accreditation or inspec-  
21           tion service approved by the Secretary.

22           “(5) PROHIBITED PERSONS.—The requirements  
23           under paragraph (2) shall include requirements to  
24           prohibit a person from receiving or maintaining li-  
25           censure for wholesale distribution if the person—

1 “(A) has been convicted of any felony for  
2 conduct relating to wholesale distribution; any  
3 felony violation of section 301(i) or 301(k); or  
4 any felony violation of section 1365 of title 18,  
5 United States Code, relating to prescription  
6 drug product tampering; or

7 “(B) has engaged in a pattern of violating  
8 the requirements of this section that presents a  
9 threat of serious adverse health consequences or  
10 death to humans.

11 “(b) REPORTING BY LICENSED WHOLESALE DIS-  
12 TRIBUTORS.—

13 “(1) ANNUAL REPORT.—Beginning not later  
14 than 1 year after the date of the enactment of this  
15 section, each person engaged in wholesale distribu-  
16 tion in interstate commerce shall submit on an an-  
17 nual basis, and update as necessary, a report to the  
18 Secretary including—

19 “(A) the wholesale distributor’s name;

20 “(B) the wholesale distributor’s address;

21 “(C) a listing of each State in which the  
22 wholesale distributor is licensed for wholesale  
23 distribution; and

24 “(D) any disciplinary actions taken by a  
25 State, the Federal Government, or a foreign

1 government during the reporting period against  
2 the wholesale distributor.

3 “(2) POSTING ON INTERNET.—The Secretary  
4 shall post on the public Internet Website of the  
5 Food and Drug Administration the name of each  
6 wholesale distributor, and the State in which each  
7 such distributor is licensed, based on reports under  
8 paragraph (1).

9 “(c) PRESERVATION OF STATE AUTHORITY.—This  
10 subchapter does not prohibit a State from—

11 “(1) licensing wholesale distributors for the  
12 conduct of wholesale distribution activities in the  
13 State in accordance with this subchapter; and

14 “(2) collecting fees from wholesale distributors  
15 in connection with such licensing,  
16 so long as the State does not require such licensure to  
17 the extent to which an entity is engaged in third-party  
18 logistics provider activities.

19 “(d) DEFINITIONS.—In this section:

20 “(1) The term ‘qualified licensing program’  
21 means a program meeting the requirements of this  
22 section and the regulations thereunder.

23 “(2) The term ‘wholesale distribution’ means  
24 the distribution of a drug subject to section

1 503(b)(1) to a person other than a consumer or pa-  
2 tient, but does not include—

3 “(A) intracompany distribution of any  
4 drug between members of an affiliated group  
5 (as defined in section 1504(a) of the Internal  
6 Revenue Code of 1986);

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

11 “(C) the distribution of a drug or an offer  
12 to distribute a drug for emergency medical rea-  
13 sons, including a public health emergency dec-  
14 laration pursuant to section 319 of the Public  
15 Health Service Act, except that a drug shortage  
16 not caused by a public health emergency shall  
17 not constitute such an emergency medical rea-  
18 son;

19 “(D) dispensing of a drug pursuant to a  
20 valid prescription executed in accordance with  
21 subsection 503(b)(1);

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

1           “(F) the distribution of a drug or an offer  
2           to distribute a drug by a charitable organization  
3           to a nonprofit affiliate of the organization to  
4           the extent otherwise permitted by law;

5           “(G) the purchase or other acquisition by  
6           a dispenser, hospital, or other health care entity  
7           of a drug for use by such dispenser, hospital, or  
8           other health care entity;

9           “(H) the distribution of a drug by the  
10          manufacturer of such drug;

11          “(I) the receipt or transfer of a drug by an  
12          authorized third-party logistics provider pro-  
13          vided that such third-party logistics provider  
14          does not take ownership of the drug;

15          “(J) the transport of a drug by a common  
16          carrier, provided that the common carrier does  
17          not take ownership of the drug;

18          “(K) the distribution of a drug, or an offer  
19          to distribute a drug, by an authorized repack-  
20          ager that has taken ownership of the drug and  
21          repacked it in accordance with section 582(e);

22          “(L) salable drug returns when conducted  
23          by a dispenser in accordance with section  
24          203.23 of title 21, Code of Federal Regulations  
25          (or any successor regulation);

1 “(M) the distribution of a combination pre-  
2 scription drug product described in section  
3 581(20)(B)(xiii);

4 “(N) the distribution of a medical conven-  
5 ience kit described in section 581(20)(B)(xiv);

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

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

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

19 “(R) the distribution of compressed med-  
20 ical gas (as defined in section 581(20)(C)); or

21 “(S) facilitating the distribution of a pre-  
22 scription drug product by providing administra-  
23 tive services, such as processing of orders and  
24 payments, without physical handling, distribu-  
25 tion, or storage of a prescription drug product.

1 “(e) EFFECTIVE DATE.—The standards required by  
2 subsection (a) shall take effect not later than 2 years after  
3 the date of the enactment of this section. The Secretary  
4 shall issue the regulations required by subsection (a) not  
5 later than 1 year after the date of the enactment of this  
6 Act.”.

7 (b) CONFORMING AMENDMENT.—Section  
8 804(a)(5)(A) of the Federal Food, Drug, and Cosmetic  
9 Act (21 U.S.C. 384(a)(5)(A)) is amended by striking  
10 “503(e)(2)(A)” and inserting “583(a)”.

11 **SEC. 5. NATIONAL LICENSURE STANDARDS FOR THIRD-**  
12 **PARTY LOGISTICS PROVIDERS.**

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

16 **“SEC. 584. NATIONAL LICENSURE STANDARDS FOR THIRD-**  
17 **PARTY LOGISTICS PROVIDERS.**

18 “(a) LICENSE REQUIREMENT.—No facility may en-  
19 gage in the activities of a third-party logistics provider in  
20 any State unless—

21 “(1) the facility is licensed—

22 “(A) by the State from which the drug is  
23 distributed by the third-party logistics provider  
24 in accordance with a qualified licensing pro-  
25 gram, if the State has such a program; or

1           “(B) by the Secretary under this section, if  
2           the State from which the drug is distributed  
3           does not have such a program; and

4           “(2) if the drug is distributed interstate and  
5           the facility is not licensed by the Secretary under  
6           paragraph (1)(B), registers with the State into  
7           which the drug is distributed if such State requires  
8           such registration.

9           “(b) REPORTING BY LICENSED THIRD-PARTY LOGIS-  
10          TICS PROVIDERS.—

11           “(1) ANNUAL REPORT.—Beginning not later  
12           than 1 year after the date of the enactment of this  
13           section, each facility engaged in the activities of a  
14           third-party logistics provider shall submit on an an-  
15           nual basis, and update as necessary, a report to the  
16           Secretary including—

17                   “(A) the facility’s name;

18                   “(B) the facility’s address;

19                   “(C) a listing of each jurisdiction (whether  
20                   State or Federal) in which the facility is li-  
21                   censed for third-party logistics provider activi-  
22                   ties; and

23                   “(D) any disciplinary actions taken by a  
24                   State or Federal licensing authority during the  
25                   reporting period against the facility.

1           “(2) POSTING ON INTERNET.—The Secretary  
2 shall post on the public Internet Website of the  
3 Food and Drug Administration the name of each  
4 third party logistics provider, and each jurisdiction  
5 (whether State or Federal) in which the provider is  
6 licensed, based on reports under paragraph (1).

7           “(c) PRESERVATION OF STATE AUTHORITY.—This  
8 subchapter does not prohibit a State from—

9           “(1) licensing third-party logistic providers for  
10 the conduct of third-party logistics provider activities  
11 in the State in accordance with this subchapter; and

12           “(2) collecting fees from third-party logistics  
13 providers in connection with such licensing,  
14 so long as the State does not require such licensure to  
15 the extent to which an entity is engaged in wholesale dis-  
16 tribution.

17           “(d) COSTS.—

18           “(1) AUTHORIZED LICENSURE FEES.—In the  
19 case of a facility engaging in the activities of a  
20 third-party logistics provider licensed by the Sec-  
21 retary under this section, the Secretary may assess  
22 and collect a reasonable fee in an amount equal to  
23 the costs to the Federal Government of establishing  
24 and administering the licensure program established,

1 and conducting period inspections, under this sec-  
2 tion.

3 “(2) ADJUSTMENT.—The Secretary shall adjust  
4 the amount of the fee under paragraph (1) on an  
5 annual basis, if necessary, to generate an amount of  
6 revenue equal to the costs referred to in such para-  
7 graph.

8 “(3) AVAILABILITY.—Fees assessed and col-  
9 lected under this subsection shall be available for ob-  
10 ligation only to the extent and in the amount pro-  
11 vided in advance in appropriations Acts. Such fees  
12 shall remain available until expended.

13 “(e) LICENSE REGULATIONS.—

14 “(1) IN GENERAL.—The Secretary shall estab-  
15 lish, by regulation, standards, terms, and conditions  
16 for licensing persons to engage in third-party logis-  
17 tics provider activities.

18 “(2) CONTENT.—The regulations under para-  
19 graph (1) shall—

20 “(A) include standards relating to eligi-  
21 bility for, and revocation and reissuance of, li-  
22 censes;

23 “(B) establish a process by which the ap-  
24 plicable licensing authority will, upon request by  
25 a third-party logistics provider that is accred-

1           ited by a third-party accreditation program ap-  
2           proved by the Secretary, issue a license to the  
3           provider;

4                   “(C) establish a process by which the Sec-  
5           retary shall issue a license to a third-party lo-  
6           gisties provider if the Secretary is not able to  
7           approve a third-party accreditation program be-  
8           cause no such program meets the Secretary’s  
9           requirements necessary for approval of such a  
10          third-party accreditation program;

11                   “(D) require that the third-party logistics  
12          provider comply with storage practices, as de-  
13          termined by the Secretary, at the provider’s fa-  
14          cilities, including—

15                           “(i) maintaining access to warehouse  
16                           space of suitable size to facilitate safe op-  
17                           erations, including a suitable area to quar-  
18                           antine suspect prescription drug product;

19                           “(ii) maintaining adequate security;  
20                           and

21                           “(iii) having written policies and pro-  
22                           cedures to—

23                                   “(I) address receipt, security,  
24                                   storage, inventory, shipment, and dis-

1           tribution of a prescription drug prod-  
2           uct;

3                   “(II) identify, record, and report  
4           confirmed losses or thefts in the  
5           United States;

6                   “(III) correct errors and inac-  
7           curacies in inventories;

8                   “(IV) provide support for manu-  
9           facturer recalls;

10                   “(V) prepare for, protect against,  
11           and address any reasonably foresee-  
12           able crisis that affects security or op-  
13           eration at the facility, such as a  
14           strike, fire, or flood;

15                   “(VI) ensure that any expired  
16           prescription drug product is seg-  
17           regated from other prescription drug  
18           products and returned to the manu-  
19           facturer or repackager or destroyed;

20                   “(VII) maintain the capability to  
21           electronically trace the receipt and  
22           outbound distribution of a prescrip-  
23           tion drug product, and supplies and  
24           records of inventory; and

1                   “(VIII) quarantine or destroy a  
2                   suspect prescription drug product if  
3                   directed to do so by the respective  
4                   manufacturer, wholesale distributor,  
5                   dispenser, or an authorized govern-  
6                   ment agency;

7                   “(E) provide for periodic inspection, as de-  
8                   termined by the Secretary, of such facility ware-  
9                   house space to ensure compliance with this sec-  
10                  tion;

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

17                  “(G) perform mandatory background  
18                  checks of the provider’s facility managers or  
19                  designated representatives of such managers;

20                  “(H) require a third-party logistics pro-  
21                  vider to provide to the applicable licensing au-  
22                  thority, upon the authority’s request, a list of  
23                  all prescription drug product manufacturers,  
24                  wholesale distributors, and dispensers for whom

1 the third-party logistics provider provides serv-  
2 ices at the provider’s facilities; and

3 “(I) include procedures under which any  
4 third-party logistics provider license—

5 “(i) will expire on the date that is 3  
6 years after issuance of the license; and

7 “(ii) may be renewed for additional 3-  
8 year periods.

9 “(f) VALIDITY OF LICENSE.—A license issued under  
10 this section shall remain valid as long as such third-party  
11 logistics provider remains accredited by the Secretary,  
12 subject to renewal under subsection (d). If the Secretary  
13 finds that the third-party accreditation program dem-  
14 onstrates that all applicable requirements for licensure  
15 under this section are met, the Secretary shall issue a li-  
16 cense under this section to a third-party logistics provider  
17 receiving accreditation.

18 “(g) QUALIFIED LICENSING PROGRAM DEFINED.—  
19 In this section, the term ‘qualified licensing program’  
20 means a program meeting the requirements of this section  
21 and the regulations thereunder.

22 “(h) EFFECTIVE DATE.—The requirements of this  
23 section shall take effect not later than 1 year after the  
24 date of the enactment of this section. The Secretary shall  
25 issue the regulations required by subsection (d) not later

1 than 180 days after the date of the enactment of this sec-  
2 tion.”.

3 **SEC. 6. PENALTIES.**

4 (a) PROHIBITED ACTS.—Section 301(t) of the Fed-  
5 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(t)) is  
6 amended—

7 (1) by striking “or” after “the requirements of  
8 section 503(d)”; and

9 (2) by striking “or the distribution of drugs in  
10 violation of section 503(e) or the failure to otherwise  
11 comply with the requirements of section 503(e)” and  
12 inserting “the failure to comply with any require-  
13 ment of section 582, engaging in the wholesale dis-  
14 tribution of a drug in violation of section 583 or the  
15 failure to otherwise comply with the requirements of  
16 section 583, or engaging in the activities of a third-  
17 party logistics provider in violation of section 584 or  
18 the failure to otherwise comply with the require-  
19 ments of section 584”.

20 (b) ENHANCED PENALTY FOR KNOWING UNLI-  
21 CENSED ACTIVITIES.—Section 303(b)(1)(D) of the Fed-  
22 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
23 333(b)(1)(D)) is amended by striking “503(e)(2)(A)” and  
24 inserting “583 or 584”.

1 (c) 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 a prescription  
5 drug product identifier as required by section 582.”.

6 **SEC. 7. UNIFORM NATIONAL POLICY.**

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

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

11 “(a) PREEMPTION OF STATE PRESCRIPTION DRUG  
12 PRODUCT TRACING AND OTHER REQUIREMENTS.—Be-  
13 ginning on the date of the enactment of the [\_\_\_\_\_ Act  
14 of 2013], no State or political subdivision of a State may  
15 establish or continue in effect any requirements for tracing  
16 drugs through the distribution system (including any re-  
17 quirements with respect to paper or electronic pedigrees,  
18 track and trace, statements of distribution history, trans-  
19 action history, or transaction statements, or verification,  
20 investigation, disposition, alerts, or recordkeeping relating  
21 to the pharmaceutical distribution supply chain system)  
22 that—

23 “(1) are inconsistent with, more stringent than,  
24 or in addition to any requirements applicable under  
25 this Act; or

1           “(2) are inconsistent with any applicable waiv-  
2           er, exception, or exemption issued by the Secretary  
3           under section 582(a).

4           “(b) STANDARDS OR LICENSURE.—

5           “(1) IN GENERAL.—Beginning on the date of  
6           the enactment of [the \_\_\_\_\_ Act of 2013], no  
7           State or political subdivision of a State may estab-  
8           lish or continue any standards, requirements, or reg-  
9           ulations with respect to wholesale drug distributor or  
10          third-party logistics provider licensure which are in-  
11          consistent with, less stringent than, in addition to,  
12          or more stringent than, the standards and require-  
13          ments under this Act.

14          “(2) LICENSING FEES.—Paragraph (1) does  
15          not affect the authority of a State to collect fees  
16          from wholesale drug distributors or third-party logis-  
17          tics providers in connection with State licensing  
18          under section 583 or 584 pursuant to a licensing  
19          program meeting the requirements of such sections.

20          “(3) SUSPENSION AND REVOCATION OF LI-  
21          CENSES.—Notwithstanding paragraph (1), a State—

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

1           “(B) upon conviction of a person for a vio-  
2           lation of Federal, State, or local controlled sub-  
3           stance laws or regulations, may provide for  
4           fines, imprisonment, or civil penalties; and

5           “(C) may regulate activities of entities li-  
6           censed pursuant to section 583 or 584 in a  
7           manner that is consistent with the provisions of  
8           this subchapter.”.

9   **SEC. 8. ELECTRONIC LABELING REQUIREMENT.**

10       Section 502(f) of the Federal Food, Drug, and Cos-  
11       metic Act (21 U.S.C. 352(f)) is amended by adding at the  
12       end the following new sentence: “Required labeling, other  
13       than immediate container or carton labels, for a drug may  
14       be made available by manufacturers and distributors solely  
15       by electronic means, provided that the labeling complies  
16       with all applicable requirements of law and the manufac-  
17       turer or distributor, as applicable, affords health care pro-  
18       fessionals and authorized dispensers (as defined in section  
19       581) the opportunity to request the labeling in paper form,  
20       and after such request, promptly provides the requested  
21       information without additional cost.”.