

[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.

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

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-
15SCRIPTION 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 illegiti-
16 mate 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 IDENTI-
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 scripted 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 illegit-
8 imate 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 IDENTI-
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 scription 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 amended—
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 DISTRIBUTORS.**
15

16 “(a) STANDARDS.—

17 “(1) IN GENERAL.—The Secretary shall establish,
18 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 distributions,
22 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.”.