

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 and Mr. MATHESON) 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-
22 tributor, or any other person authorized by law
23 to dispense or administer prescription drugs

1 and the affiliated warehouses or distribution
2 centers of such persons under common owner-
3 ship and control that do not act as a wholesale
4 distributor; and

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

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

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

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

24 “(4) DISTRIBUTE OR DISTRIBUTION.—The
25 terms ‘distribute’ and ‘distribution’ mean the sale,

1 purchase, trade, delivery, handling, or storage of a
2 prescription drug product.

3 “(5) ILLEGITIMATE PRESCRIPTION DRUG PROD-
4 UCT.—The term ‘illegitimate prescription drug prod-
5 uct’ means a prescription drug product which a
6 manufacturer, repackager, wholesale distributor,
7 third-party logistics provider, or dispenser has con-
8 firmed—

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 person that manufactures such pre-
18 scription drug product on behalf of the person
19 described in subparagraph (A);

20 “(C) a co-licensed partner of the person
21 described in subparagraph (A) that obtains the
22 prescription drug product directly from the per-
23 son described in subparagraph (A) or (B); or

24 “(D) a person that—

1 “(i) is a member of an affiliated
2 group (as defined in section 1504(a) of the
3 Internal Revenue Code of 1986) to which
4 a person described in subparagraph (A) or
5 (C) is also a member; and

6 “(ii) receives the prescription drug
7 product directly from a person described in
8 subparagraph (A), (B), or (C).

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

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

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

1 “(11) PRESCRIPTION DRUG PRODUCT IDENTIFI-
2 FIER.—The term ‘prescription drug product identi-
3 fier’ means a standardized graphic that—

4 “(A) includes the standardized numerical
5 identifier, lot number, and expiration date of a
6 prescription drug product; and

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

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

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

22 “(14) RETURNS PROCESSOR.—The terms ‘re-
23 turns processor’ mean a person who owns or oper-
24 ates an establishment that provides for the disposi-
25 tion of or otherwise processes saleable and nonsale-

1 able prescription drug product received from an au-
2 thorized trading partner such that the prescription
3 drug product may be processed for credit to the pur-
4 chaser, manufacturer, seller, or disposed of for no
5 further distribution.

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

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

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

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

20 “(A) is used to uniquely identify each
21 package or homogenous case of the prescription
22 drug product; and

23 “(B) is composed of the National Drug
24 Code that corresponds to the specific prescrip-
25 tion drug product (including the particular

1 package configuration) combined with a unique
2 alphanumeric serial number of up to 20 char-
3 acters.

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

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

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

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

19 “(18) THIRD-PARTY LOGISTICS PROVIDER.—
20 The term ‘third-party logistics provider’ means an
21 entity that provides or coordinates warehousing, dis-
22 tribution, or other logistics services of a prescription
23 drug product in interstate commerce on behalf of a
24 manufacturer, wholesale distributor, or dispenser of
25 a prescription drug product, but does not take own-

1 ership of the prescription drug product, nor have re-
2 sponsibility to direct the sale or disposition of, the
3 prescription drug product.

4 “(19) TRADING PARTNER.—The term ‘trading
5 partner’ means—

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

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

21 “(20) TRANSACTION.—

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

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

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

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

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

20 “(iv) the dispensing of a prescription
21 drug product pursuant to a valid prescrip-
22 tion executed in accordance with section
23 503(b)(1);

24 “(v) the distribution of prescription
25 drug product samples by a manufacturer

1 or a licensed wholesale distributor in ac-
2 cordance with section 503(d);

3 “(vi) the distribution of blood or blood
4 components intended for transfusion;

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

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

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

23 “(x) the dispensing of a prescription
24 drug product approved under section
25 512(b);

1 “(xi) the transfer of prescription drug
2 products to or from any facility that is li-
3 censed by the Nuclear Regulatory Commis-
4 sion or by a State pursuant to an agree-
5 ment with such Commission under section
6 274 of the Atomic Energy Act of 1954 (42
7 U.S.C. 2021);

8 “(xii) the purchase or other acquisi-
9 tion, by a hospital or other health care en-
10 tity that is a member of a group pur-
11 chasing organization, of a prescription
12 drug product for use by such hospital or
13 health care entity from the group pur-
14 chasing organization or from other hos-
15 pitals or health care entities that are mem-
16 bers of such organizations;

17 “(xiii) the distribution of a combina-
18 tion prescription drug product that con-
19 sists of—

20 “(I) a prescription drug product
21 comprised of two or more components
22 that are each a drug, biological pre-
23 scription drug product, or device and
24 that are physically, chemically, or oth-

1 erwise combined or mixed and pro-
2 duced as a single entity;

3 “(II) two or more separate pre-
4 scription drug products packaged to-
5 gether in a single package or as a unit
6 and comprised of a drug and device or
7 a device and biological prescription
8 drug product; or

9 “(III) two or more finished med-
10 ical devices plus one or more drug or
11 biological prescription drug products
12 which are packaged together in a
13 medical convenience kit described in
14 clause (xiv);

15 “(xiv) the distribution of a medical
16 convenience kit which is a collection of fin-
17 ished products (consisting of devices or
18 drugs) assembled in kit form strictly for
19 the convenience of the purchaser or user
20 if—

21 “(I) the medical convenience kit
22 is assembled in an establishment that
23 is registered with the Food and Drug
24 Administration as a medical device
25 manufacturer;

1 “(II) the person who manufactur-
2 ers the medical convenience kit pur-
3 chased the prescription drug product
4 directly from the manufacturer or
5 from a wholesale distributor that pur-
6 chased the prescription drug product
7 directly from the manufacturer;

8 “(III) the person who manufac-
9 turers the medical convenience kit
10 does not alter the primary container
11 or label of the prescription drug prod-
12 uct as purchased from the manufac-
13 turer or wholesale distributor;

14 “(IV) the medical convenience kit
15 does not contain a controlled sub-
16 stance (as defined in section 102 of
17 the Controlled Substances Act); and

18 “(V) the prescription drug prod-
19 ucts contained in the medical conven-
20 ience kit are—

21 “(aa) intravenous solutions
22 intended for the replenishment of
23 fluids and electrolytes;

1 “(bb) drugs intended to
2 maintain the equilibrium of water
3 and minerals in the body;

4 “(cc) drugs intended for irri-
5 gation or reconstitution;

6 “(dd) anesthetics;

7 “(ee) anticoagulants;

8 “(ff) vasopressors; or

9 “(gg) sympathicomimetics;

10 “(xv) the distribution of an intra-
11 venous prescription drug product that, by
12 its formulation, is intended for the replen-
13 ishment of fluids and electrolytes (such as
14 sodium, chloride, and potassium) or cal-
15 ories (such as dextrose and amino acids);

16 “(xvi) the distribution of an intra-
17 venous prescription drug product used to
18 maintain the equilibrium of water and min-
19 erals in the body, such as dialysis solu-
20 tions;

21 “(xvii) the distribution of a prescrip-
22 tion drug product that is intended for irri-
23 gation or reconstitution, or sterile water,
24 whether intended for such purposes or for
25 injection; or

1 “(xviii) the distribution of compressed
2 medical gas.

3 “(C) COMPRESSED MEDICAL GAS.—For
4 purposes of subparagraph (B)(xviii), the term
5 ‘compressed medical gas’ means any substance
6 in its gaseous or cryogenic liquid form that
7 meets medical purity standards and has appli-
8 cation in a medical or homecare environment,
9 including oxygen and nitrous oxide.

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

12 “(A) includes the transaction information
13 for each transaction conducted with respect to
14 a prescription drug product beginning with the
15 manufacturer or initial purchase distributor for
16 each prior transaction going back to the manu-
17 facturer of the prescription drug product or to
18 the initial purchase distributor; and

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

20 “(22) TRANSACTION INFORMATION.—The term
21 ‘transaction information’ means—

22 “(A) the proprietary or established name
23 or names of the prescription drug product;

24 “(B) the strength and dosage form of the
25 prescription drug product;

1 “(C) the National Drug Code number of
2 the prescription drug product;

3 “(D) the container size;

4 “(E) the number of containers;

5 “(F) the lot number of the prescription
6 drug product;

7 “(G) the date of the transaction;

8 “(H) the date of the shipment, if different
9 from the date of the transaction;

10 “(I) the business name and address of the
11 person from whom ownership is being trans-
12 ferred; and

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

15 “(23) TRANSACTION STATEMENT.—The ‘trans-
16 action statement’ is a statement, which states that
17 the manufacturer, repackager, wholesale distributor,
18 third-party logistics provider, or dispenser transfer-
19 ring ownership in a transaction—

20 “(A) is authorized;

21 “(B) received transaction information and
22 a transaction statement as required under sec-
23 tion 582 from the prior owner of the prescrip-
24 tion drug product;

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

3 “(D) did not knowingly and intentionally
4 provide false transaction information; and

5 “(E) did not knowingly and intentionally
6 alter the transaction history.

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

9 “(A) mean determining whether the pre-
10 scription drug product identifier affixed to, or
11 imprinted upon, a package or homogeneous case
12 of the prescription drug product corresponds to
13 the standardized numerical identifier or lot
14 number, and expiration date assigned to the
15 prescription drug product by the manufacturer
16 or the repackager, as applicable; and

17 “(B) include making the determination
18 under subparagraph (A) using human-readable
19 or machine-readable methods.

20 “(25) WHOLESALE DISTRIBUTOR.—The term
21 ‘wholesale distributor’—

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

24 “(B) excludes—

1 “(i) a manufacturer, a co-licensed
2 partner of a manufacturer, or a third-party
3 logistics provider, or a dispenser who does
4 not engage in such wholesale distribution;

5 “(ii) a repackager engaged in such
6 wholesale distribution; or

7 “(iii) the distribution of **[add: pre-**
8 **scription drug]** product or an offer to dis-
9 tribute **[add: prescription drug]** product
10 by an authorized repackager that has
11 taken ownership or possession of the **[add:**
12 **prescription drug]** product and repacked
13 **[the prescription drug product in accord-**
14 **ance with the requirements of section**
15 **582(e).]**

16 **“SEC. 582. REQUIREMENTS.**

17 “(a) IN GENERAL.—

18 “(1) COMPLIANCE REQUIRED.—An entity that
19 is a manufacturer, repackager, wholesale distributor,
20 third-party logistics provider, or dispenser shall com-
21 ply with the requirements of this section. If an enti-
22 ty meets the definition of more than one of the enti-
23 ties referred to in the preceding sentence, such enti-
24 ty shall comply with all applicable requirements of

1 this section, but shall not be required to **[revised:**
2 comply with duplicative**]** requirements.

3 “(2) STANDARDS.—The Secretary shall, in con-
4 sultation with other appropriate Federal officials,
5 manufacturers, repackagers, wholesale distributors,
6 third-party logistics providers, and dispensers, estab-
7 lish, by regulation, standards for the exchange of
8 transaction information for purposes of complying
9 with this section. The standards established under
10 this paragraph shall be in accordance with a form
11 developed by a widely recognized international stand-
12 ards development organization. The Secretary shall
13 publish such standards not later than two years
14 after the date of the enactment of the **[_____ Act**
15 **of 2013]**.

16 “(3) WAIVERS, EXCEPTIONS, AND EXEMP-
17 TIONS.—Not later than 3 years after the date of the
18 enactment of the **[_____ Act of 2013]**, the Sec-
19 retary shall promulgate a regulation to—

20 “(A) establish a process by which the Sec-
21 retary may grant, at the request of an author-
22 ized manufacturer, repackager, wholesale dis-
23 tributor, or dispenser, a waiver from any of the
24 requirements of this section—

1 “(i) if the Secretary determines that
2 such requirements would result in an
3 undue economic hardship; or

4 “(ii) for emergency medical reasons,
5 including a public health emergency dec-
6 laration pursuant to section 319 of the
7 Public Health Service Act;

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

12 “(i) a manufacturer or repackager
13 may request a waiver with respect to pre-
14 scription drug products that are packaged
15 in a container too small or otherwise un-
16 able to accommodate a label with sufficient
17 space to bear the information required for
18 compliance with such requirement; and

19 “(ii) the Secretary determines whether
20 to waive such requirement; and

21 “(C) establish a process by which the Sec-
22 retary may add the prescription drug products
23 or transactions that are exempt from the re-
24 quirements of this section.

1 “(4) GRANDFATHERED PERSONS AND PRE-
2 SCRIPTION DRUG PRODUCTS.—

3 “(A) IN GENERAL.—Not later than 3 years
4 after the date of the enactment of the [_____
5 Act of 2013], the Secretary shall specify, by
6 regulation, whether and under what cir-
7 cumstances the prescription drug product iden-
8 tifier requirement under paragraph (2) of sub-
9 sections (b), (c), (d), and (e) shall apply to a
10 prescription drug product that is in the supply
11 chain on the date of the enactment of the
12 [_____] Act of 2013].

13 “(B) THIRD-PARTY LOGISTICS PROVIDER
14 LICENSES.—Until the date that is 1 year after
15 the effective date of the third-party logistics
16 provider licensing requirements under section
17 584, a third-party logistics provider shall be
18 considered ‘licensed’ under section 581(6)(B)
19 unless the Secretary has made a finding that
20 the third-party logistics provider does not utilize
21 good handling and distribution practices and
22 publishes notice thereof.

23 “(C) LABEL CHANGES.—Changes made to
24 package labels solely to incorporate the pre-
25 scription drug product identifier may be sub-

1 mitted to the Secretary in the annual report of
2 an establishment, in accordance with section
3 314.70(d) of chapter 21, Code of Federal Regu-
4 lations (or any successor regulation).

5 “(b) MANUFACTURER REQUIREMENTS.—

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

8 “(A) IN GENERAL.—Beginning not later
9 than 5 years after the date of the enactment of
10 the [_____ Act of 2013], a manufacturer
11 shall—

12 “(i) prior to each transaction in which
13 such manufacturer transfers ownership of
14 a prescription drug product, provide the
15 subsequent owner with the transaction his-
16 tory and a transaction statement; and

17 “(ii) maintain the transaction infor-
18 mation for each such transaction for not
19 less than 3 years after the date of the
20 transaction.

21 “(B) REQUESTS FOR INFORMATION.—

22 Upon a request by the Secretary or other ap-
23 propriate Federal or State official, in the event
24 of a recall or for the purpose of investigating a
25 suspect prescription drug product or an illegit-

1 imate prescription drug product, a manufac-
2 turer shall, not later than 2 business days after
3 receiving the request or in such reasonable time
4 as determined by the Secretary, provide to the
5 Secretary or other official, the applicable trans-
6 action history and transaction statement for the
7 prescription drug product.

8 “(2) PRESCRIPTION DRUG PRODUCT IDENTI-
9 FIER.—Beginning not later than 5 years after the
10 date of the enactment of the [_____] Act of 2013],
11 a manufacturer shall affix or imprint a prescription
12 drug product identifier on each package and homog-
13 enous case of a prescription drug product intended
14 to be introduced in a transaction. Such manufac-
15 turer shall maintain a copy of the prescription drug
16 product identifier for such prescription drug product
17 for not less than 3 years after the date of the trans-
18 action.

19 “(3) AUTHORIZED TRADING PARTNERS.—Be-
20 ginning not later than 5 years after the date of the
21 enactment of the [_____] Act of 2013], a manufac-
22 turer shall ensure that each of its trading partners
23 is authorized.

24 “(4) LIST OF AUTHORIZED DISTRIBUTORS OF
25 RECORD.—Beginning not later than 5 years after

1 the date of enactment of **the _____ Act of 2013**,
2 each manufacturer of a prescription drug shall—

3 “(A) maintain a list of the authorized dis-
4 tributors of record of such drug at the cor-
5 porate offices of such manufacturer;

6 “(B) make such list publicly available, in-
7 cluding placement on the Internet website of
8 such manufacturer; and

9 “(C) update such list not less than once
10 per quarter.

11 “(5) VERIFICATION.—Beginning not later than
12 5 years after the date of the enactment of the
13 **_____ Act of 2013**, a manufacturer shall imple-
14 ment systems and processes to enable the manufac-
15 turer to comply with the following requirements:

16 “(A) SUSPECT PRESCRIPTION DRUG PROD-
17 UCT.—

18 “(i) IN GENERAL.—Upon making a
19 determination that a prescription drug
20 product in the possession or control of the
21 manufacturer is a suspect prescription
22 drug product, or upon receiving a request
23 for verification from the Secretary that a
24 prescription drug product within the pos-
25 session or control of a manufacturer is a

1 suspect prescription drug product, a manu-
2 facturer shall promptly conduct an inves-
3 tigation in coordination with trading part-
4 ners, as applicable, to determine whether
5 the prescription drug product is an illegit-
6 imate prescription drug product. Such in-
7 vestigation shall include—

8 “(I) verifying the prescription
9 drug product at the package level;

10 “(II) validating any applicable
11 transaction history in the possession
12 of the manufacturer; and

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

17 “(ii) CLEARED PRESCRIPTION DRUG
18 PRODUCT.—If the manufacturer deter-
19 mines that a suspect prescription drug
20 product is not an illegitimate prescription
21 drug product, the manufacturer shall
22 promptly notify the Secretary of such de-
23 termination and such prescription drug
24 product may be further distributed.

1 “(iii) RECORDS.—A manufacturer
2 shall keep records of its investigation of a
3 suspect prescription drug product for not
4 less than 3 years after the conclusion of
5 the investigation.

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

8 “(i) IN GENERAL.—Upon determining
9 that a prescription drug product in the
10 possession or control of a manufacturer is
11 an illegitimate prescription drug product,
12 the manufacturer shall—

13 “(I) quarantine such prescription
14 drug product from prescription drug
15 product intended for distribution; and

16 “(II) provide for the disposition
17 of the illegitimate prescription drug
18 product.

19 “(ii) TRADING PARTNER.—Upon de-
20 termining that a prescription drug product
21 in the possession or control of a trading
22 partner is an illegitimate prescription drug
23 product, the manufacturer shall take rea-
24 sonable steps to assist a trading partner to

1 provide for the disposition of the illegit-
2 imate prescription drug product.

3 “(iii) MAKING A NOTIFICATION.—
4 Upon determining that a prescription drug
5 product in the possession or control of the
6 manufacturer is an illegitimate prescrip-
7 tion drug product, the manufacturer shall
8 notify the Secretary of such determination
9 not later than 24 hours after making such
10 determination. The Secretary shall deter-
11 mine whether additional trading partner
12 notification is appropriate.

13 “(iv) RESPONDING TO A NOTIFICA-
14 TION.—Upon the receipt of a notification
15 from the Secretary that a determination
16 has been made that a prescription drug
17 product is an illegitimate prescription drug
18 product, a manufacturer shall—

19 “(I) identify all illegitimate pre-
20 scription drug products that are sub-
21 ject to such notification and in the
22 possession or control of the manufac-
23 turer, including any prescription drug
24 product that is subsequently received;
25 and

1 “(II) perform the activities de-
2 scribed in clause (i).

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

8 “(C) ELECTRONIC DATABASE.—A manu-
9 facturer may satisfy the requirements of this
10 paragraph through the use of a secure elec-
11 tronic database developed and operated by the
12 manufacturer or another entity. The owner of
13 such database shall establish the requirements
14 and processes to respond to requests and may
15 provide for data access to other members of the
16 pharmaceutical distribution supply chain, as ap-
17 propriate. The development and operation of
18 such a database shall not relieve a manufac-
19 turer of the requirement under this paragraph
20 to respond to a verification request submitted
21 by means other than a secure electronic data-
22 base.

23 “(D) RETURNED PRESCRIPTION DRUG
24 PRODUCT.—Upon receipt of a returned pre-
25 scription drug product that the manufacturer

1 intends to further distribute, before further dis-
2 tributing such prescription drug product, the
3 manufacturer shall—

4 “(i) verify the prescription drug prod-
5 uct identifier for each sealed homogeneous
6 case of such prescription drug product; or

7 “(ii) if such prescription drug product
8 is not in a sealed homogeneous case, verify
9 the prescription drug product identifier on
10 each package.

11 “(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

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

14 “(A) IN GENERAL.—Beginning not later
15 than 7 years after the date of the enactment of
16 the [_____ Act of 2013], a wholesale dis-
17 tributor shall—

18 “(i) not accept ownership of a pre-
19 scription drug product unless the previous
20 owner prior to the transaction provides the
21 applicable transaction history and a trans-
22 action statement for the prescription drug
23 product;

24 “(ii) prior to each transaction in
25 which the wholesale distributor transfers

1 ownership of a prescription drug product
2 provide the subsequent owner with trans-
3 action history and a transaction statement
4 for the prescription drug product;

5 “(iii) notwithstanding clause (ii), if
6 the wholesale distributor purchased the
7 prescription drug product directly from the
8 manufacturer, its exclusive distributor, or
9 a repackager that purchased directly from
10 the manufacturer or its authorized dis-
11 tributor of record—

12 “(I) provide an initial purchase
13 transaction statement on the invoice
14 to the customer, stating that the
15 wholesale distributor purchased the
16 prescription drug product package di-
17 rectly from the manufacturer, exclu-
18 sive distributor, or repackager;

19 “(II) make available to the imme-
20 diate subsequent recipient of such
21 prescription drug product the infor-
22 mation required under clause (ii)
23 through any combination of self-gen-
24 erated paper, electronic data, or man-
25 ufacturer provided information on the

1 prescription drug product package;
2 and

3 “(III) for purposes of subclauses
4 (I) and (II), need not include any
5 transactions occurring before the
6 transfer of the prescription drug prod-
7 uct to the wholesale distributor; and

8 “(iv) maintain the transaction infor-
9 mation for each transaction described in
10 clauses (i) and (ii) for not less than 3
11 years after the transaction.

12 “(B) RETURNS EXCEPTION.—

13 “(i) SALEABLE RETURNS.—Notwith-
14 standing subparagraph (A), a wholesale
15 distributor may—

16 “(I) accept returned prescription
17 drug product from a dispenser; and

18 “(II) distribute such returned
19 prescription drug product without pro-
20 viding the transaction history.

21 “(ii) NONSALEABLE RETURNS.—A
22 wholesale distributor may return a non-
23 saleable prescription drug to the manufac-
24 turer or repackager, to the wholesale dis-
25 tributor from whom such prescription drug

1 was purchased, or to a person acting on
2 behalf of such a person, including a re-
3 turns processor, without providing the in-
4 formation required under subparagraph
5 (A).

6 “(C) REQUESTS FOR INFORMATION.—
7 Upon a request by the Secretary or other ap-
8 propriate Federal or State official, in the event
9 of a recall or for the purpose of investigating a
10 suspect prescription drug product or an illegiti-
11 mate prescription drug product a wholesale dis-
12 tributor shall, not later than 2 business days
13 after receiving the request or in such other rea-
14 sonable time as determined by the Secretary,
15 provide the applicable transaction history and
16 transaction statements for the prescription drug
17 product.

18 “(2) PRESCRIPTION DRUG PRODUCT IDENTIFI-
19 FIER.—Beginning not later than 7 years after the
20 date of the enactment of the [_____ Act of 2013],
21 a wholesale distributor may engage in transactions
22 involving a prescription drug product only if such
23 prescription drug product is encoded with a prescrip-
24 tion drug product identifier, except as provided in
25 subsection (a)(4).

1 “(3) AUTHORIZED TRADING PARTNERS.—Be-
2 ginning not later than 3 years after the date of the
3 enactment of the [_____ Act of 2013], a wholesale
4 distributor shall ensure that each of its trading part-
5 ners is authorized.

6 “(4) VERIFICATION.—Beginning not later than
7 7 years after the date of the enactment of the
8 [_____ Act of 2013], a wholesale distributor shall
9 implement systems to enable the wholesale dis-
10 tributor to comply with the following requirements:

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

13 “(i) IN GENERAL.—Upon making a
14 determination that a prescription drug
15 product in the possession or control of the
16 wholesale distributor is a suspect prescrip-
17 tion drug product, or upon receiving a re-
18 quest for verification from the Secretary
19 that a prescription drug product within the
20 possession or control of a wholesale dis-
21 tributor is a suspect prescription drug
22 product, a wholesale distributor shall
23 promptly conduct an investigation to deter-
24 mine whether the prescription drug prod-

1 uct is an illegitimate prescription drug
2 product. Such investigation shall include—

3 “(I) verifying a package of the
4 prescription drug product;

5 “(II) validating any applicable
6 transaction history in the possession
7 of the wholesale distributor; and

8 “(III) otherwise investigating to
9 determine whether the prescription
10 drug product is an illegitimate pre-
11 scription drug product.

12 “(ii) **CLEARED PRESCRIPTION DRUG**
13 **PRODUCT.**—If the wholesale distributor de-
14 termines that a suspect prescription drug
15 product is not an illegitimate prescription
16 drug product, the wholesale distributor
17 shall promptly notify the Secretary of such
18 determination and such prescription drug
19 product may be further distributed.

20 “(iii) **RECORDS.**—A wholesale dis-
21 tributor shall keep records of its investiga-
22 tion of a suspect prescription drug product
23 for not less than 3 years after the conclu-
24 sion of the investigation.

1 “(B) ILLEGITIMATE PRESCRIPTION DRUG
2 PRODUCT.—

3 “(i) IN GENERAL.—Upon determining
4 that a prescription drug product in the
5 possession or control of a wholesale dis-
6 tributor is an illegitimate prescription drug
7 product, the wholesale distributor shall—

8 “(I) quarantine such prescription
9 drug product within the possession or
10 control of the manufacturer from pre-
11 scription drug product intended for
12 distribution; and

13 “(II) provide for the disposition
14 of the illegitimate prescription drug
15 product within the possession or con-
16 trol of the wholesale distributor.

17 “(ii) TRADING PARTNER.—Upon de-
18 termining that a prescription drug product
19 in the possession or control of a trading
20 partner is an illegitimate prescription drug
21 product, the wholesale distributor shall
22 take reasonable steps to assist a trading
23 partner to provide for the disposition of
24 the illegitimate prescription drug product.

1 “(iii) MAKING A NOTIFICATION.—
2 Upon determining that a prescription drug
3 product in the possession or control of the
4 wholesale distributor is an illegitimate pre-
5 scription drug product, the wholesale dis-
6 tributor shall notify the Secretary of such
7 determination not later than 24 hours
8 after making such determination. The Sec-
9 retary shall determine whether additional
10 trading partner notification is appropriate.

11 “(iv) RESPONDING TO A NOTIFICA-
12 TION.—Upon the receipt of a notification
13 from the Secretary that a determination
14 has been made that a prescription drug
15 product is an illegitimate prescription drug
16 product, a wholesale distributor shall—

17 “(I) identify all illegitimate pre-
18 scription drug product subject to such
19 notification that is in the possession
20 or control of the wholesale distributor,
21 including any prescription drug prod-
22 uct that is subsequently received; and

23 “(II) perform the activities de-
24 scribed in clause (i).

1 “(v) RECORDS.—A wholesale dis-
2 tributor shall keep records of the dispo-
3 sition of an illegitimate prescription drug
4 product for not less than 3 years after the
5 conclusion of the disposition.

6 “(C) ELECTRONIC DATABASE.—A whole-
7 sale distributor may satisfy the requirements of
8 this paragraph through the use of a secure elec-
9 tronic database developed and operated by the
10 manufacturer or another entity. The owner of
11 such database shall establish the requirements
12 and processes to respond to requests and may
13 provide for data access to other members of the
14 pharmaceutical distribution supply chain, as ap-
15 propriate. The development and operation of
16 such a database shall not relieve a wholesale
17 distributor of the requirement under this para-
18 graph to respond to a verification request sub-
19 mitted by means other than a secure electronic
20 database.

21 “(D) RETURNED PRESCRIPTION DRUG
22 PRODUCT.—Upon receipt of a returned pre-
23 scription drug product that the wholesale dis-
24 tributor intends to further distribute, before

1 further distributing such prescription drug
2 product, the wholesale distributor shall—

3 “(i) verify the prescription drug prod-
4 uct identifier for each sealed homogeneous
5 case of such prescription drug product; or

6 “(ii) if such prescription drug product
7 is not in a sealed homogeneous case, verify
8 the prescription drug product identifier on
9 each package.

10 “(d) DISPENSER REQUIREMENTS.—

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

13 “(A) IN GENERAL.—Beginning not later
14 than 8 years after the date of the enactment of
15 the [_____ Act of 2013], a dispenser—

16 “(i) shall not accept ownership of a
17 prescription drug product, unless the pre-
18 vious owner prior to the transaction, pro-
19 vides transaction history and a transaction
20 statement;

21 “(ii) prior to each transaction in
22 which the dispenser transfers ownership of
23 a prescription drug product (but not in-
24 cluding dispensing to a patient or returns)
25 shall provide the subsequent owner with

1 transaction history and a transaction state-
2 ment for the prescription drug product, ex-
3 cept that the requirements of this clause
4 shall not apply to sales by a dispenser to
5 another dispenser to fulfill a specific pa-
6 tient need; and

7 “(iii) shall maintain transaction infor-
8 mation for a period of not less than 3
9 years after the date of the transaction.

10 “(B) AGREEMENTS WITH THIRD PAR-
11 TIES.—A dispenser may enter into a written
12 agreement with a third party, including an au-
13 thorized wholesale distributor, under which the
14 third party confidentially maintains the trans-
15 action information required to be maintained
16 under this subsection on behalf of the dis-
17 penser. If a dispenser enters into such an
18 agreement, the dispenser shall maintain a copy
19 of the written agreement.

20 “(C) RETURNS EXCEPTION.—

21 “(i) SALEABLE RETURNS.—Notwith-
22 standing subparagraph (A)(ii), a dispenser
23 may return prescription drug product to
24 the trading partner from which the dis-
25 penser obtained the prescription drug

1 product without providing the information
2 required under such subparagraph.

3 “(ii) NONSALEABLE RETURNS.—Not-
4 withstanding subparagraph (A)(ii), a dis-
5 penser may return a nonsaleable prescrip-
6 tion drug to the manufacturer or repack-
7 ager, to the wholesale distributor from
8 whom such prescription drug was pur-
9 chased, to a returns processor, or to a per-
10 son acting on behalf of such persons with-
11 out providing the information required
12 under such subparagraph.

13 “(D) REQUESTS FOR INFORMATION.—
14 Upon a request by the Secretary or other ap-
15 propriate Federal or State official, in the event
16 of a recall or for the purpose of investigating a
17 suspect prescription drug product or an illegit-
18 imate prescription drug product, a dispenser
19 shall, not later than 2 business days after re-
20 ceiving the request or in another such reason-
21 able time as determined by the Secretary, pro-
22 vide lot-level transaction information.

23 “(2) PRESCRIPTION DRUG PRODUCT IDENTI-
24 FIER.—Beginning not later than 8 years after the
25 date of the enactment of the [_____ Act of 2013],

1 a dispenser may engage in transactions involving a
2 prescription drug product only if such prescription
3 drug product is encoded with a prescription drug
4 product identifier, except as provided in subsection
5 (a)(4).

6 “(3) AUTHORIZED TRADING PARTNERS.—Be-
7 ginning not later than 3 years after the date of the
8 enactment of the [_____ Act of 2013], a dispenser
9 shall ensure that each of its trading partners is au-
10 thorized.

11 “(4) VERIFICATION.—Beginning not later than
12 8 years after the date of the enactment of [_____
13 Act of 2013], a dispenser shall implement systems
14 to enable the dispenser to comply with the following
15 requirements:

16 “(A) SUSPECT PRESCRIPTION DRUG PROD-
17 UCT.—

18 “(i) IN GENERAL.—Upon making a
19 determination that a prescription drug
20 product in the possession or control of the
21 dispenser is a suspect prescription drug
22 product, or upon receiving a request for
23 verification from the Secretary that a pre-
24 scription drug product within the posses-
25 sion or control of a dispenser is a suspect

1 prescription drug product, a dispenser
2 shall promptly conduct an investigation to
3 determine whether the prescription drug
4 product is an illegitimate prescription drug
5 product. Such investigation shall include—

6 “(I) verifying whether the lot
7 number of a suspect prescription drug
8 product corresponds with the lot num-
9 ber for such prescription drug prod-
10 uct;

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

14 “(III) 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 determining
9 that a prescription drug product in the
10 possession or control of a dispenser is an
11 illegitimate prescription drug product, the
12 dispenser shall—

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

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

22 “(ii) TRADING PARTNERS.—Upon de-
23 termining that a prescription drug product
24 in the possession or control of a trading
25 partner is an illegitimate prescription drug

1 product, the dispenser shall take reason-
2 able steps to assist a trading partner to
3 provide for the disposition of the illegit-
4 imate prescription drug product.

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

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

21 “(I) identify all illegitimate pre-
22 scription drug products that are sub-
23 ject to such notification and in the
24 possession or control of the dispenser,

1 including any prescription drug prod-
2 uct that is subsequently received; and

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

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

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

25 “(e) REPACKAGER REQUIREMENTS.—

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

3 “(A) IN GENERAL.—Beginning not later
4 than 6 years after the date of the enactment of
5 the [_____ Act of 2013], a repackager
6 shall—

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

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

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

21 “(iv) maintain records that allow the
22 repackager to associate the prescription
23 drug product identifier the repackager af-
24 fixes or imprints with the prescription drug
25 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 3 years after the date of the enactment of
18 the [_____ Act of 2013], a repackager shall en-
19 sure that each of its trading partners is authorized.

20 “(4) VERIFICATION.—Beginning not later than
21 6 years after the date of the enactment of [_____
22 Act of 2013], a repackager shall implement systems
23 to enable the repackager to comply with the fol-
24 lowing 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 repackager is a suspect prescription drug
7 product, or upon receiving a request for
8 verification from the Secretary that a pre-
9 scription drug product within the posses-
10 sion or control of a repackager is a suspect
11 prescription drug product, a repackager
12 shall promptly conduct an investigation to
13 determine whether the prescription drug
14 product is an illegitimate prescription drug
15 product, including—

16 “(I) verifying the prescription
17 drug product at the package level;

18 “(II) validating any applicable
19 transaction information in the posses-
20 sion of the repackager; 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 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 determining
17 that a prescription drug product in the
18 possession or control of a repackager is an
19 illegitimate prescription drug product, the
20 repackager shall—

21 “(I) quarantine such prescription
22 drug product within the possession or
23 control of the repackager from pre-
24 scription drug product intended for
25 distribution; and

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

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

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

23 “(iv) RESPONDING TO A NOTIFICA-
24 TION.—Upon the receipt of a notification
25 from the Secretary that a determination

1 has been made that a prescription drug
2 product is an illegitimate prescription drug
3 product, a repackager shall—

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

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

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

18 “(C) ELECTRONIC DATABASE.—A repack-
19 ager may satisfy the requirements of this para-
20 graph through the use of a secure electronic
21 database developed and operated by the manu-
22 facturer or another entity. The owner of such
23 database shall establish the requirements and
24 processes to respond to requests and may pro-
25 vide for data access to other members of the

1 pharmaceutical distribution supply chain, as ap-
2 propriate. The development and operation of
3 such a database shall not relieve a repackager
4 of the requirement under this paragraph to re-
5 spond to a verification request submitted by
6 means other than a secure electronic database.

7 “(D) RETURNED PRESCRIPTION DRUG
8 PRODUCT.—Upon receipt of a returned pre-
9 scription drug product that the repackager in-
10 tends to further distribute, before further dis-
11 tributing such prescription drug product, the
12 repackager shall—

13 “(i) verify the prescription drug prod-
14 uct identifier for each sealed homogeneous
15 case of such prescription drug product; or

16 “(ii) if such prescription drug product
17 is not in a sealed homogeneous case, verify
18 the prescription drug product identifier on
19 each package.

20 “(f) THIRD-PARTY LOGISTICS PROVIDER REQUIRE-
21 MENTS.—

22 “(1) AUTHORIZED TRADING PARTNERS.—Be-
23 ginning 3 years after the date of the enactment of
24 the [_____ Act of 2013], a third-party logistics

1 provider shall ensure that each of its trading part-
2 ners is authorized.

3 “(2) VERIFICATION.—Beginning not later than
4 7 years after the date of the enactment of the
5 **【_____ Act of 2013】**, a third-party logistics pro-
6 vider shall implement systems to enable the third-
7 party logistics provider to comply with the following
8 requirements:

9 “(A) SUSPECT PRESCRIPTION DRUG PROD-
10 UCT.—

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

22 “(ii) CLEARED PRESCRIPTION DRUG
23 PRODUCT.—If the owner of the prescrip-
24 tion drug product notifies the third-party
25 logistics provider of the determination that

1 a suspect prescription drug product is not
2 an illegitimate prescription drug product,
3 such prescription drug product may be fur-
4 ther distributed.

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

11 “(B) ILLEGITIMATE PRESCRIPTION DRUG
12 PRODUCT.—

13 “(i) IN GENERAL.—Upon determining
14 that a prescription drug product in the
15 possession or control of a third-party logis-
16 tics provider is an illegitimate prescription
17 drug product, the third-party logistics pro-
18 vider shall—

19 “(I) quarantine such prescription
20 drug product within the possession or
21 control of the third-party logistics pro-
22 vider from prescription drug product
23 intended for distribution;

24 “(II) promptly notify the owner
25 of such prescription drug product of

1 the need to provide for the disposition
2 of such prescription drug product; and

3 “(III) promptly transfer posses-
4 sion of the prescription drug product
5 to the owner of such prescription drug
6 product to provide for the disposition
7 of the prescription drug product.

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

18 “(iii) RESPONDING TO A NOTIFICA-
19 TION.—Upon the receipt of a notification
20 from the Secretary, a third-party logistics
21 provider shall—

22 “(I) identify all illegitimate pre-
23 scription drug product subject to such
24 notification that is in the possession
25 or control of the third-party logistics

1 provider, including any prescription
2 drug product that is subsequently re-
3 ceived; and

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

6 “(iv) RECORDS.—A third-party logis-
7 tics provider shall keep records of the ac-
8 tivities described in clauses (i) and (ii)
9 with respect to an illegitimate prescription
10 drug product for not less than 3 years
11 after the conclusion of the disposition.

12 “(g) DROP SHIPMENTS.—This section does not apply
13 to any entity, notwithstanding its status as a wholesale
14 distributor or repackager, or other status that is not in-
15 volved in the physical handling, distribution, or storage of
16 a prescription drug product. For purposes of this sub-
17 section, facilitating the distribution of a prescription drug
18 product by providing various administrative services, in-
19 cluding processing of orders and payments, shall not, by
20 itself, be construed as being involved in the handling, dis-
21 tribution, or storage of a prescription drug product.”.

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

23 (a) PILOT PROJECTS.—

24 (1) IN GENERAL.—Not later than 2 years after
25 the date of the enactment of this Act, the Secretary

1 shall establish 1 or more pilot projects in coordina-
2 tion with manufacturers, repackagers, wholesale dis-
3 tributors, third-party logistics providers, and dis-
4 pensers to explore and evaluate methods to enhance
5 the safety and security of the pharmaceutical dis-
6 tribution supply chain.

7 (2) CONTENT.—

8 (A) IN GENERAL.—The Secretary shall en-
9 sure that the pilot projects under paragraph (1)
10 collectively—

11 (i) reflect the diversity of the pharma-
12 ceutical distribution supply chain; and

13 (ii) include participants representative
14 of every sector within the pharmaceutical
15 distribution supply chain, including partici-
16 pants representative of small businesses.

17 (B) PROJECT DESIGN.—The pilot projects
18 shall be designed to—

19 (i) utilize the prescription drug prod-
20 uct identifier for tracing of a prescription
21 drug product, which utilization may in-
22 clude—

23 (I) verification of the prescription
24 drug product identifier of a prescrip-
25 tion drug product; and

1 (II) the use of aggregation and
2 inference;

3 (ii) improve the technical capabilities
4 of each sector within the pharmaceutical
5 supply chain to comply with systems and
6 processes needed to utilize the prescription
7 drug product identifiers to enhance tracing
8 of a prescription drug product; and

9 (iii) conduct such other activities as
10 the Secretary determines appropriate to
11 explore and evaluate methods to enhance
12 the safety and security of the pharma-
13 ceutical distribution supply chain.

14 (b) PUBLIC MEETINGS.—

15 (1) IN GENERAL.—Not later than 6 months
16 after the date of the enactment of this Act, and at
17 least every 6 months thereafter until the submission
18 of the report required by subsection (d)(2), the Sec-
19 retary shall hold a public meeting to enhance the
20 safety and security of the pharmaceutical distribu-
21 tion supply chain. In conducting such meetings, the
22 Secretary shall take all measures reasonable and
23 practicable to ensure the protection of confidential
24 commercial information and trade secrets.

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

5 (A) Best practices in each of the sectors
6 within the pharmaceutical distribution supply
7 chain to implement the requirements of section
8 582 of the Federal Food, Drug, and Cosmetic
9 Act, as added by section 2.

10 (B) The costs and benefits of implementa-
11 tion of such section 582, including the impact
12 on each pharmaceutical distribution supply
13 chain sector and on public health.

14 (C) Whether additional electronic
15 traceability requirements, including tracing of
16 prescription drug product at the package level,
17 are feasible, cost effective, overly burdensome
18 on small businesses, and needed to protect pub-
19 lic health.

20 (D) The systems and processes needed to
21 utilize the prescription drug product identifiers
22 to enhance tracing of prescription drug product
23 at the package level.

24 (E) The technical capabilities and legal au-
25 thorities, if any, needed to establish an elec-

1 tronic system that provides for enhanced trac-
2 ing of prescription drug product at the package
3 level.

4 (F) The impact that the requirements, sys-
5 tems, processes, capabilities, and legal authori-
6 ties referred to in subparagraphs (C), (D), and
7 (E) would have on patient safety, the drug sup-
8 ply, cost and regulatory burden, the timeliness
9 of patient access to prescription drugs, and
10 small businesses.

11 (c) STUDY OF THE PHARMACEUTICAL DISTRIBUTION
12 SUPPLY CHAIN.—

13 (1) IN GENERAL.—The Comptroller General of
14 the United States shall conduct a study to examine
15 implementation of the requirements established
16 under subchapter H of chapter V of the Federal
17 Food, Drug, and Cosmetic Act, as added by section
18 2, in order to inform the regulations promulgated
19 under this section.

20 (2) CONSIDERATION.—In conducting the study
21 under this subsection, the Comptroller General shall
22 provide for stakeholder input and shall consider the
23 following:

1 (A) The implementation of the require-
2 ments established under such subchapter H
3 with respect to—

4 (i) the ability of the health care sys-
5 tem collectively to maintain patient access
6 to medicines;

7 (ii) the scalability of such require-
8 ments, including with respect to prescrip-
9 tion drug product lines; and

10 (iii) the capability of different sectors
11 within the pharmaceutical distribution sup-
12 ply chain, including small businesses, to
13 affix and utilize the prescription drug
14 product identifier.

15 (B) The need for additional legal authori-
16 ties and activities to address additional gaps in
17 the pharmaceutical distribution supply chain, if
18 any, after the implementation of the require-
19 ments established under such subchapter H
20 with respect to—

21 (i) the systems and processes needed
22 to enhance tracing of prescription drug
23 product at the package level;

24 (ii) the impact, feasibility, and cost ef-
25 fectiveness that additional requirements

1 pursuant to this section would have on
2 each pharmaceutical distribution supply
3 chain sector and the public health; and

4 (iii) the systems and processes needed
5 to enhance interoperability among trading
6 partners.

7 (C) Risks to the security and privacy of
8 data collected, maintained, or exchanged pursu-
9 ant to the requirements established under such
10 subchapter H.

11 (d) REPORTS.—

12 (1) GAO REPORT.—Not later than 10 years
13 after the date of the enactment of this Act, the
14 Comptroller General shall submit to the Committee
15 on Energy and Commerce of the House of Rep-
16 resentatives and the Committee on Health, Edu-
17 cation, Labor, Pensions of the Senate a report on
18 the results of the study conducted under subsection
19 (c).

20 (2) FDA REPORT.—Not later than 10 years
21 after the date of the enactment of this Act, the Sec-
22 retary shall submit to the Committee on Energy and
23 Commerce of the House of Representatives and the
24 Committee on Health, Education, Labor, and Pen-
25 sions of the Senate a report on the results of the

1 pilot program conducted under subsection (a), tak-
2 ing into consideration the comments received during
3 the public meetings conducted under subsection (b).

4 (e) DEFINITIONS.—In this section:

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

9 (2) The term “Secretary” means the Secretary
10 of Health and Human Services, acting through the
11 Commissioner of Food and Drugs.

12 **SEC. 4. NATIONAL STANDARDS FOR WHOLESALE DISTRIBUTORS.**
13

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

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

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

22 (2) in subchapter H of chapter V of the Federal
23 Food, Drug, and Cosmetic Act, as added by section
24 2, by adding at the end the following:

1 **“SEC. 583. NATIONAL STANDARDS FOR WHOLESALE DIS-**
2 **TRIBUTORS.**

3 “(a) STANDARDS.—

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

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

10 “(A) the storage and handling of drugs
11 subject to section 503(b)(1), including facility
12 requirements;

13 “(B) the establishment and maintenance of
14 records of the distributions of such drugs;

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

18 “(D) mandatory background checks and
19 fingerprinting of facility managers or des-
20 ignated representatives;

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

23 “(F) the mandatory physical inspection of
24 any facility to be used in wholesale distribution
25 within a reasonable timeframe from the initial

1 application for licensure of the wholesale dis-
2 tributor; and

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

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

9 “(A) An applicant that is not a govern-
10 ment-owned-and-operated wholesale distributor,
11 for the issuance or renewal of a wholesale dis-
12 tributor license, shall submit a surety bond of
13 \$100,000 or other equivalent means of security
14 acceptable to the applicable licensing authority.

15 “(B) For purposes of subparagraph (A),
16 the applicable licensing authority may accept a
17 surety bond less than \$100,000 if the annual
18 gross receipts of the previous tax year for the
19 wholesale distributor is \$10,000,000 or less, in
20 which case the surety bond may not be less
21 than \$25,000.

22 “(C) If a wholesale distributor can provide
23 evidence that it possesses the required bond in
24 a State, the requirement for a bond in another
25 State is waived.

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

5 “(A) the government of the State in which
6 the facility is located; or

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

9 “(5) PROHIBITED PERSONS.—The requirements
10 under paragraph (2) shall include requirements to
11 prohibit a person from receiving or maintaining li-
12 censure for wholesale distribution if the person—

13 “(A) has been convicted of any felony for
14 conduct relating to wholesale distribution; any
15 felony violation of section 301(i) or 301(k); or
16 any felony violation of section 1365 of title 18,
17 United States Code, relating to prescription
18 drug product tampering; or

19 “(B) has engaged in a pattern of violating
20 the requirements of this section that presents a
21 threat of serious adverse health consequences or
22 death to humans.

23 “(b) REPORTING BY LICENSED WHOLESALE DIS-
24 TRIBUTORS.—

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

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

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

9 “(C) a listing of each State in which the
10 wholesale distributor is licensed for wholesale
11 distribution; and

12 “(D) any disciplinary actions taken by a
13 State, the Federal Government, or a foreign
14 government during the reporting period against
15 the wholesale distributor.

16 “(2) POSTING ON INTERNET.—The Secretary
17 shall post on the public Internet Website of the
18 Food and Drug Administration the name of each
19 wholesale distributor, and the State in which each
20 such distributor is licensed, based on reports under
21 paragraph (1).

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

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

4 “(2) collecting fees from wholesale distributors
5 in connection with such licensing,

6 so long as the State does not require such licensure to
7 the extent to which an entity is engaged in third-party
8 logistics provider activities.

9 “(d) DEFINITIONS.—In this section:

10 “(1) The term ‘qualified licensing program’
11 means a program meeting the requirements of this
12 section and the regulations thereunder.

13 “(2) The term ‘wholesale distribution’ means
14 the distribution of a drug subject to section
15 503(b)(1) to a person other than a consumer or pa-
16 tient, but does not include—

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

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

1 “(C) the distribution of a drug or an offer
2 to distribute a drug for emergency medical rea-
3 sons, including a public health emergency dec-
4 laration pursuant to section 319 of the Public
5 Health Service Act, except that a drug shortage
6 not caused by a public health emergency shall
7 not constitute such an emergency medical rea-
8 son;

9 “(D) dispensing of a drug pursuant to a
10 valid prescription executed in accordance with
11 subsection 503(b)(1);

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

15 “(F) the distribution of a drug or an offer
16 to distribute a drug by a charitable organization
17 to a nonprofit affiliate of the organization to
18 the extent otherwise permitted by law;

19 “(G) the purchase or other acquisition by
20 a dispenser, hospital, or other health care entity
21 of a drug for use by such dispenser, hospital, or
22 other health care entity;

23 “(H) the distribution of a drug by the
24 manufacturer of such drug;

1 “(I) the receipt or transfer of a drug by an
2 authorized third-party logistics provider pro-
3 vided that such third-party logistics provider
4 does not take ownership of the drug;

5 “(J) the transport of a drug by a common
6 carrier, provided that the common carrier does
7 not take ownership of the drug;

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

12 “(L) salable drug returns when conducted
13 by a dispenser in accordance with section
14 203.23 of title 21, Code of Federal Regulations
15 (or any successor regulation);

16 “(M) the distribution of a combination pre-
17 scription drug product described in section
18 581(20)(B)(xiii);

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

21 “(O) the distribution of an intravenous
22 drug that, by its formulation, is intended for
23 the replenishment of fluids and electrolytes
24 (such as sodium, chloride, and potassium) or
25 calories (such as dextrose and amino acids);

1 “(P) the distribution of an intravenous
2 drug used to maintain the equilibrium of water
3 and minerals in the body, such as dialysis solu-
4 tions;

5 “(Q) the distribution of a drug that is in-
6 tended for irrigation or reconstitution, or sterile
7 water, whether intended for such purposes or
8 for injection;

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

11 “(S) facilitating the distribution of a pre-
12 scription drug product by providing administra-
13 tive services, such as processing of orders and
14 payments, without physical handling, distribu-
15 tion, or storage of a prescription drug product.

16 “(e) EFFECTIVE DATE.—The standards required by
17 subsection (a) shall take effect not later than 2 years after
18 the date of the enactment of this section. The Secretary
19 shall issue the regulations required by subsection (a) not
20 later than 1 year after the date of the enactment of this
21 Act.”.

22 (b) CONFORMING AMENDMENT.—Section
23 804(a)(5)(A) of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 384(a)(5)(A)) is amended by striking
25 “503(e)(2)(A)” and inserting “583(a)”.

1 **SEC. 5. NATIONAL LICENSURE STANDARDS FOR THIRD-**
2 **PARTY LOGISTICS PROVIDERS.**

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

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

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

11 “(1) the facility is licensed—

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

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

19 “(2) the facility is licensed by the State into
20 which the drug is distributed in accordance with a
21 qualified licensing program, if the drug is distrib-
22 uted interstate, and if such State has such a pro-
23 gram and requires such licensure.

24 “(b) REPORTING BY LICENSED THIRD-PARTY LOGIS-
25 TICS PROVIDERS.—

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

7 “(A) the facility’s name;

8 “(B) the facility’s address;

9 “(C) a listing of each jurisdiction (whether
10 State or Federal) in which the facility is li-
11 censed for third-party logistics provider activi-
12 ties; and

13 “(D) any disciplinary actions taken by a
14 State or Federal licensing authority during the
15 reporting period against the facility.

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

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

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

4 “(2) collecting fees from third-party logistics
5 providers in connection with such licensing,

6 so long as the State does not require such licensure to
7 the extent to which an entity is engaged in wholesale dis-
8 tribution.

9 “(d) LICENSE REGULATIONS.—

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

14 “(2) CONTENT.—The regulations under para-
15 graph (1) shall—

16 “(A) include standards relating to eligi-
17 bility for, and revocation and reissuance of, li-
18 censes;

19 “(B) establish a process by which the ap-
20 plicable licensing authority will, upon request by
21 a third-party logistics provider that is accred-
22 ited by a third-party accreditation program ap-
23 proved by the Secretary, issue a license to the
24 provider;

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

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

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

16 “(ii) maintaining adequate security;
17 and

18 “(iii) having written policies and pro-
19 cedures to—

20 “(I) address receipt, security,
21 storage, inventory, shipment, and dis-
22 tribution of a prescription drug prod-
23 uct;

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

4 “(III) correct errors and inac-
5 curacies in inventories;

6 “(IV) provide support for manu-
7 facturer recalls;

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

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

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

23 “(VIII) quarantine or destroy a
24 suspect prescription drug product if
25 directed to do so by the respective

1 manufacturer, wholesale distributor,
2 dispenser, or an authorized govern-
3 ment agency;

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

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

14 “(G) perform mandatory background
15 checks of the provider’s facility managers or
16 designated representatives of such managers;

17 “(H) require a third-party logistics pro-
18 vider to provide to the applicable licensing au-
19 thority, upon the authority’s request, a list of
20 all prescription drug product manufacturers,
21 wholesale distributors, and dispensers for whom
22 the third-party logistics provider provides serv-
23 ices at the provider’s facilities; and

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

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

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

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

14 “(f) QUALIFIED LICENSING PROGRAM DEFINED.—In
15 this section, the term ‘qualified licensing program’ means
16 a program meeting the requirements of this section and
17 the regulations thereunder.

18 “(g) EFFECTIVE DATE.—The requirements of this
19 section shall take effect not later than 1 year after the
20 date of the enactment of this section. The Secretary shall
21 issue the regulations required by subsection (d) not later
22 than 180 days after the date of the enactment of this
23 Act.”.

1 **SEC. 6. PENALTIES.**

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

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

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

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

23 (c) MISBRANDING.—Section 502 of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amend-
25 ed by adding at the end the following:

1 “(bb) If it is a drug and it fails to bear a prescription
2 drug product identifier as required by section 582.”.

3 **SEC. 7. UNIFORM NATIONAL POLICY.**

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

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

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

20 “(1) are inconsistent with, more stringent than,
21 or in addition to any requirements applicable under
22 this Act; or

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

1 “(b) STANDARDS OR LICENSURE.—

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

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

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

19 “(A) may provide for the suspension or
20 revocation of licenses issued by the State for
21 violations of the laws of such State;

22 “(B) upon conviction of a person for a vio-
23 lation of Federal, State, or local controlled sub-
24 stance laws or regulations, may provide for
25 fines, imprisonment, or civil penalties; and

1 “(C) may regulate activities of entities li-
2 censed pursuant to section 583 or 584 in a
3 manner that is consistent with the provisions of
4 this subchapter.”.

5 **SEC. 8. ELECTRONIC LABELING REQUIREMENT.**

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