

113TH CONGRESS
1ST SESSION

H. R. 1919

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

IN THE HOUSE OF REPRESENTATIVES

MAY 9, 2013

Mr. LATTA (for himself, Mr. MATHESON, Mr. UPTON, Mr. DINGELL, Mr. CASIDY, Mrs. BLACKBURN, Mr. MCKINLEY, Mr. ROGERS of Michigan, Mr. BURGESS, Mr. SHIMKUS, Mr. GUTHRIE, Mr. JOHNSON of Ohio, and Mr. SCHNEIDER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 “Safeguarding America’s Pharmaceuticals 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

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

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

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

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

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

7 “(A) IN GENERAL.—The term ‘package’
8 means the smallest individual saleable unit of
9 prescription drug product for distribution in
10 interstate commerce by a manufacturer or re-
11 packager that is intended by the manufacturer
12 for ultimate sale to the dispenser of such pre-
13 scription drug product.

14 “(B) INDIVIDUAL SALEABLE UNIT.—The
15 term ‘individual saleable unit’ means the small-
16 est container of prescription drug product intro-
17 duced into interstate commerce by the manufac-
18 turer or repackager that is intended by the
19 manufacturer for individual sale to a dispenser.

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

23 “(10) PRESCRIPTION DRUG PRODUCT.—The
24 term ‘prescription drug product’ means a prescrip-
25 tion drug in a finished dosage form for administra-

1 tion to a patient without substantial further manu-
2 facturing (such as capsules, tablets, and lyophilized
3 prescription drug products before reconstitution).

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

7 “(A) includes the standardized numerical
8 identifier, lot number, and expiration date of a
9 prescription drug product; and

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

15 “(12) QUARANTINE.—The term ‘quarantine’
16 means to store or identify a product, for the purpose
17 of preventing distribution or transfer of the product,
18 in a physically separate area clearly identified for
19 such use, or through use of other procedures such
20 as automated designation.

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

1 “(14) RETURN.—The term ‘return’ means pro-
2 viding prescription drug product to the authorized
3 trading partner or trading partners from which such
4 prescription drug product was purchased, or to a re-
5 turns processor for handling of such prescription
6 drug product.

7 “(15) RETURNS PROCESSOR.—The terms ‘re-
8 turns processor’ mean a person who owns or oper-
9 ates an establishment that provides for the disposi-
10 tion of or otherwise processes saleable and nonsale-
11 able prescription drug product received from an au-
12 thorized trading partner such that the prescription
13 drug product may be processed for credit to the pur-
14 chaser, manufacturer, seller, or disposed of for no
15 further distribution.

16 “(16) SPECIFIC PATIENT NEED.—The term
17 ‘specific patient need’—

18 “(A) means with respect to the transfer of
19 a prescription drug product from one pharmacy
20 to another, to fill a prescription for an identi-
21 fied patient; and

22 “(B) does not include the transfer of a
23 prescription drug product from one pharmacy
24 to another for the purpose of increasing or re-

1 plenishing stock in anticipation of a potential
2 need.

3 “(17) STANDARDIZED NUMERICAL IDENTIFI-
4 FIER.—The term ‘standardized numerical identifier’
5 means a set of numbers or characters that—

6 “(A) is used to uniquely identify each
7 package or homogenous case of the prescription
8 drug product; and

9 “(B) is composed of the National Drug
10 Code that corresponds to the specific prescrip-
11 tion drug product (including the particular
12 package configuration) combined with a unique
13 alphanumeric serial number of up to 20 char-
14 acters.

15 “(18) SUSPECT PRESCRIPTION DRUG PROD-
16 UCT.—The term ‘suspect prescription drug product’
17 means a prescription drug product for which there
18 is reason to believe that such prescription drug prod-
19 uct—

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

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

1 “(C) appears otherwise unfit for distribu-
2 tion such that the prescription drug product
3 would result in serious adverse health con-
4 sequences or death to humans.

5 “(19) THIRD-PARTY LOGISTICS PROVIDER.—
6 The term ‘third-party logistics provider’ means an
7 entity that provides or coordinates warehousing, dis-
8 tribution, or other logistics services of a prescription
9 drug product in interstate commerce on behalf of a
10 manufacturer, wholesale distributor, or dispenser of
11 a prescription drug product, but does not take own-
12 ership of the prescription drug product, nor have re-
13 sponsibility to direct the sale or disposition of, the
14 prescription drug product.

15 “(20) TRADING PARTNER.—The term ‘trading
16 partner’ means—

17 “(A) a manufacturer, repackager, whole-
18 sale distributor, or dispenser from whom a
19 manufacturer, repackager, wholesale dis-
20 tributor, or dispenser accepts ownership of a
21 prescription drug product or to whom a manu-
22 facturer, repackager, wholesale distributor, or
23 dispenser transfers ownership of a prescription
24 drug product; or

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

8 “(21) TRANSACTION.—

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

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

15 “(i) intracompany distribution of any
16 prescription drug product between mem-
17 bers of an affiliated group (as defined in
18 section 1504(a) of the Internal Revenue
19 Code of 1986);

20 “(ii) the distribution of a prescription
21 drug product among hospitals or other
22 health care entities that are under common
23 control;

24 “(iii) the distribution of a prescription
25 drug product for emergency medical rea-

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

7 “(iv) the dispensing of a prescription
8 drug product pursuant to a valid prescrip-
9 tion executed in accordance with section
10 503(b)(1);

11 “(v) the distribution of prescription
12 drug product samples by a manufacturer
13 or a licensed wholesale distributor in ac-
14 cordance with section 503(d);

15 “(vi) the distribution of blood or blood
16 components intended for transfusion;

17 “(vii) the distribution of minimal
18 quantities of prescription drug product by
19 a licensed retail pharmacy to a licensed
20 practitioner for office use;

21 “(viii) the distribution of a prescrip-
22 tion drug product by a charitable organiza-
23 tion to a nonprofit affiliate of the organiza-
24 tion to the extent otherwise permitted by
25 law;

1 “(ix) the distribution of a prescription
2 drug product pursuant to the sale or merg-
3 er of a pharmacy or pharmacies or a
4 wholesale distributor or wholesale distribu-
5 tors, except that any records required to be
6 maintained for the prescription drug prod-
7 uct shall be transferred to the new owner
8 of the pharmacy or pharmacies or whole-
9 sale distributor or wholesale distributors;

10 “(x) the dispensing of a prescription
11 drug product approved under section
12 512(b);

13 “(xi) the transfer of prescription drug
14 products to or from any facility that is li-
15 censed by the Nuclear Regulatory Commis-
16 sion or by a State pursuant to an agree-
17 ment with such Commission under section
18 274 of the Atomic Energy Act of 1954 (42
19 U.S.C. 2021);

20 “(xii) the distribution of a combina-
21 tion product that consists of—

22 “(I) a product comprised of two
23 or more components that are each a
24 drug, biological product, or device and
25 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 prod-
4 ucts packaged together in a single
5 package or as a unit and comprised of
6 a drug and device or a device and bio-
7 logical product; or

8 “(III) two or more finished de-
9 vices plus one or more drug or biologi-
10 cal products which are packaged to-
11 gether in a medical convenience kit
12 described in clause (xiv);

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

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

24 “(II) the person who manufactur-
25 ers the medical convenience kit pur-

1 chased the prescription drug product
2 directly from the manufacturer or
3 from a wholesale distributor that pur-
4 chased the prescription drug product
5 directly from the manufacturer;

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

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

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

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

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

- 1 “(cc) drugs intended for irri-
2 gation or reconstitution;
3 “(dd) anesthetics;
4 “(ee) anticoagulants;
5 “(ff) vasopressors; or
6 “(gg) sympathicomimetics;
7 “(xiv) the distribution of an intra-
8 venous prescription drug product that, by
9 its formulation, is intended for the replen-
10 ishment of fluids and electrolytes (such as
11 sodium, chloride, and potassium) or cal-
12 ories (such as dextrose and amino acids);
13 “(xv) the distribution of an intra-
14 venous prescription drug product used to
15 maintain the equilibrium of water and min-
16 erals in the body, such as dialysis solu-
17 tions;
18 “(xvi) the distribution of a prescrip-
19 tion drug product that is intended for irri-
20 gation or reconstitution, or sterile water,
21 whether intended for such purposes or for
22 injection; or
23 “(xvii) the distribution of compressed
24 medical gas.

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

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

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

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

18 “(23) TRANSACTION INFORMATION.—The term
19 ‘transaction information’ means—

20 “(A) the proprietary or established name
21 or names of the prescription drug product;

22 “(B) the strength and dosage form of the
23 prescription drug product;

24 “(C) the National Drug Code number of
25 the prescription drug product;

1 “(D) the container size;

2 “(E) the number of containers;

3 “(F) the lot number of the prescription
4 drug product;

5 “(G) the date of the transaction;

6 “(H) the business name and address of the
7 person from whom ownership is being trans-
8 ferred; and

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

11 “(24) TRANSACTION STATEMENT.—The ‘trans-
12 action statement’ is a statement, which states that
13 the manufacturer, repackager, wholesale distributor,
14 third-party logistics provider, or dispenser transfer-
15 ring ownership in a transaction—

16 “(A) is authorized;

17 “(B) received transaction information and
18 a transaction statement as required under sec-
19 tion 582 from the prior owner of the prescrip-
20 tion drug product;

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

23 “(D) did not knowingly and intentionally
24 provide false transaction information; and

1 “(E) did not knowingly and intentionally
2 alter the transaction history.

3 “(25) VERIFICATION AND VERIFY.—The terms
4 ‘verification’ and ‘verify’—

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

13 “(B) include making the determination
14 under subparagraph (A) using human-readable
15 or machine-readable methods.

16 “(26) WHOLESALE DISTRIBUTOR.—The term
17 ‘wholesale distributor’—

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

20 “(B) excludes—

21 “(i) a manufacturer, a co-licensed
22 partner of a manufacturer, or a third-party
23 logistics provider, or a dispenser who does
24 not engage in such wholesale distribution;

1 “(ii) a repackager engaged in such
2 wholesale distribution; or

3 “(iii) the distribution of prescription
4 drug product or an offer to distribute pre-
5 scription drug product by an authorized re-
6 packager that has taken ownership or pos-
7 session of the prescription drug product
8 and repacked the prescription drug prod-
9 uct in accordance with the requirements of
10 section 582(e).

11 **“SEC. 582. REQUIREMENTS.**

12 “(a) IN GENERAL.—

13 “(1) COMPLIANCE REQUIRED.—An entity that
14 is a manufacturer, repackager, wholesale distributor,
15 third-party logistics provider, or dispenser shall com-
16 ply with the requirements of this section. If an enti-
17 ty meets the definition of more than one of the enti-
18 ties referred to in the preceding sentence, such enti-
19 ty shall comply with all applicable requirements of
20 this section, but shall not be required to comply with
21 duplicative requirements.

22 “(2) STANDARDS.—The Secretary shall, in con-
23 sultation with other appropriate Federal officials,
24 manufacturers, repackagers, wholesale distributors,
25 third-party logistics providers, and dispensers, estab-

1 lish, by regulation, standards for the exchange of
2 transaction information for purposes of complying
3 with this section. The standards established under
4 this paragraph shall be in accordance with a form
5 developed by a widely recognized international stand-
6 ards development organization. In establishing such
7 standards, the Secretary shall consider the feasibility
8 of establishing standardized documentation to be
9 used by all members of the pharmaceutical distribu-
10 tion supply chain to convey the transaction history
11 and transaction statement to the subsequent owner
12 of a prescription drug product. The Secretary shall
13 publish such standards not later than 180 days after
14 the date of the enactment of the Safeguarding
15 America’s Pharmaceuticals Act of 2013.

16 “(3) WAIVERS, EXCEPTIONS, AND EXEMP-
17 TIONS.—Not later than one year after the date of
18 the enactment of the Safeguarding America’s Phar-
19 maceuticals Act of 2013, the Secretary shall promul-
20 gate a regulation to—

21 “(A) establish a process by which the Sec-
22 retary may grant, at the request of an author-
23 ized manufacturer, repackager, wholesale dis-
24 tributor, or dispenser, a waiver from any of the
25 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 one
4 year after the date of the enactment of the
5 Safeguarding America’s Pharmaceuticals Act of
6 2013, the Secretary shall specify, by regulation,
7 whether and under what circumstances the pre-
8 scription drug product identifier requirement
9 under paragraph (2) of subsections (b), (c), (d),
10 and (e) shall apply to a prescription drug prod-
11 uct that is in the supply chain on the date of
12 the enactment of the Safeguarding America’s
13 Pharmaceuticals Act of 2013.

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

24 “(C) LABEL CHANGES.—Changes made to
25 package labels solely to incorporate the pre-

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

6 “(b) MANUFACTURER REQUIREMENTS.—

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

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

11 “(i) prior to, or at the time of, each
12 transaction in which such manufacturer
13 transfers ownership of a prescription drug
14 product, provide the subsequent owner
15 with the transaction history and a trans-
16 action 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 Safeguarding America’s
11 Pharmaceuticals Act of 2013, a manufacturer shall
12 affix or imprint a prescription drug product identi-
13 fier on each package and homogenous case of a pre-
14 scription drug product intended to be introduced in
15 a transaction. Such manufacturer shall maintain a
16 copy of the prescription drug product identifier for
17 such prescription drug product for not less than 3
18 years after the date of the transaction.

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

23 “(4) LIST OF AUTHORIZED DISTRIBUTORS OF
24 RECORD.—Beginning not later than January 1,

1 2015, each manufacturer of a prescription drug
2 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 January 1, 2015, a manufacturer shall implement
13 systems and processes to enable the manufacturer to
14 comply with the following requirements:

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

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

1 facturer shall promptly conduct an inves-
2 tigation in coordination with trading part-
3 ners, as applicable, to determine whether
4 the prescription drug product is an illegit-
5 imate prescription drug product. Beginning
6 not later than 5 years after the date of the
7 enactment of the Safeguarding America’s
8 Pharmaceuticals Act of 2013, such inves-
9 tigation shall include—

10 “(I) verifying the prescription
11 drug product at the package level;

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

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

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

1 termination and such prescription drug
2 product may be further distributed.

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

8 “(B) ILLEGITIMATE PRESCRIPTION DRUG
9 PRODUCT.—

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

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

18 “(II) provide for the disposition
19 of the illegitimate prescription drug
20 product.

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

1 sonable steps to assist a trading partner to
2 provide for the disposition of the illegit-
3 imate prescription drug product.

4 “(iii) MAKING A NOTIFICATION.—

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

14 “(iv) RESPONDING TO A NOTIFICA-
15 TION.—Upon the receipt of a notification

16 from the Secretary that a determination
17 has been made that a prescription drug
18 product is an illegitimate prescription drug
19 product, a manufacturer shall—

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

1 product that is subsequently received;
2 and

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

5 “(v) RECORDS.—A manufacturer 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 manu-
11 facturer 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 respond to requests and may
17 provide for data access to other members of the
18 pharmaceutical distribution supply chain, as ap-
19 propriate. The development and operation of
20 such a database shall not relieve a manufac-
21 turer of the requirement under this paragraph
22 to respond to a verification request submitted
23 by means other than a secure electronic data-
24 base.

1 “(D) RETURNED PRESCRIPTION DRUG
2 PRODUCT.—Beginning not later than 5 years
3 after the date of the enactment of the Safe-
4 guarding America’s Pharmaceuticals Act of
5 2013, upon receipt of a returned prescription
6 drug product that the manufacturer intends to
7 further distribute, before further distributing
8 such prescription drug product, the manufac-
9 turer shall—

10 “(i) verify the prescription drug prod-
11 uct identifier for each sealed homogeneous
12 case of such prescription drug product; or

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

17 “(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

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

20 “(A) IN GENERAL.—Beginning not later
21 than April 1, 2015, a wholesale distributor
22 shall—

23 “(i) not accept ownership of a pre-
24 scription drug product unless the previous
25 owner prior to, or at the time of, the trans-

1 action provides the applicable transaction
2 history and a transaction statement for the
3 prescription drug product;

4 “(ii) prior to, or at the time of, each
5 transaction in which the wholesale dis-
6 tributor transfers ownership of a prescrip-
7 tion drug product—

8 “(I) in the case that the whole-
9 sale distributor purchased the pre-
10 scription drug product directly from
11 the manufacturer, provide the subse-
12 quent owner with transaction history
13 and a transaction statement for the
14 prescription drug product; or

15 “(II) in the case that the whole-
16 sale distributor did not purchase the
17 prescription drug product directly
18 from the manufacturer, the exclusive
19 distributor of the manufacturer, or a
20 repackager that purchased directly
21 from the manufacturer, provide the
22 subsequent owner with transaction
23 history beginning with the wholesale
24 distributor that did purchase the
25 product directly from the manufac-

1 turer, the exclusive distributor of the
2 manufacturer, or a repackager that
3 purchased directly from the manufac-
4 turer;

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 without a transaction
18 history from a dispenser; and

19 “(II) distribute such returned
20 prescription drug product with a
21 transaction history that begins with
22 the wholesale distributor that so ac-
23 cepted the returned product.

24 “(ii) NONSALEABLE RETURNS.—A
25 wholesale distributor may return a non-

1 saleable prescription drug to the manufac-
2 turer or repackager, to the wholesale dis-
3 tributor from whom such prescription drug
4 was purchased, or to a person acting on
5 behalf of such a person, including a re-
6 turns processor, without providing the in-
7 formation required under subparagraph
8 (A).

9 “(C) REQUESTS FOR INFORMATION.—

10 Upon a request by the Secretary or other ap-
11 propriate Federal or State official, in the event
12 of a recall or for the purpose of investigating a
13 suspect prescription drug product or an illegit-
14 imate prescription drug product a wholesale dis-
15 tributor shall, not later than 2 business days
16 after receiving the request or in such other rea-
17 sonable time as determined by the Secretary,
18 provide the applicable transaction history and
19 transaction statements for the prescription drug
20 product.

21 “(2) PRESCRIPTION DRUG PRODUCT IDENTI-
22 FIER.—Beginning not later than 7 years after the
23 date of the enactment of the Safeguarding America’s
24 Pharmaceuticals Act of 2013, a wholesale distributor
25 may engage in transactions involving a prescription

1 drug product only if such prescription drug product
2 is encoded with a prescription drug product identi-
3 fier, except as provided in subsection (a)(4).

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

8 “(4) VERIFICATION.—Beginning not later than
9 April 1, 2015, a wholesale distributor shall imple-
10 ment systems to enable the wholesale distributor to
11 comply with the following requirements:

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 the
17 wholesale distributor is a suspect prescrip-
18 tion drug product, or upon receiving a re-
19 quest for verification from the Secretary
20 that a prescription drug product within the
21 possession or control of a wholesale dis-
22 tributor is a suspect prescription drug
23 product, a wholesale distributor shall
24 promptly conduct an investigation to deter-
25 mine whether the prescription drug prod-

1 uct is an illegitimate prescription drug
2 product. Beginning not later than 7 years
3 after the date of the enactment of the
4 Safeguarding America’s Pharmaceuticals
5 Act of 2013, such investigation shall in-
6 clude—

7 “(I) verifying a package of the
8 prescription drug product;

9 “(II) validating any applicable
10 transaction history in the possession
11 of the wholesale distributor; and

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

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

24 “(iii) RECORDS.—A wholesale dis-
25 tributor shall keep records of its investiga-

1 tion of a suspect prescription drug product
2 for not less than 3 years after the conclu-
3 sion of the investigation.

4 “(B) ILLEGITIMATE PRESCRIPTION DRUG
5 PRODUCT.—

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

13 “(I) quarantine such prescription
14 drug product within the possession or
15 control of the manufacturer from pre-
16 scription drug product intended for
17 distribution; and

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

22 “(ii) TRADING PARTNER.—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 wholesale distributor shall
2 take reasonable steps to assist a trading
3 partner to provide for the disposition of
4 the illegitimate 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 wholesale distributor is an illegitimate pre-
9 scription drug product, the wholesale dis-
10 tributor shall notify the Secretary of such
11 determination not later than 24 hours
12 after making such determination. The Sec-
13 retary shall determine whether additional
14 trading partner notification 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 wholesale distributor shall—

21 “(I) identify all illegitimate pre-
22 scription drug product subject to such
23 notification that is in the possession
24 or control of the wholesale distributor,

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 wholesale dis-
6 tributor shall keep records of the disposi-
7 tion of an illegitimate prescription drug
8 product for not less than 3 years after the
9 conclusion of the disposition.

10 “(C) ELECTRONIC DATABASE.—A whole-
11 sale distributor may satisfy the requirements of
12 this 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 respond to requests and may
17 provide for data access to other members of the
18 pharmaceutical distribution supply chain, as ap-
19 propriate. The development and operation of
20 such a database shall not relieve a wholesale
21 distributor 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.

1 “(D) RETURNED PRESCRIPTION DRUG
2 PRODUCT.—Beginning not later than 7 years
3 after the date of the enactment of the Safe-
4 guarding America’s Pharmaceuticals Act of
5 2013, upon receipt of a returned prescription
6 drug product that the wholesale distributor in-
7 tends to further distribute, before further dis-
8 tributing such prescription drug product, the
9 wholesale distributor shall—

10 “(i) verify the prescription drug prod-
11 uct identifier for each sealed homogeneous
12 case of such prescription drug product; or

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

17 “(d) DISPENSER REQUIREMENTS.—

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

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

22 “(i) shall not accept ownership of a
23 prescription drug product, unless the pre-
24 vious owner prior to, or at the time of, the

1 transaction, provides transaction history
2 and a transaction statement;

3 “(ii) prior to, or at the time of, each
4 transaction in which the dispenser trans-
5 fers ownership of a prescription drug prod-
6 uct (but not including dispensing to a pa-
7 tient or returns) shall provide the subse-
8 quent owner with transaction history and a
9 transaction statement for the prescription
10 drug product, except that the requirements
11 of this clause shall not apply to sales by a
12 dispenser to another dispenser to fulfill a
13 specific patient need; and

14 “(iii) shall maintain transaction infor-
15 mation for a period of not less than 3
16 years after the date of the transaction.

17 “(B) AGREEMENTS WITH THIRD PAR-
18 TIES.—A dispenser may enter into a written
19 agreement with a third party, including an au-
20 thorized wholesale distributor, under which the
21 third party confidentially maintains the trans-
22 action information required to be maintained
23 under this subsection on behalf of the dis-
24 penser. If a dispenser enters into such an

1 agreement, the dispenser shall maintain a copy
2 of the written agreement.

3 “(C) RETURNS EXCEPTION.—

4 “(i) SALEABLE RETURNS.—Notwith-
5 standing subparagraph (A)(ii), a dispenser
6 may return prescription drug product to
7 the trading partner from which the dis-
8 penser obtained the prescription drug
9 product without providing the information
10 required under such subparagraph.

11 “(ii) NONSALEABLE RETURNS.—Not-
12 withstanding subparagraph (A)(ii), a dis-
13 penser may return a nonsaleable prescrip-
14 tion drug to the manufacturer or repack-
15 ager, to the wholesale distributor from
16 whom such prescription drug was pur-
17 chased, to a returns processor, or to a per-
18 son acting on behalf of such persons with-
19 out providing the information required
20 under such subparagraph.

21 “(D) 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 dispenser
2 shall, not later than 2 business days after re-
3 ceiving the request or in another such reason-
4 able time as determined by the Secretary, pro-
5 vide lot level transaction information.

6 “(2) PRESCRIPTION DRUG PRODUCT IDENTIFI-
7 FIER.—Beginning not later than 8 years after the
8 date of the enactment of the Safeguarding America’s
9 Pharmaceuticals Act of 2013, a dispenser may en-
10 gage in transactions involving a prescription drug
11 product only if such prescription drug product is en-
12 coded with a prescription drug product identifier, ex-
13 cept as provided in subsection (a)(4).

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

18 “(4) VERIFICATION.—Beginning not later than
19 January 1, 2015, a dispenser shall implement sys-
20 tems to enable the dispenser to comply with the fol-
21 lowing 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 dispenser is a suspect prescription drug
3 product, or upon receiving a request for
4 verification from the Secretary that a pre-
5 scription drug product within the posses-
6 sion or control of a dispenser is a suspect
7 prescription drug product, a dispenser
8 shall promptly conduct an investigation to
9 determine whether the prescription drug
10 product is an illegitimate prescription drug
11 product. Such investigation shall include—

12 “(I) verifying whether the lot
13 number of a suspect prescription drug
14 product corresponds with the lot num-
15 ber for such prescription drug prod-
16 uct;

17 “(II) beginning 8 years after the
18 date of the enactment of the Safe-
19 guarding America’s Pharmaceuticals
20 Act of 2013, verifying that the prod-
21 uct identifier of at least 3 packages or
22 10 percent of such suspect prescrip-
23 tion drug product, whichever is great-
24 er, or all packages, if there are fewer
25 than 3, corresponds with the prescrip-

1 tion drug product identifier for such
2 product;

3 “(III) validating any applicable
4 transaction history in the possession
5 of the dispenser; and

6 “(IV) otherwise investigating to
7 determine whether the prescription
8 drug product is an illegitimate pre-
9 scription drug product.

10 “(ii) CLEARED PRESCRIPTION DRUG
11 PRODUCT.—If the dispenser makes the de-
12 termination that a suspect prescription
13 drug product is not an illegitimate pre-
14 scription drug product, the dispenser shall
15 promptly notify the Secretary of such de-
16 termination and such prescription drug
17 product may be further dispensed.

18 “(iii) RECORDS.—A dispenser shall
19 keep records of its investigation of a sus-
20 pect prescription drug product for not less
21 than 3 years after the conclusion of the in-
22 vestigation.

23 “(B) ILLEGITIMATE PRESCRIPTION DRUG
24 PRODUCT.—

1 “(i) IN GENERAL.—Upon receiving
2 notice that a manufacturer of a prescrip-
3 tion drug product has determined that a
4 prescription drug product in the possession
5 or control of a dispenser is an illegitimate
6 prescription drug product, the dispenser
7 shall—

8 “(I) quarantine such prescription
9 drug product within the possession or
10 control of the dispenser from prescrip-
11 tion drug product intended for dis-
12 tribution; and

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

17 “(ii) TRADING PARTNERS.—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 dispenser shall take reason-
22 able steps to assist a trading partner to
23 provide for the disposition of the illegit-
24 imate 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 dispenser is an illegitimate prescription
5 drug product, the dispenser shall notify the
6 Secretary of such determination not later
7 than 24 hours after making such deter-
8 mination. The Secretary shall determine
9 whether additional trading partner notifi-
10 cation 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 dispenser shall—

17 “(I) identify all illegitimate pre-
18 scription drug products that are sub-
19 ject to such notification and in the
20 possession or control of the dispenser,
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 dispenser shall
2 keep records of the disposition of an illegit-
3 imate prescription drug product for not
4 less than 3 years after the conclusion of
5 the disposition.

6 “(C) ELECTRONIC DATABASE.—A dis-
7 penser may satisfy the requirements of this
8 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 enable responding to requests
13 and may provide for data access to other mem-
14 bers of the pharmaceutical distribution supply
15 chain, as appropriate. The development and op-
16 eration of such a database shall not relieve a
17 dispenser 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 “(e) REPACKAGER REQUIREMENTS.—

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

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

1 “(i) not accept ownership of a pre-
2 scription drug product unless the previous
3 owner, prior to, or at the time of, the
4 transaction, provides transaction history
5 and a transaction statement for the pre-
6 scription drug product;

7 “(ii) prior to, or at the time of, each
8 transaction in which the repackager trans-
9 fers ownership of a prescription drug prod-
10 uct, provide the subsequent owner with
11 transaction history and a transaction state-
12 ment;

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

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

24 “(B) NONSALEABLE RETURNS.—A repack-
25 ager may return a nonsaleable prescription

1 drug product to the manufacturer or repack-
2 ager, to the wholesale distributor from whom
3 such prescription drug product was purchased,
4 or to a person acting on behalf of such a per-
5 son, including a returns processor, without pro-
6 viding the information required under subpara-
7 graph (A)(ii).

8 “(C) REQUESTS FOR INFORMATION.—

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

20 “(2) PRESCRIPTION DRUG PRODUCT IDENTI-
21 FIER.—Beginning not later than 6 years after the
22 date of the enactment of the Safeguarding America’s
23 Pharmaceuticals Act of 2013, a repackager—

24 “(A) shall affix or imprint a prescription
25 drug product identifier to each package and ho-

1 mogenous case of prescription drug product in-
2 tended to be introduced in a transaction;

3 “(B) shall maintain the prescription drug
4 product identifier for such prescription drug
5 product for not less than 3 years after the date
6 of the transaction; and

7 “(C) may engage in transactions involving
8 a prescription drug product only if such pre-
9 scription drug product is encoded with a pre-
10 scription drug product identifier except as pro-
11 vided in subsection (a)(4).

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

15 “(4) VERIFICATION.—Beginning not later than
16 January 1, 2015, a repackager shall implement sys-
17 tems to enable the repackager to comply with the
18 following requirements:

19 “(A) SUSPECT PRESCRIPTION DRUG PROD-
20 UCT.—

21 “(i) IN GENERAL.—Upon making a
22 determination that a prescription drug
23 product in the possession or control of the
24 repackager is a suspect prescription drug
25 product, or upon receiving a request for

1 verification from the Secretary that a pre-
2 scription drug product within the posses-
3 sion or control of a repackager is a suspect
4 prescription drug product, a repackager
5 shall promptly conduct an investigation to
6 determine whether the prescription drug
7 product is an illegitimate prescription drug
8 product, including—

9 “(I) beginning not later than 6
10 years after the date of the enactment
11 of the Safeguarding America’s Phar-
12 maceuticals Act of 2013, verifying the
13 prescription drug product at the pack-
14 age level;

15 “(II) validating any applicable
16 transaction information in the posses-
17 sion of the repackager; and

18 “(III) otherwise investigating to
19 determine whether the prescription
20 drug product is an illegitimate pre-
21 scription drug product.

22 “(ii) CLEARED PRESCRIPTION DRUG
23 PRODUCT.—If the repackager determines
24 that a suspect prescription drug product is
25 not an illegitimate prescription drug prod-

1 uct, the repackager shall promptly notify
2 the Secretary of such determination and
3 such prescription drug product may be fur-
4 ther distributed.

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

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

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

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

24 “(II) provide for the disposition
25 of the illegitimate prescription drug

1 product within the possession or con-
2 trol of the repackager.

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

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

21 “(iv) RESPONDING TO A NOTIFICA-
22 TION.—Upon the receipt of a notification
23 from the Secretary that a determination
24 has been made that a prescription drug

1 product is an illegitimate prescription drug
2 product, a repackager shall—

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

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

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

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

1 appropriate. The development and operation of
2 such a database shall not relieve a repackager
3 of the requirement under this paragraph to re-
4 spond to a verification request submitted by
5 means other than a secure electronic database.

6 “(D) RETURNED PRESCRIPTION DRUG
7 PRODUCT.—Beginning not later than 6 years
8 after the date of the enactment of the Safe-
9 guarding America’s Pharmaceuticals Act of
10 2013, upon receipt of a returned prescription
11 drug product that the repackager intends to
12 further distribute, before further distributing
13 such prescription drug product, the repackager
14 shall—

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

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

22 “(f) THIRD-PARTY LOGISTICS PROVIDER REQUIRE-
23 MENTS.—

24 “(1) AUTHORIZED TRADING PARTNERS.—Be-
25 ginning on January 1, 2015, 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 January 1, 2015, a third-party logistics provider
5 shall implement systems to enable the third-party lo-
6 gistics provider to comply with the following require-
7 ments:

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

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

21 “(ii) CLEARED PRESCRIPTION DRUG
22 PRODUCT.—If the owner of the prescrip-
23 tion drug product notifies the third-party
24 logistics provider of the determination that
25 a suspect prescription drug product is not

1 an illegitimate prescription drug product,
2 such prescription drug product may be fur-
3 ther distributed.

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

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

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

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

1 “(II) promptly notify the owner
2 of such prescription drug product of
3 the need to provide for the disposition
4 of such prescription drug product; and

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

10 “(ii) MAKING A NOTIFICATION.—

11 Upon determining that a prescription drug
12 product in the possession or control of the
13 third-party logistics provider is an illegit-
14 imate prescription drug product, the third-
15 party logistics provider shall notify the
16 Secretary not later than 24 hours after
17 making such determination. The Secretary
18 shall determine whether additional trading
19 partner notification is appropriate.

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

24 “(I) identify all illegitimate pre-
25 scription drug product subject to such

1 notification that is in the possession
2 or control of the third-party logistics
3 provider, including any prescription
4 drug product that is subsequently re-
5 ceived; and

6 “(II) perform the activities de-
7 scribed in clause (i).

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

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

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

25 (a) PILOT PROJECTS.—

1 (1) IN GENERAL.—Not later than 2 years after
2 the date of the enactment of this Act, the Secretary
3 shall establish one or more pilot projects in coordi-
4 nation with manufacturers, repackagers, wholesale
5 distributors, third-party logistics providers, and dis-
6 pensers to explore and evaluate methods to enhance
7 the safety and security of the pharmaceutical dis-
8 tribution supply chain.

9 (2) CONTENT.—

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

13 (i) reflect the diversity of the pharma-
14 ceutical distribution supply chain; and

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

19 (B) PROJECT DESIGN.—The pilot projects
20 shall be designed to—

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

- 1 (I) verification of the prescription
2 drug product identifier of a prescrip-
3 tion drug product; and
- 4 (II) the use of aggregation and
5 inference;
- 6 (ii) improve the technical capabilities
7 of each sector within the pharmaceutical
8 supply chain to comply with systems and
9 processes needed to utilize the prescription
10 drug product identifiers to enhance tracing
11 of a prescription drug product; and
- 12 (iii) conduct such other activities as
13 the Secretary determines appropriate to
14 explore and evaluate methods to enhance
15 the safety and security of the pharma-
16 ceutical distribution supply chain.

17 (b) PUBLIC MEETINGS.—

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

1 practicable to ensure the protection of confidential
2 commercial information and trade secrets.

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

7 (A) Best practices in each of the sectors
8 within the pharmaceutical distribution supply
9 chain to implement the requirements of section
10 582 of the Federal Food, Drug, and Cosmetic
11 Act, as added by section 2.

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

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

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

1 (E) The technical capabilities and legal au-
2 thorities, if any, needed to establish an elec-
3 tronic system that provides for enhanced trac-
4 ing of prescription drug product at the package
5 level.

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

13 (c) STUDY OF THE PHARMACEUTICAL DISTRIBUTION
14 SUPPLY CHAIN.—

15 (1) IN GENERAL.—The Comptroller General of
16 the United States shall conduct a study to examine
17 implementation of the requirements established
18 under subchapter H of chapter V of the Federal
19 Food, Drug, and Cosmetic Act, as added by section
20 2, in order to inform the regulations promulgated
21 under this section.

22 (2) CONSIDERATION.—In conducting the study
23 under this subsection, the Comptroller General shall
24 provide for stakeholder input and shall consider the
25 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) SMALL DISPENSERS.—

12 (1) IN GENERAL.—Not later than 10 years
13 after the date of the enactment of this Act, the Sec-
14 retary shall enter into a contract with a private,
15 independent consulting firm with relevant expertise
16 to conduct a technology and software study on the
17 feasibility of dispensers that have 25 or fewer full-
18 time employees conducting interoperable, electronic
19 tracing of prescription drug products at the package
20 level.

21 (2) CONDITION.—As a condition of the award
22 of a contract under paragraph (1), the private inde-
23 pendent consulting firm awarded such contract shall
24 agree to consult with dispensers that have 25 or

1 fewer full-time employees when conducting the study
2 under such subparagraph.

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

8 (A) is readily accessible to such dispensers;

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

11 (C) can be integrated into business prac-
12 tices, such as interoperability with wholesale
13 distributors, for such dispensers.

14 (4) PUBLICATION.—The Secretary shall pub-
15 lish—

16 (A) the statement of work for the study
17 conducted under paragraph (1) for public com-
18 ment not later than 30 days before commencing
19 the study; and

20 (B) the final version of such study for pub-
21 lic comment not later than 30 days after such
22 study is completed.

23 (5) REPORT TO CONGRESS.—Not later than 30
24 days after the date on which the study conducted
25 under paragraph (1) is completed, the Secretary

1 shall submit to the Committee on Energy and Com-
2 merce of the House of Representatives and the Com-
3 mittee on Health, Education, Labor, and Pensions
4 of the Senate, a report on the findings of the study
5 and any recommendations to improve the technology
6 and software available to small dispensers for pur-
7 poses of conducting electronic, interoperable tracing
8 of prescription drug products at the package level.

9 (6) PUBLIC MEETING.—Not later than 180
10 days after the date on which the study conducted
11 under paragraph (1) is completed, the Secretary
12 shall hold a public meeting at which members of the
13 public, including stakeholders, may present their
14 views on the study.

15 (e) REPORTS.—

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

24 (2) FDA REPORT.—Not later than 12 years
25 after the date of the enactment of this Act, the Sec-

1 retary shall submit to the Committee on Energy and
2 Commerce of the House of Representatives and the
3 Committee on Health, Education, Labor, and Pen-
4 sions of the Senate a report on the results of the
5 pilot program conducted under subsection (a), tak-
6 ing into consideration—

7 (A) the comments received during the pub-
8 lic meetings conducted under subsection (b);
9 and

10 (B) the results of the study conducted, and
11 the public comments received during the public
12 meeting held, under subsection (d).

13 (f) ESTABLISHMENT OF ADDITIONAL REQUIRE-
14 MENTS.—

15 (1) IN GENERAL.—Notwithstanding any other
16 provision of this Act, including the amendments
17 made by this Act, not earlier than January 1, 2027,
18 and not later than March 1, 2027, the Secretary
19 shall issue proposed regulations that establish addi-
20 tional requirements to prevent a suspect product, il-
21 legitimate product, or a product that is counterfeit,
22 stolen, diverted, or otherwise unfit for distribution
23 from entering into or being further distributed in
24 the supply chain, including—

1 (A) requirements related to the use of
2 interoperable electronic systems and tech-
3 nologies for enhanced tracing of prescription
4 drug product at the package level, which may
5 include verification of the prescription drug
6 product identifier of a package of prescription
7 drug product and enhanced verification of sale-
8 able returns;

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

15 (C) requirements related to the use of ag-
16 gregation, inference, and other methods, if de-
17 termined to be necessary components of the
18 systems and technologies referred to in sub-
19 paragraph (A); and

20 (D) other data transmission and mainte-
21 nance requirements and interoperability stand-
22 ards.

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

1 (A) with respect to dispensers, allowing a
2 dispenser to enter into a written agreement
3 with a third party, including an authorized
4 wholesale distributor, under which—

5 (i) the third party confidentially main-
6 tains any information required to be main-
7 tained under such requirements for the
8 dispenser; and

9 (ii) the dispenser maintains a copy of
10 the written agreement and is not relieved
11 of the other obligations of the dispenser
12 under such requirements;

13 (B) establishing a process by which an au-
14 thorized manufacturer, repackager, wholesale
15 distributor, or dispenser may request a waiver
16 from any such requirements if the Secretary de-
17 termines that such requirements would result in
18 an undue economic hardship on the manufac-
19 turer, wholesale distributor, or dispenser;

20 (C) not requiring the adoption of specific
21 business systems by a member of the pharma-
22 ceutical supply chain for the maintenance and
23 transmission of prescription drug product trac-
24 ing data; and

1 (D) prescribing alternative methods of
2 compliance for small businesses, as specified in
3 paragraph (4).

4 (3) CONSIDERATIONS.—In issuing proposed
5 regulations under paragraph (1), the Secretary shall
6 consider—

7 (A) the results of the pilot project con-
8 ducted under subsection (a);

9 (B) the public meetings held under sub-
10 section (b);

11 (C) the studies conducted under sub-
12 sections (c) and (d);

13 (D) the reports submitted under subsection
14 (e);

15 (E) the public health benefits of such regu-
16 lations compared with the cost of compliance
17 with the requirements contained in such regula-
18 tions, including with respect to entities of vary-
19 ing sizes and capabilities; and

20 (F) the diversity of the pharmaceutical dis-
21 tribution supply chain by providing appropriate
22 flexibility for each sector in the supply chain,
23 including small businesses.

24 (4) SMALL BUSINESS PROTECTION.—The Sec-
25 retary, taking into consideration the study conducted

1 under paragraph (d), shall, if the Secretary deter-
2 mines that the requirements established pursuant to
3 paragraph (1) would result in an undue economic
4 hardship on small businesses, provide for alternative
5 methods of compliance with any such requirement by
6 small businesses, including—

7 (A) establishing timelines for such compli-
8 ance (including compliance by dispensers with
9 25 or fewer full-time employees) that do not im-
10 pose undue economic hardship for small busi-
11 nesses, including dispensers with respect to
12 which the study concluded has insufficient
13 hardware and software to conduct interoper-
14 able, electronic tracing of prescription drug
15 products at the package level; and

16 (B) establishing a process by which a dis-
17 penser may request a waiver from any such re-
18 quirement.

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

21 (A) issue a notice of proposed rulemaking
22 that includes a copy of the proposed rule;

23 (B) provide for a period of not less than
24 60 days for comments on the proposed rule;
25 and

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

4 (6) SUNSET.—The requirements regarding the
5 provision and receipt of transaction history and
6 transaction statements under section 582 of the
7 Federal Food, Drug, and Cosmetic Act, as added by
8 section 2, shall cease to be effective on the date on
9 which the regulations issued under this section are
10 fully implemented.

11 (g) DEFINITIONS.—In this section:

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

16 (2) The term “Secretary” means the Secretary
17 of Health and Human Services, acting through the
18 Commissioner of Food and Drugs.

19 **SEC. 4. NATIONAL STANDARDS FOR WHOLESALE DISTRIBUTORS.**
20

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

24 (1) in section 503 of such Act (21 U.S.C. 353),
25 by striking “(e)(1)(A)” and all that follows through

1 “(3) For purposes of this subsection and subsection
2 (d)—” and inserting the following:

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

4 (2) in subchapter H of chapter V of the Federal
5 Food, Drug, and Cosmetic Act, as added by section
6 2, by adding at the end the following:

7 **“SEC. 583. NATIONAL STANDARDS FOR WHOLESALE DIS-**
8 **TRIBUTORS.**

9 “(a) STANDARDS.—

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

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

16 “(A) the storage and handling of drugs
17 subject to section 503(b)(1), including facility
18 requirements;

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

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

1 “(D) mandatory background checks and
2 fingerprinting of facility managers or des-
3 ignated representatives;

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

6 “(F) the mandatory physical inspection of
7 any facility to be used in wholesale distribution
8 within a reasonable timeframe from the initial
9 application for licensure of the wholesale dis-
10 tributor; and

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

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

17 “(A) An applicant that is not a govern-
18 ment-owned-and-operated wholesale distributor,
19 for the issuance or renewal of a wholesale dis-
20 tributor license, shall submit a surety bond of
21 \$100,000 or other equivalent means of security
22 acceptable to the applicable licensing authority.

23 “(B) For purposes of subparagraph (A),
24 the applicable licensing authority may accept a
25 surety bond less than \$100,000 if the annual

1 gross receipts of the previous tax year for the
2 wholesale distributor is \$10,000,000 or less, in
3 which case the surety bond may not be less
4 than \$25,000.

5 “(C) If a wholesale distributor can provide
6 evidence that it possesses the required bond in
7 a State, the requirement for a bond in another
8 State is waived.

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

13 “(A) the government of the State in which
14 the facility is located; or

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

17 “(5) PROHIBITED PERSONS.—The requirements
18 under paragraph (2) shall include requirements to
19 prohibit a person from receiving or maintaining li-
20 censure for wholesale distribution if the person—

21 “(A) has been convicted of any felony for
22 conduct relating to wholesale distribution; any
23 felony violation of section 301(i) or 301(k); or
24 any felony violation of section 1365 of title 18,

1 United States Code, relating to prescription
2 drug product tampering; or

3 “(B) has engaged in a pattern of violating
4 the requirements of this section that presents a
5 threat of serious adverse health consequences or
6 death to humans.

7 “(b) REPORTING BY LICENSED WHOLESALE DIS-
8 TRIBUTORS.—

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

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

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

17 “(C) a listing of each State in which the
18 wholesale distributor is licensed for wholesale
19 distribution; and

20 “(D) any disciplinary actions taken by a
21 State, the Federal Government, or a foreign
22 government during the reporting period against
23 the wholesale distributor.

24 “(2) POSTING ON INTERNET.—The Secretary
25 shall post on the public Internet Website of the

1 Food and Drug Administration the name of each
2 wholesale distributor, and the State in which each
3 such distributor is licensed, based on reports under
4 paragraph (1).

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

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

10 “(2) collecting fees from wholesale distributors
11 in connection with such licensing,

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

15 “(d) DEFINITION.—In this section, the term ‘whole-
16 sale distribution’ means the distribution of a drug subject
17 to section 503(b)(1) to a person other than a consumer
18 or patient, but does not include—

19 “(1) intracompany distribution of any drug be-
20 tween members of an affiliated group (as defined in
21 section 1504(a) of the Internal Revenue Code of
22 1986);

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

1 “(3) the distribution of a drug or an offer to
2 distribute a drug for emergency medical reasons, in-
3 cluding a public health emergency declaration pursu-
4 ant to section 319 of the Public Health Service Act,
5 except that a drug shortage not caused by a public
6 health emergency shall not constitute such an emer-
7 gency medical reason;

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

11 “(5) the distribution of minimal quantities of
12 drug by a licensed retail pharmacy to a licensed
13 practitioner for office use;

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

18 “(7) the purchase or other acquisition by a dis-
19 penser, hospital, or other health care entity of a
20 drug for use by such dispenser, hospital, or other
21 health care entity;

22 “(8) the distribution of a drug by the manufac-
23 turer of such drug;

24 “(9) the receipt or transfer of a drug by an au-
25 thorized third-party logistics provider provided that

1 such third-party logistics provider does not take
2 ownership of the drug;

3 “(10) the transport of a drug by a common car-
4 rier, provided that the common carrier does not take
5 ownership of the drug;

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

10 “(12) saleable drug returns when conducted by
11 a dispenser in accordance with section 203.23 of
12 title 21, Code of Federal Regulations (or any suc-
13 cessor regulation);

14 “(13) the distribution of a combination pre-
15 scription drug product described in section
16 581(20)(B)(xiii);

17 “(14) the distribution of a medical convenience
18 kit described in section 581(21)(B)(xiv);

19 “(15) the distribution of an intravenous drug
20 that, by its formulation, is intended for the replen-
21 ishment of fluids and electrolytes (such as sodium,
22 chloride, and potassium) or calories (such as dex-
23 trose and amino acids);

1 “(16) the distribution of an intravenous drug
2 used to maintain the equilibrium of water and min-
3 erals in the body, such as dialysis solutions;

4 “(17) the distribution of a drug that is intended
5 for irrigation or reconstitution, or sterile water,
6 whether intended for such purposes or for injection;

7 “(18) the distribution of compressed medical
8 gas (as defined in section 581(21)(C)); or

9 “(19) facilitating the distribution of a prescrip-
10 tion drug product by providing administrative serv-
11 ices, such as processing of orders and payments,
12 without physical handling, distribution, or storage of
13 a prescription drug product.

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

20 (b) CONFORMING AMENDMENT.—Section
21 804(a)(5)(A) of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 384(a)(5)(A)) is amended by striking
23 “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) if the drug is distributed interstate and
20 the facility is not licensed by the Secretary under
21 paragraph (1)(B), registers with the State into
22 which the drug is distributed if such State requires
23 such registration.

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) COSTS.—

10 “(1) AUTHORIZED LICENSURE FEES.—In the
11 case of a facility engaging in the activities of a
12 third-party logistics provider licensed by the Sec-
13 retary under this section, the Secretary may assess
14 and collect a reasonable fee in an amount equal to
15 the costs to the Federal Government of establishing
16 and administering the licensure program established,
17 and conducting period inspections, under this sec-
18 tion.

19 “(2) ADJUSTMENT.—The Secretary shall adjust
20 the amount of the fee under paragraph (1) on an
21 annual basis, if necessary, to generate an amount of
22 revenue equal to the costs referred to in such para-
23 graph.

24 “(3) AVAILABILITY.—Fees assessed and col-
25 lected under this subsection shall be available for ob-

1 ligation only to the extent and in the amount pro-
2 vided in advance in appropriations Acts. Such fees
3 shall remain available until expended.

4 “(e) LICENSE REGULATIONS.—

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

9 “(2) CONTENT.—The regulations under para-
10 graph (1) shall—

11 “(A) include standards relating to eligi-
12 bility for, and revocation and reissuance of, li-
13 censes;

14 “(B) establish a process by which the ap-
15 plicable licensing authority will, upon request by
16 a third-party logistics provider that is accred-
17 ited by a third-party accreditation program ap-
18 proved by the Secretary, issue a license to the
19 provider;

20 “(C) establish a process by which the Sec-
21 retary shall issue a license to a third-party lo-
22 gistics provider if the Secretary is not able to
23 approve a third-party accreditation program be-
24 cause no such program meets the Secretary’s

1 requirements necessary for approval of such a
2 third-party accreditation program;

3 “(D) require that the third-party logistics
4 provider comply with storage practices, as de-
5 termined by the Secretary, at the provider’s fa-
6 cilities, including—

7 “(i) maintaining access to warehouse
8 space of suitable size to facilitate safe op-
9 erations, including a suitable area to quar-
10 antine suspect prescription drug product;

11 “(ii) maintaining adequate security;
12 and

13 “(iii) having written policies and pro-
14 cedures to—

15 “(I) address receipt, security,
16 storage, inventory, shipment, and dis-
17 tribution of a prescription drug prod-
18 uct;

19 “(II) identify, record, and report
20 confirmed losses or thefts in the
21 United States;

22 “(III) correct errors and inac-
23 curacies in inventories;

24 “(IV) provide support for manu-
25 facturer recalls;

1 “(V) prepare for, protect against,
2 and address any reasonably foresee-
3 able crisis that affects security or op-
4 eration at the facility, such as a
5 strike, fire, or flood;

6 “(VI) ensure that any expired
7 prescription drug product is seg-
8 regated from other prescription drug
9 products and returned to the manu-
10 facturer or repackager or destroyed;

11 “(VII) maintain the capability to
12 electronically trace the receipt and
13 outbound distribution of a prescrip-
14 tion drug product, and supplies and
15 records of inventory; and

16 “(VIII) quarantine or destroy a
17 suspect prescription drug product if
18 directed to do so by the respective
19 manufacturer, wholesale distributor,
20 dispenser, or an authorized govern-
21 ment agency;

22 “(E) provide for periodic inspection, as de-
23 termined by the Secretary, of such facility ware-
24 house space to ensure compliance with this sec-
25 tion;

1 “(F) prohibit a facility from having as a
2 manager or designated representative anyone
3 convicted of any felony violation of section
4 301(i) or 301(k) or any felony violation of sec-
5 tion 1365 of title 18, United States Code, relat-
6 ing to prescription drug product tampering;

7 “(G) perform mandatory background
8 checks of the provider’s facility managers or
9 designated representatives of such managers;

10 “(H) require a third-party logistics pro-
11 vider to provide to the applicable licensing au-
12 thority, upon the authority’s request, a list of
13 all prescription drug product manufacturers,
14 wholesale distributors, and dispensers for whom
15 the third-party logistics provider provides serv-
16 ices at the provider’s facilities; and

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

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

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

23 “(f) VALIDITY OF LICENSE.—A license issued under
24 this section shall remain valid as long as such third-party
25 logistics provider remains accredited by the Secretary,

1 subject to renewal under subsection (d). If the Secretary
2 finds that the third-party accreditation program dem-
3 onstrates that all applicable requirements for licensure
4 under this section are met, the Secretary shall issue a li-
5 cense under this section to a third-party logistics provider
6 receiving accreditation.

7 “(g) QUALIFIED LICENSING PROGRAM DEFINED.—
8 In this section, the term ‘qualified licensing program’
9 means a program meeting the requirements of this section
10 and the regulations thereunder.

11 “(h) EFFECTIVE DATE.—The requirements of this
12 section shall take effect not later than 1 year after the
13 date of the enactment of this section. The Secretary shall
14 issue the regulations required by subsection (d) not later
15 than 180 days after the date of the enactment of this sec-
16 tion.”.

17 **SEC. 6. PENALTIES.**

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

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

23 (2) by striking “or the distribution of drugs in
24 violation of section 503(e) or the failure to otherwise
25 comply with the requirements of section 503(e)” and

1 inserting “the failure to comply with any require-
2 ment of section 582, engaging in the wholesale dis-
3 tribution of a drug in violation of section 583 or the
4 failure to otherwise comply with the requirements of
5 section 583, or engaging in the activities of a third-
6 party logistics provider in violation of section 584 or
7 the failure to otherwise comply with the require-
8 ments of section 584”.

9 (b) ENHANCED PENALTY FOR KNOWING UNLI-
10 CENSED ACTIVITIES.—Section 303(b)(1)(D) of the Fed-
11 eral Food, Drug, and Cosmetic Act (21 U.S.C.
12 333(b)(1)(D)) is amended by striking “503(e)(2)(A)” and
13 inserting “583 or 584”.

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

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

19 **SEC. 7. UNIFORM NATIONAL POLICY.**

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

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

24 “(a) PREEMPTION OF STATE PRESCRIPTION DRUG
25 PRODUCT TRACING AND OTHER REQUIREMENTS.—Be-

1 ginning on the date of the enactment of the Safeguarding
2 America’s Pharmaceuticals Act of 2013, no State or polit-
3 ical subdivision of a State may establish or continue in
4 effect any requirements for tracing drugs through the dis-
5 tribution system (including any requirements with respect
6 to paper or electronic pedigrees, track and trace, state-
7 ments of distribution history, transaction history, or
8 transaction statements, or verification, investigation, dis-
9 position, alerts, or recordkeeping relating to the pharma-
10 ceutical distribution supply chain system) that—

11 “(1) are inconsistent with, more stringent than,
12 or in addition to any requirements applicable under
13 this Act; or

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

17 “(b) STANDARDS OR LICENSURE.—

18 “(1) IN GENERAL.—Beginning on the date of
19 the enactment of Safeguarding America’s Pharma-
20 ceuticals Act of 2013, no State or political subdivi-
21 sion of a State may establish or continue any stand-
22 ards, requirements, or regulations with respect to
23 wholesale drug distributor or third-party logistics
24 provider licensure which are inconsistent with, less
25 stringent than, in addition to, or more stringent

1 than, the standards and requirements under this
2 Act.

3 “(2) LICENSING FEES.—Paragraph (1) does
4 not affect the authority of a State to collect fees
5 from wholesale drug distributors or third-party logis-
6 tics providers in connection with State licensing
7 under section 583 or 584 pursuant to a licensing
8 program meeting the requirements of such sections.

9 “(3) ENFORCEMENT, SUSPENSION, AND REV-
10 OCATION OF LICENSES.—Notwithstanding paragraph
11 (1), a State—

12 “(A) may take administrative action, in-
13 cluding fines, to enforce a licensure requirement
14 promulgated by the State in accordance with
15 this Act;

16 “(B) may provide for the suspension or
17 revocation of licenses issued by the State for
18 violations of the laws of such State;

19 “(C) upon conviction of a person for a vio-
20 lation of Federal, State, or local controlled sub-
21 stance laws or regulations, may provide for
22 fines, imprisonment, or civil penalties; and

23 “(D) may regulate activities of entities li-
24 censed pursuant to section 583 or 584 in a

1 manner that is consistent with the provisions of
2 this subchapter.”.

3 **SEC. 8. ELECTRONIC LABELING REQUIREMENT.**

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

○