

113TH CONGRESS
1ST SESSION

H. R. 1919

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Safeguarding America’s Pharmaceuticals Act of 2013”.

4 (b) TABLE OF CONTENTS.—The table of contents of
5 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.

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

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

10 **“Subchapter H—Pharmaceutical Distribution**
11 **Supply Chain**

12 **“SEC. 581. DEFINITIONS.**

13 “In this subchapter:

14 “(1) AUTHORIZED.—The term ‘authorized’
15 means—

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

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

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

1 “(A) subject to subparagraph (C), means a
2 retail pharmacy, hospital pharmacy, a group of
3 chain pharmacies under common ownership and
4 control, or any other person authorized by law
5 to dispense or administer prescription drugs, to
6 the extent such pharmacy, group, or person
7 does not act as a wholesale distributor;

8 “(B) includes warehouses and distribution
9 centers under common ownership or control of
10 entities described in subparagraph (A) that are
11 members of an affiliated group pursuant to sec-
12 tion 1504(a) of the Internal Revenue Code of
13 1986, to the extent such warehouses and dis-
14 tribution centers do not act as a wholesale dis-
15 tributor; and

16 “(C) does not include a person who only
17 dispenses prescription drug product to be used
18 in animals in accordance with section
19 512(a)(5).

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

23 “(A) means the removal of such prescrip-
24 tion drug product, or taking measures to pre-
25 vent the introduction of such prescription drug

1 product, from the pharmaceutical distribution
2 supply chain; and

3 “(B) may include disposal, return of the
4 prescription drug product for disposal, or other
5 appropriate handling and other actions such as
6 retaining a sample of the prescription drug
7 product for additional physical examination or
8 laboratory analysis by a manufacturer or regu-
9 latory or law enforcement agency.

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

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

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

19 “(B) is intentionally adulterated such that
20 the prescription drug product would result in
21 serious adverse health consequences or death to
22 humans; or

23 “(C) is otherwise unfit for distribution
24 such that the prescription drug product is rea-

1 sonably likely to cause serious adverse human
2 health consequences or death.

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

4 “(A) in the case of a wholesale distributor,
5 having a valid license to make wholesale dis-
6 tributions consistent with the standards under
7 section 583;

8 “(B) in the case of a third-party logistics
9 provider, having a valid license to engage in the
10 activities of a third-party logistics provider in
11 accordance with section 584; and

12 “(C) in the case of a dispenser, having a
13 valid license to dispense prescription drugs
14 under State law.

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

18 “(A) a person that holds an application ap-
19 proved under section 505 or a license issued
20 under section 351 of the Public Health Service
21 Act for such prescription drug product, or if
22 such prescription drug product is not the sub-
23 ject of an approved application or license, the
24 person who manufactured the prescription drug
25 product;

1 “(B) a co-licensed partner of the person
2 described in subparagraph (A) that obtains the
3 prescription drug product directly from the per-
4 son described in such subparagraph; or

5 “(C) a person that—

6 “(i) is a member of an affiliated
7 group (as defined in section 1504(a) of the
8 Internal Revenue Code of 1986) to which
9 a person described in subparagraph (A) or
10 (B) is also a member; and

11 “(ii) receives the prescription drug
12 product directly from a person described in
13 subparagraph (A) or (B).

14 “(8) PACKAGE.—

15 “(A) IN GENERAL.—The term ‘package’
16 means the smallest individual saleable unit of
17 prescription drug product for distribution in
18 interstate commerce by a manufacturer or re-
19 packager that is intended by the manufacturer
20 for ultimate sale to the dispenser of such pre-
21 scription drug product.

22 “(B) INDIVIDUAL SALEABLE UNIT.—The
23 term ‘individual saleable unit’ means the small-
24 est container of prescription drug product intro-
25 duced into interstate commerce by the manufac-

1 turer or repackager that is intended by the
2 manufacturer for individual sale to a dispenser.

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

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

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

15 “(A) includes the standardized numerical
16 identifier, lot number, and expiration date of a
17 prescription drug product; and

18 “(B) is in both human-readable form and
19 on a machine-readable data carrier that con-
20 forms to the standards developed by a widely
21 recognized international standards development
22 organization.

23 “(12) QUARANTINE.—The term ‘quarantine’
24 means to store or identify a product, for the purpose
25 of preventing distribution or transfer of the product,

1 in a physically separate area clearly identified for
2 such use, or through use of other procedures such
3 as automated designation.

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

8 “(14) RETURN.—The term ‘return’ means pro-
9 viding prescription drug product to the authorized
10 trading partner or trading partners from which such
11 prescription drug product was purchased or received,
12 or to a returns processor for handling of such pre-
13 scription drug product.

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

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

1 “(A) means with respect to the transfer of
2 a prescription drug product from one pharmacy
3 to another, to fill a prescription for an identi-
4 fied patient; and

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

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

13 “(A) is used to uniquely identify each
14 package or homogenous case of the prescription
15 drug product; and

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

22 “(18) SUSPECT PRESCRIPTION DRUG PROD-
23 UCT.—The term ‘suspect prescription drug product’
24 means a prescription drug product for which there

1 is reason to believe that such prescription drug prod-
2 uct—

3 “(A) is potentially counterfeit, diverted, or
4 stolen;

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

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

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

23 “(20) TRADING PARTNER.—The term ‘trading
24 partner’ means—

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

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

16 “(21) TRANSACTION.—

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

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

23 “(i) intracompany distribution of any
24 prescription drug product, including be-
25 tween members of an affiliated group (as

1 defined in section 1504(a) of the Internal
2 Revenue Code of 1986);

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

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

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

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

23 “(vi) the distribution of blood or blood
24 components intended for transfusion;

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

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

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

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

22 “(xi) the transfer of prescription drug
23 products to or from any facility that is li-
24 censed by the Nuclear Regulatory Commis-
25 sion or by a State pursuant to an agree-

1 ment with such Commission under section
2 274 of the Atomic Energy Act of 1954 (42
3 U.S.C. 2021);

4 “(xii) the distribution of a combina-
5 tion product that consists of—

6 “(I) a product comprised of two
7 or more components that are each a
8 drug, biological product, or device and
9 that are physically, chemically, or oth-
10 erwise combined or mixed and pro-
11 duced as a single entity;

12 “(II) two or more separate prod-
13 ucts packaged together in a single
14 package or as a unit and comprised of
15 a drug and device or a device and bio-
16 logical product; or

17 “(III) two or more finished de-
18 vices plus one or more drug or biologi-
19 cal products which are packaged to-
20 gether in a medical convenience kit
21 described in clause (xiii);

22 “(xiii) the distribution of a medical
23 convenience kit which is a collection of fin-
24 ished products (consisting of devices or
25 drugs) assembled in kit form strictly for

1 the convenience of the purchaser or user
2 if—

3 “(I) the medical convenience kit
4 is assembled in an establishment that
5 is registered with the Food and Drug
6 Administration as a medical device
7 manufacturer;

8 “(II) the person who manufactur-
9 ers the medical convenience kit pur-
10 chased the prescription drug product
11 directly from the manufacturer or
12 from a wholesale distributor that pur-
13 chased the prescription drug product
14 directly from the manufacturer;

15 “(III) the person who manufac-
16 turers the medical convenience kit
17 does not alter the primary container
18 or label of the prescription drug prod-
19 uct as purchased from the manufac-
20 turer or wholesale distributor;

21 “(IV) the medical convenience kit
22 does not contain a controlled sub-
23 stance (as defined in section 102 of
24 the Controlled Substances Act); and

1 “(V) the prescription drug prod-
2 ucts contained in the medical conven-
3 ience kit are—

4 “(aa) intravenous solutions
5 intended for the replenishment of
6 fluids and electrolytes;

7 “(bb) drugs intended to
8 maintain the equilibrium of water
9 and minerals in the body;

10 “(cc) drugs intended for irri-
11 gation or reconstitution;

12 “(dd) anesthetics;

13 “(ee) anticoagulants;

14 “(ff) vasopressors; or

15 “(gg) sympathicomimetics;

16 “(xiv) the distribution of an intra-
17 venous prescription drug product that, by
18 its formulation, is intended for the replen-
19 ishment of fluids and electrolytes (such as
20 sodium, chloride, and potassium) or cal-
21 ories (such as dextrose and amino acids);

22 “(xv) the distribution of an intra-
23 venous prescription drug product used to
24 maintain the equilibrium of water and min-

1 erals in the body, such as dialysis solu-
2 tions;

3 “(xvi) the distribution of a prescrip-
4 tion drug product that is intended for irri-
5 gation or reconstitution, or sterile water,
6 whether intended for such purposes or for
7 injection;

8 “(xvii) the distribution of compressed
9 medical gas; or

10 “(xviii)(I) the distribution of a prod-
11 uct by a dispenser, or a wholesale dis-
12 tributor acting at the direction of the dis-
13 penser, to a repackager registered under
14 section 510 for the purpose of repackaging
15 the drug for use by that dispenser or an-
16 other health care entity that is under the
17 dispenser’s ownership or control, so long as
18 the dispenser retains ownership of the pre-
19 scription drug product; and

20 “(II) the saleable or nonsaleable re-
21 turn by such repackager of such prescrip-
22 tion drug product.

23 “(C) COMPRESSED MEDICAL GAS.—For
24 purposes of subparagraph (B)(xvii), the term
25 ‘compressed medical gas’ means any substance

1 in its gaseous or cryogenic liquid form that
2 meets medical purity standards and has appli-
3 cation in a medical or homecare environment,
4 including oxygen and nitrous oxide.

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

7 “(A) includes the transaction information
8 for each transaction conducted with respect to
9 a prescription drug product beginning with the
10 manufacturer or initial purchase distributor;
11 and

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

13 “(23) TRANSACTION INFORMATION.—The term
14 ‘transaction information’ means—

15 “(A) the proprietary or established name
16 or names of the prescription drug product;

17 “(B) the strength and dosage form of the
18 prescription drug product;

19 “(C) the National Drug Code number of
20 the prescription drug product;

21 “(D) the container size;

22 “(E) the number of containers;

23 “(F) the lot number of the prescription
24 drug product;

25 “(G) the date of the transaction;

1 “(H) the business name and address of the
2 person from whom ownership is being trans-
3 ferred; and

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

6 “(24) TRANSACTION STATEMENT.—The ‘trans-
7 action statement’ is a statement, which states that
8 the manufacturer, repackager, wholesale distributor,
9 third-party logistics provider, or dispenser transfer-
10 ring ownership in a transaction—

11 “(A) is authorized;

12 “(B) received transaction information and
13 a transaction statement as required under sec-
14 tion 582 from the prior owner of the prescrip-
15 tion drug product;

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

18 “(D) did not knowingly and intentionally
19 provide false transaction information; and

20 “(E) did not knowingly and intentionally
21 alter the transaction history.

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

24 “(A) mean determining whether the pre-
25 scription drug product identifier affixed to, or

1 imprinted upon, a package or homogeneous case
2 of the prescription drug product corresponds to
3 the standardized numerical identifier or lot
4 number, and expiration date assigned to the
5 prescription drug product by the manufacturer
6 or the repackager, as applicable; and

7 “(B) include making the determination
8 under subparagraph (A) using human-readable
9 or machine-readable methods.

10 “(26) WHOLESALE DISTRIBUTOR.—The term
11 ‘wholesale distributor’—

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

14 “(B) excludes—

15 “(i) a manufacturer, a co-licensed
16 partner of a manufacturer, or a third-party
17 logistics provider, or a dispenser who does
18 not engage in such wholesale distribution;

19 “(ii) a repackager engaged in such
20 wholesale distribution; or

21 “(iii) the distribution of prescription
22 drug product or an offer to distribute pre-
23 scription drug product by an authorized re-
24 packager that has taken ownership or pos-
25 session of the prescription drug product

1 and repacked the prescription drug prod-
2 uct in accordance with the requirements of
3 section 582(e).

4 **“SEC. 582. REQUIREMENTS.**

5 “(a) IN GENERAL.—

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

15 “(2) STANDARDS.—The Secretary shall, in con-
16 sultation with other appropriate Federal officials,
17 manufacturers, repackagers, wholesale distributors,
18 third-party logistics providers, and dispensers, estab-
19 lish, by regulation, standards for the exchange of
20 transaction history and transaction statement (in
21 paper or electronic form) for purposes of complying
22 with this section. The standards established under
23 this paragraph shall be in accordance with a form
24 developed by a widely recognized international stand-
25 ards development organization. In establishing such

1 standards, the Secretary shall consider the feasibility
2 of establishing standardized documentation to be
3 used by all members of the pharmaceutical distribu-
4 tion supply chain to convey the transaction history
5 and transaction statement to the subsequent owner
6 of a prescription drug product. The Secretary shall
7 publish such standards not later than 180 days after
8 the date of the enactment of the Safeguarding
9 America’s Pharmaceuticals Act of 2013.

10 “(3) WAIVERS, EXCEPTIONS, AND EXEMP-
11 TIONS.—Not later than one year after the date of
12 the enactment of the Safeguarding America’s Phar-
13 maceuticals Act of 2013, the Secretary shall promul-
14 gate a regulation to—

15 “(A) establish a process by which the Sec-
16 retary may grant, at the request of an author-
17 ized manufacturer, repackager, wholesale dis-
18 tributor, or dispenser, a waiver from any of the
19 requirements of this section—

20 “(i) if the Secretary determines that
21 such requirements would result in an
22 undue economic hardship; or

23 “(ii) for emergency medical reasons,
24 including a public health emergency dec-

1 laration pursuant to section 319 of the
2 Public Health Service Act;

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

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

14 “(ii) the Secretary determines whether
15 to waive such requirement; and

16 “(C) establish a process by which the Sec-
17 retary may add the prescription drug products
18 or transactions that are exempt from the re-
19 quirements of this section.

20 “(4) GRANDFATHERED PERSONS AND PRE-
21 SCRIPTION DRUG PRODUCTS.—

22 “(A) IN GENERAL.—Not later than one
23 year after the date of the enactment of the
24 Safeguarding America’s Pharmaceuticals Act of
25 2013, the Secretary shall specify, by regulation,

1 whether and under what circumstances the pre-
2 scription drug product identifier requirement
3 under paragraph (2) of subsections (b), (c), (d),
4 and (e) shall apply to a prescription drug prod-
5 uct that is in the supply chain or in a manufac-
6 turer’s inventory on the date of the enactment
7 of the Safeguarding America’s Pharmaceuticals
8 Act of 2013.

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

19 “(C) LABEL CHANGES.—Changes made to
20 package labels solely to incorporate the pre-
21 scription drug product identifier may be sub-
22 mitted to the Secretary in the annual report of
23 an establishment, in accordance with section
24 314.70(d) of chapter 21, Code of Federal Regu-
25 lations (or any successor regulation).

1 “(b) MANUFACTURER REQUIREMENTS.—

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

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

6 “(i) prior to, or at the time of, each
7 transaction in which such manufacturer
8 transfers ownership of a prescription drug
9 product—

10 “(I) until the date that is 5
11 years after the date of the enactment
12 of the Safeguarding America’s Phar-
13 maceuticals Act of 2013, provide the
14 subsequent owner with the transaction
15 history and a transaction statement in
16 a single document in paper or elec-
17 tronic form; and

18 “(II) on or after such date, pro-
19 vide the subsequent owner with the
20 transaction history and a transaction
21 statement in electronic form; and

22 “(ii) maintain the transaction infor-
23 mation for each such transaction for not
24 less than 3 years after the date of the
25 transaction.

1 “(B) REQUESTS FOR INFORMATION.—

2 Upon a request by the Secretary or other ap-
3 propriate Federal or State official, in the event
4 of a recall or for the purpose of investigating a
5 suspect prescription drug product or an illegit-
6 imate prescription drug product, a manufac-
7 turer shall, not later than 2 business days after
8 receiving the request or in such reasonable time
9 as determined by the Secretary, provide to the
10 Secretary or other official, the applicable trans-
11 action history and transaction statement for the
12 prescription drug product.

13 “(2) PRESCRIPTION DRUG PRODUCT IDENTI-
14 FIER.—Beginning not later than 5 years after the
15 date of the enactment of the Safeguarding America’s
16 Pharmaceuticals Act of 2013, a manufacturer shall
17 affix or imprint a prescription drug product identi-
18 fier on each package and homogenous case of a pre-
19 scription drug product intended to be introduced in
20 a transaction. Such manufacturer shall maintain the
21 information in the prescription drug product identi-
22 fier for such prescription drug product for not less
23 than 3 years after the date of the transaction.

24 “(3) AUTHORIZED TRADING PARTNERS.—Be-
25 ginning not later than January 1, 2015, a manufac-

1 turer shall ensure that each of its trading partners
2 is authorized.

3 “(4) LIST OF AUTHORIZED DISTRIBUTORS OF
4 RECORD.—Beginning not later than January 1,
5 2015, each manufacturer of a prescription drug
6 shall—

7 “(A) maintain a list of the authorized dis-
8 tributors of record of such drug at the cor-
9 porate offices of such manufacturer;

10 “(B) make such list publicly available, in-
11 cluding placement on the Internet Website of
12 such manufacturer; and

13 “(C) update such list not less than once
14 per quarter.

15 “(5) VERIFICATION.—Beginning not later than
16 January 1, 2015, a manufacturer shall implement
17 systems and processes to enable the manufacturer to
18 comply with the 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 manufacturer is a suspect prescription
25 drug product, or upon receiving a request

1 for verification from the Secretary that a
2 prescription drug product within the pos-
3 session or control of a manufacturer is a
4 suspect prescription drug product, a manu-
5 facturer shall promptly conduct an inves-
6 tigation in coordination with trading part-
7 ners, as applicable, to determine whether
8 the prescription drug product is an illegit-
9 imate prescription drug product. Beginning
10 not later than 5 years after the date of the
11 enactment of the Safeguarding America’s
12 Pharmaceuticals Act of 2013, such inves-
13 tigation shall include—

14 “(I) verifying the prescription
15 drug product at the package level;

16 “(II) validating any applicable
17 transaction history in the possession
18 of the manufacturer; and

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

23 “(ii) CLEARED PRESCRIPTION DRUG
24 PRODUCT.—If the manufacturer deter-
25 mines that a suspect prescription drug

1 product is not an illegitimate prescription
2 drug product, the manufacturer shall
3 promptly notify the Secretary of such de-
4 termination and such prescription drug
5 product may be further distributed.

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

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

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

18 “(I) quarantine such prescription
19 drug product from prescription drug
20 product intended for distribution; and

21 “(II) provide for the disposition
22 of the illegitimate prescription drug
23 product.

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

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

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

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

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

1 possession or control of the manufac-
2 turer, including any prescription drug
3 product that is subsequently received;
4 and

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

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

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

1 by means other than a secure electronic data-
2 base.

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

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

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

19 “(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

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

22 “(A) IN GENERAL.—Beginning not later
23 than April 1, 2015, a wholesale distributor
24 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 trans-
4 action provides the applicable transaction
5 history and a transaction statement for the
6 prescription drug product;

7 “(ii) subject to clause (iv), prior to, or
8 at the time of, each transaction in which
9 the wholesale distributor transfers owner-
10 ship of a prescription drug product—

11 “(I) in the case that the whole-
12 sale distributor purchased the pre-
13 scription drug product directly from
14 the manufacturer, the exclusive dis-
15 tributor of the manufacturer, or a re-
16 packager that purchased directly from
17 the manufacturer, provide the subse-
18 quent owner with transaction history
19 and a transaction statement for the
20 prescription drug product—

21 “(aa) if the subsequent
22 owner is a dispenser, on a single
23 document in paper or electronic
24 form; or

1 “(bb) if the subsequent
2 owner is a wholesale distributor,
3 through any combination of self-
4 generated paper, electronic data,
5 or manufacturer-provided infor-
6 mation on the product package;

7 “(II) in the case that the whole-
8 sale distributor did not purchase the
9 prescription drug product as described
10 in subclause (I)—

11 “(aa) provide the subsequent
12 owner with the transaction his-
13 tory and a transaction statement
14 beginning with the wholesale dis-
15 tributor that did so purchase the
16 prescription drug product in
17 paper or electronic form; or

18 “(bb) pursuant to a written
19 agreement between the wholesale
20 distributor and a dispenser,
21 maintain the transaction history
22 and transaction statement on be-
23 half of the dispenser and if re-
24 quested by the dispenser, provide
25 the transaction history and

1 transaction statement to the dis-
2 penser in paper or electronic
3 form in a timely manner so as to
4 permit the dispenser to comply
5 with requests pursuant to sub-
6 section (d)(1)(D);

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

11 “(iv) on or after the date that is 5
12 years after the date of the enactment of
13 the Safeguarding America’s Pharma-
14 ceuticals Act of 2013, provide the trans-
15 action history and transaction statement in
16 electronic form.

17 “(B) INCLUSION OF LOT NUMBER IN
18 TRANSACTION HISTORY.—Until the date that is
19 5 years after the date of the enactment of the
20 Safeguarding America’s Pharmaceuticals Act of
21 2013, the transaction history provided by a
22 wholesale distributor under this paragraph shall
23 not be required to include the lot number of the
24 product or the initial date of the transaction
25 from the manufacturer (as such terms are used

1 in subparagraphs (F) and (G) of section
2 581(23)).

3 “(C) RETURNS EXCEPTION.—

4 “(i) SALEABLE RETURNS.—Notwith-
5 standing subparagraph (A), a wholesale
6 distributor may—

7 “(I) accept returned prescription
8 drug product without a transaction
9 history from a dispenser or repack-
10 ager; and

11 “(II) distribute such returned
12 prescription drug product with a
13 transaction history that begins with
14 the wholesale distributor that so ac-
15 cepted the returned product.

16 “(ii) NONSALEABLE RETURNS.—A
17 wholesale distributor may return a non-
18 saleable prescription drug to the manufac-
19 turer or repackager, to the wholesale dis-
20 tributor from whom such prescription drug
21 was purchased, or to a person acting on
22 behalf of such a person, including a re-
23 turns processor, without providing the in-
24 formation required under subparagraph
25 (A).

1 “(D) REQUESTS FOR INFORMATION.—

2 Upon a request by the Secretary or other ap-
3 propriate Federal or State official, in the event
4 of a recall or for the purpose of investigating a
5 suspect prescription drug product or an illegit-
6 imate prescription drug product a wholesale dis-
7 tributor shall, not later than 2 business days
8 after receiving the request or in such other rea-
9 sonable time as determined by the Secretary,
10 provide the applicable transaction history and
11 transaction statements for the prescription drug
12 product.

13 “(2) PRESCRIPTION DRUG PRODUCT IDENTI-
14 FIER.—Beginning not later than 7 years after the
15 date of the enactment of the Safeguarding America’s
16 Pharmaceuticals Act of 2013, a wholesale distributor
17 may engage in transactions involving a prescription
18 drug product only if such prescription drug product
19 is encoded with a prescription drug product identi-
20 fier, except as provided in subsection (a)(4).

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

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

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

7 “(i) IN GENERAL.—Upon making a
8 determination that a prescription drug
9 product in the possession or control of the
10 wholesale distributor is a suspect prescrip-
11 tion drug product, or upon receiving a re-
12 quest for verification from the Secretary
13 that a prescription drug product within the
14 possession or control of a wholesale dis-
15 tributor is a suspect prescription drug
16 product, a wholesale distributor shall
17 promptly conduct an investigation to deter-
18 mine whether the prescription drug prod-
19 uct is an illegitimate prescription drug
20 product. Beginning not later than 7 years
21 after the date of the enactment of the
22 Safeguarding America’s Pharmaceuticals
23 Act of 2013, such investigation shall in-
24 clude—

1 “(I) verifying a package of the
2 prescription drug product;

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

6 “(III) 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 wholesale distributor de-
12 termines that a suspect prescription drug
13 product is not an illegitimate prescription
14 drug product, the wholesale distributor
15 shall promptly notify the Secretary of such
16 determination and such prescription drug
17 product may be further distributed.

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

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 wholesale distributor is an
6 illegitimate prescription drug product, the
7 wholesale distributor shall—

8 “(I) quarantine such prescription
9 drug product within the possession or
10 control of the wholesale distributor
11 from prescription drug product in-
12 tended for distribution; and

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

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

1 “(iii) MAKING A NOTIFICATION.—

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

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

17 “(I) identify all illegitimate pre-
18 scription drug products subject to
19 such notification that are in the pos-
20 session or control of the wholesale dis-
21 tributor, including any such prescrip-
22 tion drug product that is subsequently
23 received; and

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

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

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

21 “(D) RETURNED PRESCRIPTION DRUG
22 PRODUCT.—Beginning not later than 7 years
23 after the date of the enactment of the Safe-
24 guarding America’s Pharmaceuticals Act of
25 2013, upon receipt of a returned prescription

1 drug product that the wholesale distributor in-
2 tends to further distribute, before further dis-
3 tributing such prescription drug product, the
4 wholesale distributor shall—

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

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

12 “(d) DISPENSER REQUIREMENTS.—

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

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

17 “(i) shall not accept ownership of a
18 prescription drug product, unless the pre-
19 vious owner prior to, or at the time of, the
20 transaction, provides transaction history
21 and a transaction statement;

22 “(ii) prior to, or at the time of, each
23 transaction in which the dispenser trans-
24 fers ownership of a prescription drug prod-
25 uct (but not including dispensing to a pa-

1 tient or returns) shall provide the subse-
2 quent owner with transaction history and a
3 transaction statement for the prescription
4 drug product, except that the requirements
5 of this clause shall not apply to sales by a
6 dispenser to another dispenser to fulfill a
7 specific patient need; and

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

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

21 “(C) RETURNS EXCEPTION.—

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

1 dispenser obtained the prescription drug
2 product without providing the information
3 required under such subparagraph.

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

14 “(D) REQUESTS FOR INFORMATION.—
15 Upon a request by the Secretary or other ap-
16 propriate Federal or State official, in the event
17 of a recall or for the purpose of investigating a
18 suspect prescription drug product or an illegit-
19 imate prescription drug product—

20 “(i) a dispenser shall not later than 2
21 business days after receiving the request or
22 in another such reasonable time as deter-
23 mined by the Secretary, provide the appli-
24 cable transaction history and transaction

1 statement which the dispenser received
2 from the previous owner;

3 “(ii) the information provided by the
4 dispenser under clause (i) is not required
5 to include the lot number of the product,
6 the initial date of the transaction, or the
7 initial date of the shipment from the man-
8 ufacturer unless such information was pro-
9 vided electronically by the previous owner,
10 manufacturer, or wholesale distributor to
11 the dispenser; and

12 “(iii) a dispenser may respond to the
13 request by providing the paper documenta-
14 tion received from the previous owner or
15 by providing electronic information.

16 “(2) PRESCRIPTION DRUG PRODUCT IDENTIFI-
17 FIER.—Beginning not later than 8 years after the
18 date of the enactment of the Safeguarding America’s
19 Pharmaceuticals Act of 2013, a dispenser may en-
20 gage in transactions involving a prescription drug
21 product only if such prescription drug product is en-
22 coded with a prescription drug product identifier, ex-
23 cept as provided in subsection (a)(4).

24 “(3) AUTHORIZED TRADING PARTNERS.—Be-
25 ginning not later than January 1, 2015, a dispenser

1 shall ensure that each of its trading partners is au-
2 thorized.

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

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

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

22 “(I) verifying whether the lot
23 number of a suspect prescription drug
24 product corresponds with the lot num-

1 ber for such prescription drug prod-
2 uct;

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

14 “(III) validating any applicable
15 transaction history in the possession
16 of the dispenser; and

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

21 “(ii) CLEARED PRESCRIPTION DRUG
22 PRODUCT.—If the dispenser makes the de-
23 termination that a suspect prescription
24 drug product is not an illegitimate pre-
25 scription drug product, the dispenser shall

1 promptly notify the Secretary of such de-
2 termination and such prescription drug
3 product may be further dispensed.

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

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

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

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

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

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

3 “(ii) TRADING PARTNERS.—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 dispenser shall take reason-
8 able steps to assist a 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 dispenser is an illegitimate prescription
15 drug product, the dispenser shall notify the
16 Secretary of such determination not later
17 than 24 hours after making such deter-
18 mination. 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 dispenser 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 dispenser,
7 including any such 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 dispenser 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 dis-
18 penser may satisfy the requirements of this
19 paragraph through the use of a secure elec-
20 tronic database developed and operated by the
21 manufacturer or another entity. The owner of
22 such database shall establish the requirements
23 and processes to enable responding to requests
24 and may provide for data access to other mem-
25 bers of the pharmaceutical distribution supply

1 chain, as appropriate. The development and op-
2 eration of such a database shall not relieve a
3 dispenser of the requirement under this para-
4 graph to respond to a verification request sub-
5 mitted by means other than a secure electronic
6 database.

7 “(e) REPACKAGER REQUIREMENTS.—

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

10 “(A) IN GENERAL.—Beginning not later
11 than April 1, 2015, with respect to a prescrip-
12 tion drug product received by a repackager
13 from a wholesale distributor, and beginning not
14 later than January 1, 2015, with respect to any
15 other prescription drug product, a repackager
16 shall—

17 “(i) not accept ownership of a pre-
18 scription drug product unless the previous
19 owner, prior to, or at the time of, the
20 transaction, provides transaction history
21 and a transaction statement for the pre-
22 scription drug product;

23 “(ii) prior to, or at the time of, each
24 transaction in which the repackager trans-
25 fers ownership of a prescription drug prod-

1 uct, provide the subsequent owner with
2 transaction history and a transaction state-
3 ment;

4 “(iii) maintain the transaction infor-
5 mation for each transaction described in
6 clause (i) or (ii) for not less than 3 years
7 after the transaction; and

8 “(iv) maintain records that allow the
9 repackager to associate the prescription
10 drug product identifier the repackager af-
11 fixes or imprints with the prescription drug
12 product identifier assigned by the original
13 manufacturer of the prescription drug
14 product.

15 “(B) RETURNS EXCEPTION.—Notwith-
16 standing subparagraph (A)(ii), a repackager
17 may return prescription drug product to the
18 trading partner from whom the repackager ob-
19 tained the prescription drug product without
20 providing the information required under such
21 subparagraph.

22 “(C) REQUESTS FOR INFORMATION.—
23 Upon a request by the Secretary or other ap-
24 propriate Federal or State official, in the event
25 of a recall or for the purpose of investigating a

1 suspect prescription drug product or an illegit-
2 imate prescription drug product, a repackager
3 shall, not later than 2 business days after re-
4 ceiving the request or in such other reasonable
5 time as determined by the Secretary, provide
6 the applicable transaction history and trans-
7 action statement for the prescription drug prod-
8 uct.

9 “(2) PRESCRIPTION DRUG PRODUCT IDENTIFI-
10 FIER.—Beginning not later than 6 years after the
11 date of the enactment of the Safeguarding America’s
12 Pharmaceuticals Act of 2013, a repackager—

13 “(A) shall affix or imprint a prescription
14 drug product identifier to each package and ho-
15 mogenous case of prescription drug product in-
16 tended to be introduced in a transaction;

17 “(B) shall maintain the prescription drug
18 product identifier for such prescription drug
19 product for not less than 3 years after the date
20 of the transaction; and

21 “(C) may engage in transactions involving
22 a prescription drug product only if such pre-
23 scription drug product is encoded with a pre-
24 scription drug product identifier except as pro-
25 vided in subsection (a)(4).

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

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

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 the
13 repackager is a suspect prescription drug
14 product, or upon receiving a request for
15 verification from the Secretary that a pre-
16 scription drug product within the posses-
17 sion or control of a repackager is a suspect
18 prescription drug product, a repackager
19 shall promptly conduct an investigation to
20 determine whether the prescription drug
21 product is an illegitimate prescription drug
22 product, including—

23 “(I) beginning not later than 6
24 years after the date of the enactment
25 of the Safeguarding America’s Phar-

1 maceuticals Act of 2013, verifying the
2 prescription drug product at the pack-
3 age level;

4 “(II) validating any applicable
5 transaction information in the posses-
6 sion of the repackager; and

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

11 “(ii) CLEARED PRESCRIPTION DRUG
12 PRODUCT.—If the repackager determines
13 that a suspect prescription drug product is
14 not an illegitimate prescription drug prod-
15 uct, the repackager shall promptly notify
16 the Secretary of such determination and
17 such prescription drug product may be fur-
18 ther distributed.

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

24 “(B) ILLEGITIMATE PRESCRIPTION DRUG
25 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 repackager is an illegitimate
6 prescription drug product, the repackager
7 shall—

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

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

17 “(ii) TRADING PARTNER.—Upon de-
18 termining that a prescription drug product
19 in the possession or control of a trading
20 partner is an illegitimate prescription drug
21 product, the repackagers shall take reason-
22 able steps to assist the 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 repackager is an illegitimate prescription
5 drug product, the repackager shall notify
6 the Secretary of such determination not
7 later than 24 hours after making such de-
8 termination. 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 repackager 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 repack-
21 ager, including any such prescription
22 drug product that is subsequently re-
23 ceived; and

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

1 “(v) RECORDS.—A repackager 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 repack-
7 ager may satisfy the requirements of this para-
8 graph through the use of a secure electronic
9 database developed and operated by the manu-
10 facturer or another entity. The owner of such
11 database shall establish the requirements and
12 processes to respond to requests and may pro-
13 vide for data access to other members of the
14 pharmaceutical distribution supply chain, as ap-
15 propriate. The development and operation of
16 such a database shall not relieve a repackager
17 of the requirement under this paragraph to re-
18 spond to a verification request submitted by
19 means other than a secure electronic database.

20 “(D) RETURNED PRESCRIPTION DRUG
21 PRODUCT.—Beginning not later than 6 years
22 after the date of the enactment of the Safe-
23 guarding America’s Pharmaceuticals Act of
24 2013, upon receipt of a returned prescription
25 drug product that the repackager intends to

1 further distribute, before further distributing
2 such prescription drug product, the repackager
3 shall—

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

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

11 “(f) THIRD-PARTY LOGISTICS PROVIDER REQUIRE-
12 MENTS.—

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

17 “(2) VERIFICATION.—Beginning not later than
18 January 1, 2015, a third-party logistics provider
19 shall implement systems to enable the third-party lo-
20 gistics provider to comply with the following require-
21 ments:

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 a
2 third-party logistics provider is a suspect
3 prescription drug product, a third-party lo-
4 gistics provider shall promptly notify the
5 owner of such prescription drug product of
6 the need to conduct an investigation to de-
7 termine whether the prescription drug
8 product is an illegitimate prescription drug
9 product.

10 “(ii) CLEARED PRESCRIPTION DRUG
11 PRODUCT.—If the owner of the prescrip-
12 tion drug product notifies the third-party
13 logistics provider of the determination that
14 a suspect prescription drug product is not
15 an illegitimate prescription drug product,
16 such prescription drug product may be fur-
17 ther distributed.

18 “(iii) RECORDS.—A third-party logis-
19 tics provider shall keep records of the ac-
20 tivities described in clauses (i) and (ii)
21 with respect to a suspect prescription drug
22 product for not less than 3 years after the
23 conclusion of the investigation.

24 “(B) ILLEGITIMATE PRESCRIPTION DRUG
25 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 third-party logistics pro-
6 vider is an illegitimate prescription drug
7 product, the third-party logistics provider
8 shall—

9 “(I) quarantine such prescription
10 drug product within the possession or
11 control of the third-party logistics pro-
12 vider from prescription drug product
13 intended for distribution;

14 “(II) promptly notify the owner
15 of such prescription drug product of
16 the need to provide for the disposition
17 of such prescription drug product; and

18 “(III) promptly transfer posses-
19 sion of the prescription drug product
20 to the owner of such prescription drug
21 product to provide for the disposition
22 of the prescription drug product.

23 “(ii) MAKING A NOTIFICATION.—
24 Upon determining that a prescription drug
25 product in the possession or control of the

1 third-party logistics provider is an illegit-
2 imate prescription drug product, the third-
3 party logistics provider shall notify the
4 Secretary not later than 24 hours after
5 making such determination. The Secretary
6 shall determine whether additional trading
7 partner notification is appropriate.

8 “(iii) RESPONDING TO A NOTIFICA-
9 TION.—Upon the receipt of a notification
10 from the Secretary, a third-party logistics
11 provider shall—

12 “(I) identify all illegitimate pre-
13 scription drug products subject to
14 such notification that are in the pos-
15 session or control of the third-party
16 logistics provider, including any such
17 prescription drug product that is sub-
18 sequently received; and

19 “(II) perform the activities de-
20 scribed in clause (i).

21 “(iv) RECORDS.—A third-party logis-
22 tics provider shall keep records of the ac-
23 tivities described in clauses (i) and (ii)
24 with respect to an illegitimate prescription

1 drug product for not less than 3 years
2 after the conclusion of the disposition.

3 “(g) DROP SHIPMENTS.—This section does not apply
4 to any entity, notwithstanding its status as a wholesale
5 distributor or repackager, or other status that is not in-
6 volved in the physical handling, distribution, or storage of
7 a prescription drug product. For purposes of this sub-
8 section, facilitating the distribution of a prescription drug
9 product by providing various administrative services, in-
10 cluding processing of orders and payments, shall not, by
11 itself, be construed as being involved in the handling, dis-
12 tribution, or storage of a prescription drug product.”.

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

14 (a) PILOT PROJECTS.—

15 (1) IN GENERAL.—Not later than 2 years after
16 the date of the enactment of this Act, the Secretary
17 shall establish one or more pilot projects in coordi-
18 nation with manufacturers, repackagers, wholesale
19 distributors, third-party logistics providers, and dis-
20 pensers to explore and evaluate methods to enhance
21 the safety and security of the pharmaceutical dis-
22 tribution supply chain.

23 (2) CONTENT.—

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

4 (i) reflect the diversity of the pharma-
5 ceutical distribution supply chain; and

6 (ii) include participants representative
7 of every sector within the pharmaceutical
8 distribution supply chain, including partici-
9 pants representative of small businesses.

10 (B) PROJECT DESIGN.—The pilot projects
11 shall be designed to—

12 (i) utilize the prescription drug prod-
13 uct identifier for tracing of a prescription
14 drug product, which utilization may in-
15 clude—

16 (I) verification of the prescription
17 drug product identifier of a prescrip-
18 tion drug product; and

19 (II) the use of aggregation and
20 inference;

21 (ii) improve the technical capabilities
22 of each sector within the pharmaceutical
23 supply chain to comply with systems and
24 processes needed to utilize the prescription

1 drug product identifiers to enhance tracing
2 of a prescription drug product; and

3 (iii) conduct such other activities as
4 the Secretary determines appropriate to
5 explore and evaluate methods to enhance
6 the safety and security of the pharma-
7 ceutical distribution supply chain.

8 (b) PUBLIC MEETINGS.—

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

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

23 (A) Best practices in each of the sectors
24 within the pharmaceutical distribution supply
25 chain to implement the requirements of section

1 582 of the Federal Food, Drug, and Cosmetic
2 Act, as added by section 2.

3 (B) The costs and benefits of implementa-
4 tion of such section 582, including the impact
5 on each pharmaceutical distribution supply
6 chain sector and on public health.

7 (C) Whether additional electronic
8 traceability requirements, including tracing of
9 prescription drug product at the package level,
10 are feasible, cost effective, overly burdensome
11 on small businesses, and needed to protect pub-
12 lic health.

13 (D) The systems and processes needed to
14 utilize the prescription drug product identifiers
15 to enhance tracing of prescription drug product
16 at the package level, including allowing for
17 verification, aggregation, and inference by each
18 sector within the pharmaceutical distribution
19 supply chain for cases, pallets, totes, and other
20 containers of aggregated prescription drug
21 product as necessary.

22 (E) The technical capabilities and legal au-
23 thorities, if any, needed to establish an elec-
24 tronic system that provides for enhanced trac-

1 ing of prescription drug product at the package
2 level.

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

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

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

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

23 (A) The implementation of the require-
24 ments established under such subchapter H
25 with respect to—

1 (i) the ability of the health care sys-
2 tem collectively to maintain patient access
3 to medicines;

4 (ii) the scalability of such require-
5 ments, including with respect to prescrip-
6 tion drug product lines; and

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

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

18 (i) the systems and processes needed
19 to enhance tracing of prescription drug
20 product at the package level, including the
21 use and evaluation of verification, aggrega-
22 tion, and inference by each sector within
23 the pharmaceutical distribution supply
24 chain as necessary;

1 (ii) the impact, feasibility, and cost ef-
2 fectiveness that additional requirements
3 pursuant to this section would have on
4 each pharmaceutical distribution supply
5 chain sector and the public health; and

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

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

13 (d) SMALL DISPENSERS.—

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

23 (2) CONDITION.—As a condition of the award
24 of a contract under paragraph (1), the private inde-
25 pendent consulting firm awarded such contract shall

1 agree to consult with dispensers that have 25 or
2 fewer full-time employees when conducting the study
3 under such subparagraph.

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

9 (A) is readily accessible to such dispensers;

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

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

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

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

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

24 (5) REPORT TO CONGRESS.—Not later than 30
25 days after the date on which the study conducted

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

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

16 (e) REPORTS.—

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

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

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

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

15 (f) ESTABLISHMENT OF ADDITIONAL REQUIRE-
16 MENTS.—

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

1 from entering into or being further distributed in
2 the supply chain, including—

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

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

17 (C) requirements related to the use of ag-
18 gregation, inference, and other methods, which
19 shall permit the use of aggregation and infer-
20 ence for cases, pallets, totes, and other con-
21 tainers of aggregated prescription drug prod-
22 ucts by each sector of the pharmaceutical dis-
23 tribution supply chain, if determined to be nec-
24 essary components of the systems and tech-
25 nologies referred to in subparagraph (A); and

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

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

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

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

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

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

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

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

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

12 (A) the results of, and public comments re-
13 sulting from, the pilot project conducted under
14 subsection (a);

15 (B) the public meetings held under sub-
16 section (b) and public comments from such
17 meetings;

18 (C) the studies conducted under sub-
19 sections (c) and (d);

20 (D) the reports submitted under subsection
21 (e);

22 (E) the public health benefits of such regu-
23 lations compared with the cost of compliance
24 with the requirements contained in such regula-

1 tions, including with respect to entities of vary-
2 ing sizes and capabilities; and

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

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

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

1 (B) establishing a process by which a dis-
2 penser may request a waiver from any such re-
3 quirement.

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

6 (A) issue a notice of proposed rulemaking
7 that includes a copy of the proposed rule;

8 (B) provide for a period of not less than
9 60 days for comments on the proposed rule;
10 and

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

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

21 (g) DEFINITIONS.—In this section:

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

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

4 **SEC. 4. NATIONAL STANDARDS FOR WHOLESALE DISTRIBUTORS.**
5 **TORS.**

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

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

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

14 (2) in section 503(e) (21 U.S.C. 353(e)), by re-
15 designating subparagraphs (A) and (B) as para-
16 graphs (1) and (2), respectively; and

17 (3) in subchapter H, as added by section 2, by
18 adding at the end the following:

19 **“SEC. 583. NATIONAL STANDARDS FOR WHOLESALE DIS-**
20 **TRIBUTORS.**

21 “(a) STANDARDS.—

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

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

4 “(A) the storage and handling of drugs
5 subject to section 503(b)(1), including facility
6 requirements;

7 “(B) the establishment and maintenance of
8 records of the distributions of such drugs;

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

12 “(D) mandatory background checks and
13 fingerprinting of facility managers or des-
14 ignated representatives;

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

17 “(F) the mandatory physical inspection of
18 any facility to be used in wholesale distribution
19 within a reasonable timeframe from the initial
20 application for licensure of the wholesale dis-
21 tributor; and

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

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

4 “(A) An applicant that is not a govern-
5 ment-owned-and-operated wholesale distributor,
6 for the issuance or renewal of a wholesale dis-
7 tributor license, shall submit a surety bond of
8 \$100,000 or other equivalent means of security
9 acceptable to the applicable licensing authority.

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

17 “(C) If a wholesale distributor can provide
18 evidence that it possesses the required bond in
19 a State, the requirement for a bond in another
20 State is waived.

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

1 “(A) the government of the State in which
2 the facility is located; or

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

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

9 “(A) has been convicted of—

10 “(i) any felony for conduct relating to
11 wholesale distribution;

12 “(ii) any felony violation of section
13 301(i) or 301(k); or

14 “(iii) any felony violation of section
15 1365 of title 18, United States Code, relat-
16 ing to prescription drug product tam-
17 pering; or

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

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

24 “(1) ANNUAL REPORT.—Beginning not later
25 than 1 year after the date of the enactment of this

1 section, each person engaged in wholesale distribu-
2 tion in interstate commerce shall submit on an an-
3 nual basis, and update as necessary, a report to the
4 Secretary including—

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

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

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

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

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

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

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

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

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

10 “(1) intracompany distribution of any drug be-
11 tween members of an affiliated group (as defined in
12 section 1504(a) of the Internal Revenue Code of
13 1986);

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

17 “(3) the distribution of a drug or an offer to
18 distribute a drug for emergency medical reasons, in-
19 cluding a public health emergency declaration pursu-
20 ant to section 319 of the Public Health Service Act,
21 except that a drug shortage not caused by a public
22 health emergency shall not constitute such an emer-
23 gency medical reason;

1 “(4) dispensing of a drug pursuant to a valid
2 prescription executed in accordance with subsection
3 503(b)(1);

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

7 “(6) the distribution of a drug or an offer to
8 distribute a drug by a charitable organization to a
9 nonprofit affiliate of the organization to the extent
10 otherwise permitted by law;

11 “(7) the purchase or other acquisition by a dis-
12 penser, hospital, or other health care entity of a
13 drug for use by such dispenser, hospital, or other
14 health care entity;

15 “(8) the distribution of a drug by the manufac-
16 turer of such drug;

17 “(9) the receipt or transfer of a drug by an au-
18 thorized third-party logistics provider provided that
19 such third-party logistics provider does not take
20 ownership of the drug;

21 “(10) the transport of a drug by a common car-
22 rier, provided that the common carrier does not take
23 ownership of the drug;

24 “(11) the distribution of a drug, or an offer to
25 distribute a drug, by an authorized repackager that

1 has taken ownership of the drug and repacked it in
2 accordance with section 582(e);

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

7 “(13) the distribution of a combination pre-
8 scription drug product described in section
9 581(20)(B)(xii);

10 “(14) the distribution of a medical convenience
11 kit described in section 581(21)(B)(xiii);

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

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

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

23 “(18) the distribution of compressed medical
24 gas (as defined in section 581(21)(C));

1 “(19) facilitating the distribution of a prescrip-
2 tion drug product by providing administrative serv-
3 ices, such as processing of orders and payments,
4 without physical handling, distribution, or storage of
5 a prescription drug product; or

6 “(20)(A) the distribution of a product by a dis-
7 penser, or a wholesale distributor acting at the di-
8 rection of the dispenser, to a repackager registered
9 under section 510 for the purpose of repackaging
10 the drug for use by that dispenser or another health
11 care entity that is under the dispenser’s ownership
12 or control, so long as the dispenser retains owner-
13 ship of the prescription drug product; and

14 “(B) the saleable or nonsaleable return by such
15 repackager of such prescription drug product.

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

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

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

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

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

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

11 “(1) the facility is licensed—

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

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

19 “(2) 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 by striking “or the distribution of drugs in viola-
21 tion of section 503(e) or the failure to otherwise comply
22 with the requirements of section 503(e)” and inserting
23 “the failure to comply with any requirement of section
24 582, engaging in the wholesale distribution of a drug in
25 violation of section 583 or the failure to otherwise comply

1 with the requirements of section 583, or engaging in the
2 activities of a third-party logistics provider in violation of
3 section 584 or the failure to otherwise comply with the
4 requirements of section 584”.

5 (b) ENHANCED PENALTY FOR KNOWING UNLI-
6 CENSED ACTIVITIES.—Section 303(b)(1)(D) of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C.
8 333(b)(1)(D)) is amended by striking “503(e)(2)(A)” and
9 inserting “583 or 584”.

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

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

15 **SEC. 7. UNIFORM NATIONAL POLICY.**

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

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

20 “(a) PREEMPTION OF STATE PRESCRIPTION DRUG
21 PRODUCT TRACING AND OTHER REQUIREMENTS.—Be-
22 ginning on the date of the enactment of the Safeguarding
23 America’s Pharmaceuticals Act of 2013, no State or polit-
24 ical subdivision of a State may establish or continue in
25 effect any requirements for tracing drugs through the dis-

1 tribution system (including any requirements with respect
2 to paper or electronic pedigrees, track and trace, state-
3 ments of distribution history, transaction history, or
4 transaction statements, or verification, investigation, dis-
5 position, alerts, or recordkeeping relating to the pharma-
6 ceutical distribution supply chain system) that—

7 “(1) are inconsistent with, more stringent than,
8 or in addition to any requirements applicable under
9 this Act; or

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

13 “(b) STANDARDS OR LICENSURE.—

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

24 “(2) LICENSING FEES.—Paragraph (1) does
25 not affect the authority of a State to collect fees

1 from wholesale drug distributors or third-party logis-
2 tics providers in connection with State licensing
3 under section 583 or 584 pursuant to a licensing
4 program meeting the requirements of such sections.

5 “(3) ENFORCEMENT, SUSPENSION, AND REV-
6 OCATION OF LICENSES.—Notwithstanding paragraph
7 (1), a State—

8 “(A) may take administrative action, in-
9 cluding fines, to enforce a licensure requirement
10 promulgated by the State in accordance with
11 this Act;

12 “(B) may provide for the suspension or
13 revocation of licenses issued by the State for
14 violations of the laws of such State;

15 “(C) upon conviction of a person for a vio-
16 lation of Federal, State, or local controlled sub-
17 stance laws or regulations, may provide for
18 fines, imprisonment, or civil penalties; and

19 “(D) may regulate activities of entities li-
20 censed pursuant to section 583 or 584 in a
21 manner that is consistent with the provisions of
22 this subchapter.”.

23 **SEC. 8. ELECTRONIC LABELING.**

24 (a) IN GENERAL.—Section 502(f) of the Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)) is

1 amended by adding at the end the following new sentence:
2 “Required labeling (other than immediate container or
3 carton labels) that is intended for use by a physician, a
4 pharmacist, or another health care professional, and that
5 provides directions for human use of a drug subject to sec-
6 tion 503(b)(1), may (except as necessary to mitigate a
7 safety risk, as specified by the Secretary in regulation) be
8 made available by electronic means instead of paper form,
9 provided that such labeling complies with all applicable re-
10 quirements of law, the manufacturer or distributor, as ap-
11 plicable, affords health care professionals and authorized
12 dispensers (as defined in section 581) the opportunity to
13 request the labeling in paper form, and after such a re-
14 quest the manufacturer or distributor promptly provides
15 the requested information without additional cost.”.

16 (b) REGULATIONS.—The Secretary of Health and
17 Human Services shall promulgate regulations imple-
18 menting the amendment made by subsection (a).

19 (c) APPLICATION.—The last sentence of section
20 502(f) of the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 352(f)), as added by subsection (a), shall apply be-
22 ginning on the earlier of—

23 (1) the effective date of final regulations pro-
24 mulgated under subsection (b); or

1 (2) the day that is 180 days after the date of
2 enactment of this Act.

Passed the House of Representatives June 3, 2013.

Attest:

Clerk.

113TH CONGRESS
1ST SESSION

H. R. 1919

AN ACT

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