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113TH CONGRESS
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H. R. 1919

[Report No. 113-93]

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

IN THE HOUSE OF REPRESENTATIVES

MAY 9, 2013

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

JUNE 3, 2013

Additional sponsors: Mr. OLSON, Mr. LONG, Mr. LATHAM, Mr. VALADAO, Mr. RUSH, Mr. VEASEY, Mr. WALBERG, and Mrs. WALORSKI

JUNE 3, 2013

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on May 9, 2013]

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

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

6 (b) *TABLE OF CONTENTS.*—*The table of contents of this*
 7 *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.

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

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

12 **“Subchapter H—Pharmaceutical Distribution**
 13 **Supply Chain**

14 **“SEC. 581. DEFINITIONS.**

15 *“In this subchapter:*

16 (1) *AUTHORIZED.*—*The term ‘authorized’*
 17 *means—*

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

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

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

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

12 “(B) includes warehouses and distribution
13 centers under common ownership or control of
14 entities described in subparagraph (A) that are
15 members of an affiliated group pursuant to sec-
16 tion 1504(a) of the Internal Revenue Code of
17 1986, to the extent such warehouses and distribu-
18 tion centers do not act as a wholesale distributor;
19 and

20 “(C) does not include a person who only
21 dispenses prescription drug product to be used in
22 animals in accordance with section 512(a)(5).

23 “(3) *DISPOSITION*.—The term ‘disposition’, with
24 respect to a prescription drug product within the pos-
25 session and control of an entity—

1 “(A) means the removal of such prescription
2 drug product, or taking measures to prevent the
3 introduction of such prescription drug product,
4 from the pharmaceutical distribution supply
5 chain; and

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

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

17 “(5) *ILLEGITIMATE PRESCRIPTION DRUG PROD-*
18 *UCT.*—The term ‘illegitimate prescription drug prod-
19 uct’ means a prescription drug product which a man-
20 ufacturer has confirmed—

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

22 “(B) is intentionally adulterated such that
23 the prescription drug product would result in se-
24 rious adverse health consequences or death to hu-
25 mans; or

1 “(C) is otherwise unfit for distribution such
2 that the prescription drug product is reasonably
3 likely to cause serious adverse human health con-
4 sequences or death.

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

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

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

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

17 “(7) MANUFACTURER.—The term ‘manufacturer’
18 means, with respect to a prescription drug product—

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

1 “(B) a co-licensed partner of the person de-
2 scribed 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 group
7 (as defined in section 1504(a) of the Inter-
8 nal Revenue Code of 1986) to which a per-
9 son described in subparagraph (A) or (B) is
10 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 man-*
2 *ufacturer for individual sale to a dispenser.*

3 “(9) *PRESCRIPTION DRUG.*—*The term ‘prescrip-*
4 *tion drug’ means a drug for human use subject to sec-*
5 *tion 503(b)(1).*

6 “(10) *PRESCRIPTION DRUG PRODUCT.*—*The term*
7 *‘prescription drug product’ means a prescription drug*
8 *in a finished dosage form for administration to a pa-*
9 *tient without substantial further manufacturing (such*
10 *as capsules, tablets, and lyophilized prescription drug*
11 *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 rec-*
21 *ognized international standards development or-*
22 *ganization.*

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 as*
3 *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 ‘returns*
15 *processor’ mean a person who owns or operates an es-*
16 *tablishment that provides for the disposition of or oth-*
17 *erwise processes saleable and nonsaleable prescription*
18 *drug product received from an authorized trading*
19 *partner such that the prescription drug product may*
20 *be processed for credit to the purchaser, manufacturer,*
21 *seller, or disposed of for no further distribution.*

22 “(16) *SPECIFIC PATIENT NEED.*—*The term ‘spe-*
23 *cific patient need’—*

24 “(A) *means with respect to the transfer of*
25 *a prescription drug product from one pharmacy*

1 to another, to fill a prescription for an identified
2 patient; and

3 “(B) does not include the transfer of a pre-
4 scription drug product from one pharmacy to
5 another for the purpose of increasing or replen-
6 ishing stock in anticipation of a potential need.

7 “(17) *STANDARDIZED NUMERICAL IDENTIFIER*.—
8 The term ‘standardized numerical identifier’ means a
9 set of numbers or characters that—

10 “(A) is used to uniquely identify each pack-
11 age or homogenous case of the prescription drug
12 product; and

13 “(B) is composed of the National Drug Code
14 that corresponds to the specific prescription drug
15 product (including the particular package con-
16 figuration) combined with a unique alpha-
17 numeric serial number of up to 20 characters.

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

23 “(A) is potentially counterfeit, diverted, or
24 stolen;

1 “(B) is potentially intentionally adulterated
2 such that the prescription drug product would
3 result in serious adverse health consequences or
4 death to humans; or

5 “(C) appears otherwise unfit for distribu-
6 tion such that the prescription drug product
7 would result in serious adverse health con-
8 sequences or death to humans.

9 “(19) *THIRD-PARTY LOGISTICS PROVIDER.*—The
10 term ‘third-party logistics provider’ means an entity
11 that provides or coordinates warehousing, distribu-
12 tion, or other logistics services of a prescription drug
13 product in interstate commerce on behalf of a manu-
14 facturer, wholesale distributor, or dispenser of a pre-
15 scription drug product, but does not take ownership
16 of the prescription drug product, nor have responsi-
17 bility to direct the sale or disposition of, the prescrip-
18 tion drug product.

19 “(20) *TRADING PARTNER.*—The term ‘trading
20 partner’ means—

21 “(A) a manufacturer, repackager, wholesale
22 distributor, or dispenser from whom a manufac-
23 turer, repackager, wholesale distributor, or dis-
24 penser accepts ownership of a prescription drug
25 product or to whom a manufacturer, repackager,

1 *wholesale distributor, or dispenser transfers own-*
2 *ership of a prescription drug product; or*

3 *“(B) a third-party logistics provider from*
4 *whom a manufacturer, repackager, wholesale dis-*
5 *tributor, or dispenser accepts possession of a pre-*
6 *scription drug product or to whom a manufac-*
7 *turer, repackager, wholesale distributor, or dis-*
8 *perser transfers possession of a prescription drug*
9 *product.*

10 “(21) TRANSACTION.—

11 “(A) IN GENERAL.—*The term ‘transaction’*
12 *means the transfer in interstate commerce of pre-*
13 *scription drug product between persons in which*
14 *a change of ownership occurs.*

15 “(B) EXEMPTIONS.—*The term ‘transaction’*
16 *does not include—*

17 “(i) *intracompany distribution of any*
18 *prescription drug product, including be-*
19 *tween members of an affiliated group (as*
20 *defined in section 1504(a) of the Internal*
21 *Revenue Code of 1986);*

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

1 “(iii) the distribution of a prescription
2 drug product for emergency medical reasons
3 including a public health emergency dec-
4 laration pursuant to section 319 of the Pub-
5 lic Health Service Act, except that a drug
6 shortage not caused by a public health
7 emergency shall not constitute an emergency
8 medical reason;

9 “(iv) the dispensing of a prescription
10 drug product pursuant to a valid prescrip-
11 tion executed in accordance with section
12 503(b)(1);

13 “(v) the distribution of prescription
14 drug product samples by a manufacturer or
15 a licensed wholesale distributor in accord-
16 ance with section 503(d);

17 “(vi) the distribution of blood or blood
18 components intended for transfusion;

19 “(vii) the distribution of minimal
20 quantities of prescription drug product by a
21 licensed retail pharmacy to a licensed prac-
22 titioner for office use;

23 “(viii) the distribution of a prescrip-
24 tion drug product by a charitable organiza-
25 tion to a nonprofit affiliate of the organiza-

1 *tion to the extent otherwise permitted by*
2 *law;*

3 *“(ix) the distribution of a prescription*
4 *drug product pursuant to the sale or merger*
5 *of a pharmacy or pharmacies or a wholesale*
6 *distributor or wholesale distributors, except*
7 *that any records required to be maintained*
8 *for the prescription drug product shall be*
9 *transferred to the new owner of the phar-*
10 *macy or pharmacies or wholesale dis-*
11 *tributor or wholesale distributors;*

12 *“(x) the dispensing of a prescription*
13 *drug product approved under section*
14 *512(b);*

15 *“(xi) the transfer of prescription drug*
16 *products to or from any facility that is li-*
17 *censed by the Nuclear Regulatory Commis-*
18 *sion or by a State pursuant to an agree-*
19 *ment with such Commission under section*
20 *274 of the Atomic Energy Act of 1954 (42*
21 *U.S.C. 2021);*

22 *“(xii) the distribution of a combina-*
23 *tion product that consists of—*

24 *“(I) a product comprised of two*
25 *or more components that are each a*

1 *drug, biological product, or device and*
2 *that are physically, chemically, or oth-*
3 *erwise combined or mixed and pro-*
4 *duced as a single entity;*

5 *“(II) two or more separate prod-*
6 *ucts packaged together in a single*
7 *package or as a unit and comprised of*
8 *a drug and device or a device and bio-*
9 *logical product; or*

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

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

20 *“(I) the medical convenience kit is*
21 *assembled in an establishment that is*
22 *registered with the Food and Drug Ad-*
23 *ministration as a medical device man-*
24 *ufacturer;*

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

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

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

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

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

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

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

6 “(dd) anesthetics;

7 “(ee) anticoagulants;

8 “(ff) vasopressors; or

9 “(gg) sympathicomimetics;

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

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

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

1 “(xvii) *the distribution of compressed*
2 *medical gas; or*

3 “(xviii)(I) *the distribution of a product*
4 *by a dispenser, or a wholesale distributor*
5 *acting at the direction of the dispenser, to*
6 *a repackager registered under section 510*
7 *for the purpose of repackaging the drug for*
8 *use by that dispenser or another health care*
9 *entity that is under the dispenser’s owner-*
10 *ship or control, so long as the dispenser re-*
11 *tains ownership of the prescription drug*
12 *product; and*

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

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

23 “(22) *TRANSACTION HISTORY.—The term ‘trans-*
24 *action history’ means a statement that—*

1 “(A) includes the transaction information
2 for each transaction conducted with respect to a
3 prescription drug product beginning with the
4 manufacturer or initial purchase distributor for
5 each prior transaction going back to the manu-
6 facturer of the prescription drug product or to
7 the initial purchase distributor; and

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

9 “(23) TRANSACTION INFORMATION.—The term
10 ‘transaction information’ means—

11 “(A) the proprietary or established name or
12 names of the prescription drug product;

13 “(B) the strength and dosage form of the
14 prescription drug product;

15 “(C) the National Drug Code number of the
16 prescription drug product;

17 “(D) the container size;

18 “(E) the number of containers;

19 “(F) the lot number of the prescription drug
20 product;

21 “(G) the date of the transaction;

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

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

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

8 “(A) is authorized;

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

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

15 “(D) did not knowingly and intentionally
16 provide false transaction information; and

17 “(E) did not knowingly and intentionally
18 alter the transaction history.

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

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

1 *number, and expiration date assigned to the pre-*
2 *scription drug product by the manufacturer or*
3 *the repackager, as applicable; and*

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

7 *“(26) WHOLESALE DISTRIBUTOR.—The term*
8 *‘wholesale distributor’—*

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

11 *“(B) excludes—*

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

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

18 *“(iii) the distribution of prescription*
19 *drug product or an offer to distribute pre-*
20 *scription drug product by an authorized re-*
21 *packager that has taken ownership or pos-*
22 *session of the prescription drug product and*
23 *repacked the prescription drug product in*
24 *accordance with the requirements of section*
25 *582(e).*

1 **“SEC. 582. REQUIREMENTS.**2 “(a) *IN GENERAL.*—

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

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

1 *prescription drug product. The Secretary shall pub-*
2 *lish such standards not later than 180 days after the*
3 *date of the enactment of the Safeguarding America’s*
4 *Pharmaceuticals Act of 2013.*

5 “(3) *WAIVERS, EXCEPTIONS, AND EXEMP-*
6 *TIONS.—Not later than one year after the date of the*
7 *enactment of the Safeguarding America’s Pharma-*
8 *ceuticals Act of 2013, the Secretary shall promulgate*
9 *a regulation to—*

10 “(A) *establish a process by which the Sec-*
11 *retary may grant, at the request of an authorized*
12 *manufacturer, repackager, wholesale distributor,*
13 *or dispenser, a waiver from any of the require-*
14 *ments of this section—*

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

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

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

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

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

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

14 “(4) GRANDFATHERED PERSONS AND PRESCRIP-
15 TION DRUG PRODUCTS.—

16 “(A) IN GENERAL.—Not later than one year
17 after the date of the enactment of the Safe-
18 guarding America’s Pharmaceuticals Act of
19 2013, the Secretary shall specify, by regulation,
20 whether and under what circumstances the pre-
21 scription drug product identifier requirement
22 under paragraph (2) of subsections (b), (c), (d),
23 and (e) shall apply to a prescription drug prod-
24 uct that is in the supply chain or in a manufac-
25 turer’s inventory on the date of the enactment of

1 *the Safeguarding America’s Pharmaceuticals Act*
2 *of 2013.*

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

13 “(C) *LABEL CHANGES.—Changes made to*
14 *package labels solely to incorporate the prescrip-*
15 *tion drug product identifier may be submitted to*
16 *the Secretary in the annual report of an estab-*
17 *lishment, in accordance with section 314.70(d) of*
18 *chapter 21, Code of Federal Regulations (or any*
19 *successor regulation).*

20 “(b) *MANUFACTURER REQUIREMENTS.—*

21 “(1) *PRESCRIPTION DRUG PRODUCT TRACING.—*

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

24 “(i) *prior to, or at the time of, each*
25 *transaction in which such manufacturer*

1 *transfers ownership of a prescription drug*
2 *product, provide the subsequent owner with*
3 *the transaction history and a transaction*
4 *statement; and*

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

9 “(B) *REQUESTS FOR INFORMATION.*—*Upon*
10 *a request by the Secretary or other appropriate*
11 *Federal or State official, in the event of a recall*
12 *or for the purpose of investigating a suspect pre-*
13 *scription drug product or an illegitimate pre-*
14 *scription drug product, a manufacturer shall,*
15 *not later than 2 business days after receiving the*
16 *request or in such reasonable time as determined*
17 *by the Secretary, provide to the Secretary or*
18 *other official, the applicable transaction history*
19 *and transaction statement for the prescription*
20 *drug product.*

21 “(2) *PRESCRIPTION DRUG PRODUCT IDENTI-*
22 *FIER.*—*Beginning not later than 5 years after the*
23 *date of the enactment of the Safeguarding America’s*
24 *Pharmaceuticals Act of 2013, a manufacturer shall*
25 *affix or imprint a prescription drug product identi-*

1 *fier on each package and homogenous case of a pre-*
2 *scription drug product intended to be introduced in*
3 *a transaction. Such manufacturer shall maintain the*
4 *information in the prescription drug product identi-*
5 *fier for such prescription drug product for not less*
6 *than 3 years after the date of the transaction.*

7 *“(3) AUTHORIZED TRADING PARTNERS.—Begin-*
8 *ning not later than January 1, 2015, a manufacturer*
9 *shall ensure that each of its trading partners is au-*
10 *thorized.*

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

14 *“(A) maintain a list of the authorized dis-*
15 *tributors of record of such drug at the corporate*
16 *offices of such manufacturer;*

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

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

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

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

3 “(i) *IN GENERAL.—Upon making a de-*
4 *termination that a prescription drug prod-*
5 *uct in the possession or control of the manu-*
6 *facturer is a suspect prescription drug*
7 *product, or upon receiving a request for*
8 *verification from the Secretary that a pre-*
9 *scription drug product within the possession*
10 *or control of a manufacturer is a suspect*
11 *prescription drug product, a manufacturer*
12 *shall promptly conduct an investigation in*
13 *coordination with trading partners, as ap-*
14 *plicable, to determine whether the prescrip-*
15 *tion drug product is an illegitimate pre-*
16 *scription drug product. Beginning not later*
17 *than 5 years after the date of the enactment*
18 *of the Safeguarding America’s Pharma-*
19 *ceuticals Act of 2013, such investigation*
20 *shall include—*

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

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

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

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

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

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

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

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

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

7 “(ii) *TRADING PARTNER*.—Upon deter-
8 mining that a prescription drug product in
9 the possession or control of a trading part-
10 ner is an illegitimate prescription drug
11 product, the manufacturer shall take reason-
12 able steps to assist a trading partner to pro-
13 vide for the disposition of the illegitimate
14 prescription drug product.

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

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

7 “(I) *identify all illegitimate pre-*
8 *scription drug products that are sub-*
9 *ject to such notification and in the pos-*
10 *session or control of the manufacturer,*
11 *including any prescription drug prod-*
12 *uct that is subsequently received; and*

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

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

20 “(C) *ELECTRONIC DATABASE.—A manufac-*
21 *turer may satisfy the requirements of this para-*
22 *graph through the use of a secure electronic data-*
23 *base developed and operated by the manufacturer*
24 *or another entity. The owner of such database*
25 *shall establish the requirements and processes to*

1 *respond to requests and may provide for data ac-*
2 *cess to other members of the pharmaceutical dis-*
3 *tribution supply chain, as appropriate. The de-*
4 *velopment and operation of such a database shall*
5 *not relieve a manufacturer of the requirement*
6 *under this paragraph to respond to a*
7 *verification request submitted by means other*
8 *than a secure electronic database.*

9 “(D) *RETURNED PRESCRIPTION DRUG*
10 *PRODUCT.—Beginning not later than 5 years*
11 *after the date of the enactment of the Safe-*
12 *guarding America’s Pharmaceuticals Act of*
13 *2013, upon receipt of a returned prescription*
14 *drug product that the manufacturer intends to*
15 *further distribute, before further distributing*
16 *such prescription drug product, the manufac-*
17 *turer shall—*

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

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

25 “(c) *WHOLESALE DISTRIBUTOR REQUIREMENTS.—*

1 “(1) *PRESCRIPTION DRUG PRODUCT TRACING.*—

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

5 “(i) *not accept ownership of a pre-*
6 *scription drug product unless the previous*
7 *owner prior to, or at the time of, the trans-*
8 *action provides the applicable transaction*
9 *history and a transaction statement for the*
10 *prescription drug product;*

11 “(ii) *prior to, or at the time of, each*
12 *transaction in which the wholesale dis-*
13 *tributor transfers ownership of a prescrip-*
14 *tion drug product—*

15 “(I) *in the case that the wholesale*
16 *distributor purchased the prescription*
17 *drug product directly from the manu-*
18 *facturer, provide the subsequent owner*
19 *with transaction history and a trans-*
20 *action statement for the prescription*
21 *drug product; or*

22 “(II) *in the case that the whole-*
23 *sale distributor did not purchase the*
24 *prescription drug product directly*
25 *from the manufacturer, the exclusive*

1 *distributor of the manufacturer, or a*
2 *repackager that purchased directly*
3 *from the manufacturer, provide the*
4 *subsequent owner with transaction his-*
5 *tory beginning with the wholesale dis-*
6 *tributor that did purchase the product*
7 *directly from the manufacturer, the ex-*
8 *clusive distributor of the manufacturer,*
9 *or a repackager that purchased directly*
10 *from the manufacturer;*

11 *“(iii) notwithstanding clause (ii), if*
12 *the wholesale distributor purchased the pre-*
13 *scription drug product directly from the*
14 *manufacturer, its exclusive distributor, or a*
15 *repackager that purchased directly from the*
16 *manufacturer or its authorized distributor*
17 *of record—*

18 *“(I) provide an initial purchase*
19 *transaction statement on the invoice to*
20 *the customer, stating that the wholesale*
21 *distributor purchased the prescription*
22 *drug product package directly from the*
23 *manufacturer, exclusive distributor, or*
24 *repackager;*

1 “(II) make available to the imme-
2 diate subsequent recipient of such pre-
3 scription drug product the information
4 required under clause (ii) through any
5 combination of self-generated paper,
6 electronic data, or manufacturer-pro-
7 vided information on the prescription
8 drug product package; and

9 “(III) for purposes of subclauses
10 (I) and (II), need not include any
11 transactions occurring before the trans-
12 fer of the prescription drug product to
13 the wholesale distributor; and

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

18 “(B) RETURNS EXCEPTION.—

19 “(i) SALEABLE RETURNS.—Notwith-
20 standing subparagraph (A), a wholesale dis-
21 tributor may—

22 “(I) accept returned prescription
23 drug product without a transaction
24 history from a dispenser or repackager;
25 and

1 “(II) distribute such returned pre-
2 scription drug product with a trans-
3 action history that begins with the
4 wholesale distributor that so accepted
5 the returned product.

6 “(ii) NONSALEABLE RETURNS.—A
7 wholesale distributor may return a nonsale-
8 able prescription drug to the manufacturer
9 or repackager, to the wholesale distributor
10 from whom such prescription drug was pur-
11 chased, or to a person acting on behalf of
12 such a person, including a returns proc-
13 essor, without providing the information re-
14 quired under subparagraph (A).

15 “(C) REQUESTS FOR INFORMATION.—Upon
16 a request by the Secretary or other appropriate
17 Federal or State official, in the event of a recall
18 or for the purpose of investigating a suspect pre-
19 scription drug product or an illegitimate pre-
20 scription drug product a wholesale distributor
21 shall, not later than 2 business days after receiv-
22 ing the request or in such other reasonable time
23 as determined by the Secretary, provide the ap-
24 plicable transaction history and transaction
25 statements for the prescription drug product.

1 “(2) *PRESCRIPTION DRUG PRODUCT IDENTIFI-*
2 *FIER.—Beginning not later than 7 years after the*
3 *date of the enactment of the Safeguarding America’s*
4 *Pharmaceuticals Act of 2013, a wholesale distributor*
5 *may engage in transactions involving a prescription*
6 *drug product only if such prescription drug product*
7 *is encoded with a prescription drug product identi-*
8 *fier, except as provided in subsection (a)(4).*

9 “(3) *AUTHORIZED TRADING PARTNERS.—Begin-*
10 *ning not later than January 1, 2015, a wholesale dis-*
11 *tributor shall ensure that each of its trading partners*
12 *is authorized.*

13 “(4) *VERIFICATION.—Beginning not later than*
14 *April 1, 2015, a wholesale distributor shall implement*
15 *systems to enable the wholesale distributor to comply*
16 *with the following requirements:*

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

19 “(i) *IN GENERAL.—Upon making a de-*
20 *termination that a prescription drug prod-*
21 *uct in the possession or control of the whole-*
22 *sale distributor is a suspect prescription*
23 *drug product, or upon receiving a request*
24 *for verification from the Secretary that a*
25 *prescription drug product within the posses-*

1 *sion or control of a wholesale distributor is*
2 *a suspect prescription drug product, a*
3 *wholesale distributor shall promptly conduct*
4 *an investigation to determine whether the*
5 *prescription drug product is an illegitimate*
6 *prescription drug product. Beginning not*
7 *later than 7 years after the date of the en-*
8 *actment of the Safeguarding America’s*
9 *Pharmaceuticals Act of 2013, such inves-*
10 *tigation shall include—*

11 *“(I) verifying a package of the*
12 *prescription drug product;*

13 *“(II) validating any applicable*
14 *transaction history in the possession of*
15 *the wholesale distributor; and*

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

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

1 *mination and such prescription drug prod-*
2 *uct may be further distributed.*

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

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

10 “(i) *IN GENERAL.—Upon receiving no-*
11 *tice that a manufacturer of a prescription*
12 *drug product has determined that a pre-*
13 *scription drug product in the possession or*
14 *control of a wholesale distributor is an ille-*
15 *gitimate prescription drug product, the*
16 *wholesale distributor shall—*

17 “(I) *quarantine such prescription*
18 *drug product within the possession or*
19 *control of the wholesale distributor*
20 *from prescription drug product in-*
21 *tended for distribution; and*

22 “(II) *provide for the disposition of*
23 *the illegitimate prescription drug prod-*
24 *uct within the possession or control of*
25 *the wholesale distributor.*

1 “(ii) *TRADING PARTNER.*—Upon deter-
2 mining that a prescription drug product in
3 the possession or control of a trading part-
4 ner is an illegitimate prescription drug
5 product, the wholesale distributor shall take
6 reasonable steps to assist a trading partner
7 to provide for the disposition of the illegit-
8 imate prescription drug product.

9 “(iii) *MAKING A NOTIFICATION.*—Upon
10 determining that a prescription drug prod-
11 uct in the possession or control of the whole-
12 sale distributor is an illegitimate prescrip-
13 tion drug product, the wholesale distributor
14 shall notify the Secretary of such deter-
15 mination not later than 24 hours after
16 making such determination. The Secretary
17 shall determine whether additional trading
18 partner notification is appropriate.

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

1 “(I) identify all illegitimate pre-
2 scription drug product subject to such
3 notification that is in the possession or
4 control of the wholesale distributor, in-
5 cluding any prescription drug product
6 that is subsequently received; and

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

9 “(v) RECORDS.—A wholesale dis-
10 tributor shall keep records of the disposition
11 of an illegitimate prescription drug product
12 for not less than 3 years after the conclusion
13 of the disposition.

14 “(C) ELECTRONIC DATABASE.—A wholesale
15 distributor may satisfy the requirements of this
16 paragraph through the use of a secure electronic
17 database developed and operated by the manu-
18 facturer or another entity. The owner of such
19 database shall establish the requirements and
20 processes to respond to requests and may provide
21 for data access to other members of the pharma-
22 ceutical distribution supply chain, as appro-
23 priate. The development and operation of such a
24 database shall not relieve a wholesale distributor
25 of the requirement under this paragraph to re-

1 *spond to a verification request submitted by*
2 *means other than a secure electronic database.*

3 *“(D) RETURNED PRESCRIPTION DRUG*
4 *PRODUCT.—Beginning not later than 7 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 wholesale distributor in-*
9 *tends to further distribute, before further distrib-*
10 *uting such prescription drug product, the whole-*
11 *sale distributor 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 *“(d) DISPENSER REQUIREMENTS.—*

20 *“(1) PRESCRIPTION DRUG PRODUCT TRACING.—*

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

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

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

3 “(ii) *prior to, or at the time of, each*
4 *transaction in which the dispenser transfers*
5 *ownership of a prescription drug product*
6 *(but not including dispensing to a patient*
7 *or returns) shall provide the subsequent*
8 *owner with transaction history and a trans-*
9 *action statement for the prescription drug*
10 *product, except that the requirements of this*
11 *clause shall not apply to sales by a dis-*
12 *penser to another dispenser to fulfill a spe-*
13 *cific patient need; and*

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

17 “(B) *AGREEMENTS WITH THIRD PARTIES.—*

18 *A dispenser may enter into a written agreement*
19 *with a third party, including an authorized*
20 *wholesale distributor, under which the third*
21 *party confidentially maintains the transaction*
22 *information required to be maintained under*
23 *this subsection on behalf of the dispenser. If a*
24 *dispenser enters into such an agreement, the dis-*

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

3 “(C) *RETURNS EXCEPTION.*—

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

11 “(ii) *NONSALEABLE RETURNS.*—*Not-*
12 *withstanding subparagraph (A)(ii), a dis-*
13 *perser may return a nonsaleable prescrip-*
14 *tion drug to the manufacturer or repack-*
15 *ager, to the wholesale distributor from*
16 *whom such prescription drug was pur-*
17 *chased, to a returns processor, or to a per-*
18 *son acting on behalf of such persons without*
19 *providing the information required under*
20 *such subparagraph.*

21 “(D) *REQUESTS FOR INFORMATION.*—*Upon*
22 *a request by the Secretary or other appropriate*
23 *Federal or State official, in the event of a recall*
24 *or for the purpose of investigating a suspect pre-*
25 *scription drug product or an illegitimate pre-*

1 *scription drug product, a dispenser shall, not*
2 *later than 2 business days after receiving the re-*
3 *quest or in another such reasonable time as de-*
4 *termined by the Secretary, provide lot level*
5 *transaction information.*

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

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

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

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

24 “(i) *IN GENERAL.—Upon making a de-*
25 *termination that a prescription drug prod-*

1 *uct in the possession or control of the dis-*
2 *penser is a suspect prescription drug prod-*
3 *uct, or upon receiving a request for*
4 *verification from the Secretary that a pre-*
5 *scription drug product within the possession*
6 *or control of a dispenser is a suspect pre-*
7 *scription drug product, a dispenser shall*
8 *promptly conduct an investigation to deter-*
9 *mine whether the prescription drug product*
10 *is an illegitimate prescription drug product.*
11 *Such investigation shall include—*

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

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

1 “(III) *validating any applicable*
2 *transaction history in the possession of*
3 *the dispenser; and*

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

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

16 “(iii) *RECORDS.—A dispenser shall*
17 *keep records of its investigation of a suspect*
18 *prescription drug product for not less than*
19 *3 years after the conclusion of the investiga-*
20 *tion.*

21 “(B) *ILLEGITIMATE PRESCRIPTION DRUG*
22 *PRODUCT.—*

23 “(i) *IN GENERAL.—Upon receiving no-*
24 *tice that a manufacturer of a prescription*
25 *drug product has determined that a pre-*

1 *scription drug product in the possession or*
2 *control of a dispenser is an illegitimate pre-*
3 *scription drug product, the dispenser*
4 *shall—*

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

10 “(II) *provide for the disposition of*
11 *the illegitimate prescription drug prod-*
12 *uct within the possession or control of*
13 *the dispenser.*

14 “(ii) *TRADING PARTNERS.—Upon de-*
15 *termining that a prescription drug product*
16 *in the possession or control of a trading*
17 *partner is an illegitimate prescription drug*
18 *product, the dispenser shall take reasonable*
19 *steps to assist a trading partner to provide*
20 *for the disposition of the illegitimate pre-*
21 *scription drug product.*

22 “(iii) *MAKING A NOTIFICATION.—Upon*
23 *determining that a prescription drug prod-*
24 *uct in the possession or control of the dis-*
25 *penster is an illegitimate prescription drug*

1 *product, the dispenser shall notify the Sec-*
2 *retary of such determination not later than*
3 *24 hours after making such determination.*
4 *The Secretary shall determine whether addi-*
5 *tional trading partner notification is ap-*
6 *propriate.*

7 “(iv) *RESPONDING TO A NOTIFICA-*
8 *TION.—Upon the receipt of a notification*
9 *from the Secretary that a determination has*
10 *been made that a prescription drug product*
11 *is an illegitimate prescription drug product,*
12 *a dispenser shall—*

13 “(I) *identify all illegitimate pre-*
14 *scription drug products that are sub-*
15 *ject to such notification and in the pos-*
16 *session or control of the dispenser, in-*
17 *cluding any prescription drug product*
18 *that is subsequently received; and*

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

21 “(v) *RECORDS.—A dispenser shall keep*
22 *records of the disposition of an illegitimate*
23 *prescription drug product for not less than*
24 *3 years after the conclusion of the disposi-*
25 *tion.*

1 “(C) *ELECTRONIC DATABASE.*—*A dispenser*
2 *may satisfy the requirements of this paragraph*
3 *through the use of a secure electronic database*
4 *developed and operated by the manufacturer or*
5 *another entity. The owner of such database shall*
6 *establish the requirements and processes to enable*
7 *responding to requests and may provide for data*
8 *access to other members of the pharmaceutical*
9 *distribution supply chain, as appropriate. The*
10 *development and operation of such a database*
11 *shall not relieve a dispenser of the requirement*
12 *under this paragraph to respond to a*
13 *verification request submitted by means other*
14 *than a secure electronic database.*

15 “(e) *REPACKAGER REQUIREMENTS.*—

16 “(1) *PRESCRIPTION DRUG PRODUCT TRACING.*—

17 “(A) *IN GENERAL.*—*Beginning not later*
18 *than April 1, 2015, with respect to a prescrip-*
19 *tion drug product received by a repackager from*
20 *a wholesale distributor, and beginning not later*
21 *than January 1, 2015, with respect to any other*
22 *prescription drug product, a repackager shall—*

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

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

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

10 *“(iii) maintain the transaction infor-*
11 *mation for each transaction described in*
12 *clause (i) or (ii) for not less than 3 years*
13 *after the transaction; and*

14 *“(iv) maintain records that allow the*
15 *repackager to associate the prescription*
16 *drug product identifier the repackager af-*
17 *fixes or imprints with the prescription drug*
18 *product identifier assigned by the original*
19 *manufacturer of the prescription drug prod-*
20 *uct.*

21 *“(B) NONSALEABLE RETURNS.—Notwith-*
22 *standing subparagraph (A)(ii), a repackager*
23 *may return prescription drug product to the*
24 *trading partner from whom the repackager ob-*
25 *tained the prescription drug product without*

1 *providing the information required under such*
2 *subparagraph.*

3 “(C) *REQUESTS FOR INFORMATION.*—*Upon*
4 *a request by the Secretary or other appropriate*
5 *Federal or State official, in the event of a recall*
6 *or for the purpose of investigating a suspect pre-*
7 *scription drug product or an illegitimate pre-*
8 *scription drug product, a repackager shall, not*
9 *later than 2 business days after receiving the re-*
10 *quest or in such other reasonable time as deter-*
11 *mined by the Secretary, provide the applicable*
12 *transaction history and transaction statement*
13 *for the prescription drug product.*

14 “(2) *PRESCRIPTION DRUG PRODUCT IDENTI-*
15 *FIER.*—*Beginning not later than 6 years after the*
16 *date of the enactment of the Safeguarding America’s*
17 *Pharmaceuticals Act of 2013, a repackager—*

18 “(A) *shall affix or imprint a prescription*
19 *drug product identifier to each package and ho-*
20 *mogenous case of prescription drug product in-*
21 *tended to be introduced in a transaction;*

22 “(B) *shall maintain the prescription drug*
23 *product identifier for such prescription drug*
24 *product for not less than 3 years after the date*
25 *of the transaction; and*

1 “(C) may engage in transactions involving
2 a prescription drug product only if such pre-
3 scription drug product is encoded with a pre-
4 scription drug product identifier except as pro-
5 vided in subsection (a)(4).

6 “(3) *AUTHORIZED TRADING PARTNERS.*—Begin-
7 ning on January 1, 2015, a repackager shall ensure
8 that each of its trading partners is authorized.

9 “(4) *VERIFICATION.*—Beginning not later than
10 January 1, 2015, a repackager shall implement sys-
11 tems to enable the repackager to comply with the fol-
12 lowing requirements:

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

15 “(i) *IN GENERAL.*—Upon making a de-
16 termination that a prescription drug prod-
17 uct in the possession or control of the re-
18 packager is a suspect prescription drug
19 product, or upon receiving a request for
20 verification from the Secretary that a pre-
21 scription drug product within the possession
22 or control of a repackager is a suspect pre-
23 scription drug product, a repackager shall
24 promptly conduct an investigation to deter-
25 mine whether the prescription drug product

1 is an illegitimate prescription drug product,
2 including—

3 “(I) beginning not later than 6
4 years after the date of the enactment of
5 the *Safeguarding America’s Pharma-*
6 *ceuticals Act of 2013, verifying the pre-*
7 *scription drug product at the package*
8 *level;*

9 “(II) validating any applicable
10 *transaction information in the posses-*
11 *sion of the repackager; and*

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

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

24 “(iii) *RECORDS.—A repackager shall*
25 *keep records of its investigation of a suspect*

1 *prescription drug product for not less than*
2 *3 years after the conclusion of the investiga-*
3 *tion.*

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

6 “(i) *IN GENERAL.—Upon receiving no-*
7 *tice that a manufacturer of a prescription*
8 *drug product has determined that a pre-*
9 *scription drug product in the possession or*
10 *control of a repackager is an illegitimate*
11 *prescription drug product, the repackager*
12 *shall—*

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

18 “(II) *provide for the disposition of*
19 *the illegitimate prescription drug prod-*
20 *uct within the possession or control of*
21 *the repackager.*

22 “(ii) *TRADING PARTNER.—Upon deter-*
23 *mining that a prescription drug product in*
24 *the possession or control of a trading part-*
25 *ner is an illegitimate prescription drug*

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

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

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

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

1 *cluding any prescription drug product*
2 *that is subsequently received; and*

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

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

10 *“(C) ELECTRONIC DATABASE.—A repack-*
11 *ager may satisfy the requirements of this para-*
12 *graph through the use of a secure electronic data-*
13 *base developed and operated by the manufacturer*
14 *or another entity. The owner of such database*
15 *shall establish the requirements and processes to*
16 *respond to requests and may provide for data ac-*
17 *cess to other members of the pharmaceutical dis-*
18 *tribution supply chain, as appropriate. The de-*
19 *velopment and operation of such a database shall*
20 *not relieve a repackager of the requirement under*
21 *this paragraph to respond to a verification re-*
22 *quest submitted by means other than a secure*
23 *electronic database.*

24 *“(D) RETURNED PRESCRIPTION DRUG*
25 *PRODUCT.—Beginning not later than 6 years*

1 *after the date of the enactment of the Safe-*
2 *guarding America’s Pharmaceuticals Act of*
3 *2013, upon receipt of a returned prescription*
4 *drug product that the repackager intends to fur-*
5 *ther distribute, before further distributing such*
6 *prescription drug product, the repackager*
7 *shall—*

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

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

15 *“(f) THIRD-PARTY LOGISTICS PROVIDER REQUIRE-*
16 *MENTS.—*

17 *“(1) AUTHORIZED TRADING PARTNERS.—Begin-*
18 *ning on January 1, 2015, a third-party logistics pro-*
19 *vider shall ensure that each of its trading partners is*
20 *authorized.*

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

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

3 “(i) *IN GENERAL.—Upon making a de-*
4 *termination that a prescription drug prod-*
5 *uct in the possession or control of a third-*
6 *party logistics provider is a suspect pre-*
7 *scription drug product, a third-party logis-*
8 *tics provider shall promptly notify the*
9 *owner of such prescription drug product of*
10 *the need to conduct an investigation to de-*
11 *termine whether the prescription drug prod-*
12 *uct is an illegitimate prescription drug*
13 *product.*

14 “(ii) *CLEARED PRESCRIPTION DRUG*
15 *PRODUCT.—If the owner of the prescription*
16 *drug product notifies the third-party logis-*
17 *tics provider of the determination that a*
18 *suspect prescription drug product is not an*
19 *illegitimate prescription drug product, such*
20 *prescription drug product may be further*
21 *distributed.*

22 “(iii) *RECORDS.—A third-party logis-*
23 *tics provider shall keep records of the activi-*
24 *ties described in clauses (i) and (ii) with re-*
25 *spect to a suspect prescription drug product*

1 *for not less than 3 years after the conclusion*
2 *of the investigation.*

3 “(B) *ILLEGITIMATE PRESCRIPTION DRUG*
4 *PRODUCT.—*

5 “(i) *IN GENERAL.—Upon receiving no-*
6 *tice that a manufacturer of a prescription*
7 *drug product has determined that a pre-*
8 *scription drug product in the possession or*
9 *control of a third-party logistics provider is*
10 *an illegitimate prescription drug product,*
11 *the third-party logistics provider shall—*

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

17 “(II) *promptly notify the owner of*
18 *such prescription drug product of the*
19 *need to provide for the disposition of*
20 *such prescription drug product; and*

21 “(III) *promptly transfer posses-*
22 *sion of the prescription drug product*
23 *to the owner of such prescription drug*
24 *product to provide for the disposition*
25 *of the prescription drug product.*

1 “(ii) *MAKING A NOTIFICATION.*—Upon
2 *determining that a prescription drug prod-*
3 *uct in the possession or control of the third-*
4 *party logistics provider is an illegitimate*
5 *prescription drug product, the third-party*
6 *logistics provider shall notify the Secretary*
7 *not later than 24 hours after making such*
8 *determination. The Secretary shall deter-*
9 *mine whether additional trading partner*
10 *notification is appropriate.*

11 “(iii) *RESPONDING TO A NOTIFICA-*
12 *TION.*—Upon the receipt of a notification
13 *from the Secretary, a third-party logistics*
14 *provider shall—*

15 “(I) *identify all illegitimate pre-*
16 *scription drug product subject to such*
17 *notification that is in the possession or*
18 *control of the third-party logistics pro-*
19 *vider, including any prescription drug*
20 *product that is subsequently received;*
21 *and*

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

24 “(iv) *RECORDS.*—A third-party logis-
25 *tics provider shall keep records of the activi-*

1 *ties described in clauses (i) and (ii) with re-*
2 *spect to an illegitimate prescription drug*
3 *product for not less than 3 years after the*
4 *conclusion of the disposition.*

5 *“(g) DROP SHIPMENTS.—This section does not apply*
6 *to any entity, notwithstanding its status as a wholesale dis-*
7 *tributor or repackager, or other status that is not involved*
8 *in the physical handling, distribution, or storage of a pre-*
9 *scription drug product. For purposes of this subsection, fa-*
10 *cilitating the distribution of a prescription drug product*
11 *by providing various administrative services, including*
12 *processing of orders and payments, shall not, by itself, be*
13 *construed as being involved in the handling, distribution,*
14 *or storage of a prescription drug product.”.*

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

16 *(a) PILOT PROJECTS.—*

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

25 *(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 par-*
9 *ticipants 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 in-*
20 *ference;*

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 ex-*
5 *plore and evaluate methods to enhance the*
6 *safety and security of the pharmaceutical*
7 *distribution supply chain.*

8 ***(b) PUBLIC MEETINGS.—***

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

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

22 ***(A) Best practices in each of the sectors***
23 *within the pharmaceutical distribution supply*
24 *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 on
5 each pharmaceutical distribution supply chain
6 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 on
11 small businesses, and needed to protect public
12 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.

17 (E) The technical capabilities and legal au-
18 thorities, if any, needed to establish an electronic
19 system that provides for enhanced tracing of pre-
20 scription drug product at the package level.

21 (F) The impact that the requirements, sys-
22 tems, processes, capabilities, and legal authori-
23 ties referred to in subparagraphs (C), (D), and
24 (E) would have on patient safety, the drug sup-
25 ply, cost and regulatory burden, the timeliness of

1 *patient access to prescription drugs, and small*
2 *businesses.*

3 (c) *STUDY OF THE PHARMACEUTICAL DISTRIBUTION*
4 *SUPPLY CHAIN.—*

5 (1) *IN GENERAL.—The Comptroller General of*
6 *the United States shall conduct a study to examine*
7 *implementation of the requirements established under*
8 *subchapter H of chapter V of the Federal Food, Drug,*
9 *and Cosmetic Act, as added by section 2, in order to*
10 *inform the regulations promulgated under this sec-*
11 *tion.*

12 (2) *CONSIDERATION.—In conducting the study*
13 *under this subsection, the Comptroller General shall*
14 *provide for stakeholder input and shall consider the*
15 *following:*

16 (A) *The implementation of the requirements*
17 *established under such subchapter H with respect*
18 *to—*

19 (i) *the ability of the health care system*
20 *collectively to maintain patient access to*
21 *medicines;*

22 (ii) *the scalability of such require-*
23 *ments, including with respect to prescrip-*
24 *tion drug product lines; and*

1 (iii) the capability of different sectors
2 within the pharmaceutical distribution sup-
3 ply chain, including small businesses, to
4 affix and utilize the prescription drug prod-
5 uct identifier.

6 (B) The need for additional legal authori-
7 ties and activities to address additional gaps in
8 the pharmaceutical distribution supply chain, if
9 any, after the implementation of the require-
10 ments established under such subchapter H with
11 respect to—

12 (i) the systems and processes needed to
13 enhance tracing of prescription drug prod-
14 uct at the package level;

15 (ii) the impact, feasibility, and cost ef-
16 fectiveness that additional requirements
17 pursuant to this section would have on each
18 pharmaceutical distribution supply chain
19 sector and the public health; and

20 (iii) the systems and processes needed
21 to enhance interoperability among trading
22 partners.

23 (C) Risks to the security and privacy of
24 data collected, maintained, or exchanged pursu-

1 *ant to the requirements established under such*
2 *subchapter H.*

3 *(d) SMALL DISPENSERS.—*

4 *(1) IN GENERAL.—Not later than 10 years after*
5 *the date of the enactment of this Act, the Secretary*
6 *shall enter into a contract with a private, inde-*
7 *pendent consulting firm with relevant expertise to*
8 *conduct a technology and software study on the feasi-*
9 *bility of dispensers that have 25 or fewer full-time*
10 *employees conducting interoperable, electronic tracing*
11 *of prescription drug products at the package level.*

12 *(2) CONDITION.—As a condition of the award of*
13 *a contract under paragraph (1), the private inde-*
14 *pendent consulting firm awarded such contract shall*
15 *agree to consult with dispensers that have 25 or fewer*
16 *full-time employees when conducting the study under*
17 *such subparagraph.*

18 *(3) STUDY CONTENT.—The study conducted*
19 *under paragraph (1) shall assess whether, with re-*
20 *spect to conducting interoperable, electronic tracing of*
21 *prescription drug products at the package level, the*
22 *necessary hardware and software—*

23 *(A) is readily accessible to such dispensers;*

24 *(B) is not prohibitively expensive to obtain,*
25 *install, and maintain for such dispensers; and*

1 (C) can be integrated into business prac-
2 tices, such as interoperability with wholesale dis-
3 tributors, for such dispensers.

4 (4) *PUBLICATION.*—The Secretary shall pub-
5 lish—

6 (A) the statement of work for the study con-
7 ducted under paragraph (1) for public comment
8 not later than 30 days before commencing the
9 study; and

10 (B) the final version of such study for pub-
11 lic comment not later than 30 days after such
12 study is completed.

13 (5) *REPORT TO CONGRESS.*—Not later than 30
14 days after the date on which the study conducted
15 under paragraph (1) is completed, the Secretary shall
16 submit to the Committee on Energy and Commerce of
17 the House of Representatives and the Committee on
18 Health, Education, Labor, and Pensions of the Sen-
19 ate, a report on the findings of the study and any rec-
20 ommendations to improve the technology and software
21 available to small dispensers for purposes of con-
22 ducting electronic, interoperable tracing of prescrip-
23 tion drug products at the package level.

24 (6) *PUBLIC MEETING.*—Not later than 180 days
25 after the date on which the study conducted under

1 paragraph (1) is completed, the Secretary shall hold
2 a public meeting at which members of the public, in-
3 cluding stakeholders, may present their views on the
4 study.

5 (e) *REPORTS.*—

6 (1) *GAO REPORT.*—Not later than 12 years after
7 the date of the enactment of this Act, the Comptroller
8 General shall submit to the Committee on Energy and
9 Commerce of the House of Representatives and the
10 Committee on Health, Education, Labor, and Pen-
11 sions of the Senate a report on the results of the study
12 conducted under subsection (c).

13 (2) *FDA REPORT.*—Not later than 12 years after
14 the date of the enactment of this Act, the Secretary
15 shall submit to the Committee on Energy and Com-
16 merce of the House of Representatives and the Com-
17 mittee on Health, Education, Labor, and Pensions of
18 the Senate a report on the results of the pilot program
19 conducted under subsection (a), taking into consider-
20 ation—

21 (A) the comments received during the public
22 meetings conducted under subsection (b); and

23 (B) the results of the study conducted, and
24 the public comments received during the public
25 meeting held, under subsection (d).

1 (f) *ESTABLISHMENT OF ADDITIONAL REQUIRE-*
2 *MENTS.—*

3 (1) *IN GENERAL.—Notwithstanding any other*
4 *provision of this Act, including the amendments made*
5 *by this Act, not earlier than January 1, 2027, and*
6 *not later than March 1, 2027, the Secretary shall*
7 *issue proposed regulations that establish additional*
8 *requirements to prevent a suspect product, illegit-*
9 *imate product, or a product that is counterfeit, stolen,*
10 *diverted, or otherwise unfit for distribution from en-*
11 *tering into or being further distributed in the supply*
12 *chain, including—*

13 (A) *requirements related to the use of inter-*
14 *operable electronic systems and technologies for*
15 *enhanced tracing of prescription drug product at*
16 *the package level, which may include verification*
17 *of the prescription drug product identifier of a*
18 *package of prescription drug product and en-*
19 *hanced verification of saleable returns;*

20 (B) *requirements related to the use of addi-*
21 *tional prescription drug product identifiers or*
22 *prescription drug product identifier technology*
23 *that meet the standards developed under section*
24 *582(a)(2) of the Federal Food, Drug, and Cos-*
25 *metic Act, as added by section 2;*

1 (C) requirements related to the use of aggre-
2 gation, inference, and other methods, if deter-
3 mined to be necessary components of the systems
4 and technologies referred to in subparagraph (A);
5 and

6 (D) other data transmission and mainte-
7 nance requirements and interoperability stand-
8 ards.

9 (2) *FLEXIBILITY.*—The requirements described in
10 paragraph (1) shall provide for flexibility for a mem-
11 ber of the pharmaceutical supply chain, by—

12 (A) with respect to dispensers, allowing a
13 dispenser to enter into a written agreement with
14 a third party, including an authorized wholesale
15 distributor, under which—

16 (i) the third party confidentially
17 maintains any information required to be
18 maintained under such requirements for the
19 dispenser; and

20 (ii) the dispenser maintains a copy of
21 the written agreement and is not relieved of
22 the other obligations of the dispenser under
23 such requirements;

24 (B) establishing a process by which an au-
25 thorized manufacturer, repackager, wholesale dis-

1 *tributor, or dispenser may request a waiver from*
2 *any such requirements if the Secretary deter-*
3 *mines that such requirements would result in an*
4 *undue economic hardship on the manufacturer,*
5 *wholesale distributor, or dispenser;*

6 *(C) not requiring the adoption of specific*
7 *business systems by a member of the pharma-*
8 *ceutical supply chain for the maintenance and*
9 *transmission of prescription drug product trac-*
10 *ing data; and*

11 *(D) prescribing alternative methods of com-*
12 *pliance for small businesses, as specified in*
13 *paragraph (4).*

14 *(3) CONSIDERATIONS.—In issuing proposed reg-*
15 *ulations under paragraph (1), the Secretary shall*
16 *consider—*

17 *(A) the results of the pilot project conducted*
18 *under subsection (a);*

19 *(B) the public meetings held under sub-*
20 *section (b);*

21 *(C) the studies conducted under subsections*
22 *(c) and (d);*

23 *(D) the reports submitted under subsection*
24 *(e);*

1 (E) the public health benefits of such regula-
2 tions compared with the cost of compliance with
3 the requirements contained in such regulations,
4 including with respect to entities of varying sizes
5 and capabilities; and

6 (F) the diversity of the pharmaceutical dis-
7 tribution supply chain by providing appropriate
8 flexibility for each sector in the supply chain, in-
9 cluding small businesses.

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

18 (A) establishing timelines for such compli-
19 ance (including compliance by dispensers with
20 25 or fewer full-time employees) that do not im-
21 pose undue economic hardship for small busi-
22 nesses, including dispensers with respect to
23 which the study concluded has insufficient hard-
24 ware and software to conduct interoperable, elec-

1 *tronic tracing of prescription drug products at*
2 *the package level; and*

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

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

8 *(A) issue a notice of proposed rulemaking*
9 *that includes a copy of the proposed rule;*

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

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

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

22 *(g) DEFINITIONS.—In this section:*

23 *(1) The terms defined in section 581 of the Fed-*
24 *eral Food, Drug, and Cosmetic Act, as added by sec-*

1 *tion 2, shall have the same meanings in this section*
2 *as such terms are given in such section 581.*

3 *(2) The term “Secretary” means the Secretary of*
4 *Health and Human Services, acting through the Com-*
5 *missioner of Food and Drugs.*

6 **SEC. 4. NATIONAL STANDARDS FOR WHOLESALE DISTRIBUTORS.**
7 **TORS.**

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

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

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

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

19 *(3) in subchapter H, as added by section 2, by*
20 *adding at the end the following:*

21 **“SEC. 583. NATIONAL STANDARDS FOR WHOLESALE DIS-**
22 **TRIBUTORS.**

23 *“(a) STANDARDS.—*

1 “(1) *IN GENERAL.*—*The Secretary shall establish,*
2 *by regulation, standards for the licensing of persons*
3 *that make wholesale distributions.*

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

7 “(A) *the storage and handling of drugs sub-*
8 *ject to section 503(b)(1), including facility re-*
9 *quirements;*

10 “(B) *the establishment and maintenance of*
11 *records of the distributions of such drugs;*

12 “(C) *the furnishing of a bond or other*
13 *equivalent means of security in accordance with*
14 *paragraph (3);*

15 “(D) *mandatory background checks and*
16 *fingerprinting of facility managers or designated*
17 *representatives;*

18 “(E) *the establishment and implementation*
19 *of qualifications for key personnel;*

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

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

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

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

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

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

23 “(4) INSPECTIONS.—To satisfy the inspection re-
24 quirement under paragraph (2)(F), the Secretary

1 *may conduct the inspection, or may accept an inspec-*
2 *tion by—*

3 “(A) *the government of the State in which*
4 *the facility is located; or*

5 “(B) *a third-party accreditation or inspec-*
6 *tion service approved by the Secretary.*

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

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

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

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

23 “(1) *ANNUAL REPORT.—Beginning not later*
24 *than 1 year after the date of the enactment of this sec-*
25 *tion, each person engaged in wholesale distribution in*

1 *interstate commerce shall submit on an annual basis,*
2 *and update as necessary, a report to the Secretary in-*
3 *cluding—*

4 *“(A) the wholesale distributor’s name;*

5 *“(B) the wholesale distributor’s address;*

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

9 *“(D) any disciplinary actions taken by a*
10 *State, the Federal Government, or a foreign gov-*
11 *ernment during the reporting period against the*
12 *wholesale distributor.*

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

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

21 *“(1) licensing wholesale distributors for the con-*
22 *duct of wholesale distribution activities in the State*
23 *in accordance with this subchapter; and*

24 *“(2) collecting fees from wholesale distributors in*
25 *connection with such licensing,*

1 *so long as the State does not require such licensure to the*
2 *extent to which an entity is engaged in third-party logistics*
3 *provider activities.*

4 “(d) *DEFINITION.—In this section, the term ‘wholesale*
5 *distribution’ means the distribution of a drug subject to sec-*
6 *tion 503(b)(1) to a person other than a consumer or patient,*
7 *but does not include—*

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

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

15 “(3) *the distribution of a drug or an offer to dis-*
16 *tribute a drug for emergency medical reasons, includ-*
17 *ing a public health emergency declaration pursuant*
18 *to section 319 of the Public Health Service Act, except*
19 *that a drug shortage not caused by a public health*
20 *emergency shall not constitute such an emergency*
21 *medical reason;*

22 “(4) *dispensing of a drug pursuant to a valid*
23 *prescription executed in accordance with subsection*
24 *503(b)(1);*

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

4 “(6) the distribution of a drug or an offer to dis-
5 tribute a drug by a charitable organization to a non-
6 profit affiliate of the organization to the extent other-
7 wise permitted by law;

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

12 “(8) the distribution of a drug by the manufac-
13 turer of such drug;

14 “(9) the receipt or transfer of a drug by an au-
15 thorized third-party logistics provider provided that
16 such third-party logistics provider does not take own-
17 ership of the drug;

18 “(10) the transport of a drug by a common car-
19 rier, provided that the common carrier does not take
20 ownership of the drug;

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

1 “(12) saleable drug returns when conducted by a
2 dispenser in accordance with section 203.23 of title
3 21, Code of Federal Regulations (or any successor reg-
4 ulation);

5 “(13) the distribution of a combination prescrip-
6 tion drug product described in section
7 581(20)(B)(xiii);

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

10 “(15) the distribution of an intravenous drug
11 that, by its formulation, is intended for the replenish-
12 ment of fluids and electrolytes (such as sodium, chlo-
13 ride, and potassium) or calories (such as dextrose and
14 amino acids);

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

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

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

23 “(19) facilitating the distribution of a prescrip-
24 tion drug product by providing administrative serv-
25 ices, such as processing of orders and payments, with-

1 *out physical handling, distribution, or storage of a*
2 *prescription drug product; or*

3 *“(20)(A) the distribution of a product by a dis-*
4 *dispenser, or a wholesale distributor acting at the direc-*
5 *tion of the dispenser, to a repackager registered under*
6 *section 510 for the purpose of repackaging the drug*
7 *for use by that dispenser or another health care entity*
8 *that is under the dispenser’s ownership or control, so*
9 *long as the dispenser retains ownership of the pre-*
10 *scription drug product; and*

11 *“(B) the saleable or nonsaleable return by such*
12 *repackager of such prescription drug product.*

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

18 *(b) CONFORMING AMENDMENT.—Section 804(a)(5)(A)*
19 *of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
20 *384(a)(5)(A)) is amended by striking “503(e)(2)(A)” and*
21 *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, Drug,*
4 *and Cosmetic Act, as amended by section 4, is further*
5 *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 does*
18 *not have such a program; and*

19 *“(2) if the drug is distributed interstate and the*
20 *facility is not licensed by the Secretary under para-*
21 *graph (1)(B), registers with the State into which the*
22 *drug is distributed if such State requires such reg-*
23 *istration.*

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 sec-
3 tion, each facility engaged in the activities of a third-
4 party logistics provider shall submit on an annual
5 basis, and update as necessary, a report to the Sec-
6 retary 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 licensed
11 for third-party logistics provider activities; and

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

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

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

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

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

6 “(d) *COSTS.—*

7 “(1) *AUTHORIZED LICENSURE FEES.—In the*
8 *case of a facility engaging in the activities of a third-*
9 *party logistics provider licensed by the Secretary*
10 *under this section, the Secretary may assess and col-*
11 *lect a reasonable fee in an amount equal to the costs*
12 *to the Federal Government of establishing and admin-*
13 *istering the licensure program established, and con-*
14 *ducting period inspections, under this section.*

15 “(2) *ADJUSTMENT.—The Secretary shall adjust*
16 *the amount of the fee under paragraph (1) on an an-*
17 *nuual basis, if necessary, to generate an amount of rev-*
18 *enue equal to the costs referred to in such paragraph.*

19 “(3) *AVAILABILITY.—Fees assessed and collected*
20 *under this subsection shall be available for obligation*
21 *only to the extent and in the amount provided in ad-*
22 *vance in appropriations Acts. Such fees shall remain*
23 *available until expended.*

24 “(e) *LICENSE REGULATIONS.—*

1 “(1) *IN GENERAL.*—*The Secretary shall establish,*
2 *by regulation, standards, terms, and conditions for li-*
3 *censing persons to engage in third-party logistics pro-*
4 *vider activities.*

5 “(2) *CONTENT.*—*The regulations under para-*
6 *graph (1) shall—*

7 “(A) *include standards relating to eligi-*
8 *bility for, and revocation and reissuance of, li-*
9 *censes;*

10 “(B) *establish a process by which the appli-*
11 *cable licensing authority will, upon request by a*
12 *third-party logistics provider that is accredited*
13 *by a third-party accreditation program ap-*
14 *proved by the Secretary, issue a license to the*
15 *provider;*

16 “(C) *establish a process by which the Sec-*
17 *retary shall issue a license to a third-party logis-*
18 *tics provider if the Secretary is not able to ap-*
19 *prove a third-party accreditation program be-*
20 *cause no such program meets the Secretary’s re-*
21 *quirements necessary for approval of such a*
22 *third-party accreditation program;*

23 “(D) *require that the third-party logistics*
24 *provider comply with storage practices, as deter-*

1 *mined by the Secretary, at the provider’s facili-*
2 *ties, including—*

3 “(i) *maintaining access to warehouse*
4 *space of suitable size to facilitate safe oper-*
5 *ations, including a suitable area to quar-*
6 *antine suspect prescription drug product;*

7 “(ii) *maintaining adequate security;*
8 *and*

9 “(iii) *having written policies and pro-*
10 *cedures to—*

11 “(I) *address receipt, security, stor-*
12 *age, inventory, shipment, and distribu-*
13 *tion of a prescription drug product;*

14 “(II) *identify, record, and report*
15 *confirmed losses or thefts in the United*
16 *States;*

17 “(III) *correct errors and inac-*
18 *curacies in inventories;*

19 “(IV) *provide support for manu-*
20 *facturer recalls;*

21 “(V) *prepare for, protect against,*
22 *and address any reasonably foreseeable*
23 *crisis that affects security or operation*
24 *at the facility, such as a strike, fire, or*
25 *flood;*

1 “(VI) ensure that any expired
2 prescription drug product is segregated
3 from other prescription drug products
4 and returned to the manufacturer or
5 repackager or destroyed;

6 “(VII) maintain the capability to
7 electronically trace the receipt and out-
8 bound distribution of a prescription
9 drug product, and supplies and records
10 of inventory; and

11 “(VIII) quarantine or destroy a
12 suspect prescription drug product if di-
13 rected to do so by the respective manu-
14 facturer, wholesale distributor, dis-
15 penser, or an authorized government
16 agency;

17 “(E) provide for periodic inspection, as de-
18 termined by the Secretary, of such facility ware-
19 house space to ensure compliance with this sec-
20 tion;

21 “(F) prohibit a facility from having as a
22 manager or designated representative anyone
23 convicted of any felony violation of section
24 301(i) or 301(k) or any felony violation of sec-

1 *tion 1365 of title 18, United States Code, relat-*
2 *ing to prescription drug product tampering;*

3 *“(G) perform mandatory background checks*
4 *of the provider’s facility managers or designated*
5 *representatives of such managers;*

6 *“(H) require a third-party logistics pro-*
7 *vider to provide to the applicable licensing au-*
8 *thority, upon the authority’s request, a list of all*
9 *prescription drug product manufacturers, whole-*
10 *sale distributors, and dispensers for whom the*
11 *third-party logistics provider provides services at*
12 *the provider’s facilities; and*

13 *“(I) include procedures under which any*
14 *third-party logistics provider license—*

15 *“(i) will expire on the date that is 3*
16 *years after issuance of the license; and*

17 *“(ii) may be renewed for additional 3-*
18 *year periods.*

19 *“(f) VALIDITY OF LICENSE.—A license issued under*
20 *this section shall remain valid as long as such third-party*
21 *logistics provider remains accredited by the Secretary, sub-*
22 *ject to renewal under subsection (d). If the Secretary finds*
23 *that the third-party accreditation program demonstrates*
24 *that all applicable requirements for licensure under this sec-*
25 *tion are met, the Secretary shall issue a license under this*

1 *section to a third-party logistics provider receiving accredi-*
2 *tation.*

3 “(g) *QUALIFIED LICENSING PROGRAM DEFINED.*—*In*
4 *this section, the term ‘qualified licensing program’ means*
5 *a program meeting the requirements of this section and the*
6 *regulations thereunder.*

7 “(h) *EFFECTIVE DATE.*—*The requirements of this sec-*
8 *tion shall take effect not later than 1 year after the date*
9 *of the enactment of this section. The Secretary shall issue*
10 *the regulations required by subsection (d) not later than*
11 *180 days after the date of the enactment of this section.”.*

12 **SEC. 6. PENALTIES.**

13 “(a) *PROHIBITED ACTS.*—*Section 301(t) of the Federal*
14 *Food, Drug, and Cosmetic Act (21 U.S.C. 331(t)) is amend-*
15 *ed by striking “or the distribution of drugs in violation of*
16 *section 503(e) or the failure to otherwise comply with the*
17 *requirements of section 503(e)” and inserting “the failure*
18 *to comply with any requirement of section 582, engaging*
19 *in the wholesale distribution of a drug in violation of sec-*
20 *tion 583 or the failure to otherwise comply with the require-*
21 *ments of section 583, or engaging in the activities of a*
22 *third-party logistics provider in violation of section 584 or*
23 *the failure to otherwise comply with the requirements of sec-*
24 *tion 584”.*

1 (b) *ENHANCED PENALTY FOR KNOWING UNLICENSED*
2 *ACTIVITIES.*—Section 303(b)(1)(D) of the Federal Food,
3 *Drug, and Cosmetic Act (21 U.S.C. 333(b)(1)(D))* is
4 *amended by striking “503(e)(2)(A)” and inserting “583 or*
5 *584”.*

6 (c) *MISBRANDING.*—Section 502 of the Federal Food,
7 *Drug, and Cosmetic Act (21 U.S.C. 352)* is amended by
8 *adding at the end the following:*

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

11 **SEC. 7. UNIFORM NATIONAL POLICY.**

12 *Subchapter H of chapter V of the Federal Food, Drug,*
13 *and Cosmetic Act, as amended by section 5, is further*
14 *amended by adding at the end the following:*

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

16 “(a) *PREEMPTION OF STATE PRESCRIPTION DRUG*
17 *PRODUCT TRACING AND OTHER REQUIREMENTS.*—*Begin-*
18 *ning on the date of the enactment of the Safeguarding*
19 *America’s Pharmaceuticals Act of 2013, no State or polit-*
20 *ical subdivision of a State may establish or continue in ef-*
21 *fect any requirements for tracing drugs through the dis-*
22 *tribution system (including any requirements with respect*
23 *to paper or electronic pedigrees, track and trace, statements*
24 *of distribution history, transaction history, or transaction*
25 *statements, or verification, investigation, disposition, alerts,*

1 *or recordkeeping relating to the pharmaceutical distribution*
2 *supply chain system) that—*

3 “(1) *are inconsistent with, more stringent than,*
4 *or in addition to any requirements applicable under*
5 *this Act; or*

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

9 “(b) *STANDARDS OR LICENSURE.—*

10 “(1) *IN GENERAL.—Beginning on the date of the*
11 *enactment of Safeguarding America’s Pharma-*
12 *ceuticals Act of 2013, no State or political subdivision*
13 *of a State may establish or continue any standards,*
14 *requirements, or regulations with respect to wholesale*
15 *drug distributor or third-party logistics provider li-*
16 *cence which are inconsistent with, less stringent*
17 *than, in addition to, or more stringent than, the*
18 *standards and requirements under this Act.*

19 “(2) *LICENSING FEES.—Paragraph (1) does not*
20 *affect the authority of a State to collect fees from*
21 *wholesale drug distributors or third-party logistics*
22 *providers in connection with State licensing under*
23 *section 583 or 584 pursuant to a licensing program*
24 *meeting the requirements of such sections.*

1 “(3) *ENFORCEMENT, SUSPENSION, AND REVOCA-*
2 *TION OF LICENSES.*—*Notwithstanding paragraph (1),*
3 *a State—*

4 “(A) *may take administrative action, in-*
5 *cluding fines, to enforce a licensure requirement*
6 *promulgated by the State in accordance with*
7 *this Act;*

8 “(B) *may provide for the suspension or rev-*
9 *ocation of licenses issued by the State for viola-*
10 *tions of the laws of such State;*

11 “(C) *upon conviction of a person for a vio-*
12 *lation of Federal, State, or local controlled sub-*
13 *stance laws or regulations, may provide for fines,*
14 *imprisonment, or civil penalties; and*

15 “(D) *may regulate activities of entities li-*
16 *censed pursuant to section 583 or 584 in a man-*
17 *ner that is consistent with the provisions of this*
18 *subchapter.”.*

19 **SEC. 8 ELECTRONIC LABELING.**

20 (a) *IN GENERAL.*—*Section 502(f) of the Federal Food,*
21 *Drug, and Cosmetic Act (21 U.S.C. 352(f)) is amended by*
22 *adding at the end the following new sentence: “Required*
23 *labeling (other than immediate container or carton labels)*
24 *that is intended for use by a physician, a pharmacist, or*
25 *another health care professional, and that provides direc-*

1 *tions for human use of a drug subject to section 503(b)(1),*
2 *may (except as necessary to mitigate a safety risk, as speci-*
3 *fied by the Secretary in regulation) be made available by*
4 *electronic means instead of paper form, provided that such*
5 *labeling complies with all applicable requirements of law,*
6 *the manufacturer or distributor, as applicable, affords*
7 *health care professionals and authorized dispensers (as de-*
8 *finied in section 581) the opportunity to request the labeling*
9 *in paper form, and after such a request the manufacturer*
10 *or distributor promptly provides the requested information*
11 *without additional cost.”.*

12 *(b) REGULATIONS.—The Secretary of Health and*
13 *Human Services shall promulgate regulations imple-*
14 *menting the amendment made by subsection (a).*

15 *(c) APPLICATION.—The last sentence of section 502(f)*
16 *of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
17 *352(f)), as added by subsection (a), shall apply beginning*
18 *on the earlier of—*

19 *(1) the effective date of final regulations promul-*
20 *gated under subsection (b); or*

21 *(2) the day that is 180 days after the date of en-*
22 *actment of this Act.*

Union Calendar No. 65

113TH CONGRESS
1ST Session

H. R. 1919

[Report No. 113-93]

A BILL

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

JUNE 3, 2013

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed