

112TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice
and referred to the Committee on _____

A BILL

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

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

8 **“Subchapter G—Pharmaceutical Distribution**
9 **Supply Chain**

10 **“SEC. 581. DEFINITIONS.**

11 “In this subchapter:

1 “(1) ALERT.—The term ‘alert’ means a notifi-
2 cation to all affected trading partners that illegit-
3 imate product has been identified in the pharma-
4 ceutical distribution supply chain or has the poten-
5 tial to enter the pharmaceutical distribution supply
6 chain.

7 “(2) AUTHORIZED.—The term ‘authorized’
8 means:

9 “(A) in the case of a manufacturer or re-
10 packager, having a valid registration in accord-
11 ance with section 510;

12 “(B) in the case of a wholesale distributor,
13 having a valid license under State law or sec-
14 tion **【583】**, as applicable, and a valid listing in
15 accordance with section **【503(e)(4)】**;

16 **【“(C) in the case of a third-party logistics**
17 provider, having a valid license under State law
18 or section **【584(a)(1)】**, as applicable, and hav-
19 ing a valid listing in accordance with **【584(b)】**;
20 and**】**

21 “(D) in the case of a dispenser, having a
22 valid license under State law.

23 “(3) DISPENSER.—The term ‘dispenser’ means
24 a retail pharmacy, hospital pharmacy, or any other
25 person authorized by law to dispense or administer

1 prescription drugs [and the affiliated warehouses or
2 distribution centers of such entities under common
3 ownership and control that do not engage in whole-
4 sale distribution]. The term ‘dispenser’ does not in-
5 clude persons who dispense product solely to be used
6 in animals in accordance with section 512(a)(5).

7 “(4) DISPOSITION.—The term ‘disposition’
8 means ensuring that product does not reenter the
9 pharmaceutical distribution supply chain, which may
10 include disposal of the product or other actions such
11 as retaining a sample of the product for further ad-
12 ditional physical examination or laboratory analysis
13 of the product by a manufacturer or regulatory or
14 law enforcement agency.

15 “(5) DISTRIBUTE OR DISTRIBUTION.—The
16 term ‘distribute’ or ‘distribution’ means the sale,
17 purchase, trade, delivery, handling, storage, receipt,
18 or brokering of prescription drugs.

19 “(6) ILLEGITIMATE PRODUCT.—The term ‘ille-
20 gitimate product’ means a product for which credible
21 evidence shows that the product—

22 “(A) is [potentially] counterfeit, diverted,
23 or stolen;

24 “(B) is [potentially] intentionally adulter-
25 ated [such that the product would result in se-

1 rious adverse health consequences or death to
2 humans**】**; or

3 “(C) **【**appears otherwise unfit for distribu-
4 tion **【**such that the product could result in seri-
5 ous adverse health consequence or death to hu-
6 mans**】】**.”

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

8 “(A) in the case of a wholesale distributor,
9 having a valid license or licenses, as applicable,
10 to engage in wholesale distribution as required
11 under **【**section 583**】**;

12 “(B) in the case of a third-party logistics
13 provider, having a valid license to engage in
14 business as a third-party logistics provider as
15 required under **【**section 584**】**; and

16 “(C) in the case of a dispenser, having a
17 valid license under State law.

18 “(8) LISTED.—The term ‘listed’ means—

19 “(A) in the case of a wholesale distributor,
20 having a current **【**listing**】** with the Secretary as
21 required under **【**section 503(e)(4)**】**; and

22 “(B) in the case of a third-party logistics
23 provider, having a current **【**listing**】** with the
24 Secretary as required under **【**section 584(b)**】**.”

1 “(9) MANUFACTURER.—The term ‘manufac-
2 turer’ means, with respect to a product—

3 “(A) the person that holds the application
4 approved under section 505 or the license
5 issued under section 351 of the Public Health
6 Service Act for the product, or if the product is
7 not the subject of an approved application or li-
8 cense, the person who manufactured the prod-
9 uct;

10 “(B) a co-licensed partner of the person
11 described in subparagraph (A) that obtains the
12 product directly from the person described in
13 subparagraph (A) or (C); or

14 “(C) a co-licensed person that manufac-
15 tures the product for a person described in sub-
16 paragraph (A) or (B).

17 “(10) PACKAGE.—The term ‘package’ means
18 the smallest individual saleable unit of product for
19 distribution in **interstate** commerce by a manufac-
20 turer or repackager that is intended by the manufac-
21 turer for ultimate sale to the dispenser of such prod-
22 uct. An individual saleable unit is the smallest con-
23 tainer of product put into interstate commerce by
24 the manufacturer that is intended by the manufac-
25 turer for individual sale to a dispenser.

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

4 “(12) PRODUCT.—The term ‘product’ means a
5 prescription drug in a finished dosage form for ad-
6 ministration to a patient without substantial further
7 manufacturing (such as capsules, tablets, and
8 lyophilized products before reconstitution).

9 “(13) PRODUCT IDENTIFIER.—The term ‘prod-
10 uct identifier’ means a standardized graphic that in-
11 cludes, in both human-readable form and on a ma-
12 chine-readable data carrier that conforms to the
13 standards developed by a widely-recognized inter-
14 national standards development organization, the
15 standardized numerical identifier, lot number, and
16 expiration date of the product.

17 “(14) REPACKAGER.—The term ‘repackager’
18 means a person who owns or operates an establish-
19 ment that repacks and relabels a product or package
20 for further sale.

21 “(15) RETURN.—The term ‘return’ means pro-
22 viding product to the trading partner from which
23 such product was purchased and for which the trad-
24 ing partner returning such product receives com-
25 pensation.

1 “(16) RETURNS PROCESSOR.—The term ‘re-
2 turns processor’ means a person who owns or oper-
3 ates an establishment that dispositions or otherwise
4 processes nonsaleable product received from an au-
5 thorized trading partner such that the product may
6 not be further distributed.

7 “(17) SPECIFIC PATIENT NEED.—The term
8 ‘specific patient need’ refers to the transfer of a
9 product from one pharmacy to another to fill a pre-
10 scription for an identified patient. Such term does
11 not include the transfer of a product from one phar-
12 macy to another for the purpose of increasing or re-
13 plenishing stock in anticipation of a potential need.

14 “(18) STANDARDIZED NUMERICAL IDENTIFIER
15 OR SNI.—The term ‘standardized numerical identi-
16 fier’ or ‘SNI’ means a set of numbers or characters
17 used to uniquely identify each package or homoge-
18 nous case that is composed of the National Drug
19 Code that corresponds to the specific product (in-
20 cluding the particular package configuration) com-
21 bined with a unique alphanumeric serial number of
22 up to 20 characters.

23 “(19) SUSPECT PRODUCT.—The term ‘suspect
24 product’ means a product for which there is reason
25 to believe that such product—

1 “(A) is **【potentially】** counterfeit, diverted,
2 or stolen;

3 “(B) is **【potentially】** intentionally adulter-
4 ated **【such that the product would result in se-**
5 rious adverse health consequences or death to
6 humans**】**; or

7 “(C) **【appears otherwise unfit for distribu-**
8 tion **【such that the product would result in se-**
9 rious adverse health consequences or death to
10 humans**】】**.

11 “(20) **THIRD-PARTY LOGISTICS PROVIDER.—**
12 The term ‘third-party logistics provider’ means an
13 establishment that warehouses, stores, segregates, or
14 prepares for shipment product on behalf of a manu-
15 facturer, wholesale distributor, health care provider,
16 or dispenser, but which does not have any ownership
17 interest in the product. The term does not include
18 a common carrier unless, in addition to transporting
19 a product, the common carrier also performs any of
20 the activities described in the preceding sentence
21 with respect to that product.

22 “(21) **TRADING PARTNER.—**The term ‘trading
23 partner’ means—

24 “(A) a manufacturer, repackager, whole-
25 sale distributor, or dispenser from whom a

1 manufacturer, repackager, wholesale dis-
2 tributor, or dispenser accepts ownership of a
3 product or to whom a manufacturer, repack-
4 ager, wholesale distributor, or dispenser trans-
5 fers ownership of a product; or

6 “(B) a third-party logistics provider from
7 whom a manufacturer, repackager, wholesale
8 distributor, or dispenser accepts possession of a
9 product or to whom a manufacturer, repack-
10 ager, wholesale distributor, or dispenser trans-
11 fers possession of a product.

12 “(22) TRANSACTION.—

13 “(A) IN GENERAL.—The term ‘transaction’
14 means the transfer of product between persons
15 in which a change of ownership occurs, includ-
16 ing a return of product.

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

19 “(i) intracompany distribution of any
20 product **■**between members of an affiliated
21 group (as defined in section 1504(a) of the
22 Internal Revenue Code of 1986)**■**;

23 “(ii) the distribution of a product or
24 an offer to distribute a product among hos-

1 pitals or other health care entities that are
2 under common control;

3 “(iii) the distribution of a product or
4 an offer to distribute a product for emer-
5 gency medical reasons including a public
6 health emergency declaration pursuant to
7 section 319 of the Public Health Service
8 Act, except that a drug shortage not
9 caused by a public health emergency shall
10 not constitute an emergency medical rea-
11 son;

12 “(iv) the dispensing of a product pur-
13 suant to a valid prescription executed in
14 accordance with section 503(b);

15 “(v) the distribution of product sam-
16 ples by a manufacturer or a licensed
17 wholesale distributor in accordance with
18 section 503(d);

19 “(vi) the distribution of blood or blood
20 components intended for transfusion;

21 “(vii) the distribution of minimal
22 quantities of product by a licensed retail
23 pharmacy to a licensed practitioner for of-
24 fice use;

1 “(viii) the distribution of a product or
2 an offer to distribute a product by a chari-
3 table organization to a nonprofit affiliate
4 of the organization to the extent otherwise
5 permitted by law;

6 “(ix) the distribution of a product
7 pursuant to the sale or merger of a phar-
8 macy or pharmacies, except that any
9 records required to be maintained for the
10 product shall be transferred to the new
11 owner of the product;

12 [“(x) the dispensing of a product ap-
13 proved under section 512(b);]

14 [“(xi) [products transferred to or
15 from any facility that is licensed by the
16 Nuclear Regulatory Commission or by a
17 State pursuant to an agreement with such
18 Commission under section 274 of the
19 Atomic Energy Act of 1954 (42 U.S.C.
20 2021)]/ [radioactive drugs or radioactive
21 biological products (as defined in section
22 600.3(ee) of title 21, Code of Federal Reg-
23 ulations) that are regulated by the Nuclear
24 Regulatory Commission [*Note from work-*

1 *ing group*: Do these differ? Do we need
2 both/either?】;】

3 【“(xii) the purchase or other acquisi-
4 tion, by a hospital or other health care en-
5 tity that is a member of a group pur-
6 chasing organization, of a product for use
7 by such hospital or health care entity from
8 the group purchasing organization or from
9 other hospitals or health care entities that
10 are members of such organizations;】

11 【“(xiii) the distribution of a medical
12 convenience kit that contains products if—
13 】

14 【“(I) the medical convenience kit
15 is assembled in an establishment that
16 is registered with the Food and Drug
17 Administration as a medical device
18 manufacturer;】

19 【“(II) the medical convenience
20 kit manufacturer purchased the prod-
21 uct directly from the manufacturer or
22 from a wholesale distributor that pur-
23 chased the prescription drug directly
24 from the manufacturer;】

1 【“(III) the medical convenience
2 kit manufacturer does not alter the
3 primary container or label of the pre-
4 scription drug as purchased from the
5 manufacturer or wholesale dis-
6 tributor;】

7 【“(IV) the medical convenience
8 kit does not contain a controlled sub-
9 stance that appears in a schedule con-
10 tained in the Comprehensive Drug
11 Abuse Prevention and Control Act of
12 1970 (21 U.S.C. 801, et seq); and】

13 【“(V) the products contained in
14 the medical kit are—】

15 【“(aa) intravenous solutions
16 intended for the replenishment of
17 fluids and electrolytes;】

18 【“(bb) products intended to
19 maintain the equilibrium of water
20 and minerals in the body;】

21 【“(cc) products intended for
22 irrigation or reconstitution;】

23 【“(dd) anesthetics;】

24 【“(ee) anticoagulants;】

25 【“(ff) vasopressors; or】

1 [“(gg)

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

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

6 “(25) TRANSACTION STATEMENT.—The ‘trans-
7 action statement’ is a **【signed】** statement, in paper
8 or electronic form, that the entity transferring own-
9 ership in a transaction—

10 “(A) is authorized as required under **【this**
11 subchapter/section 582**】**;

12 “(B) received the product from a person
13 that is authorized as **【required under this sub-**
14 chapter/section 582**】**/**【as described in para-**
15 graph (2)**】**;

16 “(C) received the transaction information
17 and transaction statement **【required under this**
18 subchapter/section 582**】**/**【as described in para-**
19 graph (2)**】** from the prior owner of the product;

20 “(D) **【had systems and processes in place**
21 to prevent shipment of suspect product or ille-
22 gitimate product as prohibited under **【this sub-**
23 chapter/section 582**】** and**】** did not knowingly
24 and intentionally ship **【suspect product or ille-**
25 gitimate**】** product; and

“(E) attests to the accuracy of the transaction information provided to the subsequent owner of the product and attests that the entity has not altered the transaction history.

1 “(ii) the distribution of a product, or
2 an offer to distribute a product among hos-
3 pitals or other health care entities which
4 are under common control;

5 “(iii) the distribution of a product or
6 an offer to distribute a product for emer-
7 gency medical reasons, including a public
8 health emergency declaration pursuant to
9 section 319 of the Public Health Service
10 Act, except that a drug shortage not
11 caused by a public health emergency shall
12 not constitute an emergency medical rea-
13 son;

14 “(iv) dispensing of a product pursuant
15 to a valid prescription executed in accord-
16 ance with subsection 503(b);

17 “(v) the distribution of minimal quan-
18 tities of product by a licensed retail phar-
19 macy to a licensed practitioner for office
20 use;

21 “(vi) the distribution of a product or
22 an offer to distribute a product by a chari-
23 table organization to a nonprofit affiliate
24 of the organization to the extent otherwise
25 permitted by law;

1 “(vii) the purchase or other acquisi-
2 tion by a dispenser, hospital, or other
3 health care entity of a drug for use by
4 such dispenser, hospital, or other health
5 care entity;

6 “(viii) the distribution of product by
7 the manufacturer of the product;

8 “(ix) the receipt or transfer of a drug
9 by an authorized third-party logistics pro-
10 vider provided that such third-party logis-
11 tics provider does not take ownership of
12 the product;

13 “(x) a common carrier that transports
14 a prescription drug, provided that the com-
15 mon carrier does not take ownership of the
16 drug;

17 “(xi) the distribution of product, or
18 an offer to distribute product by an au-
19 thorized repackager that has taken owner-
20 ship of the product and repacked it in ac-
21 cordance with this **【subchapter】/【section**
22 **582(e)】**;

23 “(xii) product returns when conducted
24 by a dispenser in accordance with section

203.23 of title 21, Code of Federal Regulations (or any successor regulation);

【“(xiii) the distribution of a medical convenience kit that contains products if—
】

【“(I) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a medical device manufacturer;】

【“(II) the medical convenience kit manufacturer purchased the product directly from the manufacturer or from a wholesale distributor that purchased the prescription drug directly from the manufacturer;】

【“(III) the medical convenience kit manufacturer does not alter the primary container or label of the prescription drug as purchased from the manufacturer or wholesale distributor;】

【“(IV) the medical convenience kit does not contain a controlled substance that appears in a schedule con-

1 tained in the Comprehensive Drug
2 Abuse Prevention and Control Act of
3 1970 (21 U.S.C. 801, et seq); and】

4 【“(V) the products contained in
5 the medical kit are—】

6 【“(aa) intravenous solutions
7 intended for the replenishment of
8 fluids and electrolytes;】

9 【“(bb) products intended to
10 maintain the equilibrium of water
11 and minerals in the body;】

12 【“(cc) products intended for
13 irrigation or reconstitution;】

14 【“(dd) anesthetics;】

15 【“(ee) anticoagulants;】

16 【“(ff) vasopressors; or】

17 【“(gg)

18 sympathicomimetics;】

19 【“(xiv) the distribution of an intra-
20 venous product that, by its formulation, is
21 intended for the replenishment of fluids
22 and electrolytes (such as sodium, chloride,
23 and potassium) or calories (such as dex-
24 trose and amino acids);】

1 【“(xv) the distribution of an intra-
2 venous product used to maintain the equi-
3 librium of water and minerals in the body,
4 such as dialysis solutions;】

5 【“(xvi) the distribution of a product
6 that is intended for irrigation or recon-
7 stitution, or sterile water, whether intended
8 for such purposes or for injection; or】

9 “(xvii) the distribution of compressed
10 medical gas, as defined in subparagraph
11 (C).

12 “(C) For purposes of subparagraph
13 (B)(xvii), the term ‘compressed medical gas’
14 means any substance in its gaseous or cryogenic
15 liquid form that meets medical purity standards
16 and has application in a medical or homecare
17 environment, including oxygen and nitrous
18 oxide.

19 【“(D) SECRETARY AUTHORITY.—The Sec-
20 retary shall, by regulation, establish a process
21 by which to add products or transactions to, or
22 remove products or transactions from, the list
23 of exempted products and transactions under
24 subparagraph (B).】

1 **“SEC. 582. REQUIREMENTS.**

2 “(a) IN GENERAL.—

3 “(1) OTHER ACTIVITIES.—Each manufacturer,
4 repackager, wholesale distributor, third-party logis-
5 tics provider, and dispenser shall comply with the re-
6 quirements set forth in this section. **【If an entity**
7 meets the definition of more than one of the entities
8 listed in the preceding sentence, such entity shall
9 comply with all applicable requirements in this sec-
10 tion, but shall not be required to duplicate require-
11 ments.**】**

12 “(2) STANDARDS.—The Secretary shall, in con-
13 sultation with other appropriate Federal officials,
14 manufacturers, repackagers, wholesale distributors,
15 dispensers, and other pharmaceutical distribution
16 supply chain stakeholders, develop standards for the
17 interoperable exchange of transaction information
18 for tracking and tracing prescription drugs. **【The**
19 standards developed under this paragraph shall com-
20 ply with a form and format developed by a widely
21 recognized international standards development or-
22 ganization.**】** The Secretary shall publish such stand-
23 ards not later than **【2 years】** after the date of en-
24 actment of the **【short title】**.

25 “(3) WAIVERS, EXCEPTIONS, AND EXEMP-
26 TIONS.—

1 “(A) IN GENERAL.—Not later than 2 years
2 after the date of enactment of the [short title],
3 the Secretary shall, by guidance—

4 “(i) establish a process by which an
5 authorized manufacturer, repackager,
6 wholesale distributor, or dispenser may re-
7 quest a waiver from any of the require-
8 ments set forth in this section if the Sec-
9 retary determines that such requirements
10 would result in an undue economic hard-
11 ship or for emergency medical reasons, in-
12 cluding a public health emergency declara-
13 tion pursuant to section 319 of the Public
14 Health Service Act; and

15 “(ii) establish a process by which the
16 Secretary may determine exceptions to the
17 product identifier requirement if a product
18 is packaged in a container too small or
19 otherwise unable to accommodate a label
20 with sufficient space to bear the informa-
21 tion required for compliance with this sec-
22 tion.

23 “(B) ADDITIONAL EXEMPTIONS.—The
24 Secretary may, at any time, by guidance, deter-
25 mine other products or transactions that shall

1 be exempt from the requirements of this sec-
2 tion.

3 “(4) SELF-EXECUTING REQUIREMENTS.—Ex-
4 cept where otherwise specified, the requirements of
5 this **【section】** may be enforced without further regu-
6 lations or guidance from the Secretary.

7 “(5) GRANDFATHERED PRODUCT.—

8 “(A) IN GENERAL.—Not later than **【【1】/**
9 **【2】** years after the date of enactment of the
10 **【short title】**], the Secretary shall finalize guid-
11 ance specifying whether and under what cir-
12 cumstances product that is not labeled with a
13 product identifier and that is in the supply
14 chain at the time of the effective date of the re-
15 quirements of this section shall be exempted
16 from the requirements of this section.

17 **【“(B) WHOLESALER LICENSES.—Notwith-**
18 standing section 581(7)(A), until the date that
19 is 1 year after the effective date of the whole-
20 sale distributor licensing **【regulations】/【re-**
21 **quirements】** under section 583, the term ‘li-
22 censed wholesaler’ shall mean a wholesaler with
23 a valid license under State law.**】**

24 **【“(C) THIRD PARTY LOGISTICS PROVIDER**
25 LICENSES.—Until the date that is 1 year after

1 the effective date of the third-party logistics
2 provider licensing **【regulations】/【requirements】**
3 under section 584, a third-party logistics pro-
4 vider **【shall be considered ‘licensed’ under sec-**
5 **tion 581(7)(B) unless the Secretary has made**
6 **a finding that the third-party logistics provider**
7 **does not utilize good handling and distribution**
8 **practices and publishes notice thereof】 【or】**
9 **【has a valid wholesale distributor license under**
10 **State law】.】**

11 **【“(D) LABEL CHANGES.—Changes made**
12 **to package labels solely to incorporate the prod-**
13 **uct identifier may be submitted to the Secretary**
14 **in the annual report of an establishment, in ac-**
15 **cordance with section 314.70(d) of chapter 21,**
16 **Code of Federal Regulations (or any successor**
17 **regulation).】**

18 **“(b) MANUFACTURER REQUIREMENTS.—**

19 **“(1) PRODUCT TRACING.—**

20 **“(A) IN GENERAL.—Beginning not later**
21 **than 【6 months】/【1 year】 after the date of en-**
22 **actment of the 【short title】, a manufacturer**
23 **shall—**

24 **“(i) not accept ownership of a product**
25 **unless the previous owner【, prior to the**

1 transaction,] provides the transaction his-
2 tory, transaction information, and a trans-
3 action statement for the product;

4 “(ii) [upon]/[before] each trans-
5 action in which such manufacturer trans-
6 fers ownership of a product, provide the
7 subsequent owner with transaction history,
8 transaction information, and a transaction
9 statement;

10 “(iii) maintain the transaction infor-
11 mation [and product identifier] for each
12 transaction for not less than [2]/[10]
13 years after the date of the transaction; and

14 “(iv) beginning not later than [18
15 months]/[4 years] after the date of enact-
16 ment of [short title], affix or imprint a
17 product identifier to each package and ho-
18 mogenous case of product intended to be
19 introduced in a transaction in commerce.

20 “(B) NONSALEABLE RETURNS.—A manu-
21 facturer may return a nonsaleable prescription
22 drug to the manufacturer or repackager, to the
23 wholesale distributor from whom such prescrip-
24 tion drug was purchased, or to a person acting
25 on behalf of such a person, including a returns

1 processor, without providing the information re-
2 quired under subparagraph (A)(ii).

3 “(2) AUTHORIZED TRADING PARTNERS.—Be-
4 ginning not later than **【3 months】/【2 years】** after
5 the date of enactment of the **【short title】**, the trad-
6 ing partners of a manufacturer may be only author-
7 ized trading partners.

8 “(3) VERIFICATION.—

9 “(A) IN GENERAL.—Beginning not later
10 than **【18 months】/【4 years】** after the date of
11 enactment of **【insert short title】**, a manufac-
12 turer shall comply with the following require-
13 ments:

14 “(i) A manufacturer shall have sys-
15 tems in place to enable the manufacturer
16 to respond to verification requests de-
17 scribed in clause (ii).

18 “(ii) Upon receiving a request for
19 verification from an authorized **【manufac-**
20 **turer,】** repackager, wholesale distributor,
21 or dispenser, a manufacturer shall, not
22 later than **【24 hours after receiving】** the
23 verification request, notify the person mak-
24 ing the request whether the product identi-
25 fier, including the standard numeric identi-

1 fier, that is the subject of the request cor-
2 responds to the product identifier affixed
3 or imprinted by the manufacturer. If the
4 manufacturer has any reason to believe the
5 product is a suspect product or illegitimate
6 product, the manufacturer shall advise the
7 person making the request of such belief at
8 the time such manufacturer responds to
9 the verification request.

10 “(B) ELECTRONIC DATABASE.—A manu-
11 facturer may satisfy the requirements of sub-
12 paragraph (A) by developing a secure electronic
13 database that can be accessed and queried by
14 appropriate members of the pharmaceutical dis-
15 tribution supply chain, except that the estab-
16 lishment and operation of such a database shall
17 not relieve a manufacturer of the requirement
18 under subparagraph (A)(ii) to respond to a
19 verification request submitted by means other
20 than the electronic database.

21 “(C) PRESUMED SUSPECT PRODUCT.—If a
22 manufacturer conducting a verification identi-
23 fies a product identifier that does not cor-
24 respond to the product identifier affixed or im-
25 printed by the manufacturer, the manufacturer

1 shall treat such product as suspect product and
2 conduct an investigation as described in para-
3 graph (4).

4 “(D) RETURNED PRODUCT.—Upon receipt
5 of a returned product that the manufacturer in-
6 tends to further distribute, before further dis-
7 tributing such product, the manufacturer shall
8 verify the product identifier for each sealed ho-
9 mogeneous case of such product or, if such
10 product is not in a sealed homogeneous case,
11 verify the product identifier on each package.

12 “(4) INVESTIGATION.—

13 “(A) IN GENERAL.—Beginning not later
14 than **【6 months】/【1 year】** after the date of en-
15 actment of the **【short title】**, a manufacturer
16 shall have systems in place to identify suspect
17 product, segregate suspect product or illegit-
18 imate product within the possession or control
19 of the manufacturer from product intended for
20 distribution, and investigate suspect product.

21 “(B) TREATMENT OF SUSPECT PROD-
22 UCT.—

23 “(i) IN GENERAL.—Upon identifying
24 a product as a suspect product, a manufac-
25 turer shall—

1 “(I) segregate such product with-
2 in the possession or control of the
3 manufacturer from product intended
4 for distribution; and

5 “(II) promptly conduct an inves-
6 tigation in coordination with affected
7 trading partners, as applicable, to de-
8 termine whether the product is an ille-
9 gitimate product, including verifying
10 product information, authenticating
11 any applicable [transaction history
12 and] transaction information in the
13 possession of the manufacturer, and
14 otherwise investigating to determine
15 whether the product is an illegitimate
16 product.

17 “(ii) CLEARED PRODUCT.—If suspect
18 product is determined not to be illegitimate
19 product, such product may be further dis-
20 tributed.

21 [“(C) RECORDS.—A manufacturer shall
22 keep records of the investigation of a suspect
23 product for not less than [2]/[10] years after
24 the conclusion of the investigation. *[Note from*

1 *working group*: This option would include prod-
2 uct investigated and cleared.]]

3 “(D) REQUESTS FOR INFORMATION.—
4 Upon a request by the Secretary or other ap-
5 propriate Federal or State official, in the event
6 of a recall or for the purpose of investigating a
7 suspect product, illegitimate product, or recalled
8 product, a manufacturer shall, not later than
9 [24 hours] after receiving the request or in
10 other such reasonable time as determined by
11 the Secretary, provide the applicable trans-
12 action information, transaction history, and
13 transaction statements for the product.

14 “(5) DISPOSITION.—

15 “(A) SYSTEMS FOR DISPOSITION OF ILLE-
16 GITIMATE PRODUCT.—Beginning not later than
17 [6 months]/[1 year] after the date of enact-
18 ment of the [short title], a manufacturer shall
19 have systems in place to—

20 “(i) properly disposition product with-
21 in the possession or control of the manu-
22 facturer, as appropriate, to ensure that il-
23 legitimate product does not enter the phar-
24 maceutical distribution supply chain; and

1 “(ii) take reasonable steps to remove
2 illegitimate product not in the possession
3 or control of the manufacturer from the
4 pharmaceutical distribution supply chain.

5 “(B) DISPOSITION OF ILLEGITIMATE
6 PRODUCT.—Upon determining that a product in
7 the possession or control of a manufacturer is
8 an illegitimate product, the manufacturer shall
9 promptly notify the Secretary and properly dis-
10 position such product.

11 【“(C) RECORDS.—A manufacturer shall
12 keep records of an investigation of an illegit-
13 imate product for not less than 【2】/【10】 years
14 after the conclusion of the investigation.】

15 “(6) ALERTS.—Beginning not later than 【6
16 months】/【1 year】 after the date of enactment of the
17 【short title】, a manufacturer shall comply with the
18 following:

19 “(A) A manufacturer shall maintain sys-
20 tems to enable the manufacturer to receive,
21 issue, and terminate alerts. Such systems shall
22 include means to identify affected trading part-
23 ners to whom alerts are required to be sent
24 under this 【section】.

1 “(B) Upon determining that a product in
2 the possession or control of the manufacturer is
3 an illegitimate product, the manufacturer shall
4 issue an alert to the Secretary and all affected
5 trading partners not later than 24 hours after
6 making such determination.

7 “(C) A manufacturer shall issue alerts to
8 the Secretary and affected trading partners not
9 later than 24 hours after determining or being
10 notified by the Secretary or a trading partner
11 that there is a high risk that a product manu-
12 factured by, or purported to be a product man-
13 ufactured by, the manufacturer is a suspect
14 product. For purposes of this subparagraph, a
15 ‘high-risk’ may include a specific high-risk that
16 could increase the risk that illegitimate product
17 will enter into distribution and other high risks,
18 as determined by the Secretary in guidance.

19 “(D) Upon a determination, in consulta-
20 tion with the Secretary, that an alert is no
21 longer necessary, a manufacturer shall promptly
22 notify affected trading partners that such alert
23 has been terminated.

24 “(E) Upon the receipt of an alert from the
25 Secretary or a trading partner, a manufacturer

1 shall identify all product subject to such alert
2 that is in the possession or control of the manu-
3 facturer, including any product that is subse-
4 quently received, and treat such product as sus-
5 pect product.

6 “(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

7 “(1) PRODUCT TRACING.—

8 “(A) IN GENERAL.—Beginning not later
9 than **【6 months】/【1 year】** after the date of en-
10 actment of the **【short title】**, a wholesale dis-
11 tributor shall—

12 “(i) not accept ownership of a product
13 unless the previous owner**【**, prior to the
14 transaction,**】** provides the transaction his-
15 tory, transaction information, and a trans-
16 action statement for the product;

17 “(ii) **【upon】/【before】** each trans-
18 action in which the wholesale distributor
19 transfers ownership of a product, provide
20 the subsequent owner with transaction his-
21 tory, transaction information, and a trans-
22 action statement for the product;

23 “(iii) maintain the transaction infor-
24 mation for each transaction described in

1 clauses (i) and (ii) for not less than **【2】**/
2 **【10】** years after the transaction; and

3 “(iv) beginning not later than **【30**
4 **months】**/**【6 years】** after the date of enact-
5 ment of **【insert short title】**, engage in
6 transactions involving product only if such
7 product is encoded with a product identi-
8 fier **【except as provided in grandfathering**
9 **provisions】**.

10 **【“(B) RETURNS 【EXCEPTION】.—】**

11 **【“(i) SALEABLE RETURNS.—Notwith-**
12 **standing subparagraph (A)(i)—】**

13 **【“(I) OPTION 1.—a wholesale**
14 **distributor shall maintain systems and**
15 **processes to allow the wholesale dis-**
16 **tributor to accept returns from dis-**
17 **pensers and associate returned prod-**
18 **uct with the transaction information**
19 **and transaction statement associated**
20 **with that product. 【Note from working**
21 **group: This option would enable dis-**
22 **pensers to return product without pro-**
23 **viding transaction information, trans-**
24 **action history, and transaction state-**
25 **ment.】】**

1 【“(II) OPTION 2.—a wholesale
2 distributor may accept returned prod-
3 uct from a dispenser only if the whole-
4 sale distributor can associate returned
5 product with the transaction informa-
6 tion and transaction statement associ-
7 ated with that product. 【For purposes
8 of this 【paragraph】, the transaction
9 information and transaction history
10 need not include transaction dates if
11 it is not reasonably practicable to ob-
12 tain such dates.】 *【Note from working*
13 *group:* This option would enable dis-
14 pensers to return product without pro-
15 viding transaction information, trans-
16 action history, and transaction state-
17 ment, if the wholesaler could match
18 the return to the associated trans-
19 action information, history, and state-
20 ment.】】

21 【“(III) OPTION 3.—a wholesale
22 distributor may accept returned prod-
23 uct from a dispenser, and, notwith-
24 standing subparagraph 【(A)(ii)】, may
25 distribute such returned product with-

1 out providing the transaction history.
2 For all future transactions, the trans-
3 action history of such product shall
4 begin with the wholesale distributor
5 that accepted and verified the re-
6 turned product.】

7 【“(IV) OPTION 4.—*Note from*
8 *working group:* Deleting subparagraph
9 (B)(i) such that there is no exception
10 for saleable returns would mean that
11 the wholesaler could not accept re-
12 turns that are not accompanied by a
13 pedigree, which means in turn a dis-
14 penser would have to maintain pedi-
15 grees to return product.】

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

1 “(2) AUTHORIZED TRADING PARTNERS.—Be-
2 ginning not later than **【3 months】/【2 years】** after
3 the date of enactment of the **【short title】**, the trad-
4 ing partners of a wholesale distributor may be only
5 authorized trading partners.

6 “(3) VERIFICATION.—Beginning not later than
7 **【30 months】/【6 years】** after the date of enactment
8 of **【insert short title】**, a wholesale distributor—

9 “(A) shall have systems in place to enable
10 the wholesale distributor to verify product as
11 required under this section;

12 “(B) upon identifying a suspect product,
13 shall verify the authenticity of the product with
14 the manufacturer or repackager that imprinted
15 or affixed the product identifier onto the prod-
16 uct;

17 “(C) upon receipt of a returned product
18 that the wholesaler distributor intends to fur-
19 ther distribute in the pharmaceutical distribu-
20 tion supply chain, before further distributing
21 such product, shall verify the product identifier
22 data for each sealed homogeneous case of such
23 product or, if such product is not in a sealed
24 homogeneous case, verify the product identifier
25 on each package; and

1 “(D) shall submit verification requests
2 under this paragraph to the manufacturer or
3 repackager through reasonable means including
4 querying an electronic database, placing a
5 phone call, or other means specified by the
6 manufacturer or repackager.

7 “(4) INVESTIGATION.—

8 “(A) IN GENERAL.—Beginning not later
9 than **【6 months】/【1 year】** after the date of en-
10 actment of the **【short title】**, a wholesale dis-
11 tributor shall—

12 “(i) have systems in place to identify
13 suspect product, segregate suspect product
14 or illegitimate product within the posses-
15 sion or control of the wholesale distributor
16 from product intended for distribution, and
17 investigate suspect product; and

18 “(ii) upon the receipt of an alert from
19 the Secretary or a trading partner, or the
20 independent observation of the wholesale
21 distributor of factors that would make the
22 product a suspect product, treat such prod-
23 uct as suspect product.

24 “(B) TREATMENT OF SUSPECT PROD-
25 UCT.—

1 “(i) IN GENERAL.—Upon identifying
2 a product as a suspect product, a wholesale
3 distributor shall—

4 “(I) segregate such product with-
5 in the possession or control of the
6 wholesale distributor from product in-
7 tended for distribution; and

8 “(II) promptly conduct an inves-
9 tigation in coordination with affected
10 trading partners, as applicable, to de-
11 termine whether the product is an ille-
12 gitimate product. Such investigation
13 shall include verifying product infor-
14 mation, authenticating any applicable
15 **【transaction history and】** transaction
16 information, and otherwise inves-
17 tigating to determine whether the
18 product is an illegitimate product.

19 “(ii) CLEARED PRODUCT.—If suspect
20 product is determined not to be illegitimate
21 product, such product may be further dis-
22 tributed.

23 **【“(C) RECORDS.—A wholesale distributor**
24 **shall keep records of the investigation of the**
25 **suspect product for not less than 【2】/【10】**

1 years after the conclusion of the investigation.

2 **【*Note from working group:* This option would**
3 **include product investigated and cleared.】】**

4 “(D) REQUESTS FOR INFORMATION.—

5 Upon a request by the Secretary or other ap-
6 propriate Federal or State official, in the event
7 of a recall or for the purpose of investigating a
8 suspect product, illegitimate product, or recalled
9 product, a wholesale distributor shall, not later
10 than **【24 hours】** after receiving the request or
11 in other such reasonable time as determined by
12 the Secretary, provide the applicable trans-
13 action information, transaction history, and
14 transaction statements for the product.

15 “(5) DISPOSITION.—

16 “(A) SYSTEMS FOR DISPOSITION OF ILLE-
17 GITIMATE PRODUCT.—Beginning not later than
18 **【6 months】/【1 year】** after the date of enact-
19 ment of the **【short title】**, a wholesale dis-
20 tributor shall have systems in place to—

21 “(i) properly disposition product with-
22 in the possession or control of the whole-
23 sale distributor, as appropriate, to ensure
24 that illegitimate product does not enter the

1 pharmaceutical distribution supply chain;
2 and

3 “(ii) take reasonable steps to remove
4 illegitimate product not in the possession
5 or control of the wholesale distributor from
6 the pharmaceutical distribution supply
7 chain.

8 “(B) DISPOSITION OF ILLEGITIMATE
9 PRODUCT.—Upon determining that a product in
10 the possession or control of a wholesale dis-
11 tributor is an illegitimate product, the wholesale
12 distributor shall promptly notify the Secretary
13 and properly disposition such product.

14 【“(C) RECORDS.—A wholesale distributor
15 shall keep records of an investigation of an ille-
16 gitimate product for not less than 【2】/【10】
17 years after the conclusion of the investigation.】

18 “(6) ALERTS.—Beginning not later than 【6
19 months】/【1 year】 after the date of enactment of the
20 【short title】, a wholesale distributor shall comply
21 with the following:

22 “(A) A wholesale distributor shall maintain
23 systems to enable the wholesale distributor to
24 receive, issue, and terminate alerts. Such sys-
25 tems shall include means to identify affected

1 trading partners to whom alerts are required to
2 be sent under this section.

3 “(B) Upon the receipt of an alert from the
4 Secretary or a trading partner, a wholesale dis-
5 tributor shall identify all product subject to
6 such alert that is in the possession or control of
7 the wholesale distributor, including any product
8 that is subsequently received, and treat such
9 product as suspect product.

10 “(C) Upon determining that a product in
11 the possession or control of the wholesale dis-
12 tributor is an illegitimate product, a wholesale
13 distributor shall issue an alert to the Secretary
14 and all affected trading partners not later than
15 24 hours after making such determination.

16 “(D) Upon a determination, in consulta-
17 tion with the Secretary, that an alert is no
18 longer necessary, a wholesale distributor shall
19 promptly notify affected trading partners that
20 such alert has been terminated.

21 “(d) DISPENSER REQUIREMENTS.—

22 “(1) PRODUCT TRACING.—

23 “(A) IN GENERAL.—Beginning not later
24 than **【6 months】/【1 year】** after the date of en-
25 actment of the **【short title】**, a dispenser—

1 “(i) shall not accept ownership of a
2 product, unless the previous owner~~],~~ prior
3 to the transaction,~~]~~ provides transaction
4 history, transaction information, and a
5 transaction statement;

6 “(ii) ~~]~~~~[~~upon~~]~~/~~]~~before~~]~~ each trans-
7 action in which the dispenser transfers
8 ownership of a product (but not including
9 dispensing to a patient), shall provide the
10 subsequent owner with transaction history,
11 transaction information, and a transaction
12 statement for the product, except that the
13 requirements of this clause shall not apply
14 to sales by a dispenser to another dis-
15 penser to fulfill a specific patient need;

16 “(iii) shall maintain transaction infor-
17 mation as necessary, but not longer than
18 ~~]~~~~[~~2~~]~~/~~]~~4~~]~~/~~]~~7~~]~~ years after the transaction to
19 respond to an alert or recall or to inves-
20 tigate suspect product; and

21 “(iv) beginning not later than ~~]~~~~[~~3~~]~~/
22 ~~]~~~~[~~7~~]~~ years after the date of enactment of
23 ~~]~~~~[~~insert short title~~]~~, may engage in trans-
24 actions involving product only if such prod-
25 uct is encoded with a product identifier

1 【except as provided in grandfathering pro-
2 visions】.

3 “(B) AGREEMENTS WITH THIRD PAR-
4 TIES.—A dispenser may enter into a written
5 agreement with a third party, including an au-
6 thorized wholesale distributor, under which the
7 third party confidentially maintains the trans-
8 action information required to be maintained
9 under this subsection on behalf of the dis-
10 penser. If a dispenser enters into such an
11 agreement, the dispenser shall maintain a copy
12 of the written agreement and shall not be re-
13 lieved of the other obligations of the dispenser
14 under this subsection.

15 【“(C) RETURNS EXCEPTION.—*Note from*
16 *working group:* If choose to do any of the re-
17 turns options (1), (2) or (3) in subsection
18 (c)(1)(B)(i), then insert clause (i):】

19 【“(i) SALEABLE RETURNS.—A dis-
20 penser may return product to the trading
21 partner from which the dispenser obtained
22 the product without providing the informa-
23 tion required under subparagraph (B).】

24 “(ii) NONSALEABLE RETURNS.—A
25 dispenser may return a nonsaleable pre-

1 scription drug to the manufacturer or re-
2 packager, to the wholesale distributor from
3 whom such prescription drug was pur-
4 chased, to a returns processor, or to a per-
5 son acting on behalf of such persons with-
6 out providing the information required
7 under subparagraph (A)(i).

8 “(2) AUTHORIZED TRADING PARTNERS.—Be-
9 ginning not later than **【3 months】**/**【2 years】** after
10 the date of enactment of the **【short title】**, the trad-
11 ing partners of a dispenser may be only authorized
12 trading partners.

13 “(3) VERIFICATION.—Beginning not later than
14 **【3】**/**【7】** years after the date of enactment of **【insert**
15 short title**】**, a dispenser—

16 “(A) shall have systems in place to enable
17 the dispenser to verify product as required
18 under this section; and

19 “(B) upon identifying a suspect product,
20 shall

21 “(i) confirm whether the lot number
22 of the suspect product corresponds with a
23 legitimate lot number for the product;

24 “(ii) verify at least **【3 packages or**
25 10% of the affected product, whichever is

1 greater, or all packages, if there are fewer
2 than 3,] with the manufacturer or repack-
3 ager that imprinted or affixed the product
4 identifier onto the product; and

5 “(iii) submit a verification request
6 under this paragraph to the manufacturer
7 or repackager through reasonable means,
8 including querying an electronic database,
9 placing a phone call, or other means speci-
10 fied by the manufacturer or repackager.

11 “(4) INVESTIGATION.—

12 “(A) IN GENERAL.—Beginning not later
13 than [6 months]/[1 year] after the date of en-
14 actment of the [short title], a dispenser shall—

15 “(i) have systems in place to identify
16 suspect product, segregate suspect product
17 or illegitimate product within the posses-
18 sion or control of the dispenser from prod-
19 uct intended for dispensing or further dis-
20 tribution, and investigate suspect product;
21 and

22 “(ii) upon the receipt of an alert from
23 the Secretary or a trading partner, or the
24 independent observation of the dispenser of
25 factors that would make the product a sus-

1 pect product, a dispenser shall treat such
2 product as suspect product.

3 “(B) TREATMENT OF SUSPECT PROD-
4 UCT.—

5 “(i) IN GENERAL.—Upon identifying
6 a product as a suspect product, a dispenser
7 shall—

8 “(I) segregate such product with-
9 in the possession or control of the dis-
10 penser from product intended for dis-
11 tribution; and

12 “(II) promptly conduct an inves-
13 tigation in coordination with affected
14 trading partners, as applicable, to de-
15 termine whether the product is an ille-
16 gitimate product, which shall include
17 verifying product information as de-
18 scribed in paragraph (3), authen-
19 ticating any applicable **【**transaction
20 history and**】** transaction information,
21 and otherwise investigating to deter-
22 mine whether the product is an illegit-
23 imate product.

24 “(ii) CLEARED PRODUCT.—If suspect
25 product is determined not to be illegitimate

1 product, such product may be dispensed or
2 further distributed.

3 **“(C) RECORDS.—**A dispenser shall keep
4 records of the investigation of the suspect prod-
5 uct for not less than **【2】/【10】** years after the
6 conclusion of the investigation. **【***Note from*
7 *working group:* This option would include prod-
8 uct investigated and cleared.**】**

9 **“(D) REQUESTS FOR INFORMATION.—**
10 Upon a request by the Secretary or other ap-
11 propriate Federal or State official, in the event
12 of a recall or for the purpose of investigating a
13 suspect, illegitimate, or recalled product, a dis-
14 penser shall, not later than **【2 business days】**
15 after receiving the request or in another such
16 reasonable time as determined by the Secretary,
17 provide lot level transaction information and the
18 immediate previous source of the product, and,
19 as applicable, the immediate subsequent recipi-
20 ent of the product.

21 **“(5) DISPOSITION.—**

22 **“(A) SYSTEMS FOR DISPOSITION OF ILLE-**
23 **GITIMATE PRODUCT.—**Beginning not later than
24 **【6 months】/【1 year】** after the date of enact-

1 ment of the [short title], a dispenser shall have
2 systems in place to—

3 “(i) properly disposition product with-
4 in the possession or control of the dis-
5 penser, as appropriate, to ensure that ille-
6 gitimate product does not enter the phar-
7 maceutical distribution supply chain; and

8 “(ii) take reasonable steps to remove
9 illegitimate product not in the possession
10 or control of the dispenser from the phar-
11 maceutical distribution supply chain.

12 “(B) DISPOSITION OF ILLEGITIMATE
13 PRODUCT.—Upon determining that a product in
14 the possession or control of the dispenser is an
15 illegitimate product, the dispenser shall prompt-
16 ly notify the Secretary and properly disposition
17 such product.

18 [“(C) RECORDS.—A dispenser shall keep
19 records of an investigation of an illegitimate
20 product for not less than [2]/[10] years after
21 the conclusion of the investigation.]

22 “(6) ALERTS.—Beginning not later than [6
23 months]/[1 year] after the date of enactment of the
24 [short title], a dispenser shall comply with the fol-
25 lowing:

1 【“(A) A dispenser shall maintain systems
2 to enable the dispenser to receive【, issue, and
3 terminate】 alerts. 【Such systems shall include
4 means to identify affected trading partners to
5 whom alerts are required to be sent under this
6 section.】】

7 “(B) Upon the receipt of an alert from the
8 Secretary or a trading partner, a dispenser
9 shall identify all product subject to such alert
10 that is in the possession or control of the dis-
11 penser, including any product that is subse-
12 quently received, and treat it as suspect prod-
13 uct.

14 【“(C) Upon determining that a product in
15 the possession or control of the dispenser is an
16 illegitimate product, the dispenser shall issue an
17 alert to the Secretary and all affected trading
18 partners not later than 24 hours after such de-
19 termination.】

20 【“(D) Upon a determination, in consulta-
21 tion with the Secretary, that an alert is no
22 longer necessary, promptly notify affected trad-
23 ing partners that such alert has been termi-
24 nated.】

25 “(e) REPACKAGER REQUIREMENTS.—

1 “(1) PRODUCT TRACING.—Beginning not later
2 than **【6 months】/【1 year】** after the date of enact-
3 ment of the **【short title】**, a repackager shall—

4 “(A) not accept ownership of a product un-
5 less the previous owner **【**, prior to the trans-
6 action,**】** provides transaction history, trans-
7 action information, and a transaction statement
8 for the product;

9 “(B) **【upon】/【before】** each transaction in
10 which the repackager transfers ownership of a
11 product, provide the subsequent owner with
12 transaction history, transaction information,
13 and a transaction statement;

14 “(C) maintain the transaction information
15 for each transaction for not less than **【2】/【10】**
16 years after the transaction;

17 “(D) beginning not later than **【2】/【5】**
18 years after the date of enactment of **【the short**
19 **title】**, affix or imprint a product identifier to
20 each package and homogenous case of product
21 intended to be reintroduced in a transaction in
22 commerce; and

23 “(E) maintain records that allow the re-
24 packager to associate the product identifier the
25 repackager affixes or imprints with the product

1 identifier assigned by the original manufacturer
2 of the product.

3 “(2) AUTHORIZED TRADING PARTNERS.—Be-
4 ginning **【3 months】**/**【2 years】** after the date of en-
5 actment of the **【short title】**, the trading partners of
6 a repackager may be only authorized trading part-
7 ners.

8 “(3) VERIFICATION.—

9 “(A) IN GENERAL.—Beginning not later
10 than **【2】**/**【5】** years after the date of enactment
11 of **【insert short title】**, a repackager shall com-
12 ply with the following requirements:

13 “(i) A repackager shall have systems
14 in place to enable the manufacturer to re-
15 spond to verification requests described in
16 clause (ii).

17 “(ii) Upon receiving a request for
18 verification from an authorized **【manufac-**
19 **turer】**, **【repackager】**, wholesale dis-
20 tributor, or dispenser, a repackager shall,
21 not later than **【24 hours】** after receiving
22 the verification request, notify the person
23 making the request whether the product
24 identifier, including the standard numeric
25 identifier, that is the subject of the request

1 corresponds to the product identifier af-
2 fixed or imprinted by the repackager. If
3 the repackager has reason to believe the
4 product is a suspect product or illegitimate
5 product, the repackager shall advise the
6 person making a verification request of
7 that information at the time it responds to
8 the verification request.

9 **【“(iii) In responding to a request for**
10 **verification under clause (ii), the repack-**
11 **ager shall consult the records described in**
12 **paragraph (1)(E) to verify the product**
13 **identifier assigned by the original manu-**
14 **facturer with the manufacturer.】**

15 **“(B) ELECTRONIC DATABASE.—A repack-**
16 **ager may satisfy the requirements of subpara-**
17 **graph (A) by developing a secure electronic**
18 **database that can be accessed and queried by**
19 **authorized members of the supply chain, except**
20 **that the establishment and operation of such a**
21 **database shall not relieve a repackager of the**
22 **requirement to comply with clauses (ii) and (iii)**
23 **of subparagraph (A) in the case of a**
24 **verification request submitted by means other**
25 **than the electronic database.**

1 “(C) PRESUMED SUSPECT PRODUCT.—If a
2 repackager conducting a verification request
3 identifies a product identifier that does not cor-
4 respond to that affixed or imprinted by the re-
5 packager, the repackager shall treat such prod-
6 uct as suspect product and conduct an inves-
7 tigation as described in paragraph (4).

8 “(D) RETURNED PRODUCT.—Upon receipt
9 of a returned product that the repackager in-
10 tends to further distribute, before further dis-
11 tributing such product, the repackager shall
12 verify the product identifier data that the re-
13 packager assigned for each sealed homogeneous
14 case of such product or, if such product is not
15 in a sealed homogeneous case, verify the prod-
16 uct identifier on each package.

17 “(4) INVESTIGATION.—

18 “(A) IN GENERAL.—Beginning not later
19 than **【6 months】/【1 year】** after the date of en-
20 actment of the **【short title】**, a repackager shall
21 have systems in place to identify suspect prod-
22 uct, segregate suspect product or illegitimate
23 product within the possession or control of the
24 repackager from product intended for distribu-
25 tion, and investigate suspect product.

1 “(B) TREATMENT OF SUSPECT PROD-
2 UCT.—

3 “(i) IN GENERAL.—Upon identifying
4 a product as a suspect product, a repack-
5 ager shall—

6 “(I) segregate such product with-
7 in the possession or control of the re-
8 packager from product intended for
9 distribution; and

10 “(II) promptly conduct an inves-
11 tigation in coordination with affected
12 trading partners, as applicable, to de-
13 termine whether the product is an ille-
14 gitimate product. Such investigation
15 shall include verifying product infor-
16 mation [that the repackager assigned
17 and the associated product informa-
18 tion assigned by the original manufac-
19 turer], authenticating any applicable
20 [transaction history and] transaction
21 information, and otherwise inves-
22 tigating to determine whether the
23 product is an illegitimate product.

24 “(ii) RECEIPT OF AN ALERT.—Upon
25 the receipt of an alert from the Secretary

1 or a trading partner, or the independent
2 observation of the repackager of factors
3 that would make the product a suspect
4 product, a repackager shall treat such
5 product as suspect product.

6 “(iii) CLEARED PRODUCT.—If suspect
7 product is determined not to be illegitimate
8 product, such product may be further dis-
9 tributed.

10 【“(C) RECORDS.—A repackager shall keep
11 records of the investigation of the suspect prod-
12 uct for not less than **【2】/【10】** years after the
13 conclusion of the investigation. **【** *Note from*
14 *working group:* This option would include prod-
15 uct investigated and cleared.**】】**

16 “(D) REQUESTS FOR INFORMATION.—
17 Upon a request by the Secretary or other ap-
18 propriate Federal or State official, in the event
19 of a recall or for the purpose of investigating a
20 suspect product, illegitimate product, or recalled
21 product, a repackager shall, not later than **【24**
22 **hours】** after receiving the request or in other
23 such reasonable time as determined by the Sec-
24 retary, provide the applicable transaction infor-

1 mation, transaction history, and transaction
2 statements for the product.

3 “(5) DISPOSITION.—

4 “(A) SYSTEMS FOR DISPOSITION OF ILLE-
5 GITIMATE PRODUCT.—Beginning not later than
6 **【6 months】/【1 year】** after the date of enact-
7 ment of the **【short title】**, a repackager shall
8 have systems in place to—

9 “(i) properly disposition product with-
10 in the possession or control of the repack-
11 ager, as appropriate, to ensure that illegit-
12 imate product does not enter the pharma-
13 ceutical distribution supply chain; and

14 “(ii) take reasonable steps to remove
15 illegitimate product not in the possession
16 or control of the repackager from the phar-
17 maceutical distribution supply chain.

18 “(B) DISPOSITION OF ILLEGITIMATE
19 PRODUCT.—Upon determining that a product in
20 the possession or control of a repackager is an
21 illegitimate product, the repackager shall prop-
22 erly disposition such product.

23 **【**“(C) RECORDS.—A repackager shall keep
24 records of an investigation of an illegitimate

1 product for not less than **【2】/【10】** years after
2 the conclusion of the investigation.】

3 “(6) ALERTS.—Beginning not later than **【6**
4 months】/【1 year】 after the date of enactment of the
5 **【short title】**, a repackager shall comply with the fol-
6 lowing:

7 “(A) A repackager shall have systems in
8 place to enable the repackager to receive, issue,
9 and terminate alerts. Such systems shall in-
10 clude means to identify affected trading part-
11 ners to whom alerts are required to be sent
12 under this section.

13 “(B) Upon the receipt of an alert from the
14 Secretary or a trading partner, a repackager
15 shall identify all product subject to such alert
16 that is in the possession or control of the re-
17 packager, including any product that is subse-
18 quently received, and treat such product as sus-
19 pect product.

20 “(C) Upon determining that a product in
21 the possession or control of the repackager is
22 an illegitimate product, the repackager shall
23 issue an alert to the Secretary and all affected
24 trading partners not later than 24 hours after
25 making such determination.

1 “(D) Upon a determination, in consulta-
2 tion with the Secretary, that an alert is no
3 longer necessary, a repackager shall promptly
4 notify affected trading partners that such alert
5 has been terminated.

6 “(f) THIRD-PARTY LOGISTICS PROVIDER REQUIRE-
7 MENTS.—

8 “(1) PRODUCT TRACING.—Beginning not later
9 than **【6 months】/【1 year】** after the date of enact-
10 ment of the **【short title】**, a third-party logistics pro-
11 vider shall—

12 “(A) not accept possession of a product
13 unless the owner of the product**【**, prior to the
14 transaction,**】** provides the transaction history,
15 transaction information, and a transaction
16 statement for the product. **【***Note from working*
17 *group*: If kept, need to require that trading
18 partners that use third-party logistics providers
19 provide this information to the third party lo-
20 gisties providers**】**;

21 **【**“(B) maintain a copy of the information
22 described in subparagraph (A) for not less than
23 **【2】/【10】** years after the transfer of possession.
24 **【***Note from working group*: Only if keep (A)**】**;
25 and**】**

1 【“(C) beginning not later than 【3】/【7】
2 years after the date of enactment of 【insert
3 short title】, a third-party logistics provider may
4 accept possession of product only if such prod-
5 uct is encoded with a product identifier 【except
6 as provided in grandfathering provisions.】】

7 “(2) TRADING PARTNERS.—Beginning 【3
8 months】/【2 years】 after the date of enactment of
9 the 【short title】, the trading partners of a third-
10 party logistics provider may be only authorized trad-
11 ing partners.

12 “(3) INVESTIGATION.—

13 “(A) IN GENERAL.—Beginning not later
14 than 【6 months】/【1 year】 after the date of en-
15 actment of the 【short title】, a third-party logis-
16 tics provider shall—

17 “(i) have systems in place to identify
18 suspect product, segregate suspect product
19 or illegitimate product within the posses-
20 sion 【or control】 of the third-party logis-
21 tics provider from product intended for
22 distribution, 【and promptly alert the trad-
23 ing partner who has ownership of the prod-
24 uct to the need to investigate suspect prod-
25 uct】; and

1 “(ii) upon the receipt of an alert from
2 the Secretary or a trading partner, or the
3 independent observation of the third-party
4 logistics provider of factors that would
5 make the product a suspect product, treat
6 such product as suspect product.

7 “(B) TREATMENT OF SUSPECT PROD-
8 UCT.—

9 “(i) IN GENERAL.—Upon identifying
10 a product as a suspect product, a third-
11 party logistics provider shall—

12 “(I) segregate such product with-
13 in the possession **【or control】** of the
14 third-party logistics provider from
15 product intended for distribution; and

16 “(II) promptly alert the trading
17 partner with ownership of the product
18 of the need to conduct an investiga-
19 tion in coordination with affected
20 trading partners, as applicable, to de-
21 termine whether the product is an ille-
22 gitimate product.

23 “(ii) CLEARED PRODUCT.—If suspect
24 product is determined not to be illegitimate
25 product by the trading partner that owns

1 the product, such product may be further
2 distributed.

3 **“(C) RECORDS.—**A third-party logistics
4 provider shall keep records of **[**compliance with
5 this paragraph**]** for not less than **[2]/[10]**
6 years after the conclusion of the investigation.
7 **[***Note from working group:* This option would
8 include product investigated and cleared.**]****”**

9 **“(D) REQUESTS FOR INFORMATION.—**
10 Upon a request by the Secretary or other ap-
11 propriate Federal or State official, in the event
12 of a recall or for the purpose of investigating a
13 suspect product, illegitimate product, or recalled
14 product, a third-party logistics provider shall,
15 not later than **[24 hours]** after receiving the
16 request or in other such reasonable time as de-
17 termined by the Secretary, provide the applica-
18 ble transaction information, transaction history,
19 and transaction statements for the product.

20 **“(4) DISPOSITION.—**

21 **“(A) SYSTEMS FOR TRANSFER OF ILLE-**
22 GITIMATE PRODUCT.—Beginning not later than
23 **[6 months]/[1 year]** after the date of enact-
24 ment of the **[short title]**, a third-party logistics
25 provider shall have systems in place to properly

1 transfer possession of product to the trading
2 partner with ownership of the product for dis-
3 position.

4 “(B) TRANSFER OF ILLEGITIMATE PROD-
5 UCT.—Upon receiving information from a trad-
6 ing partner or the Secretary that a product in
7 the possession of the third-party logistics pro-
8 vider is an illegitimate product, the third-party
9 logistics provider shall promptly transfer pos-
10 session of the product to the trading partner
11 with ownership of the product for disposition of
12 such product.

13 【“(C) RECORDS.—A third-party logistics
14 provider shall keep records of 【compliance with
15 this paragraph】 for not less than 【2】/【10】
16 years after the conclusion of the investigation.】

17 “(5) ALERTS.—Beginning not later than 【6
18 months】/【1 year】 after the date of enactment of the
19 【short title】, a third-party logistics provider shall
20 have systems in place to enable the third-party logis-
21 tics provider to receive alerts.

22 “(g) SUNSET.—The requirements regarding the pro-
23 vision and receipt of transaction information, transaction
24 history, and transaction statements under 【subsections
25 (b)(1), (c)(1), (d)(1), (e)(1), and (f)(1)】 shall cease to be

1 effective upon the full implementation of the regulations
2 promulgated under subsection (c) of section 3 of **[[insert**
3 short title**]]**, as provided in paragraph (6) of such sec-
4 tion.”.

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

6 **[(a) PILOT PROJECTS.—]**

7 **[(1) IN GENERAL.—**Not later than **[18**
8 months**]/[4 years]** after the date of enactment of
9 this Act, the Secretary shall establish 1 or more
10 pilot projects in coordination with pharmaceutical
11 manufacturers, repackagers, wholesale distributors,
12 third-party logistics providers, and dispensers to ex-
13 plore and evaluate methods to **[[automatically verify**
14 all product and to**]]** rapidly and effectively detect
15 and identify suspect product throughout the phar-
16 maceutical distribution chain.**]**

17 **[(2) CONTENT.—**

18 **[(A) IN GENERAL.—**The Secretary shall
19 ensure that the pilot projects under paragraph
20 (1) reflect the diversity of the pharmaceutical
21 distribution supply chain and that the projects
22 overall include participants representative of
23 every sector and subsector, including both large
24 and small businesses, except that not every pilot

1 project shall be required to capture every sec-
2 tor, subsector, or business size.】

3 【(B) PROJECT DESIGN.—The pilot
4 projects shall be designed to—】

5 【(i) utilize product identifier data for
6 product tracing, including the use of ag-
7 gregation and inference;】

8 【(ii) improve the technical capabilities
9 of each sector and subsector to comply
10 with an interoperable, electronic, unit-level
11 package tracing system; and】

12 【(iii) 【complete other activities】/【ful-
13 fill other goals】 as determined by the Sec-
14 retary.】

15 【(b) PUBLIC MEETINGS.—】

16 【(1) IN GENERAL.—Not later than 【6
17 months】/【2 years】 after the date of enactment of
18 this Act, and at least every 【6 months】/【1 year】
19 thereafter, the Secretary shall hold a public meeting
20 to explore and evaluate methods to 【automatically
21 verify all product and to】 rapidly and effectively de-
22 tect and identify suspect product throughout the
23 pharmaceutical distribution chain.】

1 **[(2) CONTENT.—**Each of the following topics
2 shall be addressed in at least one of the public meet-
3 ings described in paragraph (1):**]**

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

9 **[(B)** The costs and benefits of implemen-
10 tation of such section 582, including the impact
11 on each pharmaceutical distribution chain sec-
12 tor and on public health.**]**

13 **[(C)** The impact of the returns exceptions
14 under subsections (c)(1)(B) and (d)(1)(C) of
15 such section 582 on the usefulness of the trans-
16 action information, transaction history, and
17 transaction statement as a means of protecting
18 public health.**]**

19 **[(D)** Whether additional electronic
20 traceability requirements, including enhanced
21 unit level capabilities or a unit level package
22 tracing system, are needed to protect public
23 health.**]**

1 **[(E)** The systems and processes needed to
2 utilize the product identifiers to enhance unit-
3 level package tracing capabilities.]

4 **[(F)** The technical capabilities and legal
5 authorities, if any, needed to establish a unit-
6 level package tracing system.]

7 **[(G)** The impact that unit-level require-
8 ments would have on patient safety, the drug
9 supply, cost and regulatory burden, and timely
10 patient access to prescription drugs.]

11 **[(H)** Other topics, as determined by the
12 Secretary.]

13 **[(3) GUIDANCE DOCUMENT.—**Not later than
14 **[6 months]** after each public meeting required
15 under this subsection, the Secretary shall publish a
16 guidance document detailing the recommendations of
17 the Secretary with respect to the subject of such
18 public meeting.]

19 **[(c) REGULATIONS.—]**

20 **[(1) ENHANCED DRUG DISTRIBUTION SECUR-**
21 **ITY.—**Notwithstanding any other provision of this
22 Act **[or the amendments made by this Act]**, not
23 earlier than **[5/8 years]** and not later than **[6/10**
24 **years]** after the date of enactment of this Act, the

1 Secretary **【shall/may】** issue proposed regulations
2 that—**】**

3 **【(A) 【require the use of interoperable elec-**
4 **tronic systems for tracking, tracing, and 【auto-**
5 **matically】 verifying product, which may include**
6 **requiring the use of additional product identi-**
7 **fiers or product identifier technology that meet**
8 **the standards developed under section**
9 **582(a)(2) of the Federal Food, Drug, and Cos-**
10 **metic Act, as added by section 2;】】**

11 **【(B) 【if dispensers are not required to**
12 **pass pedigree in Phase I:】 【require dispensers**
13 **to provide transaction information, transaction**
14 **history and a transaction statement upon trans-**
15 **ferring ownership of a product to a trading**
16 **partner】;】**

17 **【(C) 【require the maintenance and provi-**
18 **sion of transaction data at the unit level under**
19 **subsections (b)(1), (c)(1), (d)(1), (e)(1), and**
20 **(f)(1) of such section 582】; and】**

21 **【(D) 【at the discretion of the Secretary,**
22 **create additional requirements to prevent drugs**
23 **that are counterfeit, stolen, diverted, or other-**
24 **wise unfit for distribution from entering into or**
25 **being further distributed in the supply chain】.】**

1 **[(2) RESTRICTIONS.—**In promulgating the reg-
2 ulations under paragraph (1), the Secretary shall—
3 **]**

4 **[(A)** not require the adoption of specific
5 business systems for the maintenance and
6 transmission of data; and**]**

7 **[(B)** not impose any new requirements on
8 dispensers that are in addition to the require-
9 ments set forth under **[subsection (d) of such**
10 section 582**].]**

11 **[(3) PROCEDURE.—**

12 **[(A)** The Secretary, in promulgating any
13 regulation pursuant to this section, shall—**]**

14 **[(i)** issue a notice of proposed rule-
15 making that includes a copy of the pro-
16 posed regulation;**]**

17 **[(ii)** provide a period of not less than
18 60 days for comments on the proposed reg-
19 ulation; and**]**

20 **[(iii)** publish the final regulation not
21 less than **[2 years]** before the effective
22 date of the regulation.**]**

23 **[(4) DEFAULT PROVISIONS.—**If the Secretary
24 has not finalized regulations under this subsection
25 by the date that is **[8/13]** years after the date of

1 enactment of this Act, **【**or if the regulations under
2 this subsection have not gone into effect by the date
3 that is **【10/15】** years after the date of enactment of
4 this Act,**】** the following shall go into effect:**】**

5 **【**(A) The exceptions for saleable returns
6 under subsections (c)(1)(B)(i) and (d)(1)(C)(i)
7 of section 582 of the Federal Food Drug, and
8 Cosmetic Act shall cease to be effective.**】**

9 **【**(B) The transaction information and
10 transaction statement as defined in section 581
11 and required under **【**section 582**】** of the Fed-
12 eral Food, Drug, and Cosmetic Act shall in-
13 clude the package identifier for each package
14 included in the transaction.**】**

15 **【**(C) The exchange of transaction informa-
16 tion and transaction statements, as defined in
17 paragraphs (24) and (25), respectively, of sec-
18 tion 581 of the Federal Food, Drug, and Cos-
19 metic Act and as required under section 582 of
20 such Act, shall be effectuated in an electronic,
21 interoperable system with automatic verification
22 of all product in accordance with the standards
23 published under section 582(a)(2) of the Fed-
24 eral Food, Drug, and Cosmetic Act.**】**

1 **[(5) DEFINITIONS.—**Reference to applicable
2 **definitions under section 581 of FFDCA?]**

3 **[(6) SUNSET.—**The requirements regarding the
4 provision and receipt of transaction information,
5 transaction history, and transaction statements
6 under section 582 of the Federal Food, Drug, and
7 Cosmetic Act, as added by section 2, shall cease to
8 be effective upon the full implementation of the reg-
9 ulations promulgated under paragraph (1).**]**

10 SEC. 4. NATIONAL LICENSURE STANDARDS FOR WHOLE-
11 SALE DISTRIBUTORS.

(a) LICENSE REQUIREMENT.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended by striking paragraph (2) and inserting the following:

16 “(2) LICENSE REQUIREMENT.—

17 “(A) IN GENERAL.—No person—

18 “(i) may engage in wholesale distribu-
19 tion of a drug subject to subsection (b) in
20 any State unless such person—

21 “(I)(aa) is licensed by the State
22 from which the drug is distributed; or

23 “(bb) if the State from which the
24 drug distributed has not established a

1 licensure requirement, is licensed by
2 the Secretary; and

3 “(II) if the drug is distributed
4 interstate, is licensed by the State
5 into which the drug is distributed if
6 the State into which the drug is dis-
7 tributed requires the licensure of
8 wholesale distributors that distribute
9 drugs into the State; and

10 “(ii) **【**except in the case of a manu-
11 facturer duly registered under section 510,
12 may engage in wholesale distribution of a
13 drug subject to subsection (b) **【**manufac-
14 tured?**】** outside the United States in any
15 State unless such person is licensed by the
16 State into which the drug is distributed.
17 **【***Note from working group: use ‘authorized’*
18 *concept here?***】**

19 “(B) STANDARDS, TERMS, AND CONDI-
20 TIONS.—The Secretary shall, by regulation, es-
21 tablish the standards, terms, and conditions for
22 the licensing of persons to make wholesale dis-
23 tributions under subparagraph (A). Such stand-
24 ards shall apply to all State and Federal li-

1 censes described in such subparagraph (A) and
2 may include—

3 “(i) requirements for the storage and
4 handling of such drugs;

5 “(ii) requirements for the establish-
6 ment and maintenance of records;

7 “(iii) standards for hiring and employ-
8 ment, including conduct of background
9 checks, fingerprinting, and prohibitions on
10 the employment of certain persons because
11 of criminal convictions or a pattern of vio-
12 lating this Act;

13 “(iv) the establishment and implemen-
14 tation of minimum qualifications and ongo-
15 ing training requirements for personnel;

16 “(v) the prohibition of certain persons
17 from engaging in wholesale distribution be-
18 cause of criminal convictions or a pattern
19 of violating this Act;

20 “(vi) the establishment of quality
21 management systems;

22 “(vii) the requirement that the whole-
23 sale distributor list with the Secretary, in
24 accordance with subsection (b);

1 **【“(C) SUSPENSION OR REVOCATION OF**
2 LISTING.—The Secretary may suspend or re-
3 voke an establishment listing in writing at any
4 time if the Secretary determines that a person
5 engaging in wholesale distribution of drugs sub-
6 ject to subsection (b) failed to comply with any
7 requirements of this Act.”.】

8 **“(5) WHOLESAL E DISTRIBUTION STAND-**
9 ARDS.—Each person who engages in wholesale dis-
10 tribution of drug subject to subsection (b) shall com-
11 ply with the standards promulgated by the Secretary
12 in accordance with paragraph (2)(B).

13 **【“(6) COSTS.—】**

14 **【“(A) AUTHORIZED LISTING FEES OF SEC-**
15 RETARY.—The Secretary may assess fees on
16 persons engaging in wholesale distribution who
17 seek to list with the Secretary under paragraph
18 (4) in such an amount necessary to reimburse
19 the Secretary for the costs associated with es-
20 tablishing and administering the establishment
21 listing program and conducting periodic inspec-
22 tions of registrants under this subsection. The
23 Secretary shall not generate surplus revenue
24 from such a reimbursement mechanism. Fees
25 authorized under this paragraph shall be col-

1 lected and available for obligation only to the
2 extent and in the amount provided in advance
3 in appropriation Acts. Such fees may remain
4 available until expended.】

5 【“(B) AUTHORIZED LICENSURE FEES OF
6 SECRETARY.—If a State does not establish a li-
7 censing program for wholesale distributors of
8 drugs, the Secretary shall license the wholesale
9 distributors located in such State and may col-
10 lect a reasonable fee to perform that service,
11 consistent with the limitation set forth in sub-
12 paragraph (A).】

13 “(C) STATE LICENSING FEES.—Nothing in
14 this Act shall prohibit States from collecting
15 fees from wholesale distributors in connection
16 with State licensing of such distributors.”.

17 (c) THIRD-PARTY LOGISTICS PROVIDERS.—Section
18 503(e) of the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 353(e)), as amended by subsection (b), is further
20 amended by adding at the end the following:

21 “(7) THIRD-PARTY LOGISTICS PROVIDERS.—

22 “(A) IN GENERAL.—Notwithstanding
23 paragraphs (2) through (6), each entity that
24 meets the definition of a third-party logistics
25 provider under section 581(20) shall obtain a li-

1 cense as a third-party logistics provider as de-
2 scribed in section **【584(a)】** and is not required
3 to obtain a license as a wholesale distributor if
4 the entity never assumes an ownership interest
5 in the product it handles.

6 “**【***Note from working group:* Same as above with
7 respect to Federal promulgation of licensure stand-
8 ards, listing and payment of listing fee to FDA, and
9 requirement that 3PL be licensed in States in which
10 they do business or send the products or FDA if the
11 States don’t play?**】**”.

12 (d) **WHOLESALE DISTRIBUTION.**—Section 503(e)(3)
13 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 353(e)(3)) is amended by striking subparagraph (B) and
15 inserting the following:

16 “(B) the term ‘wholesale distribution’
17 means the activities of a wholesale distributor,
18 as described in section 581(27).”.

19 (e) **LICENSURE STANDARDS.**—Subchapter G of chap-
20 ter V of the Federal Food, Drug, and Cosmetic Act, as
21 added by section 2, is amended by adding at the end the
22 following:

1 **“SEC. 583. NATIONAL LICENSURE STANDARDS FOR WHOLE-**
2 **SALE DISTRIBUTORS.**

3 **【“PART —I--*OPTION I*】**

4 “.”.

5 **【(a) OPTION (I)(A).—Defer to the Secretary of**
6 **Health and Human Services to promulgate the licensure**
7 **requirements through notice and comment rulemaking.】**

8 **【(b) OPTION (I)(B).—Defer to the Secretary of**
9 **Health and Human Services to promulgate the licensure**
10 **requirements through notice and comment rulemaking,**
11 **but limit the potential licensing requirements to the fol-**
12 **lowing areas of interest:】**

13 **【(1) Required information that must be sub-**
14 **mitted to the licensing authority (eg, names, ad-**
15 **resses, etc.).】**

16 **【(2) Basic qualifications/background check (eg,**
17 **no felony convictions, etc.).】**

18 **【(3) Appropriate education of personnel em-**
19 **ployed by licensee.】**

20 **【(4) Requirements for the storage and handling**
21 **of prescription drugs, including requirements related**
22 **to facility cleanliness and security.】**

23 **【(5) Requirements related to the establishment**
24 **and maintenance of appropriate records.】**

25 **【(6) Filing of a bond as a condition of licen-**
26 **sure.】**

[PART II—OPTION II]

1

2

3 **[(a) IN GENERAL.—**Codify the requirements that
4 currently appear in part 205 of title 21, Code of Federal
5 Regulations to create a uniform standard that can be ap-
6 plied across all States (as opposed to minimum standards
7 that can be dramatically supplemented by the States), but
8 modify them as appropriate in the definitions and record-
9 keeping sections to ensure consistency with other require-
10 ments in this bill.]

11 **[(b) REQUIREMENTS TO OBTAIN OR RENEW A LI-**
12 **CENSE.—[See 21 CFR 205.5]** The following information
13 shall be submitted by a wholesale drug distributor as part
14 of the license described in **[cross cite to section III]** and
15 as part of any renewal of such license:]

16 **[(1) The name, full business address, and tele-**
17 **phone number of the licensee;]**

18 **[(2) All trade or business names used by the li-**
19 **censee;]**

20 **[(3) Addresses, telephone numbers, and the**
21 **names of contact persons for all facilities used by**
22 **the licensee for the storage, handling, and distribu-**
23 **tion of prescription drugs;]**

24 **[(4) The type of ownership or operation (i.e.,**
25 **partnership, corporation, or sole proprietorship);**
26 **and]**

1 **[(5) The name(s) of the owner and/or operator**
2 **of the licensee, including—]**

3 **[(A) if a person, the name of the person;]**

4 **[(B) if a partnership, the name of each**
5 **partner, and the name of the partnership;]**

6 **[(C) if a corporation, the name and title of**
7 **each corporate officer and director, the cor-**
8 **porate names, and the name of the State of in-**
9 **corporation; and]**

10 **[(D) if a sole proprietorship, the full name**
11 **of the sole proprietor and the name of the busi-**
12 **ness entity.]**

13 **[(c) STATE LICENSES.—A single license shall suffice**
14 **in any one State for a business entity operating more than**
15 **one facility within that State, or for a parent entity with**
16 **divisions, subsidiaries, and/or affiliate companies within**
17 **that State when operations are conducted at more than**
18 **one location and there exists joint ownership and control**
19 **among all the entities.]**

20 **[(d) CHANGES.—Changes in any information in sub-**
21 **section (d) of this section shall be submitted to the licens-**
22 **ing authority within 30 days of such change.]**

23 **[(e) DENIAL OF APPLICATION.—[See 21 CFR**
24 **205.6] The licensing authority may refuse to license a**

1 wholesale distributor based on any of the following fac-
2 tors:】

3 【(1) Any convictions of the applicant or licensee
4 under any Federal, State, or local laws relating to
5 drug samples, wholesale or retail drug distribution,
6 or distribution of controlled substances.】

7 【(2) Any felony convictions of the applicant or
8 licensee under Federal, State, or local laws.】

9 【(3) The applicant or licensee’s past experience
10 in the manufacture or distribution of prescription
11 drugs, including controlled substances.】

12 【(4) The furnishing by the applicant or licensee
13 of false or fraudulent material in any application
14 made in connection with drug manufacturing or dis-
15 tribution.】

16 【(5) Suspension or revocation by Federal,
17 State, or local government of any license currently
18 or previously held by the applicant or licensee for
19 the manufacture or distribution of any drugs, includ-
20 ing controlled substances.】

21 【(6) Failure to comply with licensing require-
22 ments under previously granted licenses, if any.】

23 【(7) Compliance with requirements to maintain
24 and/or make available to the licensing authority or

1 to Federal, State, or local law enforcement officials
2 those records required under this section.】

3 【(8) The licensing authority shall have the
4 right to deny a license to an applicant if it deter-
5 mines that the granting of such a license would not
6 be in the public interest.】

7 【(f) VERIFICATION OF CREDENTIALS.—【See 21
8 CFR 205.7】 The State licensing authority shall require
9 that personnel employed in wholesale distribution have ap-
10 propriate education and/or experience to assume responsi-
11 bility for positions related to compliance with State licens-
12 ing requirements. 【See preemption language, below, for
13 application of 21 CFR 205.8】.】

14 【(g) STORAGE AND HANDLING.—【See 21 CFR
15 205.50】 The following requirements for the storage and
16 handling of prescription drugs, and for the establishment
17 and maintenance of prescription drug distribution records,
18 shall apply to wholesale drug distributors and their offi-
19 cers, agents, representatives, and employees:】

20 【(1) FACILITIES.—All facilities at which pre-
21 scription drugs are stored, warehoused, handled,
22 held, offered, marketed, or displayed shall—】

23 【(A) be of suitable size and construction to
24 facilitate cleaning, maintenance, and proper op-
25 erations;】

1 **[(B) have storage areas designed to pro-**
2 **vide adequate lighting, ventilation, temperature,**
3 **sanitation, humidity, space, equipment, and se-**
4 **curity conditions;]**

5 **[(C) have a quarantine area for storage of**
6 **prescription drugs that are outdated, damaged,**
7 **deteriorated, misbranded, or adulterated, or**
8 **that are in immediate or sealed, secondary con-**
9 **tainers that have been opened;]**

10 **[(D) be maintained in a clean and orderly**
11 **condition; and]**

12 **[(E) be free from infestation by insects,**
13 **rodents, birds, or vermin of any kind.]**

14 **[(2) SECURITY.—All facilities used for whole-**
15 **sale drug distribution shall be secure from unauthor-**
16 **ized entry.]**

17 **[(A) Access from outside the premises**
18 **shall be kept to a minimum and be well-con-**
19 **trolled.]**

20 **[(B) The outside perimeter of the prem-**
21 **ises shall be well-lighted.]**

22 **[(C) Entry into areas where prescription**
23 **drugs are held shall be limited to authorized**
24 **personnel.]**

1 **[(D)** All facilities shall be equipped with
2 an alarm system to detect entry after hours.]

3 **[(E)** All facilities shall be equipped with a
4 security system that will provide suitable pro-
5 tection against theft and diversion. When ap-
6 propriate, the security system shall provide pro-
7 tection against theft or diversion that is facili-
8 tated or hidden by tampering with computers or
9 electronic records.]

10 **[(3) STORAGE.—**All prescription drugs shall be
11 stored at appropriate temperatures and under appro-
12 priate conditions in accordance with requirements, if
13 any, in the labeling of such drugs, or with require-
14 ments in the current edition of an official compen-
15 dium, such as the United States Pharmacopeia/National
16 Formulary..]

17 **[(A)** If no storage requirements are estab-
18 lished for a prescription drug, the drug may be
19 held at “controlled” room temperature, as de-
20 fined in an official compendium, to help ensure
21 that its identity, strength, quality, and purity
22 are not adversely affected.]

23 **[(B)** Appropriate manual,
24 electromechanical, or electronic temperature
25 and humidity recording equipment, devices,

1 and/or logs shall be utilized to document proper
2 storage of prescription drugs.】

3 【(C) The recordkeeping requirements in
4 【paragraph (f)】 of this section shall be followed
5 for all stored drugs.】

6 【(4) EXAMINATION OF MATERIALS.—

7 【(A) Upon receipt, each outside shipping
8 container shall be visually examined for identity
9 and to prevent the acceptance of contaminated
10 prescription drugs or prescription drugs that
11 are otherwise unfit for distribution. This exam-
12 ination shall be adequate to reveal container
13 damage that would suggest possible contamina-
14 tion or other damage to the contents.】

15 【(B) Each outgoing shipment shall be
16 carefully inspected for identity of the prescrip-
17 tion drug products and to ensure that there is
18 no delivery of prescription drugs that have been
19 damaged in storage or held under improper
20 conditions.】

21 【(C) The recordkeeping requirements in
22 【paragraph (f)】 of this section shall be followed
23 for all incoming and outgoing prescription
24 drugs.】

1 **[(5) RETURNED, DAMAGED, AND OUTDATED**
2 **PRESCRIPTION DRUGS.—**

3 **[(A) Prescription drugs that are outdated,**
4 **damaged, deteriorated, misbranded, or adulter-**
5 **ated shall be quarantined and physically sepa-**
6 **rated from other prescription drugs until they**
7 **are destroyed or returned to their supplier.】**

8 **[(B) Any prescription drugs whose imme-**
9 **diate or sealed outer or sealed secondary con-**
10 **tainers have been opened or used shall be iden-**
11 **tified as such, and shall be quarantined and**
12 **physically separated from other prescription**
13 **drugs until they are either destroyed or re-**
14 **turned to the supplier.】**

15 **[(C) If the conditions under which a pre-**
16 **scription drug has been returned cast doubt on**
17 **the drug's safety, identity, strength, quality, or**
18 **purity, then the drug shall be destroyed, or re-**
19 **turned to the supplier, unless examination, test-**
20 **ing, or other investigation proves that the drug**
21 **meets appropriate standards of safety, identity,**
22 **strength, quality, and purity. In determining**
23 **whether the conditions under which a drug has**
24 **been returned cast doubt on the drug's safety,**
25 **identity, strength, quality, or purity, the whole-**

1 sale drug distributor shall consider, among
2 other things, the conditions under which the
3 drug has been held, stored, or shipped before or
4 during its return and the condition of the drug
5 and its container, carton, or labeling, as a re-
6 sult of storage or shipping.】

7 【(D) The recordkeeping requirements in
8 【paragraph (f)】 of this section shall be followed
9 for all outdated, damaged, deteriorated, mis-
10 branded, or adulterated prescription drugs.】

11 【(6) RECORDKEEPING.—

12 【(A) Wholesale drug distributors shall es-
13 tablish and maintain inventories and records of
14 all transactions regarding the receipt and dis-
15 tribution or other disposition of prescription
16 drugs consistent with the requirements in
17 【cross cite to section I】.】

18 【(B) Inventories and records shall be made
19 available for inspection and photocopying by au-
20 thorized Federal, State, or local law enforce-
21 ment agency officials for a period of 3 years
22 after the date of their creation.】

23 【(C) Records described in this section that
24 are kept at the inspection site or that can be
25 immediately retrieved by computer or other

1 electronic means shall be readily available for
2 authorized inspection during the retention pe-
3 riod. Records kept at a central location apart
4 from the inspection site and not electronically
5 retrievable shall be made available for inspec-
6 tion within 2 working days of a request by an
7 authorized official of a Federal, State, or local
8 law enforcement agency.】

9 【(7) WRITTEN POLICIES AND PROCEDURES.—

10 Wholesale drug distributors shall establish, main-
11 tain, and adhere to written policies and procedures,
12 which shall be followed for the receipt, security, stor-
13 age, inventory, and distribution of prescription
14 drugs, including policies and procedures for identi-
15 fying, recording, and reporting losses or thefts, and
16 for correcting all errors and inaccuracies in inven-
17 tories. Wholesale drug distributors shall include in
18 their written policies and procedures the following:】

19 【(A) A procedure whereby the oldest ap-
20 proved stock of a prescription drug product is
21 distributed first. The procedure may permit de-
22 viation from this requirement, if such deviation
23 is temporary and appropriate.】

24 【(B) A procedure to be followed for han-
25 dling recalls and withdrawals of prescription

1 drugs. Such procedure shall be adequate to deal
2 with recalls and withdrawals due to—】

3 【(i) any action initiated at the request
4 of the Food and Drug Administration or
5 other Federal, State, or local law enforce-
6 ment or other government agency, includ-
7 ing the State licensing agency;】

8 【(ii) any voluntary action by the man-
9 ufacturer to remove defective or potentially
10 defective drugs from the market; or】

11 【(iii) any action undertaken to pro-
12 mote public health and safety by replacing
13 of existing merchandise with an improved
14 product or new package design.】

15 【(C) A procedure to ensure that wholesale
16 drug distributors prepare for, protect against,
17 and handle any crisis that affects security or
18 operation of any facility in the event of strike,
19 fire, flood, or other natural disaster, or other
20 situations of local, State, or national emer-
21 gency.】

22 【(D) A procedure to ensure that any out-
23 dated prescription drugs shall be segregated
24 from other drugs and either returned to the
25 manufacturer or destroyed. This procedure shall

1 provide for written documentation of the dis-
2 position of outdated prescription drugs. This
3 documentation shall be maintained for 2 years
4 after disposition of the outdated drugs.】

5 【(8) RESPONSIBLE PERSONS.—Wholesale drug
6 distributors shall establish and maintain lists of offi-
7 cers, directors, managers, and other persons in
8 charge of wholesale drug distribution, storage, and
9 handling, including a description of their duties and
10 a summary of their qualifications.】

11 【(9) COMPLIANCE WITH FEDERAL, STATE, AND
12 LOCAL LAW.—Wholesale drug distributors shall op-
13 erate in compliance with applicable Federal, State,
14 and local laws and regulations.】

15 【(A) Wholesale drug distributors shall per-
16 mit authorized Federal, State, and local law en-
17 forcement officials to enter and inspect their
18 premises and delivery vehicles, and to audit
19 their records and written operating procedures,
20 at reasonable times and in a reasonable man-
21 ner, to the extent authorized by law.】

22 【(B) Wholesale drug distributors that deal
23 in controlled substances shall register with the
24 appropriate State controlled substance author-
25 ity and with the Drug Enforcement Administra-

1 tion, and shall comply with all applicable State,
2 local, and DEA regulations.】

3 【(10) SALVAGING AND REPROCESSING.—Whole-
4 sale drug distributors shall be subject to the provi-
5 sions of any applicable Federal, State, or local laws
6 or regulations that relate to prescription drug prod-
7 uct salvaging or reprocessing, including parts 207,
8 210, and 211 of this chapter.】

9 **【PART III—OPTION III】**

10

11 【(a) IN GENERAL.—The Secretary shall by regula-
12 tion issue guidelines establishing standards, terms, and
13 conditions for the licensing of person to make wholesale
14 distributions of prescription drugs.】

15 【(b) GUIDELINES.—Such guidelines shall prescribe
16 requirements for—】

17 【(1) the storage and handling of such drugs,
18 including facility requirements;】

19 【(2) the establishment and maintenance of
20 records of the distributions of such drugs;】

21 【(3) the furnishing of a bond or other equiva-
22 lent means of security if—】

23 【(A) an applicant that is not a government
24 owned and operated wholesale distributor, for
25 the issuance or renewal of a wholesale dis-

1 tributor license shall submit a surety bond of
2 one hundred thousand dollars or other equiva-
3 lent means of security acceptable to the State;】

4 【(B) for purposes of subclause (I), the
5 State or other applicable authority may accept
6 a surety bond less than one hundred thousand
7 dollars if the annual gross receipts of the pre-
8 vious tax year for the wholesaler is \$10,000,000
9 or less, in which case the surety bond shall be
10 \$25,000; and】

11 【(C) if a wholesale distributor can provide
12 evidence that it possesses the required bond in
13 another State, the requirement for a bond in a
14 second State is waived;】

15 【(4) mandatory background checks and
16 fingerprinting of facility managers or designated
17 representatives;】

18 【(5) the establishment and implementation of
19 qualifications for key personnel;】

20 【(6) the mandatory physical inspection of any
21 facility to be used in wholesale distribution within a
22 reasonable time frame from the initial application of
23 the facility; and】

1 **[(7) in accordance with [subparagraph (d)],**
2 the prohibition of certain persons from receiving or
3 maintaining licensure for wholesale distribution.]

4 **[(c) INSPECTIONS.—To satisfy the inspection re-**
5 quirement the State or Federal licensing authority may
6 conduct the inspection, or may accept an inspection by the
7 facility’s resident State, or a third party accreditation or
8 inspection service approved by the Secretary.]

9 **[(d) GUIDELINES.—The guidelines under subpara-**
10 graph shall include requirements to prohibit a person from
11 receiving or maintaining licensure for wholesale distribu-
12 tion if the person—]

13 **[(1) has been convicted of any felony for con-**
14 duct relating to wholesale distribution, any felony
15 violation of [subsection (i) or (k)] of section 301 of
16 this Act, or any felony violation of section 1365 of
17 title 18, United States Code, relating to product
18 tampering; or]

19 **[(2) has engaged in a pattern of violating the**
20 requirements of this section, or State requirements
21 for licensure, that presents a threat of serious ad-
22 verse health consequences or death to humans.]

23 **[(e) EFFECTIVE DATE.—Not later than 180 days**
24 after the date of enactment of this Act, the Secretary shall
25 by regulation issue the guidelines. Such regulations shall

1 take effect upon the expiration of 2 years after the date
2 such regulations are published.】

3 **【PART IV—*OPTION IV*】**

4

5 **【(a) IN GENERAL.—**The Secretary shall by regula-
6 tion issue guidelines establishing standards, terms, and
7 conditions for the licensing of person to make wholesale
8 distributions of prescription drugs.】

9 **【(b) GUIDELINES.—**Such guidelines shall prescribe
10 requirements for—】

11 **【(1) SEE SECTION 4160 OF THE CALIFORNIA**
12 **BUSINESS AND PROFESSIONS CODE.—**

13 **【(A) A person may not act as a wholesaler**
14 **of any dangerous drug or dangerous device un-**
15 **less he or she has obtained a license from the**
16 **board.】**

17 **【(B) Upon approval by the board and the**
18 **payment of the required fee, the board shall**
19 **issue a license to the applicant.】**

20 **【(C) A separate license shall be required**
21 **for each place of business owned or operated by**
22 **a wholesaler. Each license shall be renewed an-**
23 **nually and shall not be transferable.】**

24 **【(D) Every wholesaler shall be supervised**
25 **or managed by a designated representative-in-**

1 charge. The designated representative shall be
2 responsible for the wholesaler's compliance with
3 State and Federal laws governing wholesalers.
4 As part of its initial application for a license,
5 and for each renewal, each wholesaler shall, on
6 a form designed by the board, provide identi-
7 fying information and the California license
8 number for a designated representative or phar-
9 macist proposed to serve as the designated rep-
10 resentative-in-charge. The proposed designated
11 representative-in-charge shall be subject to ap-
12 proval by the board. The board shall not issue
13 or renew a wholesaler license without identifica-
14 tion of an approved designated representative-
15 in-charge for the wholesaler.】

16 【(E) Every wholesaler shall notify the
17 board in writing, on a form designed by the
18 board, within 30 days of the date when a des-
19 ignated representative-in-charge ceases to act as
20 the designated representative-in-charge, and
21 shall on the same form propose another des-
22 ignated representative or pharmacist to take
23 over as the designated representative-in-charge.
24 The proposed replacement designated represent-
25 ative-in-charge shall be subject to approval by

1 the board. If disapproved, the wholesaler shall
2 propose another replacement within 15 days of
3 the date of disapproval, and shall continue to
4 name proposed replacements until a designated
5 representative-in-charge is approved by the
6 board.】

7 【(F) A drug manufacturer premises li-
8 censed by the Food and Drug Administration or
9 licensed pursuant to Section 111615 of the
10 Health and Safety Code that only distributes
11 dangerous drugs and dangerous devices of its
12 own manufacture is exempt from this section
13 and section 4161.】

14 【(G) The board may issue a temporary li-
15 cense, upon conditions and for periods of time
16 as the board determines to be in the public in-
17 terest. A temporary license fee shall be shall be
18 required in an amount established by the board
19 as specified in 【subdivision (f)】 of section
20 4400. When needed to protect public safety, a
21 temporary license may be issued for a period
22 not to exceed 180 days, subject to terms and
23 conditions that the board deems necessary. If
24 the board determines that a temporary license
25 was issued by mistake or denies the application

1 for a permanent license, the temporary license
2 shall terminate upon either personal service of
3 the notice of termination upon the licenseholder
4 or service by certified mail, return receipt re-
5 quested, at the licenseholder's address of record
6 with the board, whichever occurs first. Neither
7 for purposes of retaining a temporary license,
8 nor for purposes of any disciplinary or license
9 denial proceeding before the board, shall the
10 temporary licenseholder be deemed to have a
11 vested property right or interest in the license.】

12 【(2) 【SEE SECTION 4161 OF THE CALIFORNIA
13 BUSINESS AND PROFESSIONS CODE】.—

14 【(A) IN GENERAL.—A person located out-
15 side this State that—】

16 【(i) ships, sells, mails, or delivers dan-
17 gerous drugs or dangerous devices into this
18 State; or】

19 【(ii) sells, brokers, or distributes dan-
20 gerous drugs or devices within this State
21 shall be considered a nonresident whole-
22 saler.】

23 【(B) A nonresident wholesaler shall be li-
24 censed by the board prior to shipping, selling,
25 mailing, or delivering dangerous drugs or dan-

1 gerous devices to a site located in this State or
2 selling, brokering, or distributing dangerous
3 drugs or devices within this State.】

4 【(C) A separate license shall be required
5 for each place of business owned or operated by
6 a nonresident wholesaler from or through which
7 dangerous drugs or dangerous devices are
8 shipped, sold, mailed, or delivered to a site lo-
9 cated in this State or sold, brokered, or distrib-
10 uted within this State. A license shall be re-
11 newed annually and shall not be transferable.】

12 【(D) The following information shall be re-
13 ported, in writing, to the board at the time of
14 initial application for licensure by a nonresident
15 wholesaler, on renewal of a nonresident whole-
16 saler license, or within 30 days of a change in
17 that information:】

18 【(i) Its agent for service of process in
19 this State.】

20 【(ii) Its principal corporate officers,
21 as specified by the board, if any.】

22 【(iii) Its general partners, as specified
23 by the board, if any.】

24 【(iv) Its owners if the applicant is not
25 a corporation or partnership.】

1 **[(E)** A report containing the information
2 in subdivision (d) shall be made within 30 days
3 of any change of ownership, office, corporate of-
4 ficer, or partner.]

5 **[(F)** A nonresident wholesaler shall comply
6 with all directions and requests for information
7 from the regulatory or licensing agency of the
8 State in which it is licensed, as well as with all
9 requests for information made by the board.]

10 **[(G)** A nonresident wholesaler shall main-
11 tain records of dangerous drugs and dangerous
12 devices sold, traded, or transferred to persons
13 in this State or within this State, so that the
14 records are in a readily retrievable form.]

15 **[(H)** A nonresident wholesaler shall at all
16 times maintain a valid, unexpired license, per-
17 mit, or registration to conduct the business of
18 the wholesaler in compliance with the laws of
19 the State in which it is a resident. An applica-
20 tion for a nonresident wholesaler license in this
21 State shall include a license verification from
22 the licensing authority in the applicant's State
23 of residence.]

24 **[(I)** The board may not issue or renew a
25 nonresident wholesaler license until the non-

1 resident wholesaler identifies a designated rep-
2 resentative-in-charge and notifies the board in
3 writing of the identity and license number of
4 the designated representative-in-charge.】

5 【(J) The designated representative-in-
6 charge shall be responsible for the nonresident
7 wholesaler's compliance with State and Federal
8 laws governing wholesalers. A nonresident
9 wholesaler shall identify and notify the board of
10 a new designated representative-in-charge with-
11 in 30 days of the date that the prior designated
12 representative-in-charge ceases to be the des-
13 igned representative in-charge.】

14 【(K) The board may issue a temporary li-
15 cense, upon conditions and for periods of time
16 as the board determines to be in the public in-
17 terest. A temporary license fee shall be \$550 or
18 another amount established by the board not to
19 exceed the annual fee for renewal of a license
20 to compound injectable sterile drug products.
21 When needed to protect public safety, a tem-
22 porary license may be issued for a period not to
23 exceed 180 days, subject to terms and condi-
24 tions that the board deems necessary. If the
25 board determines that a temporary license was

1 issued by mistake or denies the application for
2 a permanent license, the temporary license shall
3 terminate upon either personal service of the
4 notice of termination upon the licenseholder or
5 service by certified mail, return receipt re-
6 quested, at the licenseholder's address of record
7 with the board, whichever occurs first. Neither
8 for purposes of retaining a temporary license,
9 nor for purposes of any disciplinary or license
10 denial proceeding before the board, shall the
11 temporary licenseholder be deemed to have a
12 vested property right or interest in the license.】

13 【(L) The registration fee shall be the fee
14 specified in subdivision (f) of section 4400.】

15 【(3) 【SEE SECTION 4162 OF THE CALIFORNIA
16 BUSINESS AND PROFESSIONS CODE】.—

17 【(A)(i) An applicant, that is not a govern-
18 ment owned and operated wholesaler, for the
19 issuance or renewal of a wholesaler license shall
20 submit a surety bond of \$100,000 or other
21 equivalent means of security acceptable to the
22 board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is
23 to secure payment of any administrative fine
24

1 imposed by the board and any cost recovery or-
2 dered pursuant to Section 125.3.】

3 【(ii) For purposes of paragraph (1), the
4 board may accept a surety bond less than one
5 hundred thousand dollars (\$100,000) if the an-
6 nual gross receipts of the previous tax year for
7 the wholesaler is ten million dollars
8 (\$10,000,000) or less, in which case the surety
9 bond shall be \$25,000.】

10 【(iii) A person to whom an approved new
11 drug application has been issued by the United
12 States Food and Drug Administration who en-
13 gages in the wholesale distribution of only the
14 dangerous drug specified in the new drug appli-
15 cation, and is licensed or applies for licensure
16 as a wholesaler, shall not be required to post a
17 surety bond as provided in paragraph (1).】

18 【(iv) For licensees subject to paragraph
19 (2) or (3), the board may require a bond up to
20 \$100,000 for any licensee who has been dis-
21 ciplined by any State or Federal agency or has
22 been issued an administrative fine pursuant to
23 this chapter.】

24 【(B) The board may make a claim against
25 the bond if the licensee fails to pay a fine with-

1 in 30 days after the order imposing the fine, or
2 costs become final.】

3 【(C) A single surety bond or other equiva-
4 lent means of security acceptable to the board
5 shall satisfy the requirement of subsection (a)
6 for all licensed sites under common control as
7 defined in section 4126.5.】

8 【(4) 【SEE SECTION 4162.5 OF THE CALIFORNIA
9 BUSINESS AND PROFESSIONS CODE】.—

10 【(A)(i) An applicant for the issuance or re-
11 newal of a nonresident wholesaler license shall
12 submit a surety bond of \$100,000, or other
13 equivalent means of security acceptable to the
14 board, such as an irrevocable letter of credit, or
15 a deposit in a trust account or financial institu-
16 tion, payable to the Pharmacy Board Contin-
17 gent Fund. The purpose of the surety bond is
18 to secure payment of any administrative fine
19 imposed by the board and any cost recovery or-
20 dered pursuant to section 125.3.】

21 【(ii) For purposes of paragraph (1), the
22 board may accept a surety bond less than
23 \$100,000 if the annual gross receipts of the
24 previous tax year for the nonresident wholesaler

1 is \$10,000,000 or less in which the surety bond
2 shall be \$25,000.】

3 【(iii) For applicants who satisfy paragraph
4 (2), the board may require a bond up to
5 \$100,000 for any nonresident wholesaler who
6 has been disciplined by any State or Federal
7 agency or has been issued an administrative
8 fine pursuant to this chapter.】

9 【(iv) A person to whom an approved new
10 drug application or a biologics license applica-
11 tion has been issued by the United States Food
12 and Drug Administration who engages in the
13 wholesale distribution of only the dangerous
14 drug specified in the new drug application or
15 biologics license application, and is licensed or
16 applies for licensure as a nonresident whole-
17 saler, shall not be required to post a surety
18 bond as provided in this section.】

19 【(B) The board may make a claim against
20 the bond if the licensee fails to pay a fine with-
21 in 30 days of the issuance of the fine or when
22 the costs become final.】

23 【(C) A single surety bond or other equiva-
24 lent means of security acceptable to the board
25 shall satisfy the requirement of subsection (a)

1 for all licensed sites under common control as
2 defined in section 4126.5.】

3 【(5) 【SEE SECTION 4167 OF THE CALIFORNIA
4 BUSINESS AND PROFESSIONS CODE】.—A wholesaler
5 shall not obtain, by purchase or otherwise, any dan-
6 gerous drugs or dangerous devices that it cannot
7 maintain, in a secure manner, on the premises li-
8 censed by the board.】

9 【(c) REVOCATION OF BOND.—The State that issues
10 a license to a wholesale distributor, or the Secretary of
11 Health and Human Services (referred to as the “Sec-
12 retary”), in the case that the Secretary licenses a whole-
13 sale distributor, may revoke the bond of an entity so li-
14 censed by such State or the Secretary, if such entity vio-
15 lates a licensure requirement under this section or a dis-
16 tribution requirement 【under section 582 of the Federal
17 Food, Drug, and Cosmetic Act.】】

18 **SEC. 5. NATIONAL LICENSURE STANDARDS FOR THIRD-**
19 **PARTY LOGISTICS PROVIDERS.**

20 【(*option 1*) Once licensure standards for wholesale
21 distributors are decided, apply an applicable subset of
22 those standards to licensure of third-party logistics pro-
23 viders.】

24 【(*option 2*) Defer to Secretary of Health and Human
25 Services to promulgate licensure standards for third-party

1 logistics providers through a notice and comment
2 rulemakings.】

3 【(*option 3*) Defer to the Secretary of Health and
4 Human Services to promulgate licensure standards for
5 third-party logistics providers through notice and com-
6 ment rulemaking, but prescribe that process as follows:】
7 Subchapter G of chapter V of the Federal Food, Drug,
8 and Cosmetic Act, as amended by section 4, is further
9 amended by adding at the end the following:

10

11 **“SEC. 584. FACILITY LICENSING REQUIREMENTS FOR**
12 **THIRD-PARTY LOGISTICS PROVIDERS.**

13 “(a) LICENSE REQUIREMENT.—No person may en-
14 gage in the activities of a third-party logistics provider in
15 any State unless such person—

16 “(1)(A) is licensed by the State from which the
17 drug is distributed; or

18 “(B) if the State from which the drug dis-
19 tributed has not established a licensure require-
20 ment, is licensed by the Secretary; and

21 “(2) if the drug is distributed interstate, is li-
22 censed by the State into which the drug is distrib-
23 uted if the State into which the drug is distributed
24 requires the licensure of third-party logistics pro-
25 viders that distribute drugs into the State.

1 **【“(b) LISTING REQUIREMENT.—】**

2 **【“(1) IN GENERAL.—Each [person]/[estab-**
3 **lishment] who engages in the activities of a third-**
4 **party logistics provider shall list such establishment**
5 **with the Secretary and, at least annually, update or**
6 **withdraw such listing.】**

7 **【“(2) REQUIRED INFORMATION.—The Sec-**
8 **retary shall specify, by guidance, the information**
9 **that a person must submit to the Secretary to meet**
10 **the [listing] requirement and may specify what**
11 **changes to such information must be submitted**
12 **more frequently than annually to maintain a valid**
13 **[listing] with the Secretary.】**

14 **【“(3) SUSPENSION OR REVOCATION OF LIST-**
15 **ING.—The Secretary may suspend or revoke a listing**
16 **[by letter]/[in writing] at any time if the Secretary**
17 **determines that a person engaged as a third-party**
18 **logistics provider has failed to comply with any re-**
19 **quirements of this [Act]/[subchapter].】**

20 **【“(c) COSTS.—】**

21 **“(1) AUTHORIZED LISTING FEES OF SEC-**
22 **RETARY.—The Secretary may assess fees on persons**
23 **engaging as third-party logistic providers who seek**
24 **to list with the Secretary under this subsection in**
25 **such an amount necessary to reimburse the Sec-**

1 retary for the costs associated with establishing and
2 administering the listing program and conducting
3 periodic inspections of registrants under this section.
4 The Secretary shall not generate surplus revenue
5 from such a reimbursement mechanism. Fees au-
6 thorized under this paragraph shall be collected and
7 available for obligation only to the extent and in the
8 amount provided in advance in appropriation Acts.
9 Such fees may remain available until expended.

10 “(2) AUTHORIZED LICENSURE FEES OF SEC-
11 RETARY.—If a State does not establish a licensure
12 program for third-party logistics providers, the Sec-
13 retary shall license the third-party logistics providers
14 located in such State and may collect a reasonable
15 fee to perform that service, consistent with the limi-
16 tation set forth in paragraph (1).

17 “(3) STATE LICENSING FEES.—Nothing in this
18 Act shall prohibit States from collecting fees from
19 third-party logistics providers in connection with
20 State licensing of such distributors.

21 “(d) LICENSE REGULATIONS.—

22 “(1) IN GENERAL.—Not later than 180 days
23 after the date of enactment of the [insert short
24 title], the Secretary shall issue regulations regarding
25 the issuance and eligibility requirements of a facility

1 license, including the revocation and re-issuance of
2 such license, to third-party logistics providers under
3 this section.

4 “(2) CONTENT.—Such regulations shall—

5 “(A) establish a process by which the Sec-
6 retary shall, upon request by a third-party lo-
7 gistics provider, issue a license to a third-party
8 logistics provider who is accredited by a third-
9 party accreditation program approved by the
10 Secretary;

11 “(B) establish a process by which the Sec-
12 retary shall issue a license to a third-party lo-
13 gistics provider if the Secretary is not able to
14 approve a third-party accreditation program be-
15 cause no such program meets the Secretary’s
16 requirements necessary for approval of such a
17 third-party accreditation program;

18 “(C) require that the entity complies with
19 good storage practices, as determined by the
20 Secretary at such facility, including—

21 “(i) maintaining access to warehouse
22 space of suitable size to facilitate safe op-
23 erations, including a suitable area to quar-
24 antine suspect product;

1 “(ii) maintaining adequate security;

2 and

3 “(iii) having written policies and pro-

4 cedures to—

5 “(I) address receipt, security,

6 storage, inventory, shipment, and dis-

7 tribution of a prescription drug;

8 “(II) identify, record, and report

9 confirmed losses or thefts in the

10 United States;

11 “(III) correct errors and inac-

12 curacies in inventories;

13 “(IV) provide support for manu-

14 facturer recalls;

15 “(V) prepare for, protect against,

16 and address any reasonably foresee-

17 able crisis that affects security or op-

18 eration at the facility, such as a

19 strike, fire, or flood;

20 “(VI) ensure that any expired

21 prescription drug is segregated from

22 other drugs and returned to the man-

23 ufacturer or re-packager or destroyed;

24 “(VII) maintain the capability to

25 electronically trace the receipt and

1 outbound distribution of a prescrip-
2 tion drug, and supplies and records of
3 inventory; and

4 “(VIII) quarantine or destroy a
5 suspect product if directed to do so by
6 the respective prescription drug man-
7 ufacturer, wholesaler, or dispenser or
8 an authorized government agency;

9 “(D) provide for periodic inspection, as de-
10 termined by the Secretary, of such facility ware-
11 house space to ensure compliance with this sec-
12 tion;

13 “(E) prohibit a facility from having as a
14 manager or designated representative anyone
15 convicted of any felony violation of section
16 301(i) or 301(k) of this Act or any violation of
17 section 1365 of title 18, United States Code re-
18 lating to product tampering;

19 “(F) perform mandatory background
20 checks of a facility manager or a designated
21 representative of such manager; and

22 “(G) require the third-party logistics pro-
23 vider to provide the Secretary, upon a request
24 by the Secretary, a list of all prescription drug
25 manufacturers, wholesale distributors, and dis-

1 pensors for whom the third-party logistics pro-
2 vider provides services at such facility.

3 “(e) VALIDITY OF LICENSE.—[A license issued
4 under this section shall remain valid as long as such third-
5 party logistics provider remains accredited by the Sec-
6 retary, but such license shall be renewed in accordance
7 with subsection (f).] If the Secretary finds that the third-
8 party accreditation program demonstrates that all applica-
9 ble requirements for licensure under this section are met,
10 [the Secretary shall treat a third-party logistics provider
11 receiving accreditation as if such provider has received a
12 license under this section].

13 [“(f) RENEWAL OF LICENSES.—The Secretary shall
14 develop procedures for license renewal. Licenses issued
15 under this section shall expire on the date that is 3 years
16 after issuance of the license. Such an expired license may
17 be renewed for additional 3-year periods according to pro-
18 cedures developed by the Secretary.]

19 [“(g) REVOCATION OF BOND.—[A State that issues
20 a license to a third-party logistics provider], or the Sec-
21 retary, in the case that the Secretary licenses a third-party
22 logistics provider, may revoke the bond of an entity so li-
23 censed by such State or the Secretary, in whole or in part,
24 if such entity violates a licensure requirement under this

1 section or a distribution requirement [under section
2 582.]]”.]

3 **SEC. 6. PENALTIES.**

4 (a) PROHIBITED ACT.—Section 301(t) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 331(t)), is
6 amended—

7 (1) by striking “or” after “the requirements of
8 section 503(d),”; and

9 (2) by inserting “, failure to comply with the
10 standards under section [582], the failure to list
11 under section [section 583 or 584, as applicable],”
12 after “in violation of section 503(e)”.

13 (b) ADULTERATION.—Section 501 of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 351), is amend-
15 ed by adding at the end the following:

16 “(k) If it is a drug and its distribution does not com-
17 ply with the standards under section 503(e) or the require-
18 ments under section 582.”.

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

22 “(bb) If it is a drug and it was distributed by a per-
23 son not authorized to distribute the product within the
24 meaning of section 581(2).”.

1 **SEC. 7. UNIFORM NATIONAL POLICY.**

2 (a) **PRODUCT TRACING REQUIREMENTS.**—Beginning
3 on the date of enactment of this Act, no State or political
4 subdivision of a State may establish or continue in effect
5 any requirements with respect to transaction history,
6 transaction information, or transaction statement of a
7 pharmaceutical product as such product changes owner-
8 ship in the supply chain (including requirements for paper
9 or electronic pedigree systems or for tracking and tracing
10 drugs throughout the distribution system) which are in-
11 consistent with, more stringent than, or in addition to, any
12 requirements applicable under this Act (or the amend-
13 ments made by this Act).

14 (b) **DISTRIBUTION AND LICENSING STANDARDS.**—

15 (1) **IN GENERAL.**—Beginning on the date of en-
16 actment of this Act, no State or political subdivision
17 of a State may establish any standards, require-
18 ments, or regulations with respect to wholesale drug
19 distributor or third-party logistics provider licensure
20 or product tracing which are inconsistent with, [less
21 stringent than,] [in addition to, or more stringent
22 than,] the standards and requirements applicable
23 under the amendments made by this Act.

24 (2) **ADMINISTRATION FEES.**—Notwithstanding
25 paragraph (1), a State may administer fee collec-
26 tions for effectuating the wholesale drug distributor

1 and third-party logistics provider licensure require-
2 ments under [sections 503(e), 583, and 584].

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

5 (A) may provide for the suspension or rev-
6 ocation of licenses issued by the State for viola-
7 tions of the laws [of such State];

8 (B) upon conviction of violations of Fed-
9 eral, State, or local drug laws or regulations,
10 may provide for fines, imprisonment, or civil
11 penalties; and

12 [(C) may regulate activities of licensure
13 entities in a manner that is consistent with the
14 distribution and licensing standards, and prod-
15 uct tracing requirements under [section 582 of
16 the Federal Food, Drug, and Cosmetic Act, as
17 added by section 2].]

18 [(c) EXCEPTION.—Nothing in subsection (a) or (b)
19 shall be construed to preempt State requirements related
20 to the distribution of prescription drugs if such require-
21 ments are not related to licensure or product tracing.
22 [Note from working group: This language would, for ex-
23 ample, preserve the current CA law that prohibits whole-
24 sale distributors from selling excessive amounts of con-
25 trolled substances].]