

113TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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

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IN THE SENATE OF THE UNITED STATES

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

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## A BILL

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

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 This Act may be cited as **["the "\_\_\_\_\_ Act"]**.

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

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

1 **“Subchapter G—Pharmaceutical Distribution**  
2 **Supply Chain**

3 **“SEC. 581. DEFINITIONS.**

4 “In this subchapter:

5 “(1) AUTHORIZED.—The term ‘authorized’  
6 means—

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

10 “(B) in the case of a wholesale distributor,  
11 having a valid license under State law or sec-  
12 tion 583, in accordance with section 582(a)(6)  
13 and complying with the licensure reporting re-  
14 quirements under section 503(e);

15 “(C) in the case of a third-party logistics  
16 provider, having a valid license under State law  
17 or section 584(a)(1), in accordance with section  
18 582(a)(7) and complying with the licensure re-  
19 porting requirements under section 584(b); and

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

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

23 “(A) means a retail pharmacy, hospital  
24 pharmacy, a group of chain pharmacies under  
25 common ownership and control that do not act

1 as a wholesale distributor, or any other person  
2 authorized by law to dispense or administer  
3 prescription drugs, and the affiliated ware-  
4 houses or distribution centers of such entities  
5 under common ownership and control that do  
6 not act as a wholesale distributor; and

7 “(B) does not include a person who only  
8 dispenses products to be used in animals in ac-  
9 cordance with section 512(a)(5).

10 “(3) DISPOSITION.—The term ‘disposition’,  
11 with respect to a product within the possession or  
12 control of an entity, means the removal of such  
13 product from the pharmaceutical distribution supply  
14 chain, which may include disposal or return of the  
15 product for disposal or other appropriate handling  
16 and other actions such as retaining a sample of the  
17 product for further additional physical examination  
18 or laboratory analysis of the product by a manufac-  
19 turer or regulatory or law enforcement agency.

20 “(4) DISTRIBUTE OR DISTRIBUTION.—The  
21 term ‘distribute’ or ‘distribution’ means the sale,  
22 purchase, trade, delivery, handling, storage, or re-  
23 ceipt of a product.

1           “(5) ILLEGITIMATE PRODUCT.—The term ‘ille-  
2           gitimate product’ means a product for which credible  
3           evidence shows that the product—

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

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

8                   “(C) is the subject of a fraudulent trans-  
9           action; or

10                  “(D) appears otherwise unfit for distribu-  
11           tion such that the product could result in seri-  
12           ous adverse health consequence or death to hu-  
13           mans.

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

15                   “(A) in the case of a wholesale distributor,  
16           having a valid license under State law or sec-  
17           tion 583, in accordance with section 582(a)(6);

18                   “(B) in the case of a third-party logistics  
19           provider, having a valid license under State law  
20           or section 584(a)(1), in accordance with section  
21           582(a)(7); and

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

24           “(7) MANUFACTURER.—

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

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

10           “(ii) a person that manufactures such  
11 product on behalf of the person described  
12 in clause (i);

13           “(iii) a co-licensed partner of the per-  
14 son described in clause (i) that obtains the  
15 product directly from the person described  
16 in clause (i) or (ii); or

17           “(iv) an affiliate of a person described  
18 in clause (i) or (iii) that receives the prod-  
19 uct directly from a person described in  
20 clause (i), (ii), or (iii).

21           “(B) AFFILIATE.—For purposes of this  
22 paragraph, the term ‘affiliate’ means a member  
23 of an affiliated group, as that term is defined  
24 in section 1504(a) of the Internal Revenue  
25 Code.

1 “(8) PACKAGE.—

2 “(A) IN GENERAL.—The term ‘package’  
3 means the smallest individual saleable unit of  
4 product for distribution by a manufacturer or  
5 repackager that is intended by the manufac-  
6 turer for ultimate sale to the dispenser of such  
7 product.

8 “(B) INDIVIDUAL SALEABLE UNIT.—For  
9 purposes of this paragraph, an ‘individual sale-  
10 able unit’ is the smallest container of product  
11 introduced into commerce by the manufacturer  
12 that is intended by the manufacturer for indi-  
13 vidual sale to a dispenser.

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

17 “(10) PRODUCT.—The term ‘product’ means a  
18 prescription drug in a finished dosage form for ad-  
19 ministration to a patient without substantial further  
20 manufacturing (such as capsules, tablets, and  
21 lyophilized products before reconstitution).

22 “(11) PRODUCT IDENTIFIER.—The term ‘prod-  
23 uct identifier’ means a standardized graphic that in-  
24 cludes, in both human-readable form and on a ma-  
25 chine-readable data carrier that conforms to the

1 standards developed by a widely-recognized inter-  
2 national standards development organization, the  
3 standardized numerical identifier, lot number, and  
4 expiration date of the product.

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

9 “(13) RETURN.—The term ‘return’ means pro-  
10 viding product to the authorized immediate trading  
11 partner from which such product was purchased, or  
12 to a returns processor or reverse logistics provider  
13 for handling of such product.

14 “(14) RETURNS PROCESSOR OR REVERSE LO-  
15 GISTICS PROVIDER.—The term ‘returns processor’ or  
16 ‘reverse logistics provider’ means a person who owns  
17 or operates an establishment that dispositions or  
18 otherwise processes saleable or nonsaleable product  
19 received from an authorized trading partner such  
20 that the product may be processed for credit to the  
21 purchaser, manufacturer, or seller or disposed of for  
22 no further distribution.

23 “(15) SPECIFIC PATIENT NEED.—The term  
24 ‘specific patient need’ refers to the transfer of a  
25 product from one pharmacy to another to fill a pre-

1        scription for an identified patient. Such term does  
2        not include the transfer of a product from one phar-  
3        macy to another for the purpose of increasing or re-  
4        plenishing stock in anticipation of a potential need.

5           “(16) STANDARDIZED NUMERICAL IDENTIFIER  
6        OR SNI.—The term ‘standardized numerical identi-  
7        fier’ or ‘SNI’ means a set of numbers or characters  
8        used to uniquely identify each package or homoge-  
9        nous case that is composed of the National Drug  
10       Code that corresponds to the specific product (in-  
11       cluding the particular package configuration) com-  
12       bined with a unique alphanumeric serial number of  
13       up to 20 characters.

14           “(17) SUSPECT PRODUCT.—The term ‘suspect  
15       product’ means a product for which there is reason  
16       to believe that such product—

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

19           “(B) is potentially intentionally adulterated  
20        such that the product would result in serious  
21        adverse health consequences or death to hu-  
22        mans;

23           “(C) is potentially the subject of a fraudu-  
24        lent transaction; or



1           “(D) appears otherwise unfit for distribu-  
2           tion such that the product would result in seri-  
3           ous adverse health consequences or death to hu-  
4           mans.

5           “(18) THIRD-PARTY LOGISTICS PROVIDER.—  
6           The term ‘third-party logistics provider’ means an  
7           entity that provides or coordinates warehousing, or  
8           other logistics services of a product in interstate  
9           commerce on behalf of a manufacturer, wholesaler,  
10          or dispenser of a product, but does not take owner-  
11          ship of the product, nor have responsibility to direct  
12          the sale or disposition of the product. The term does  
13          not include a common carrier unless, in addition to  
14          transporting a product, the common carrier also per-  
15          forms any of the activities described in the preceding  
16          sentence.

17          “(19) TRADING PARTNER.—The term ‘trading  
18          partner’ means—

19                 “(A) a manufacturer, repackager, whole-  
20                 sale distributor, or dispenser from whom a  
21                 manufacturer, repackager, wholesale dis-  
22                 tributor, or dispenser accepts direct ownership  
23                 of a product or to whom a manufacturer, re-  
24                 packager, wholesale distributor, or dispenser  
25                 transfers direct ownership of a product; or

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

7           “(20) TRANSACTION.—

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

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

13                 “(i) intracompany distribution of any  
14                 product between members of an affiliated  
15                 group (as defined in section 1504(a) of the  
16                 Internal Revenue Code of 1986);

17                 “(ii) the distribution of a product  
18                 among hospitals or other health care enti-  
19                 ties that are under common control;

20                 “(iii) the distribution of a product for  
21                 emergency medical reasons including a  
22                 public health emergency declaration pursu-  
23                 ant to section 319 of the Public Health  
24                 Service Act, except that a drug shortage  
25                 not caused by a public health emergency

1 shall not constitute an emergency medical  
2 reason;

3 “(iv) the dispensing of a product pur-  
4 suant to a valid prescription executed in  
5 accordance with section 503(b)(1);

6 “(v) the distribution of product sam-  
7 ples by a manufacturer or a licensed  
8 wholesale distributor in accordance with  
9 section 503(d);

10 “(vi) the distribution of blood or blood  
11 components intended for transfusion;

12 “(vii) the distribution of minimal  
13 quantities of product by a licensed retail  
14 pharmacy to a licensed practitioner for of-  
15 fice use;

16 “(viii) the sale, purchase, or trade of  
17 a drug or an offer to sell, purchase, or  
18 trade a drug by a charitable organization  
19 described in section 501(c)(3) of the Inter-  
20 nal Revenue Code of 1954 to a nonprofit  
21 affiliate of the organization to the extent  
22 otherwise permitted by law;

23 “(ix) the distribution of a product  
24 pursuant to the sale or merger of a phar-  
25 macy or pharmacies or a wholesale dis-

1 tributor or wholesale distributors, except  
2 that any records required to be maintained  
3 for the product shall be transferred to the  
4 new owner of the pharmacy or pharmacies  
5 or wholesale distributor or wholesale dis-  
6 tributors;

7 “(x) the dispensing of a product ap-  
8 proved under section 512(b);

9 “(xi) products transferred to or from  
10 any facility that is licensed by the Nuclear  
11 Regulatory Commission or by a State pur-  
12 suant to an agreement with such Commis-  
13 sion under section 274 of the Atomic En-  
14 ergy Act of 1954 (42 U.S.C. 2021);

15 “(xii) a combination product that is—

16 “(I) a product comprised of a de-  
17 vice and 1 or more other regulated  
18 components (such as a drug/device,  
19 biologic/device, or drug/device/biologic)  
20 that are physically, chemically, or oth-  
21 erwise combined or mixed and pro-  
22 duced as a single entity;

23 “(II) 2 or more separate prod-  
24 ucts packaged together in a single  
25 package or as a unit and comprised of

1 a drug and device products or device  
2 and biological product; or

3 “(III) 2 or more finished medical  
4 devices plus one or more drug or bio-  
5 logical products which are packaged  
6 together in what is referred to as a  
7 ‘medical convenience kit’ as described  
8 in clause (xiii);

9 “(xiii) the distribution of a collection  
10 of finished medical devices or a collection  
11 of finished drug or biological products as-  
12 sembled in kit form strictly for the conven-  
13 ience of the purchaser or user (to be  
14 known as a ‘medical convenience kit’) if—

15 “(I) the medical convenience kit  
16 is assembled in an establishment that  
17 is registered with the Food and Drug  
18 Administration as a device manufac-  
19 turer;

20 “(II) the person who manufactur-  
21 ers a medical convenience kit pur-  
22 chased the product directly from the  
23 manufacturer or from a wholesale dis-  
24 tributor that purchased the product  
25 directly from the manufacturer;

1 “(III) the person who manufac-  
2 turers a medical convenience kit does  
3 not alter the primary container or  
4 label of the product as purchased  
5 from the manufacturer or wholesale  
6 distributor;

7 “(IV) the medical convenience kit  
8 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; and

13 “(V) the products contained in  
14 the medical convenience 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) sympathicomimetics;

2 “(xiv) the distribution of an intra-  
3 venous product that, by its formulation, is  
4 intended for the replenishment of fluids  
5 and electrolytes (such as sodium, chloride,  
6 and potassium) or calories (such as dex-  
7 trose and amino acids);

8 “(xv) the distribution of an intra-  
9 venous product used to maintain the equi-  
10 librium of water and minerals in the body,  
11 such as dialysis solutions;

12 “(xvi) the distribution of a product  
13 that is intended for irrigation or recon-  
14 stitution, or sterile water, whether intended  
15 for such purposes or for injection; or

16 “(xvii) the distribution of compressed  
17 medical gas, as defined in section 575.

18 “(21) TRANSACTION HISTORY.—The term  
19 ‘transaction history’ means a statement in paper or  
20 electronic form, including the transaction informa-  
21 tion for each prior transaction going back to the  
22 manufacturer of the product.

23 “(22) TRANSACTION INFORMATION.—The term  
24 ‘transaction information’ means—

1           “(A) the proprietary or established name  
2 or names of the product;

3           “(B) the strength and dosage form of the  
4 product;

5           “(C) the National Drug Code number of  
6 the product;

7           “(D) the container size;

8           “(E) the number of containers;

9           “(F) the lot number of the product;

10          “(G) the date of the transaction;

11          “(H) the date of the shipment, if different  
12 from the date of the transaction;

13          “(I) the business name and address of the  
14 person from whom ownership is being trans-  
15 ferred; and

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

18          “(23) TRANSACTION STATEMENT.—The ‘trans-  
19 action statement’ is a statement, in paper or elec-  
20 tronic form, that the entity transferring ownership  
21 in a transaction—

22           “(A) is authorized as required under **the**  
23 \_\_\_\_\_ **Act**];



1           “(B) received the product from a person  
2           that is authorized as required under [the  
3           \_\_\_\_\_ Act];

4           “(C) received transaction information and  
5           a transaction statement from the prior owner of  
6           the product, as required under section 582;

7           “(D) did not knowingly ship a suspect or  
8           illegitimate product;

9           “(E) had systems and processes in place to  
10          comply with verification requirements under  
11          section 582;

12          “(F) did not knowingly provide false trans-  
13          action information; and

14          “(G) did not knowingly alter the trans-  
15          action history.

16          “(24) VERIFICATION OR VERIFY.—The term  
17          ‘verification’ or ‘verify’ means determining whether  
18          the product identifier affixed to, or imprinted upon,  
19          a package or homogeneous case corresponds to the  
20          standardized numerical identifier or lot number, and  
21          expiration date assigned to the product by the man-  
22          ufacturer or the repackager, as applicable in accord-  
23          ance with section 582.

24          “(25) WHOLESALE DISTRIBUTOR.—The term  
25          ‘wholesale distributor’ means a person (other than a

1 manufacturer, a manufacturer’s co-licensed partner,  
2 a third-party logistics provider, or repackager) en-  
3 gaged in wholesale distribution (as defined in section  
4 503(e)(4)).

5 **“SEC. 582. REQUIREMENTS.**

6 “(a) IN GENERAL.—

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

16 “(2) INITIAL STANDARDS.—

17 “(A) IN GENERAL.—The Secretary shall,  
18 in consultation with other appropriate Federal  
19 officials, manufacturers, repackagers, wholesale  
20 distributors, third-party logistics providers, dis-  
21 pensers, and other pharmaceutical distribution  
22 supply chain stakeholders, issue a draft guid-  
23 ance document that establishes standards for  
24 the interoperable exchange of transaction infor-  
25 mation for compliance with subsections (a), (b),

1 (c), (d), (e), and (f). The standards established  
2 under this paragraph shall take into consider-  
3 ation the standards established under section  
4 505D and shall comply with a form and format  
5 developed by a widely recognized international  
6 standards development organization.

7 “(B) PUBLICATION.—The Secretary shall  
8 publish the standards established under sub-  
9 paragraph (A) not later than 1 year after the  
10 date of enactment of the [\_\_\_\_\_ Act].

11 “(3) WAIVERS, EXCEPTIONS, AND EXEMP-  
12 TIONS.—

13 “(A) IN GENERAL.—Not later than 2 years  
14 after the date of enactment of the  
15 [\_\_\_\_\_ Act], the Secretary shall, by  
16 guidance—

17 “(i) establish a process by which an  
18 authorized manufacturer, repackager,  
19 wholesale distributor, or dispenser may re-  
20 quest a waiver from any of the require-  
21 ments set forth in this section if the Sec-  
22 retary determines that such requirements  
23 would result in an undue economic hard-  
24 ship or for emergency medical reasons, in-  
25 cluding a public health emergency declara-

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

3                   “(ii) establish a process by which the  
4                   Secretary determines exceptions, and a  
5                   process through which a manufacturer or  
6                   repackager may request such an exception,  
7                   to the requirements relating to product  
8                   identifiers if a product is packaged in a  
9                   container too small or otherwise unable to  
10                  accommodate a label with sufficient space  
11                  to bear the information required for com-  
12                  pliance with this section; and

13                  “(iii) establish a process by which the  
14                  Secretary may determine other products or  
15                  transactions that shall be exempt from the  
16                  requirements of this section.

17                  “(B) CONTENT.—The guidance issued  
18                  under subparagraph (A) shall include a process  
19                  for the biennial review and renewal of such  
20                  waivers, exceptions, and exemptions, as applica-  
21                  ble.

22                  “(C) PROCESS.—In issuing the guidance  
23                  under this section, the Secretary shall provide  
24                  an effective date that is not later than 180 days  
25                  prior to the date on which manufacturers are

1 required to affix or imprint a product identifier  
2 to each package and homogenous case of prod-  
3 uct intended to be introduced in a transaction  
4 into commerce consistent with this section.

5 “(4) SELF-EXECUTING REQUIREMENTS.—Ex-  
6 cept where otherwise specified, the requirements of  
7 this section may be enforced without further regula-  
8 tions or guidance from the Secretary.

9 “(5) GRANDFATHERING PRODUCT.—

10 “(A) PRODUCT IDENTIFIER.—Not later  
11 than 1 year after the date of enactment of [the  
12 \_\_\_\_\_ Act,] the Secretary shall finalize  
13 guidance specifying whether and under what  
14 circumstances product that is not labeled with  
15 a product identifier and that is in the pharma-  
16 ceutical distribution supply chain at the time of  
17 the effective date of the requirements of this  
18 section shall be exempted from the require-  
19 ments of this section.

20 “(B) TRACING.—For a product that en-  
21 tered the pharmaceutical distribution supply  
22 chain prior to the date that is 270 days after  
23 the date of enactment of [the \_\_\_\_\_  
24 Act]—

1           “(i) authorized trading partners shall  
2           be exempt from providing transaction in-  
3           formation as required under subsections  
4           (b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii),  
5           and (e)(1)(A)(ii) of this section;

6           “(ii) transaction history required  
7           under this section shall begin with the  
8           owner of such product on such date; and

9           “(iii) the owners of such product on  
10          such date shall be exempt from asserting  
11          receipt of transaction information and  
12          transaction statement from the prior owner  
13          as required under this section.

14          “(6) WHOLESALER LICENSES.—Notwith-  
15          standing section 581(6)(A), until the effective date  
16          of the wholesale distributor licensing regulations  
17          under section 583, the term ‘licensed’ or ‘author-  
18          ized’, as it relates to a wholesale distributor, shall  
19          mean a wholesale distributor with a valid license  
20          under State law.

21          “(7) THIRD-PARTY LOGISTICS PROVIDER LI-  
22          CENSES.—Until the effective date of the third-party  
23          logistics provider licensing regulations under section  
24          584, a third-party logistics provider shall be consid-  
25          ered ‘licensed’ under section 581(6)(B) unless the

1 Secretary has made a finding that the third-party lo-  
2 gistics provider does not utilize good handling and  
3 distribution practices and publishes notice thereof.

4 “(8) LABEL CHANGES.—Changes made to pack-  
5 age labels solely to incorporate the product identifier  
6 may be submitted to the Secretary in the annual re-  
7 port of an establishment, in accordance with section  
8 314.70(d) of chapter 21, Code of Federal Regula-  
9 tions (or any successor regulation).

10 “(9) PRODUCT IDENTIFIERS.—With respect to  
11 any requirement relating to product identifiers under  
12 this subchapter—

13 “(A) the applicable data shall be included  
14 in a linear or two-dimensional data matrix  
15 barcode unless the Secretary allows, through  
16 guidance, persons to use other technologies for  
17 data instead of or in addition to these tech-  
18 nologies; and

19 “(B) verification of the product identifier  
20 may occur by using human-readable or ma-  
21 chine-readable methods.

22 “(b) MANUFACTURER REQUIREMENTS.—

23 “(1) PRODUCT TRACING.—

24 “(A) IN GENERAL.—Beginning not later  
25 than 270 days after the date of enactment of

1           【the \_\_\_\_\_ Act】, a manufacturer  
2 shall—

3                   “(i) prior to, or at the time of, each  
4 transaction in which such manufacturer  
5 transfers ownership of a product, or trans-  
6 fers possession of a product to a third-  
7 party logistics provider, provide the subse-  
8 quent recipient with transaction history,  
9 transaction information, and a transaction  
10 statement; and

11                   “(ii) maintain the transaction infor-  
12 mation for each transaction for not less  
13 than 6 years after the date of the trans-  
14 action.

15                   “(B) REQUESTS FOR INFORMATION.—  
16 Upon a request by the Secretary or other ap-  
17 propriate Federal or State official, in the event  
18 of a recall or for the purpose of investigating a  
19 suspect product or an illegitimate product, a  
20 manufacturer shall, not later than 24 hours  
21 after receiving the request or in other such rea-  
22 sonable time as determined by the Secretary,  
23 based on the circumstances of the request, pro-  
24 vide the applicable transaction information,



1 transaction history, and transaction statement  
2 for the product.

3 “(2) PRODUCT IDENTIFIER.—Beginning not  
4 later than 4 years after the date of enactment of  
5 **【the \_\_\_\_\_ Act】**, a manufacturer shall affix  
6 or imprint a product identifier to each package and  
7 homogenous case of a product intended to be intro-  
8 duced in a transaction into commerce. Such manu-  
9 facturer shall maintain the product identifier infor-  
10 mation for such product for not less than 6 years  
11 after the date of the transaction.

12 “(3) AUTHORIZED TRADING PARTNERS.—Be-  
13 ginning not later than 1 year after the date of enact-  
14 ment of **【the \_\_\_\_\_ Act】**, the trading part-  
15 ners of a manufacturer may be only authorized trad-  
16 ing partners.

17 “(4) VERIFICATION.—Beginning not later than  
18 1 year after the date of enactment of **【the**  
19 **\_\_\_\_\_ Act】**, a manufacturer shall have sys-  
20 tems in place to enable the manufacturer to comply  
21 with the following requirements:

22 “(A) SUSPECT PRODUCT.—

23 “(i) IN GENERAL.—Upon making a  
24 determination that a product in the posses-  
25 sion or control of the manufacturer is a

1 suspect product, or upon receiving a re-  
2 quest for verification from the Secretary  
3 that has made a determination that a  
4 product within the possession or control of  
5 a manufacturer is a suspect product, a  
6 manufacturer shall—

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

11 “(II) promptly conduct an inves-  
12 tigation in coordination with trading  
13 partners, as applicable, to determine  
14 whether the product is an illegitimate  
15 product, which shall include validating  
16 any applicable transaction history and  
17 transaction information in the posses-  
18 sion of the manufacturer and other-  
19 wise investigating to determine wheth-  
20 er the product is an illegitimate prod-  
21 uct, and, beginning 4 years after the  
22 date of enactment of **the**  
23 \_\_\_\_\_ **Act**], verifying the  
24 product at the package level.

1           “(ii) CLEARED PRODUCT.—If the  
2 manufacturer makes the determination  
3 that a suspect product is not an illegit-  
4 imate product, the manufacturer shall  
5 promptly notify the Secretary, if applica-  
6 ble, of such determination and such prod-  
7 uct may be further distributed.

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

12           “(B) ILLEGITIMATE PRODUCT.—

13           “(i) IN GENERAL.—Upon determining  
14 that a product in the possession or control  
15 of a manufacturer is an illegitimate prod-  
16 uct, the manufacturer shall, in a manner  
17 consistent with the systems and processes  
18 of such manufacturer—

19           “(I) quarantine such product  
20 within the possession or control of the  
21 manufacturer from product intended  
22 for distribution;

23           “(II) disposition the illegitimate  
24 product within the possession or con-  
25 trol of the manufacturer; and

1                   “(III) take reasonable and appro-  
2                   priate steps to assist a trading part-  
3                   ner to disposition an illegitimate prod-  
4                   uct not in the possession or control of  
5                   the manufacturer.

6                   “(ii) MAKING A NOTIFICATION.—

7                   “(I) ILLEGITIMATE PRODUCT.—  
8                   Upon determining that a product in  
9                   the possession or control of the manu-  
10                  facturer is an illegitimate product, the  
11                  manufacturer shall notify the Sec-  
12                  retary and all immediate trading part-  
13                  ners that the manufacturer has reason  
14                  to believe may have received such ille-  
15                  gitimate product of such determina-  
16                  tion not later than 24 hours after  
17                  making such determination.

18                  “(II) HIGH RISK OF ILLEGIT-  
19                  IMACY.—A manufacturer shall notify  
20                  the Secretary and immediate trading  
21                  partners that the manufacturer has  
22                  reason to believe may have received a  
23                  product manufactured by, or pur-  
24                  ported to be a product manufactured  
25                  by, the manufacturer not later than

1 24 hours after determining or being  
2 notified by the Secretary or a trading  
3 partner that there is a high risk that  
4 such product is an illegitimate prod-  
5 uct. For purposes of this subclause, a  
6 ‘high risk’ may include a specific  
7 high-risk that could increase the likeli-  
8 hood that illegitimate product will  
9 enter the pharmaceutical distribution  
10 supply chain and other high risks as  
11 determined by the Secretary in guid-  
12 ance pursuant to subsection (i).

13 “(iii) RESPONDING TO A NOTIFICA-  
14 TION.—Upon the receipt of a notification  
15 from the Secretary or a trading partner  
16 that a determination has been made that a  
17 product is an illegitimate product, a manu-  
18 facturer shall identify all illegitimate prod-  
19 uct subject to such notification that is in  
20 the possession or control of the manufac-  
21 turer, including any product that is subse-  
22 quently received, and shall perform the ac-  
23 tivities described in subparagraph (A).

24 “(iv) TERMINATING A NOTIFICA-  
25 TION.—Upon making a determination, in

1           consultation with the Secretary, that a no-  
2           tification is no longer necessary, a manu-  
3           facturer shall promptly notify immediate  
4           trading partners that the manufacturer no-  
5           tified pursuant to clause (ii) that such no-  
6           tification has been terminated.

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

11          “(C) REQUESTS FOR VERIFICATION.—Be-  
12          ginning 4 years after the date of enactment of  
13          【the \_\_\_\_\_ Act】, upon receiving a re-  
14          quest for verification from an authorized re-  
15          packager, wholesale distributor, or dispenser  
16          that is in possession or control of a product  
17          they believe to be manufactured by such manu-  
18          facturer, a manufacturer shall, not later than  
19          24 hours after receiving the verification request  
20          or in other such reasonable time as determined  
21          by the Secretary, based on the circumstances of  
22          the request, notify the person making the re-  
23          quest whether the product identifier, including  
24          the standard numeric identifier, that is the sub-  
25          ject of the request corresponds to the product

1 identifier affixed or imprinted by the manufac-  
2 turer. If a manufacturer responding to a  
3 verification request identifies a product identi-  
4 fier that does not correspond to that affixed or  
5 imprinted by the manufacturer, the manufac-  
6 turer shall treat such product as suspect prod-  
7 uct and conduct an investigation as described in  
8 subparagraph (A). If the manufacturer has rea-  
9 son to believe the product is an illegitimate  
10 product, the manufacturer shall advise the per-  
11 son making the request of such belief at the  
12 time such manufacturer responds to the  
13 verification request.

14 “(D) ELECTRONIC DATABASE.—A manu-  
15 facturer may satisfy the requirements of this  
16 paragraph by developing a secure electronic  
17 database or utilizing a secure electronic data-  
18 base developed or operated by another entity.  
19 The owner of such database shall establish the  
20 requirements and processes to respond to re-  
21 quests and may provide for data access to other  
22 members of the pharmaceutical distribution  
23 supply chain, as appropriate. The development  
24 and operation of such a database shall not re-  
25 lieve a manufacturer of the requirement under

1 this paragraph to respond to a verification re-  
2 quest submitted by means other than a secure  
3 electronic database.

4 “(E) SALEABLE RETURNED PRODUCT.—  
5 Beginning 4 years after the date of enactment  
6 of [the \_\_\_\_\_ Act] (except as provided  
7 pursuant to subsection (a)(5)), upon receipt of  
8 a returned product that the manufacturer in-  
9 tends to further distribute, before further dis-  
10 tributing such product, the manufacturer shall  
11 verify the product identifier for each sealed ho-  
12 mogeneous case of such product or, if such  
13 product is not in a sealed homogeneous case,  
14 verify the product identifier on each package.

15 “(F) NONSALEABLE RETURNED PROD-  
16 UCT.—A manufacturer may return a nonsale-  
17 able product to the manufacturer or repack-  
18 ager, to the wholesale distributor from whom  
19 such product was purchased, or to a person act-  
20 ing on behalf of such a person, including a re-  
21 turns processor, without providing the informa-  
22 tion required under paragraph (1)(A)(i).

23 “(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

24 “(1) PRODUCT TRACING.—



1           “(A) IN GENERAL.—Beginning not later  
2 than 270 days after the date of enactment of  
3 **【the \_\_\_\_\_ Act】**, the following require-  
4 ments shall apply to wholesale distributors:

5           “(i) A wholesale distributor shall not  
6 accept ownership of a product unless the  
7 previous owner prior to, or at the time of,  
8 the transaction provides the transaction  
9 history, transaction information, and a  
10 transaction statement for the product, as  
11 applicable under this subparagraph.

12           “(ii)(I) If the wholesale distributor  
13 purchased a product directly from the  
14 manufacturer, the exclusive distributor of  
15 the manufacturer, or a repackager that  
16 purchased directly from the manufacturer,  
17 then prior to, or at the time of, each trans-  
18 action in which the wholesale distributor  
19 transfers ownership of a product, the  
20 wholesale distributor shall provide to the  
21 subsequent purchaser—

22           “(aa) a transaction statement,  
23 which shall state that such wholesale  
24 distributor, or a member of the affili-  
25 ated group of such wholesale dis-

1 tributor, purchased the product di-  
2 rectly from the manufacturer, exclu-  
3 sive distributor of the manufacturer,  
4 or repackager that purchased directly  
5 from the manufacturer; and

6 “(bb) subject to subclause (II),  
7 the transaction history and trans-  
8 action information.

9 “(II) For purposes of transactions de-  
10 scribed in subclause (I), transaction his-  
11 tory and transaction information shall not  
12 include the lot number of the product, the  
13 initial transaction date, or the initial ship-  
14 ment date from the manufacturer (as de-  
15 fined in subparagraphs (F), (G), and (H)  
16 of section 581(22)). Nothing in this section  
17 shall be construed to require that the  
18 transaction history, transaction informa-  
19 tion, or transaction statement be provided  
20 in a particular format or consolidated on  
21 one document or data record. Transaction  
22 history and transaction information may  
23 be provided through any combination of  
24 self-generated paper, electronic data, or

1 manufacturer provided information on the  
2 product package.

3 “(iii) If the wholesale distributor did  
4 not purchase a product directly from the  
5 manufacturer, the exclusive distributor of  
6 the manufacturer, or a repackager that  
7 purchased directly from the manufacturer,  
8 as described in clause (ii), then prior to, or  
9 at the time of, each transaction or subse-  
10 quent transaction, the wholesale distributor  
11 shall—

12 “(I) provide to the subsequent  
13 purchaser a transaction statement,  
14 transaction history, and transaction  
15 information; and

16 “(II) provide the information de-  
17 scribed in subclause (I) to a subse-  
18 quent purchaser through any com-  
19 bination of self-generated paper, elec-  
20 tronic data, or manufacturer provided  
21 information on the product package.

22 “(iv) For the purposes of clause  
23 (iii)(I), the transaction history supplied  
24 shall begin only with the wholesale dis-  
25 tributor described in clause (ii)(I), but the

1 wholesale distributor described in clause  
2 (iii) shall inform the subsequent purchaser  
3 that such wholesale distributor received a  
4 direct purchase statement from the manu-  
5 facturer, the exclusive distributor of the  
6 manufacturer, or a repackager that pur-  
7 chased directly from the manufacturer,  
8 and shall identify the manufacturer, exclu-  
9 sive distributor of the manufacturer, or re-  
10 packager that purchased directly from the  
11 manufacturer from which the direct pur-  
12 chase statement was received.

13 “(v) A wholesale distributor shall  
14 maintain the transaction information for  
15 each transaction described in clauses (i),  
16 (ii), and (iii) for not less than 6 years after  
17 the date of the transaction.

18 “(B) RETURNS.—

19 “(i) SALEABLE RETURNS.—Notwith-  
20 standing subparagraph (A)(i), the fol-  
21 lowing shall apply:

22 “(I) REQUIREMENTS.—Until the  
23 date that is 6 years after the date of  
24 enactment of [the \_\_\_\_\_  
25 Act] (except as provided pursuant to

1 subsection (a)(5)), a wholesale dis-  
2 tributor may accept returned product  
3 from a dispenser pursuant to the  
4 terms and conditions of any agree-  
5 ment between the parties, and, not-  
6 withstanding subparagraph (A)(ii),  
7 may distribute such returned product  
8 without providing the transaction his-  
9 tory. For transactions subsequent to  
10 the return, the transaction history of  
11 such product shall begin with the  
12 wholesale distributor that accepted the  
13 returned product, consistent with the  
14 requirements of this subsection.

15 “(II) ENHANCED REQUIRE-  
16 MENTS.—Beginning 6 years after the  
17 date of enactment of [the  
18 \_\_\_\_\_ Act] (except as pro-  
19 vided pursuant to subsection (a)(5)),  
20 a wholesale distributor may accept re-  
21 turned product from a dispenser only  
22 if the wholesale distributor can asso-  
23 ciate returned product with the trans-  
24 action information and transaction  
25 statement associated with that prod-

1           uct. For all transactions after such  
2           date, the transaction history, as appli-  
3           cable, of such product shall begin with  
4           the wholesale distributor that accepted  
5           and verified the returned product. For  
6           purposes of this subparagraph, the  
7           transaction information and trans-  
8           action history, as applicable, need not  
9           include transaction dates if it is not  
10          reasonably practicable to obtain such  
11          dates.

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

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

1 suspect product or an illegitimate product a  
2 wholesale distributor shall, not later than 24  
3 hours after receiving the request or in other  
4 such reasonable time as determined by the Sec-  
5 retary, based on the circumstances of the re-  
6 quest, provide the applicable transaction infor-  
7 mation, transaction history, and transaction  
8 statement for the product.

9 “(2) PRODUCT IDENTIFIER.—Beginning 6  
10 years after the date of enactment of [the  
11 \_\_\_\_\_ Act], a wholesale distributor may en-  
12 gage in transactions involving a product only if such  
13 product is encoded with a product identifier (except  
14 as provided pursuant to subsection (a)(5)).

15 “(3) AUTHORIZED TRADING PARTNERS.—Be-  
16 ginning not later than 1 year after the date of enact-  
17 ment of [the \_\_\_\_\_ Act], the trading part-  
18 ners of a wholesale distributor may be only author-  
19 ized trading partners.

20 “(4) VERIFICATION.—Beginning not later than  
21 1 year after the date of enactment of [the  
22 \_\_\_\_\_ Act], a wholesale distributor shall  
23 have systems in place to enable the wholesale dis-  
24 tributor to comply with the following requirements:

25 “(A) SUSPECT PRODUCT.—

1           “(i) IN GENERAL.—Upon making a  
2           determination that a product in the posses-  
3           sion or control of the wholesale distributor  
4           is a suspect product, or upon receiving a  
5           request for verification from the Secretary  
6           that has made a determination that a  
7           product within the possession or control of  
8           a wholesale distributor is a suspect prod-  
9           uct, a wholesale distributor shall—

10                   “(I) segregate such product with-  
11                   in the possession or control of the  
12                   wholesale distributor from product in-  
13                   tended for distribution; and

14                   “(II) promptly conduct an inves-  
15                   tigation in coordination with trading  
16                   partners, as applicable, to determine  
17                   whether the product is an illegitimate  
18                   product, which shall include validating  
19                   any applicable transaction history and  
20                   transaction information in the posses-  
21                   sion of the wholesale distributor and  
22                   otherwise investigating to determine  
23                   whether the product is an illegitimate  
24                   product, and, beginning 6 years after  
25                   the date of enactment of [the



1 \_\_\_\_\_ Act] (except as pro-  
2 vided pursuant to subsection (a)(5)),  
3 verifying the product at the package  
4 level.

5 “(ii) CLEARED PRODUCT.—If the  
6 wholesale distributor determines that a  
7 suspect product is not an illegitimate prod-  
8 uct, the wholesale distributor shall prompt-  
9 ly notify the Secretary, if applicable, of  
10 such determination and such product may  
11 be further distributed.

12 “(iii) RECORDS.—A wholesale dis-  
13 tributor shall keep records of the investiga-  
14 tion of a suspect product for not less than  
15 6 years after the conclusion of the inves-  
16 tigation.

17 “(B) ILLEGITIMATE PRODUCT.—

18 “(i) IN GENERAL.—Upon determining  
19 that a product in the possession or control  
20 of a wholesale distributor is an illegitimate  
21 product, the wholesale distributor shall, in  
22 a manner that is consistent with the sys-  
23 tems and processes of such wholesale dis-  
24 tributor—



1 from the Secretary or a trading partner  
2 that a determination has been made that a  
3 product is an illegitimate product, a whole-  
4 sale distributor shall identify all illegit-  
5 imate product subject to such notification  
6 that is in the possession or control of the  
7 wholesale distributor, including any prod-  
8 uct that is subsequently received, and shall  
9 perform the activities described in subpara-  
10 graph (A).

11 “(iv) TERMINATING A NOTIFICA-  
12 TION.—Upon a determination, in consulta-  
13 tion with the Secretary, that a notification  
14 is no longer necessary, a wholesale dis-  
15 tributor shall promptly notify immediate  
16 trading partners that the wholesale dis-  
17 tributor notified pursuant to clause (ii)  
18 that such notification has been terminated.

19 “(v) RECORDS.—A wholesale dis-  
20 tributor shall keep records of the disposi-  
21 tion of an illegitimate product for not less  
22 than 6 years after the conclusion of the  
23 disposition.

24 “(C) ELECTRONIC DATABASE.—A whole-  
25 sale distributor may satisfy the requirements of

1 this paragraph by developing a secure electronic  
2 database or utilizing a secure electronic data-  
3 base developed or operated by another entity.  
4 The owner of such database shall establish the  
5 requirements and processes to respond to re-  
6 quests and may provide for data access to other  
7 members of the pharmaceutical distribution  
8 supply chain, as appropriate. The development  
9 and operation of such a database shall not re-  
10 lieve a wholesale distributor of the requirement  
11 under this paragraph to respond to a  
12 verification request submitted by means other  
13 than a secure electronic database.

14 “(D) VERIFICATION OF SALEABLE RE-  
15 TURNED PRODUCT.—Beginning 6 years after  
16 the date of enactment of [the \_\_\_\_\_  
17 Act], upon receipt of a returned product that  
18 the wholesale distributor intends to further dis-  
19 tribute, before further distributing such prod-  
20 uct, the wholesale distributor shall verify the  
21 product identifier for each sealed homogeneous  
22 case of such product or, if such product is not  
23 in a sealed homogeneous case, verify the prod-  
24 uct identifier on each package.

25 “(d) DISPENSER REQUIREMENTS.—

1 “(1) PRODUCT TRACING.—

2 “(A) IN GENERAL.—Beginning 270 days  
3 after the date of enactment of [the  
4 \_\_\_\_\_ Act], a dispenser—

5 “(i) shall not accept ownership of a  
6 product, unless the previous owner prior  
7 to, or at the time of, the transaction, pro-  
8 vides transaction history, transaction infor-  
9 mation, and a transaction statement;

10 “(ii) prior to, or at the time of, each  
11 transaction in which the dispenser trans-  
12 fers ownership of a product (but not in-  
13 cluding dispensing to a patient or returns)  
14 shall provide the subsequent owner with  
15 transaction history, transaction informa-  
16 tion, and a transaction statement for the  
17 product, except that the requirements of  
18 this clause shall not apply to sales by a  
19 dispenser to another dispenser to fulfill a  
20 specific patient need; and

21 “(iii) shall maintain transaction infor-  
22 mation as necessary, but not longer than 6  
23 years after the transaction to investigate a  
24 suspect product.

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

13           “(C) RETURNS.—

14           “(i) SALEABLE RETURNS.—A dis-  
15 penser may return product to the trading  
16 partner from which the dispenser obtained  
17 the product without providing the informa-  
18 tion required under subparagraph (B).

19           “(ii) NONSALEABLE RETURNS.—A  
20 dispenser may return a nonsaleable prod-  
21 uct to the manufacturer or repackager, to  
22 the wholesale distributor from whom such  
23 product was purchased, to a returns proc-  
24 essor, or to a person acting on behalf of  
25 such persons without providing the infor-

1                   mation required under subparagraph  
2                   (A)(i).

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 or an illegitimate product, a dispenser  
8                   shall, not later than 2 business days after re-  
9                   ceiving the request or in another such reason-  
10                  able time as determined by the Secretary, based  
11                  on the circumstances of the request, provide lot  
12                  level transaction information.

13                  “(2) PRODUCT IDENTIFIER.—Beginning not  
14                  later than 7 years after the date of enactment of  
15                  【the \_\_\_\_\_ Act】, a dispenser may engage in  
16                  transactions involving a product only if such product  
17                  is encoded with a product identifier (except as pro-  
18                  vided pursuant to subsection (a)(5)).

19                  “(3) AUTHORIZED TRADING PARTNERS.—Be-  
20                  ginning not later than 1 year after the date of enact-  
21                  ment of 【the \_\_\_\_\_ Act】, the trading part-  
22                  ners of a dispenser may be only authorized trading  
23                  partners.

24                  “(4) VERIFICATION.—Beginning not later than  
25                  1 year after the date of enactment of 【the

1 \_\_\_\_\_ Act], a dispenser shall have systems  
2 in place to enable the dispenser to comply with the  
3 following requirements:

4 “(A) SUSPECT PRODUCT.—

5 “(i) IN GENERAL.—Upon making a  
6 determination that a product in the posses-  
7 sion or control of the dispenser is a suspect  
8 product, or upon receiving a request for  
9 verification from the Secretary that has  
10 made a determination that a product with-  
11 in the possession or control of a dispenser  
12 is a suspect product, a dispenser shall—

13 “(I) segregate such product with-  
14 in the possession or control of the dis-  
15 penser from product intended for dis-  
16 tribution; and

17 “(II) promptly conduct an inves-  
18 tigation in coordination with trading  
19 partners, as applicable, to determine  
20 whether the product is an illegitimate  
21 product.

22 “(ii) INVESTIGATION.—An investiga-  
23 tion conducted under clause (i)(II) shall in-  
24 clude—



1                   “(I) beginning 7 years after the  
2                   date of enactment of [the  
3                   \_\_\_\_\_ Act], verifying wheth-  
4                   er the lot number of a suspect product  
5                   corresponds with the lot number for  
6                   such product;

7                   “(II) beginning 7 years after the  
8                   date of enactment of such Act,  
9                   verifying that the product identifier of  
10                  at least 3 packages or 10 percent of  
11                  such suspect product, whichever is  
12                  greater, or all packages, if there are  
13                  fewer than 3, corresponds with the  
14                  product identifier for such product;

15                  “(III) validating any applicable  
16                  transaction history and transaction in-  
17                  formation in the possession of the dis-  
18                  penser; and

19                  “(IV) otherwise investigating to  
20                  determine whether the product is an  
21                  illegitimate product.

22                  “(iii) CLEARED PRODUCT.—If the dis-  
23                  penser makes the determination that a sus-  
24                  pect product is not an illegitimate product,  
25                  the dispenser shall promptly notify the

1 Secretary, if applicable, of such determina-  
2 tion and such product may be further dis-  
3 tributed or dispensed.

4 “(iv) RECORDS.—A dispenser shall  
5 keep records of the investigation of a sus-  
6 pect product for not less than 6 years after  
7 the conclusion of the investigation.

8 “(B) ILLEGITIMATE PRODUCT.—

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

13 “(I) disposition the illegitimate  
14 product within the possession or con-  
15 trol of the dispenser; and

16 “(II) take reasonable and appro-  
17 priate steps to assist a trading part-  
18 ner to disposition an illegitimate prod-  
19 uct not in the possession or control of  
20 the dispenser.

21 “(ii) MAKING A NOTIFICATION.—

22 Upon determining that a product in the  
23 possession or control of the dispenser is an  
24 illegitimate product, the dispenser shall no-  
25 tify the Secretary and all immediate trad-

1 ing partners that the dispenser has reason  
2 to believe may have received such illegit-  
3 imate product of such determination not  
4 later than 24 hours after making such de-  
5 termination.

6 “(iii) RESPONDING TO A NOTIFICA-  
7 TION.—Upon the receipt of a notification  
8 from the Secretary or a trading partner  
9 that a determination has been made that a  
10 product is an illegitimate product, a dis-  
11 penser shall identify all illegitimate product  
12 subject to such notification that is in the  
13 possession or control of the dispenser, in-  
14 cluding any product that is subsequently  
15 received, and shall perform the activities  
16 described in subparagraph (A).

17 “(iv) TERMINATING A NOTIFICA-  
18 TION.—Upon making a determination, in  
19 consultation with the Secretary, that a no-  
20 tification is no longer necessary, a dis-  
21 penser shall promptly notify immediate  
22 trading partners that the dispenser notified  
23 pursuant to clause (ii) that such notifica-  
24 tion has been terminated.



1 owner with transaction history, transaction  
2 information, and a transaction statement;  
3 and

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

8 “(B) NONSALEABLE RETURNS.—A repack-  
9 ager may return a nonsaleable product to the  
10 manufacturer or repackager, or to the wholesale  
11 distributor from whom such product was pur-  
12 chased, or to a person acting on behalf of such  
13 a person, including a returns processor, without  
14 providing the information required under sub-  
15 paragraph (A)(ii).

16 “(C) 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 or an illegitimate product, a re-  
21 packager shall, not later than 24 hours after re-  
22 ceiving the request or in other such reasonable  
23 time as determined by the Secretary, based on  
24 the circumstances of the request, provide the  
25 applicable transaction information, transaction

1 history and transaction statement for the prod-  
2 uct.

3 “(2) PRODUCT IDENTIFIER.—Beginning not  
4 later than 5 years after enactment of [the  
5 \_\_\_\_\_ Act], a repackager—

6 “(A) shall a fix or imprint a product iden-  
7 tifier to each package and homogenous case of  
8 product intended to be introduced in a trans-  
9 action in commerce;

10 “(B) shall maintain the product identifier  
11 information for such product for not less than  
12 6 years after the date of the transaction;

13 “(C) may engage in transactions involving  
14 a product only if such product is encoded with  
15 a product identifier (except as provided pursu-  
16 ant to subsection (a)(5)); and

17 “(D) maintain records for not less than 6  
18 years to allow the repackager to associate the  
19 product identifier the repackager affixes or im-  
20 prints with the product identifier assigned by  
21 the original manufacturer of the product.

22 “(3) AUTHORIZED TRADING PARTNERS.—Be-  
23 ginning 1 year after the date of enactment of [the  
24 \_\_\_\_\_ Act], the trading partners of a re-  
25 packager may be only authorized trading partners.



1 transaction information in the posses-  
2 sion of the repackager and otherwise  
3 investigating to determine whether the  
4 product is an illegitimate product,  
5 and, beginning 5 years after the date  
6 of enactment of [the \_\_\_\_\_  
7 Act] (except as provided pursuant to  
8 subsection (a)(5)), verifying the prod-  
9 uct at the package level.

10 “(ii) CLEARED PRODUCT.—If the re-  
11 packager makes the determination that a  
12 suspect product is not an illegitimate prod-  
13 uct, the repackager shall promptly notify  
14 the Secretary, if applicable, of such deter-  
15 mination and such product may be further  
16 distributed.

17 “(iii) RECORDS.—A repackager shall  
18 keep records of the investigation of a sus-  
19 pect product for not less than 6 years after  
20 the conclusion of the investigation.

21 “(B) ILLEGITIMATE PRODUCT.—

22 “(i) IN GENERAL.—Upon determining  
23 that a product in the possession or control  
24 of a repackager is an illegitimate product,  
25 the repackager shall, in a manner that is



1 consistent with the systems and processes  
2 of such repackager—

3 “(I) disposition the illegitimate  
4 product within the possession or con-  
5 trol of the repackager; and

6 “(II) take reasonable and appro-  
7 priate steps to assist a trading part-  
8 ner to disposition an illegitimate prod-  
9 uct not in the possession or control of  
10 the repackager.

11 “(ii) MAKING A NOTIFICATION.—  
12 Upon determining that a product in the  
13 possession or control of the repackager is  
14 an illegitimate product, the repackager  
15 shall notify the Secretary and all imme-  
16 diate trading partners that the repackager  
17 has reason to believe may have received the  
18 illegitimate product of such determination  
19 not later than 24 hours after making such  
20 determination.

21 “(iii) RESPONDING TO A NOTIFICA-  
22 TION.—Upon the receipt of a notification  
23 from the Secretary or a trading partner, a  
24 repackager shall identify all illegitimate  
25 product subject to such notification that is

1 in the possession or control of the repack-  
2 ager, including any product that is subse-  
3 quently received, and shall perform the ac-  
4 tivities described in subparagraph (A).

5 “(iv) TERMINATING A NOTIFICA-  
6 TION.—Upon a determination, in consulta-  
7 tion with the Secretary, that a notification  
8 is no longer necessary, a repackager shall  
9 promptly notify immediate trading part-  
10 ners that the repackager notified pursuant  
11 to clause (ii) that such notification has  
12 been terminated.

13 “(v) RECORDS.—A repackager shall  
14 keep records of the disposition of an illegit-  
15 imate product for not less than 6 years  
16 after the conclusion of the disposition.

17 “(C) REQUESTS FOR VERIFICATION.—Be-  
18 ginning 5 years after enactment of [the  
19 \_\_\_\_\_ Act], upon receiving a request  
20 for verification from an authorized manufac-  
21 turer, wholesale distributor, or dispenser that is  
22 in possession or control of a product they be-  
23 lieve to be repackaged by such repackager, a re-  
24 packager shall, not later than 24 hours after re-  
25 ceiving the verification request or in other such

1 reasonable time as determined by the Secretary,  
2 based on the circumstances of the request, no-  
3 tify the person making the request whether the  
4 product identifier, including the standard nu-  
5 meric identifier, that is the subject of the re-  
6 quest corresponds to the product identifier af-  
7 fixed or imprinted by the repackager. If a re-  
8 packager responding to a verification request  
9 identifies a product identifier that does not cor-  
10 respond to that affixed or imprinted by the re-  
11 packager, the repackager shall treat such prod-  
12 uct as suspect product and conduct an inves-  
13 tigation as described in subparagraph (A). If  
14 the repackager has reason to believe the prod-  
15 uct is an illegitimate product, the repackager  
16 shall advise the person making the request of  
17 such belief at the time such manufacturer re-  
18 sponds to the verification request.

19 “(D) ELECTRONIC DATABASE.—A repack-  
20 ager may satisfy the requirements of paragraph  
21 (4) by developing a secure electronic database  
22 or utilizing a secure electronic database devel-  
23 oped or operated by another entity. The owner  
24 of such database shall establish the require-  
25 ments and processes to respond to requests and

1           may provide for data access to other members  
2           of the pharmaceutical distribution supply chain,  
3           as appropriate. The development and operation  
4           of such a database shall not relieve a repack-  
5           ager of the requirement under paragraph (4) to  
6           respond to a verification request submitted by  
7           means other than a secure electronic database.

8           “(E) VERIFICATION OF SALEABLE RE-  
9           TURNED PRODUCT.—Beginning 5 years after  
10          the date of enactment of [the \_\_\_\_\_  
11          Act], upon receipt of a returned product that  
12          the repackager intends to further distribute, be-  
13          fore further distributing such product, the re-  
14          packager shall verify the product identifier for  
15          each sealed homogeneous case of such product  
16          or, if such product is not in a sealed homo-  
17          geneous case, verify the product identifier on  
18          each package.

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

21                 “(1) IN GENERAL.—Beginning not later than  
22          270 days after the date of enactment of [the  
23          \_\_\_\_\_ Act], a third-party logistics provider  
24          shall—

1           “(A) not accept possession of a product  
2 unless the owner of the product provides the  
3 transaction history, transaction information,  
4 and a transaction statement for the product;

5           “(B) maintain a copy of the information  
6 described in subparagraph (A) for not less than  
7 6 years after the transfer of possession; and

8           “(C) upon a request by the Secretary or  
9 other appropriate Federal or State official, in  
10 the event of a recall or for the purpose of inves-  
11 tigating a suspect product or an illegitimate  
12 product, not later than 24 hours after receiving  
13 the request or in other such reasonable time as  
14 determined by the Secretary based on the cir-  
15 cumstances of the request, provide the applica-  
16 ble transaction information, transaction history,  
17 and transaction statement for the product

18           “(2) PRODUCT TRACING.—Beginning not later  
19 than 6 years after the date of enactment of **the**  
20 \_\_\_\_\_ **Act**], a third-party logistics provider  
21 may accept possession of product only if such prod-  
22 uct is encoded with a product identifier (except as  
23 provided pursuant to subsection (a)(5)).

24           “(3) AUTHORIZED TRADING PARTNERS.—Be-  
25 ginning 1 year after the date of enactment of **the**

1 \_\_\_\_\_ Act], the trading partners of a third-  
2 party logistics provider may be only authorized trad-  
3 ing partners.

4 “(4) VERIFICATION.—Beginning not later than  
5 1 year after the date of enactment of [the  
6 \_\_\_\_\_ Act], a third-party logistics provider  
7 shall have systems in place to enable the third-party  
8 logistics provider to comply with the following re-  
9 quirements:

10 “(A) SUSPECT PRODUCT.—

11 “(i) IN GENERAL.—Upon making a  
12 determination that a product in the posses-  
13 sion or control of a third-party logistics  
14 provider is a suspect product, a third-party  
15 logistics provider shall—

16 “(I) segregate such product with-  
17 in the possession or control of the  
18 third-party logistics provider from  
19 product intended for distribution; and

20 “(II) promptly notify the owner  
21 of such product of the need to conduct  
22 an investigation to determine whether  
23 the product is an illegitimate product.

24 “(ii) CLEARED PRODUCT.—If the  
25 owner of the product notifies the third-

1 party logistics provider of the determina-  
2 tion that a suspect product is not an ille-  
3 gitimate product, such product may be fur-  
4 ther distributed.

5 “(iii) RECORDS.—A third-party logis-  
6 tics provider shall keep records of the ac-  
7 tivities described in subclauses (I) and (II)  
8 of clause (i), as such subclauses relate to  
9 a suspect product, for not less than 6  
10 years after the conclusion of the investiga-  
11 tion.

12 “(B) ILLEGITIMATE PRODUCT.—

13 “(i) IN GENERAL.—Upon determining  
14 that a product in the possession or control  
15 of a third-party logistics provider is an ille-  
16 gitimate product, the third-party logistics  
17 provider shall—

18 “(I) promptly notify the owner of  
19 such product of the need to dispo-  
20 sition such product; and

21 “(II) promptly transfer posses-  
22 sion of the product to the owner of  
23 such product to disposition the prod-  
24 uct.

1           “(ii) MAKING A NOTIFICATION.—  
2           Upon determining that a product in the  
3           possession or control of the third-party lo-  
4           gistics provider is an illegitimate product,  
5           the third-party logistics provider shall no-  
6           tify the Secretary not later than 24 hours  
7           after making such determination.

8           “(iii) RESPONDING TO A NOTIFICA-  
9           TION.—Upon the receipt of a notification  
10          from the Secretary, a third-party logistics  
11          provider shall identify all illegitimate prod-  
12          uct subject to such notification that is in  
13          the possession or control of the third-party  
14          logistics provider, including any product  
15          that is subsequently received, and shall  
16          perform the activities described in subpara-  
17          graph (A).

18          “(iv) TERMINATING A NOTIFICA-  
19          TION.—Upon making a determination, in  
20          consultation with the Secretary and the  
21          owner of such product, that a notification  
22          is no longer necessary, a third-party logis-  
23          tics provider shall promptly terminate such  
24          notification.



1                   “(v) RECORDS.—A third-party logis-  
2                   tics provider shall keep records of the ac-  
3                   tivities described in subclauses (I) and (II)  
4                   of clause (i) as such subclauses relate to  
5                   an illegitimate product for not less than 6  
6                   years after the conclusion of the disposi-  
7                   tion.

8                   “(g) DROP SHIPMENTS.—This section shall not apply  
9                   to any entity, notwithstanding the status of such entity  
10                  as a wholesale distributor, relabeler, repackager, or other  
11                  status, or transaction that is not involved in the physical  
12                  handling, distribution, or storage of a product. For pur-  
13                  poses of this section, facilitating the distribution of a prod-  
14                  uct by providing various administrative services, including  
15                  processing of orders and payments, shall not by itself, be  
16                  construed as being involved in the handling, distribution,  
17                  or storage of a product.”.

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

19                  (a) IN GENERAL.—Section 582 of the Federal Food,  
20                  Drug, and Cosmetic Act, as added by section 2, is amend-  
21                  ed by adding at the end the following:

22                  “(h) ENHANCED DRUG DISTRIBUTION SECURITY.—

23                         “(1) IN GENERAL.—On the date that is 10  
24                         years after the date of enactment of the  
25                         【\_\_\_\_\_ Act】, the following interoperable,

1 electronic tracing of product at the package level re-  
2 quirements shall go into effect:

3 “(A) The transaction information and the  
4 transaction statements as required under this  
5 section shall be exchanged in an interoperable,  
6 electronic manner in accordance with the stand-  
7 ards established under the guidance issued pur-  
8 suant to paragraphs (3) and (4) of subsection  
9 (i), including any revision of such guidance  
10 issued in accordance with paragraph (5) of such  
11 subsection.

12 “(B) The transaction information required  
13 under this section shall include the product  
14 identifier at the package level for each package  
15 included in the transaction.

16 “(C) Systems and processes for verification  
17 of product at the package level shall be required  
18 in accordance with the standards established  
19 under the guidance issued pursuant to sub-  
20 section (a)(2) and the guidances issued pursu-  
21 ant to paragraphs (2),(3), and (4) of subsection  
22 (i), including any revision of such guidances  
23 issued in accordance with paragraph (5) of such  
24 subsection, which may include the use of aggre-  
25 gation and inference as necessary.

1           “(D) The systems and processes necessary  
2           to promptly respond with the transaction infor-  
3           mation and transaction statement for a product  
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 purposes of investigating  
7           a suspect product or an illegitimate product  
8           shall be required.

9           “(E) The systems and processes necessary  
10          to promptly facilitate gathering the information  
11          necessary to produce the transaction informa-  
12          tion for each transaction going back to the  
13          manufacturer, as applicable, upon request by  
14          the Secretary (or other appropriate Federal or  
15          State official), in the event of a recall or for the  
16          purposes of investigating a suspect product or  
17          an illegitimate product shall be required.

18          “(F) A wholesale distributor shall maintain  
19          systems and processes to allow the wholesale  
20          distributor to accept saleable returns from dis-  
21          pensers only if the wholesale distributor can as-  
22          sociate returned product with the transaction  
23          information and the transaction statement asso-  
24          ciated with that product.

25          “(2) COMPLIANCE.—

1           “(A) INFORMATION MAINTENANCE AGREE-  
2           MENT.—A dispenser shall be permitted to enter  
3           into a written agreement with a third party, in-  
4           cluding an authorized wholesale distributor,  
5           under which the third party shall confidentially  
6           maintain any information required to be main-  
7           tained under this section. If a dispenser enters  
8           into such an agreement, the dispenser shall  
9           maintain a copy of the written agreement and  
10          shall not be relieved of the other obligations of  
11          the dispenser under this subsection.

12          “(B) ALTERNATIVE METHODS.—The Sec-  
13          retary, taking into consideration the assessment  
14          conducted under paragraph (3), shall provide  
15          for alternative methods of compliance with any  
16          of the requirements set forth in paragraph (1),  
17          including—

18                 “(i) establishing timelines for compli-  
19                 ance by small businesses (including small  
20                 business dispensers with 25 or fewer full  
21                 time employees) with such requirements, in  
22                 order to ensure that such requirements do  
23                 not impose undue economic hardship for  
24                 small businesses, including small business  
25                 dispensers for whom the criteria set forth

1 in the assessment under paragraph (3) is  
2 not met, if the Secretary determines that  
3 such requirements under paragraph (1)  
4 would result in undue economic hardship;  
5 and

6 “(ii) establishing a process by which a  
7 dispenser may request a waiver from any  
8 of the requirements set forth in paragraph  
9 (1) if the Secretary determines that such  
10 requirements would result in an undue eco-  
11 nomic hardship.

12 “(3) ASSESSMENT.—

13 “(A) IN GENERAL.—Not later than the  
14 date that is 18 months after the Secretary  
15 issues the final guidance required under sub-  
16 section (i), the Secretary shall enter into con-  
17 tract with a private, independent consulting  
18 firm with expertise to conduct a technology and  
19 software assessment that looks at the feasibility  
20 of dispensers with 25 or fewer full-time employ-  
21 ees conducting interoperable, electronic tracing  
22 of products at the package level. In no case  
23 may such assessment commence later than 7.5  
24 years after the date of enactment of the  
25 **[\_\_\_\_\_ Act]**.



1 graph (A) for public comment prior to be-  
2 ginning the assessment;

3 “(ii) publish the final assessment for  
4 public comment not later than 30 calendar  
5 days after receiving such assessment; and

6 “(iii) hold a public meeting not later  
7 than 180 calendar days after receiving the  
8 final assessment at which public stake-  
9 holders may present their views on the as-  
10 sessment.

11 “(4) PROCEDURE.—Notwithstanding section  
12 553 of title 5, United States Code, the Secretary, in  
13 promulgating any regulation pursuant to this sec-  
14 tion, shall—

15 “(A) provide appropriate flexibility by—

16 “(i) not requiring the adoption of spe-  
17 cific business systems for the maintenance  
18 and transmission of data;

19 “(ii) prescribing alternative methods  
20 of compliance for any of the requirements  
21 set forth in paragraph (1) or set forth in  
22 regulations implementing such require-  
23 ments, including timelines—

24 “(I) for small businesses to com-  
25 ply with the requirements set forth in

1 the regulations in order to ensure that  
2 such requirements do not impose  
3 undue economic hardship for small  
4 businesses (including small business  
5 dispensers for whom the criteria set  
6 forth in the assessment under para-  
7 graph (3) is not met), if the Secretary  
8 determines that such requirements  
9 would result in undue economic hard-  
10 ship; and

11 “(II) which shall include estab-  
12 lishing a process by which a dispenser  
13 may request a waiver from any of the  
14 requirements set forth in such regula-  
15 tions if the Secretary determines that  
16 such requirements would result in an  
17 undue economic hardship; and

18 “(iii) taking into consideration—

19 “(I) the results of pilot projects,  
20 including pilot projects pursuant to  
21 this section;

22 “(II) the public meetings held  
23 and related guidance documents  
24 issued under this section;



1                   “(III) the public health benefits  
2                   of any additional regulations in com-  
3                   parison to the cost of compliance with  
4                   such requirements, including on enti-  
5                   ties of varying sizes and capabilities;

6                   “(IV) the diversity of the phar-  
7                   maceutical distribution supply chain  
8                   by providing appropriate flexibility for  
9                   each sector, including both large and  
10                  small businesses; and

11                  “(V) the assessment pursuant to  
12                  paragraph (3) with respect to small  
13                  business dispensers, including related  
14                  public comment and the public meet-  
15                  ing, and requirements under this sec-  
16                  tion;

17                  “(B) issue a notice of proposed rulemaking  
18                  that includes a copy of the proposed regulation;

19                  “(C) provide a period of not less than 60  
20                  days for comments on the proposed regulation;  
21                  and

22                  “(D) publish the final regulation not less  
23                  than 2 years prior to the effective date of the  
24                  regulation.

25                  “(i) GUIDANCE DOCUMENTS.—

1           “(1) IN GENERAL.—For the purposes of facili-  
2           tating the successful and efficient adoption of se-  
3           cure, interoperable product tracing at the package  
4           level in order to enhance drug distribution security  
5           and further protect the public health, the Secretary  
6           shall issue the guidance documents as provided for  
7           in this subsection.

8           “(2) SUSPECT AND ILLEGITIMATE PRODUCT.—

9           “(A) IN GENERAL.—Not later than 180  
10           days after enactment of the **【**\_\_\_\_\_ **】**  
11           Act**】**, the Secretary shall issue a guidance docu-  
12           ment to aid trading partners in the identifica-  
13           tion of a suspect product and notification termi-  
14           nation. Such guidance document shall—

15                   “(i) identify specific scenarios that  
16                   could significantly increase the risk of a  
17                   suspect product entering the pharma-  
18                   ceutical distribution supply chain;

19                   “(ii) provide recommendation on how  
20                   trading partners may identify such product  
21                   and make a determination if the product is  
22                   a suspect product as soon as practicable;  
23                   and

24                   “(iii) set forth the process by which  
25                   manufacturers, repackagers, wholesale dis-



1            ceutical distribution supply chain may, in  
2            the most efficient manner practicable, infer  
3            the contents of a case, pallet, or other ag-  
4            gregate of individual packages or con-  
5            tainers of product, from a product identi-  
6            fier associated with the case, pallet, or  
7            other aggregate, without opening each  
8            case, pallet, or other aggregate or other-  
9            wise individually scanning each package;  
10           and

11           “(ii) identify methods and processes  
12           to enhance tracing of product at the pack-  
13           age level, such as enhanced verification ac-  
14           tivities, the use of aggregation and infer-  
15           ence, processes that utilize the product  
16           identifiers to enhance tracing of product at  
17           the package level, or package security fea-  
18           tures.

19           “(B) PROCEDURE.—In issuing the guid-  
20           ance under subparagraph (A), and in revising  
21           such guidance, if applicable, the Secretary shall  
22           follow the procedure set forth in paragraph (5).

23           “(4) STANDARDS FOR INTEROPERABLE DATA  
24           EXCHANGE.—

1           “(A) IN GENERAL.—In order to enhance  
2 tracing of a product at the package level, the  
3 Secretary, not later than 18 months after con-  
4 ducting a public meeting on the interoperable  
5 standards necessary to enhance the security of  
6 the pharmaceutical distribution supply chain,  
7 shall update the guidance issued pursuant to  
8 subsection (a)(2), as necessary and appropriate,  
9 and finalize such guidance document so that  
10 the guidance document—

11           “(i) identifies and makes rec-  
12 ommendation with respect to the standards  
13 necessary for adoption in order to support  
14 the secure, interoperable electronic data  
15 exchange among the pharmaceutical dis-  
16 tribution supply chain that comply with a  
17 form and format developed by a widely rec-  
18 ognized international standards develop-  
19 ment organization;

20           “(ii) takes into consideration stand-  
21 ards established pursuant to subsection  
22 (a)(2) and section 505D;

23           “(iii) facilitates the creation of a uni-  
24 form process or methodology for product  
25 tracing; and

1                   “(iv) ensures the protection of con-  
2                   fidential commercial information and trade  
3                   secrets.

4                   “(B) PROCEDURE.—In issuing the guid-  
5                   ance under subparagraph (A), and in revising  
6                   such guidance, if applicable, the Secretary shall  
7                   follow the procedure set forth in paragraph (5).

8                   “(5) PROCEDURE.—In issuing or revising any  
9                   guidance issued pursuant to this subsection or sub-  
10                  section (h), except the initial guidance issued under  
11                  paragraph (2)(A), the Secretary shall—

12                  “(A) publish a notice in the Federal Reg-  
13                  ister for a period not less than 30 days an-  
14                  nouncing that the draft or revised draft guid-  
15                  ance is available;

16                  “(B) post the draft guidance document on  
17                  the Internet Web site of the Food and Drug  
18                  Administration and make such draft guidance  
19                  document available in hard copy;

20                  “(C) provide an opportunity for comment  
21                  and review and take into consideration any  
22                  comments received;

23                  “(D) revise the draft guidance, as appro-  
24                  priate;

1           “(E) publish a notice in the Federal Reg-  
2           ister for a period not less than 30 days an-  
3           nouncing that the final guidance or final revised  
4           guidance is available;

5           “(F) post the final guidance document on  
6           the Internet Website of the Food and Drug Ad-  
7           ministration and make such final guidance doc-  
8           ument available in hard copy; and

9           “(G) provide for an effective date of not  
10          earlier than 1 year after such guidance becomes  
11          final.

12          “(j) PUBLIC MEETINGS.—

13           “(1) IN GENERAL.—The Secretary shall hold  
14          not less than 3 public meetings to enhance the safe-  
15          ty and security of the pharmaceutical distribution  
16          supply chain and provide for comment. The Sec-  
17          retary may hold the first such public meeting not  
18          earlier than 1 year after the date of enactment of  
19          the **【\_\_\_\_\_ Act】**. In carrying out the public  
20          meetings described in this paragraph, the Secretary  
21          shall—

22           “(A) prioritize topics necessary to inform  
23          the issuance of the guidance described in para-  
24          graphs (3) and (4) of subsection (i); and

1           “(B) take all measures reasonable and  
2           practicable to ensure the protection of confiden-  
3           tial commercial information and trade secrets.

4           “(2) CONTENT.—Each of the following topics  
5           shall be addressed in at least one of the public meet-  
6           ings described in paragraph (1):

7           “(A) An assessment of the steps taken  
8           under subsections (b) through (f) to build ca-  
9           pacity for a unit-level system, including the im-  
10          pact of the requirements of such subsections  
11          on—

12           “(i) the ability of the health care sys-  
13           tem collectively to maintain patient access  
14           to medicines;

15           “(ii) the scalability of such require-  
16           ments, including as it relates to product  
17           lines; and

18           “(iii) the capability of different sec-  
19           tors and subsectors, including both large  
20           and small businesses, to affix and utilize  
21           the product identifier.

22           “(B) The system attributes necessary to  
23           support the requirements set forth under sub-  
24           section (h), including the standards necessary  
25           for adoption in order to support the secure,



1 interoperable electronic data exchange among  
2 sectors within the pharmaceutical distribution  
3 supply chain.

4 “(C) Best practices in each of the different  
5 sectors within the pharmaceutical distribution  
6 supply chain to implement the requirements of  
7 this section.

8 “(D) The costs and benefits of the imple-  
9 mentation of this section, including the impact  
10 on each pharmaceutical distribution supply  
11 chain sector and on public health.

12 “(E) Whether electronic tracing require-  
13 ments, including tracing of product at the pack-  
14 age level are feasible, cost-effective and needed  
15 to protect public health.

16 “(F) The systems and processes needed to  
17 utilize the product identifiers to enhance tracing  
18 of product at the package level.

19 “(G) The technical capabilities and legal  
20 authorities, if any, needed to establish an inter-  
21 operable, electronic system that provides for  
22 tracing of product at the package level.

23 “(H) The impact that such additional re-  
24 quirements would have on patient safety, the

1 drug supply, cost and regulatory burden, and  
2 timely patient access to prescription drugs.

3 “(I) Other topics, as determined appro-  
4 priate by the Secretary.

5 “(k) PILOT PROJECTS.—

6 “(1) IN GENERAL.—The Secretary shall estab-  
7 lish 1 or more pilot projects, in coordination with  
8 authorized manufacturers, repackagers, wholesale  
9 distributors, third-party logistics providers, and dis-  
10 pensers, to explore and evaluate methods to enhance  
11 the safety and security of the pharmaceutical dis-  
12 tribution supply chain. Such projects shall build  
13 upon efforts, in existence as of the date of enact-  
14 ment of the **【\_\_\_\_\_ Act】**, to enhance the  
15 safety and security of the pharmaceutical distribu-  
16 tion supply chain, take into consideration any pilot  
17 projects conducted prior to such date of enactment,  
18 and inform the draft and final guidance under para-  
19 graphs (3) and (4) of subsection (i).

20 “(2) CONTENT.—

21 “(A) IN GENERAL.—The Secretary shall  
22 ensure that the pilot projects under paragraph  
23 (1) reflect the diversity of the pharmaceutical  
24 distribution supply chain and that the pilot  
25 projects, when taken as a whole, include partici-

1 pants representative of every sector, including  
2 both large and small businesses.

3 “(B) PROJECT DESIGN.—The pilot  
4 projects under paragraph (1) shall be designed  
5 to—

6 “(i) utilize the product identifier for  
7 tracing of a product, which may include  
8 verification of the product identifier of a  
9 product, including the use of aggregation  
10 and inference;

11 “(ii) improve the technical capabilities  
12 of each sector and subsector to comply  
13 with systems and processes needed to uti-  
14 lize the product identifiers to enhance trac-  
15 ing of a product;

16 “(iii) identify system attributes that  
17 are necessary to implement the require-  
18 ments established under this section; and

19 “(iv) complete other activities as de-  
20 termined by the Secretary.

21 “(l) SUNSET.—The following requirements shall have  
22 no force or effect beginning on the date that is 10 years  
23 after the date of enactment of the **【\_\_\_\_\_ Act】**:

24 “(1) The provision and receipt of transaction  
25 history under this section.

1           “(2) The requirements set forth for returns  
2           under subsection (c)(1)(B)(i).

3           “(m) RULE OF CONSTRUCTION.—The requirements  
4           set forth in subsections (h)(4), (j), and (k) shall not be  
5           construed as a condition, prohibition, or precedent for pre-  
6           cluding or delaying the provisions becoming effective pur-  
7           suant to subsection (h).”.

8           **SEC. 4. NATIONAL LICENSURE STANDARDS FOR WHOLE-**  
9           **SALE DISTRIBUTORS.**

10           (a) LICENSE REQUIREMENT.—Section 503(e) of the  
11           Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e))  
12           is amended by striking paragraphs (1), (2), and (3) and  
13           inserting the following:

14           “(1) LICENSE REQUIREMENT.—Subject to sec-  
15           tion 583:

16           “(A) IN GENERAL.—No person—

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

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

22           “(bb) if the State from which the  
23           drug distributed has not established a  
24           licensure requirement, is licensed by  
25           the Secretary; and

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

8                   “(ii) except in the case of a manufac-  
9 turer registered under section 510, may  
10 engage in wholesale distribution of a drug  
11 subject to subsection (b) from outside the  
12 United States into a State unless such per-  
13 son is compliant with the licensure require-  
14 ments of such State, if such State licenses  
15 wholesale distributors, or the Secretary, if  
16 such State does not license wholesale dis-  
17 tributors.

18                   “(B) LICENSE STANDARDS.—Each Federal  
19 and State license described in subparagraph (A)  
20 shall meet the standards, terms, and conditions  
21 established by the Secretary under section 583.

22                   “(2) LICENSURE REPORTING AND DATABASE.—

23                   “(A) LICENSURE REPORTING.—Beginning  
24 1 year after the date of enactment of **the**  
25 \_\_\_\_\_ **Act**], any person who owns or

1 operates an establishment that engages in  
2 wholesale distribution shall report to the Sec-  
3 retary, on an annual basis pursuant to a sched-  
4 ule determined by the Secretary—

5 “(i) the State by which the person is  
6 licensed and the appropriate identification  
7 number of such license; and

8 “(ii) the name and address of each fa-  
9 cility at which, and all trade names under  
10 which, the person conducts business.

11 “(B) DATABASE.—Not later than 1 year  
12 after the date of enactment of [the  
13 \_\_\_\_\_ Act], the Secretary shall estab-  
14 lish a database of licensed wholesale distribu-  
15 tors. Such database shall—

16 “(i) identify each wholesale distributor  
17 by name, address, and the State where  
18 such wholesale distributor is appropriately  
19 licensed to engage in wholesale distribu-  
20 tion;

21 “(ii) be available to the public on the  
22 Internet Web site of the Food and Drug  
23 Administration; and

24 “(iii) be regularly updated on a sched-  
25 ule determined by the Secretary.

1 “(3) COSTS.—

2 “(A) AUTHORIZED LICENSURE FEES OF  
3 SECRETARY.—If a State does not establish a li-  
4 censing program for persons engaged in the  
5 wholesale distribution of a drug subject to sub-  
6 section (b), the Secretary shall license a person  
7 engaged in wholesale distribution located in  
8 such State and may collect a reasonable fee in  
9 such amount necessary to reimburse the Sec-  
10 retary for costs associated with establishing and  
11 administering the licensure program and con-  
12 ducting periodic inspections under this section.  
13 The Secretary shall adjust fee rates as needed  
14 on an annual basis to generate only the amount  
15 of revenue needed to perform this service. Fees  
16 authorized under this paragraph shall be col-  
17 lected and available for obligation only to the  
18 extent and in the amount provided in advance  
19 in appropriations Acts. Such fees are authorized  
20 to remain available until expended.

21 “(B) STATE LICENSING FEES.—Nothing in  
22 this Act shall prohibit States from collecting  
23 fees from wholesale distributors in connection  
24 with State licensing of such distributors.”.

1 (b) WHOLESALE DISTRIBUTION.—Section 503(e) of  
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 353(e)), as amended by subsection (a), is further amended  
4 by adding at the end the following:

5 “(4) For the purposes of this subsection and  
6 subsection (d), the term ‘wholesale distribution’  
7 means the distribution of a drug subject to sub-  
8 section (b) to a person other than a consumer or pa-  
9 tient, or receipt of a drug subject to subsection (b)  
10 by a person other than the consumer or patient, but  
11 does not include—

12 “(A) intracompany distribution of any  
13 drug between members of an affiliated group  
14 (as defined in section 1504(a) of the Internal  
15 Revenue Code of 1986);

16 “(B) the distribution of a drug, or an offer  
17 to distribute a drug among hospitals or other  
18 health care entities which are under common  
19 control;

20 “(C) the distribution of a drug or an offer  
21 to distribute a drug for emergency medical rea-  
22 sons, including a public health emergency dec-  
23 laration pursuant to section 319 of the Public  
24 Health Service Act, except that a drug shortage



1 not caused by a public health emergency shall  
2 not constitute an emergency medical reason;

3 “(D) the dispensing of a drug pursuant to  
4 a valid prescription executed in accordance with  
5 section 503(b)(1);

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

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

13 “(G) the purchase or other acquisition by  
14 a dispenser, hospital, or other health care entity  
15 of a drug for use by such dispenser, hospital, or  
16 other health care entity;

17 “(H) the distribution of a drug by the  
18 manufacturer of such drug;

19 “(I) the receipt or transfer of a drug by an  
20 authorized third-party logistics provider pro-  
21 vided that such third-party logistics provider  
22 does not take ownership of the drug;

23 “(J) a common carrier that transports a  
24 drug, provided that the common carrier does  
25 not take ownership of the drug;

1           “(K) the distribution of a drug, or an offer  
2           to distribute a drug by an authorized repack-  
3           ager that has taken ownership or possession of  
4           the drug and repacks it in accordance with sec-  
5           tion 582(e);

6           “(L) salable drug returns when conducted  
7           by a dispenser;

8           “(M) the distribution of a medical conven-  
9           ience kit which is a collection of finished drug  
10          or biologic products assembled in kit form  
11          strictly for the convenience of the purchaser or  
12          user if—

13               “(i) the medical convenience kit is as-  
14               sembled in an establishment that is reg-  
15               istered with the Food and Drug Adminis-  
16               tration as a device manufacturer;

17               “(ii) the person who manufactures  
18               the medical convenience kit purchased the  
19               finished drug or biologic product directly  
20               from the manufacturer or from a wholesale  
21               distributor that purchased the product di-  
22               rectly from the manufacturer;

23               “(iii) the person who manufactures a  
24               medical convenience kit does not alter the  
25               primary container or label of the product

1 as purchased from the manufacturer or  
2 wholesale distributor;

3 “(iv) the medical convenience kit does  
4 not contain a controlled substance that ap-  
5 pears in a schedule contained in the Com-  
6 prehensive Drug Abuse Prevention and  
7 Control Act of 1970 (21 U.S.C. 801, et  
8 seq); and

9 “(v) the products contained in the  
10 medical kit are—

11 “(I) intravenous solutions in-  
12 tended for the replenishment of fluids  
13 and electrolytes;

14 “(II) drugs intended to maintain  
15 the equilibrium of water and minerals  
16 in the body;

17 “(III) drugs intended for irriga-  
18 tion or reconstitution;

19 “(IV) anesthetics;

20 “(V) anticoagulants;

21 “(VI) vasopressors; or

22 “(VII) sympathicomimetics;

23 “(N) the distribution of an intravenous  
24 drug that, by its formulation, is intended for  
25 the replenishment of fluids and electrolytes

1 (such as sodium, chloride, and potassium) or  
2 calories (such as dextrose and amino acids);

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

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

11 “(Q) the distribution of compressed med-  
12 ical gas, as defined in section 575;

13 “(R) facilitating the distribution of a prod-  
14 uct by providing solely administrative services,  
15 including processing of orders and payments; or

16 “(S) the transfer of a product by a hos-  
17 pital or other health care entity to a repackager  
18 registered under section 510 for the purpose of  
19 repackaging the drug for use by that hospital,  
20 or other health care entity and other health  
21 care entities that are under common control, if  
22 ownership of the drug remains with the hospital  
23 or other health care entity at all times.”.

24 (c) **THIRD-PARTY LOGISTICS PROVIDERS.**—Section  
25 503(e) of the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 353(e)), as amended by subsection (a), is further  
2 amended by adding at the end the following:

3 “(5) **THIRD-PARTY LOGISTICS PROVIDERS.**—  
4 Notwithstanding paragraphs (1) through (4), each  
5 entity that meets the definition of a third-party lo-  
6 gistics provider under section 581(18) shall obtain a  
7 license as a third-party logistics provider as de-  
8 scribed in section 584(a) and is not required to ob-  
9 tain a license as a wholesale distributor if the entity  
10 never assumes an ownership interest in the product  
11 it handles.”.

12 (d) **LICENSURE STANDARDS.**—Subchapter G of chap-  
13 ter V of the Federal Food, Drug, and Cosmetic Act, as  
14 added by section 2, is amended by adding at the end the  
15 following:

16 **“SEC. 583. NATIONAL LICENSURE STANDARDS FOR WHOLE-**  
17 **SALE DISTRIBUTORS.**

18 “(a) **IN GENERAL.**—The Secretary shall, not later  
19 than 1 year after the date of enactment of the  
20 **【\_\_\_\_\_ Act】**, by regulation establish minimum  
21 standards, terms, and conditions for the licensing of per-  
22 sons under section 503(e)(1).

23 “(b) **CONTENT.**—The standards established under  
24 subsection (a) shall apply to all State and Federal licenses

1 described under section 503(e)(1) and shall prescribe min-  
2 imum requirements for—

3 “(1) the storage and handling of such drugs,  
4 including facility requirements;

5 “(2) the establishment and maintenance of  
6 records of the distributions of such drugs;

7 “(3) the furnishing of a bond or other equiva-  
8 lent means of security if—

9 “(A) an applicant that is not a government  
10 owned and operated wholesale distributor, for  
11 the issuance or renewal of a wholesale dis-  
12 tributor license shall submit a surety bond of  
13 one hundred thousand dollars or other equiva-  
14 lent means of security acceptable to the State;

15 “(B) for purposes of subparagraph (A),  
16 the State or other applicable authority may ac-  
17 cept a surety bond less than \$100,000 if the  
18 annual gross receipts of the previous tax year  
19 for the wholesaler is \$10,000,000 or less, in  
20 which case the surety bond shall be \$25,000;  
21 and

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

1           “(4) mandatory background checks and  
2           fingerprinting of facility managers or designated  
3           representatives;

4           “(5) the establishment and implementation of  
5           qualifications for key personnel;

6           “(6) the mandatory physical inspection of any  
7           facility to be used in wholesale distribution within a  
8           reasonable time frame from the initial application of  
9           the facility and to be conducted by the licensing au-  
10          thority or by the State, consistent with subsection  
11          (c); and

12          “(7) in accordance with subsection (d), the pro-  
13          hibition of certain persons from receiving or main-  
14          taining licensure for wholesale distribution.

15          “(c) INSPECTIONS.—To satisfy the inspection re-  
16          quirement the Federal or State licensing authority may  
17          conduct the inspection, or may accept an inspection by the  
18          State in which the facility is located, or by a third-party  
19          accreditation or inspection service approved by the Sec-  
20          retary or the State licensing such wholesale distributor.

21          “(d) PROHIBITED PERSONS.—The standards estab-  
22          lished under subsection (a) shall include requirements to  
23          prohibit a person from receiving or maintaining licensure  
24          for wholesale distribution if the person—

1           “(1) has been convicted of any felony for con-  
2           duct relating to wholesale distribution, any felony  
3           violation of subsection (i) or (k) of section 301, or  
4           any felony violation of section 1365 of title 18,  
5           United States Code, relating to product tampering;  
6           or

7           “(2) has engaged in a pattern of violating the  
8           requirements of this section, or State requirements  
9           for licensure, that presents a threat of serious ad-  
10          verse health consequences or death to humans.

11          “(e) REQUIREMENTS.—The Secretary, in promul-  
12          gating any regulation pursuant to this section, shall, not-  
13          withstanding section 553 of title 5, United States Code—

14                 “(1) issue a notice of proposed rulemaking that  
15                 includes a copy of the proposed regulation;

16                 “(2) provide a period of not less than 60 days  
17                 for comments on the proposed regulation; and

18                 “(3) provide that the final regulation take effect  
19                 on the date that is 2 years after the date such final  
20                 regulation is published.”.

21         **SEC. 5. NATIONAL LICENSURE STANDARDS FOR THIRD-**  
22                         **PARTY LOGISTICS PROVIDERS.**

23                 Subchapter G of chapter V of the Federal Food,  
24                 Drug, and Cosmetic Act, as amended by section 4, is fur-  
25                 ther amended by adding at the end the following:



1 **“SEC. 584. NATIONAL LICENSURE STANDARDS FOR THIRD-**  
2 **PARTY LOGISTICS PROVIDERS.**

3 “(a) LICENSE REQUIREMENT.—No third-party logis-  
4 ties provider in any State may conduct activities in any  
5 State unless each facility of such third-party logistics pro-  
6 vider—

7 “(1)(A) is licensed by the State from which the  
8 drug is distributed by the third-party logistics pro-  
9 vider, in accordance with the regulations promul-  
10 gated under subsection (d); or

11 “(B) if the State from which the drug distrib-  
12 uted by the third-party logistics provider has not es-  
13 tablished a licensure requirement, is licensed by the  
14 Secretary, in accordance with the regulations pro-  
15 mulgated under subsection (d); and

16 “(2) if the drug is distributed interstate, is li-  
17 censed by the State into which the drug is distrib-  
18 uted by the third-party logistics provider if such  
19 State licenses third-party logistics providers that dis-  
20 tribute drugs into the State and the third-party lo-  
21 gistics provider is not licensed by the Secretary as  
22 described in paragraph (1)(B).

23 “(b) LICENSURE REPORTING.—Beginning 1 year  
24 after the date of enactment of **【the \_\_\_\_\_ Act】**,  
25 a facility of a third-party logistics provider shall report

1 to the Secretary, on an annual basis pursuant to a sched-  
2 ule determined by the Secretary—

3 “(1) the State by which the facility is licensed  
4 and the appropriate identification number of such li-  
5 cense; and

6 “(2) the name and address of the facility, and  
7 all trade names under which, such facility conducts  
8 business.

9 “(c) COSTS.—

10 “(1) AUTHORIZED LICENSURE FEES OF SEC-  
11 RETARY.—If a State does not establish a licensing  
12 program for a third-party logistics provider, the Sec-  
13 retary shall license the third-party logistics provider  
14 located in such State and may collect a reasonable  
15 fee in such amount necessary to reimburse the Sec-  
16 retary for costs associated with establishing and ad-  
17 ministering the licensure program and conducting  
18 periodic inspections under this section. The Sec-  
19 retary shall adjust fee rates as needed on an annual  
20 basis to generate only the amount of revenue needed  
21 to perform this service. Fees authorized under this  
22 paragraph shall be collected and available for obliga-  
23 tion only to the extent and in the amount provided  
24 in advance in appropriations Acts. Such fees are au-  
25 thorized to remain available until expended.

1 “(2) STATE LICENSING FEES.—

2 “(A) STATE ESTABLISHED PROGRAM.—

3 Nothing in this Act shall prohibit a State that  
4 has established a program to license a third-  
5 party logistics provider from collecting fees  
6 from a third-party logistics provider for such a  
7 license.

8 “(B) NO STATE ESTABLISHED PRO-

9 GRAM.—A State that does not establish a pro-  
10 gram to license a third-party logistics provider  
11 in accordance with this section shall be prohib-  
12 ited from collecting a State licensing fee from  
13 a third-party logistics provider.

14 “(d) LICENSE REGULATIONS.—

15 “(1) IN GENERAL.—Not later than 1 year after  
16 the date of enactment of **【the \_\_\_\_\_ Act】**,  
17 the Secretary shall issue regulations regarding the  
18 minimum issuance and eligibility requirements for li-  
19 censing under subsection (a), including the revoca-  
20 tion and reissuance of such license, to third-party lo-  
21 gistics providers under this section.

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

23 “(A) establish a process by which a third-  
24 party accreditation program approved by the  
25 Secretary shall, upon request by a third-party

1 logistics provider, issue a license to each third-  
2 party logistics provider that meets the min-  
3 imum requirements set forth in this section;

4 “(B) establish a process by which the Sec-  
5 retary shall issue a license to each third-party  
6 logistics provider that meets the minimum re-  
7 quirements set forth in this section if the Sec-  
8 retary is not able to approve a third-party ac-  
9 creditation program because no such program  
10 meets the Secretary’s requirements necessary  
11 for approval of such a third-party accreditation  
12 program;

13 “(C) require that the entity complies with  
14 storage practices, as determined by the Sec-  
15 retary for such facility, including—

16 “(i) maintaining access to warehouse  
17 space of suitable size to facilitate safe op-  
18 erations, including a suitable area to quar-  
19 antine suspect product;

20 “(ii) maintaining adequate security;  
21 and

22 “(iii) having written policies and pro-  
23 cedures to—

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1           “(I) address receipt, security,  
2 storage, inventory, shipment, and dis-  
3 tribution of a product;

4           “(II) identify, record, and report  
5 confirmed losses or thefts in the  
6 United States;

7           “(III) correct errors and inac-  
8 curacies in inventories;

9           “(IV) provide support for manu-  
10 facturer recalls;

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

16           “(VI) ensure that any expired  
17 product is segregated from other  
18 products and returned to the manu-  
19 facturer or re-packager or destroyed;

20           “(VII) maintain the capability to  
21 electronically trace the receipt and  
22 outbound distribution of a product,  
23 and supplies and records of inventory;  
24 and

1                   “(VIII) quarantine or destroy a  
2                   suspect product if directed to do so by  
3                   the respective manufacturer, wholesale  
4                   distributor, dispenser or an authorized  
5                   government agency;

6                   “(D) provide for periodic inspection by the  
7                   licensing authority, as determined by the Sec-  
8                   retary, of such facility warehouse space to en-  
9                   sure compliance with this section;

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

16                  “(F) provide for mandatory background  
17                  checks of a facility manager or a designated  
18                  representative of such manager; and

19                  “(G) require a third-party logistics pro-  
20                  vider to provide the Secretary, upon a request  
21                  by the Secretary, a list of all product manufac-  
22                  turers, wholesale distributors, and dispensers  
23                  for whom the third-party logistics provider pro-  
24                  vides services at such facility.

1           “(3) PROCEDURE.—In promulgating the regula-  
2           tions under this subsection, the Secretary shall, not-  
3           withstanding section 553 of title 5, United States  
4           Code—

5                   “(A) issue a notice of proposed rulemaking  
6                   that includes a copy of the proposed regulation;

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

10                   “(C) provide that the final regulation takes  
11                   effect upon the expiration of 1 year after the  
12                   date that such final regulation is issued.

13           “(e) 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   **SEC. 6. PENALTIES.**

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

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

1           (2) by inserting “, failure to comply with the  
2 requirements under section 582, the failure to report  
3 under section 584, as applicable,” after “in violation  
4 of section 503(e)”.

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

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

10 **SEC. 7. UNIFORM NATIONAL POLICY.**

11           (a) PRODUCT TRACING AND OTHER REQUIRE-  
12 MENTS.—Beginning on the date of enactment of this Act,  
13 no State or political subdivision of a State may establish  
14 or continue in effect any requirements for tracing drugs  
15 through the distribution system (including any require-  
16 ments with respect to statements of distribution history,  
17 transaction history, transaction information, or trans-  
18 action statement of a pharmaceutical product as such  
19 product changes ownership in the supply chain, or  
20 verification, investigation, disposition, notification, or  
21 record-keeping relating to such systems, including paper  
22 or electronic pedigree systems or for tracking and tracing  
23 drugs throughout the distribution system) which are in-  
24 consistent with, more stringent than, or in addition to, any  
25 requirements applicable under this Act (or the amend-



1 ments made by this Act) or regulations issued thereunder,  
2 or which are inconsistent with—

3 (1) any waiver, exception, or exemption issued  
4 by the Secretary under subsection (a) of sections  
5 581 and 582 of the Federal Food, Drug, and Cos-  
6 metic Act (as added by this Act); or

7 (2) any restrictions specified in section 582 of  
8 the Federal Food, Drug, and Cosmetic Act (as  
9 added by this Act).

10 (b) DISTRIBUTION AND LICENSING STANDARDS.—

11 (1) IN GENERAL.—Beginning on the date of en-  
12 actment of this Act, no State or political subdivision  
13 of a State may establish or continue any standards,  
14 requirements, or regulations with respect to whole-  
15 sale drug distributor or third-party logistics provider  
16 licensure that are less stringent than the standards  
17 and requirements applicable under section 503(e) of  
18 the Federal Food, Drug, and Cosmetic Act (as  
19 amended by this Act), in the case of a wholesale dis-  
20 tributor, or section 584 of the Federal Food, Drug,  
21 and Cosmetic Act (as added by this Act), in the case  
22 of a third-party logistics provider.

23 (2) STATE REGULATION OF THIRD-PARTY LO-  
24 GISTICS PROVIDERS.—No State shall regulate third-  
25 party logistics providers as wholesale distributors.

1           (3) ADMINISTRATION FEES.—Notwithstanding  
2 paragraph (1), a State may administer fee collec-  
3 tions for effectuating the wholesale drug distributor  
4 and third-party logistics provider licensure require-  
5 ments under sections 503(e), 583, and 584 of the  
6 Federal Food, Drug, and Cosmetic Act (as amended  
7 and added by this Act).

8           (4) ENFORCEMENT, SUSPENSION, AND REVOCA-  
9 TION OF LICENSES.—Notwithstanding paragraph  
10 (1), a State—

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

15           (B) may provide for the suspension or rev-  
16 ocation of licenses issued by the State for viola-  
17 tions of the laws of such State;

18           (C) upon conviction of violations of Fed-  
19 eral, State, or local drug laws or regulations,  
20 may provide for fines, imprisonment, or civil  
21 penalties; and

22           (D) may regulate activities of licensed enti-  
23 ties in a manner that is consistent with product  
24 tracing requirements under section 582 of the

1 Federal Food, Drug, and Cosmetic Act (as  
2 added by this Act).

3 (c) EXCEPTION.—Nothing in subsection (a) or (b)  
4 shall be construed to preempt State requirements related  
5 to the distribution of prescription drugs if such require-  
6 ments are not related to product tracing as described in  
7 subsection (a), including any requirements applicable  
8 under this Act (or the amendments made by this Act) or  
9 regulations issued under this Act (or such amendments).