



Sen. Terry Link

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1 AMENDMENT TO SENATE BILL 509

2 AMENDMENT NO. \_\_\_\_\_. Amend Senate Bill 509, AS AMENDED, by  
3 replacing everything after the enacting clause with the  
4 following:

5 "Section 1. Short title. This Act may be cited as the  
6 Wholesale Licensure and Prescription Medication Integrity Act.

7 Section 5. Definitions. In this Act:

8 "Authentication" means to affirmatively verify, before any  
9 wholesale distribution of a prescription drug occurs, that each  
10 transaction listed on the pedigree has occurred.

11 "Authorized distributor of record" means a wholesale  
12 distributor with whom a manufacturer has established an ongoing  
13 relationship to distribute the manufacturer's prescription  
14 drug. An ongoing relationship is deemed to exist between a  
15 wholesale distributor and a manufacturer when the wholesale  
16 distributor, including any affiliated group of the wholesale

1 distributor, as defined in Section 1504 of the Internal Revenue  
2 Code, complies with either of the following:

3 (1) the wholesale distributor has a written agreement  
4 currently in effect with the manufacturer evidencing the  
5 ongoing relationship; or

6 (2) the wholesale distributor is listed on the  
7 manufacturer's current list of authorized distributors of  
8 record, which is updated by the manufacturer on no less  
9 than a monthly basis.

10 "Chain pharmacy warehouse" means a physical location for  
11 prescription drugs that acts as a central warehouse and  
12 performs intracompany sales or transfers of the drugs to a  
13 group of chain pharmacies that have the same common ownership  
14 and control. Notwithstanding any other provision of this Act, a  
15 chain pharmacy warehouse shall be considered part of the normal  
16 distribution channel.

17 "Co-licensed partner or product" means an instance where 2  
18 or more parties have the right to engage in the manufacturing  
19 or marketing of a prescription drug, consistent with the FDA's  
20 implementation of the Prescription Drug Marketing Act.

21 "Department" means the Department of Financial and  
22 Professional Regulation.

23 "Drop shipment" means the sale of a prescription drug to a  
24 wholesale distributor by the manufacturer of the prescription  
25 drug, or that manufacturer's co-licensed product partner, that  
26 manufacturer's third party logistics provider, or that

1 manufacturer's exclusive distributor, whereby the wholesale  
2 distributor or chain pharmacy warehouse takes title but not  
3 physical possession of such prescription drug and the wholesale  
4 distributor invoices the pharmacy, chain pharmacy warehouse,  
5 or other person authorized by law to dispense or administer  
6 such drug to a patient and the pharmacy, chain pharmacy  
7 warehouse or other authorized person receives delivery of the  
8 prescription drug directly from the manufacturer, that  
9 manufacturer's third party logistics provider, or that  
10 manufacturer's exclusive distributor.

11 "Facility" means a facility of a wholesale distributor  
12 where prescription drugs are stored, handled, repackaged, or  
13 offered for sale.

14 "FDA" means the United States Food and Drug Administration.

15 "Manufacturer" means a person licensed or approved by the  
16 FDA to engage in the manufacture of drugs or devices,  
17 consistent with the definition of "manufacturer" set forth in  
18 the FDA's regulations and guidances implementing the  
19 Prescription Drug Marketing Act.

20 "Manufacturer's exclusive distributor" means anyone who  
21 contracts with a manufacturer to provide or coordinate  
22 warehousing, distribution, or other services on behalf of a  
23 manufacturer and who takes title to that manufacturer's  
24 prescription drug, but who does not have general responsibility  
25 to direct the sale or disposition of the manufacturer's  
26 prescription drug. A manufacturer's exclusive distributor must

1 be licensed as a wholesale distributor under this Act and, in  
2 order to be considered part of the normal distribution channel,  
3 must also be an authorized distributor of record.

4 "Normal distribution channel" means a chain of custody for  
5 a prescription drug that goes, directly or by drop shipment,  
6 from (i) a manufacturer of the prescription drug, (ii) that  
7 manufacturer to that manufacturer's co-licensed partner, (iii)  
8 that manufacturer to that manufacturer's third-party logistics  
9 provider, or (iv) that manufacturer to that manufacturer's  
10 exclusive distributor to:

11 (1) a pharmacy or to other designated persons  
12 authorized by law to dispense or administer the drug to a  
13 patient;

14 (2) a wholesale distributor to a pharmacy or other  
15 designated persons authorized by law to dispense or  
16 administer the drug to a patient;

17 (3) a wholesale distributor to a chain pharmacy  
18 warehouse to that chain pharmacy warehouse's intracompany  
19 pharmacy to a patient or other designated persons  
20 authorized by law to dispense or administer the drug; or

21 (4) a chain pharmacy warehouse to the chain pharmacy  
22 warehouse's intracompany pharmacy or other designated  
23 persons authorized by law to dispense or administer the  
24 drug.

25 "Pedigree" means a document or electronic file containing  
26 information that records each wholesale distribution of any

1 given prescription drug.

2 "Prescription drug" means any drug, including any  
3 biological product (except for blood and blood components  
4 intended for transfusion or biological products that are also  
5 medical devices), required by federal law or regulation to be  
6 dispensed only by a prescription, including finished dosage  
7 forms and bulk drug substances subject to Section 503(b) of the  
8 federal Food, Drug and Cosmetic Act.

9 "Repackage" means repackaging or otherwise changing the  
10 container, wrapper, or labeling to further the distribution of  
11 a prescription drug, excluding that completed by the pharmacist  
12 responsible for dispensing product to a patient.

13 "Third party logistics provider" means anyone who  
14 contracts with a prescription drug manufacturer to provide or  
15 coordinate warehousing, distribution, or other services on  
16 behalf of a manufacturer, but does not take title to the  
17 prescription drug or have general responsibility to direct the  
18 prescription drug's sale or disposition. A third party  
19 logistics provider must be licensed as a wholesale distributor  
20 under this Act and, in order to be considered part of the  
21 normal distribution channel, must also be an authorized  
22 distributor of record.

23 "Wholesale distributor" means anyone engaged in the  
24 wholesale distribution of prescription drugs, including  
25 without limitation manufacturers; repackagers; own-label  
26 distributors; private-label distributors; jobbers; brokers;

1 warehouses, including manufacturers' and distributors'  
2 warehouses; manufacturer's exclusive distributors; and  
3 authorized distributors of record; drug wholesalers or  
4 distributors; independent wholesale drug traders; specialty  
5 wholesale distributors; third party logistics providers; and  
6 retail pharmacies that conduct wholesale distribution; and  
7 chain pharmacy warehouses that conduct wholesale distribution.  
8 In order to be considered part of the normal distribution  
9 channel, a wholesale distributor must also be an authorized  
10 distributor of record.

11 "Wholesale distribution" means the distribution of  
12 prescription drugs to persons other than a consumer or patient,  
13 but does not include any of the following:

14 (1) Intracompany sales of prescription drugs, meaning  
15 (i) any transaction or transfer between any division,  
16 subsidiary, parent or affiliated or related company under  
17 common ownership and control of a corporate entity or (ii)  
18 any transaction or transfer between co-licensees of a  
19 co-licensed product.

20 (2) The sale, purchase, distribution, trade, or  
21 transfer of a prescription drug or offer to sell, purchase,  
22 distribute, trade, or transfer a prescription drug for  
23 emergency medical reasons.

24 (3) The distribution of prescription drug samples by  
25 manufacturers' representatives.

26 (4) Drug returns, when conducted by a hospital, health

1 care entity, or charitable institution in accordance with  
2 federal regulation.

3 (5) The sale of minimal quantities of prescription  
4 drugs by retail pharmacies to licensed practitioners for  
5 office use.

6 (6) The sale, purchase, or trade of a drug, an offer to  
7 sell, purchase, or trade a drug, or the dispensing of a  
8 drug pursuant to a prescription.

9 (7) The sale, transfer, merger, or consolidation of all  
10 or part of the business of a pharmacy or pharmacies from or  
11 with another pharmacy or pharmacies, whether accomplished  
12 as a purchase and sale of stock or business assets.

13 (8) The sale, purchase, distribution, trade, or  
14 transfer of a prescription drug from one authorized  
15 distributor of record to one additional authorized  
16 distributor of record when the manufacturer has stated in  
17 writing to the receiving authorized distributor of record  
18 that the manufacturer is unable to supply the prescription  
19 drug and the supplying authorized distributor of record  
20 states in writing that the prescription drug being supplied  
21 had until that time been exclusively in the normal  
22 distribution channel.

23 (9) The delivery of or the offer to deliver a  
24 prescription drug by a common carrier solely in the common  
25 carrier's usual course of business of transporting  
26 prescription drugs when the common carrier does not store,

1 warehouse, or take legal ownership of the prescription  
2 drug.

3 (10) The sale or transfer from a retail pharmacy or  
4 chain pharmacy warehouse of expired, damaged, returned, or  
5 recalled prescription drugs to the original manufacturer  
6 or to a third party returns processor.

7 Section 10. Licensure required.

8 (a) Every resident wholesale distributor who engages in the  
9 wholesale distribution of prescription drugs must be licensed  
10 by the Department, and every non-resident wholesale  
11 distributor must be licensed in this State if it ships  
12 prescription drugs into this State, in accordance with this  
13 Act, before engaging in wholesale distributions of wholesale  
14 prescription drugs. The Department shall exempt manufacturers  
15 distributing their own FDA-approved drugs and devices from the  
16 requirements of this Section, to the extent not required by  
17 federal law or regulation, unless particular requirements are  
18 deemed necessary and appropriate following rulemaking.

19 (b) The Department shall require without limitation all of  
20 the following information from each applicant for licensure  
21 under this Act:

22 (1) The name, full business address, and telephone  
23 number of the licensee.

24 (2) All trade or business names used by the licensee.

25 (3) Addresses, telephone numbers, and the names of



1 contact persons for all facilities used by the licensee for  
2 the storage, handling, and distribution of prescription  
3 drugs.

4 (4) The type of ownership or operation, such as a  
5 partnership, corporation, or sole proprietorship.

6 (5) The name of the owner or operator of the wholesale  
7 distributor, including:

8 (A) if a person, the name of the person;

9 (B) if a partnership, the name of each partner and  
10 the name of the partnership;

11 (C) if a corporation, the name and title of each  
12 corporate officer and director, the corporate names,  
13 and the name of the state of incorporation; and

14 (D) if a sole proprietorship, the full name of the  
15 sole proprietor and the name of the business entity.

16 (6) A list of all licenses and permits issued to the  
17 applicant by any other state that authorizes the applicant  
18 to purchase or possess prescription drugs.

19 (7) The name of the designated representative for the  
20 wholesale distributor, together with the personal  
21 information statement and fingerprints, as required under  
22 subsection (c) of this Section.

23 (8) Any additional information required by the  
24 Department.

25 (c) Each wholesale distributor must designate an  
26 individual representative who shall serve as the contact person

1 for the Department. This representative must provide the  
2 Department with all of the following information:

3 (1) The person's places of residence for the past 7  
4 years.

5 (2) The person's date and place of birth.

6 (3) The person's occupations, positions of employment,  
7 and offices held during the past 7 years and the principal  
8 business and address of any business, corporation, or other  
9 organization in which each such office of the person was  
10 held or in which each such occupation or position of  
11 employment was carried on.

12 (4) Information concerning whether the person has  
13 been, during the past 7 years, the subject of any  
14 proceeding for the revocation of any license or any  
15 criminal violation and, if so, the nature of the proceeding  
16 and the disposition of the proceeding.

17 (5) Information concerning whether, during the past 7  
18 years, the person has been enjoined, either temporarily or  
19 permanently, by a court of competent jurisdiction from  
20 violating any federal or State law regulating the  
21 possession, control, or distribution of prescription drugs  
22 or criminal violations, together with details concerning  
23 any such event.

24 (6) A description of any involvement by the person with  
25 any business, including any investments, other than the  
26 ownership of stock in a publicly traded company or mutual

1 fund, during the past 7 years, which manufactured,  
2 administered, prescribed, distributed, or stored  
3 pharmaceutical products and any lawsuits in which such  
4 businesses were named as a party.

5 (7) A description of any misdemeanor or felony criminal  
6 offense of which the person, as an adult, was found guilty,  
7 regardless of whether adjudication of guilt was withheld or  
8 whether the person pled guilty or nolo contendere. If the  
9 person indicates that a criminal conviction is under appeal  
10 and submits a copy of the notice of appeal of that criminal  
11 offense, the applicant must, within 15 days after the  
12 disposition of the appeal, submit to the Department a copy  
13 of the final written order of disposition.

14 (8) A photograph of the person taken within the  
15 previous 180 days.

16 The designated representative must also submit his or her  
17 fingerprints to the Department to be checked against the  
18 Department of State Police and Federal Bureau of Investigation  
19 criminal history record databases now and hereafter filed, in a  
20 manner prescribed by the Department and must receive and  
21 complete continuing training in applicable federal and State  
22 laws governing the wholesale distribution of prescription  
23 drugs.

24 (d) Any information required to be submitted to the  
25 Department under subsections (b) and (c) of this Section shall  
26 be provided under oath.

1 (e) The Department may not issue a wholesale distributor  
2 license to an applicant, unless the Department first:

3 (1) conducts a physical inspection of the facility at  
4 the address provided by the applicant as required under  
5 item (1) of subsection (b) of this Section; and

6 (2) determines that the designated representative  
7 meets each of the following qualifications:

8 (A) He or she is at least 21 years of age.

9 (B) He or she has been employed full-time for at  
10 least 3 years in a pharmacy or with a wholesale  
11 distributor in a capacity related to the dispensing and  
12 distribution of, and recordkeeping relating to,  
13 prescription drugs.

14 (C) He or she is employed by the applicant full  
15 time in a managerial level position.

16 (D) He or she is actively involved in and aware of  
17 the actual daily operation of the wholesale  
18 distributor.

19 (E) He or she is physically present at the facility  
20 of the applicant during regular business hours, except  
21 when the absence of the designated representative is  
22 authorized, including without limitation sick leave  
23 and vacation leave.

24 (F) He or she is serving in the capacity of a  
25 designated representative for only one applicant at a  
26 time, except where more than one licensed wholesale

1 distributor is co-located in the same facility and such  
2 wholesale distributors are members of an affiliated  
3 group, as defined in Section 1504 of the Internal  
4 Revenue Code.

5 (G) He or she does not have any convictions under  
6 any federal, State, or local laws relating to wholesale  
7 or retail prescription drug distribution or  
8 distribution of controlled substances.

9 (H) He or she does not have any felony convictions  
10 under federal, State, or local laws.

11 (f) If a wholesale distributor distributes prescription  
12 drugs from more than one facility, the wholesale distributor  
13 shall obtain a license for each facility.

14 (g) The information provided under this Section may not be  
15 disclosed to any person or entity other than the Department or  
16 another government entity in need of such information for  
17 licensing or monitoring purposes.

18 Section 15. License renewal. In accordance with each  
19 license renewal, the Department shall send to each licensee a  
20 form setting forth the information that the licensee provided  
21 to the Department in the licensee's original application for  
22 licensure under Section 10 of this Act. Within 30 days after  
23 receiving the form, the wholesale distributor must identify and  
24 state under oath to the Department any and all changes or  
25 corrections to the information originally submitted to the

1 Department. The Department may suspend or revoke the license of  
2 a licensee if the Department determines that the licensee no  
3 longer qualifies for the license originally issued under this  
4 Act.

5 Section 20. Bond required. The Department shall require  
6 every wholesale distributor applying for licensure under this  
7 Act to submit a bond of at least \$100,000 or another equivalent  
8 means of security acceptable to the Department, such as an  
9 irrevocable letter of credit or a deposit in a trust account or  
10 financial institution, payable to a fund established by the  
11 Department. Chain pharmacy warehouses that are not engaged in  
12 wholesale distribution are exempt from the bond requirement of  
13 this Section. The purpose of the bond is to secure payment of  
14 any fines or penalties imposed by the Department and any fees  
15 and costs incurred by the Department regarding that license,  
16 which are authorized under State law and which the licensee  
17 fails to pay 30 days after the fines, penalties, or costs  
18 become final. The Department may make a claim against the bond  
19 or security until one year after the licensee's license ceases  
20 to be valid. A single bond may suffice to cover all facilities  
21 operated by an applicant in this State.

22 The Department shall establish a fund, separate from its  
23 other accounts, in which to deposit the wholesale distributor  
24 bonds required under this Section.

1 Section 25. Restrictions on transactions.

2 (a) A licensee shall receive prescription drug returns or  
3 exchanges from a pharmacy or chain pharmacy warehouse pursuant  
4 to the terms and conditions of the agreement between the  
5 wholesale distributor and the pharmacy or chain pharmacy  
6 warehouse. Returns of expired, damaged, recalled, or otherwise  
7 non-saleable pharmaceutical products shall be distributed by  
8 the receiving wholesale distributor only to either the original  
9 manufacturer or a third party returns processor, and such  
10 returns or exchanges, including any redistribution by a  
11 receiving wholesaler, shall not be subject to the pedigree  
12 requirements of Section 30 of this Act, so long as they are  
13 exempt from the pedigree requirement of the FDA's currently  
14 applicable Prescription Drug Marketing Act guidance. Both  
15 licensees under this Act and pharmacies shall be accountable  
16 for administering their returns process and ensuring that the  
17 aspects of this operation are secure and do not permit the  
18 entry of adulterated and counterfeit product.

19 (b) A manufacturer or wholesale distributor licensed under  
20 this Act may furnish prescription drugs only to a person  
21 licensed by the appropriate state licensing authorities.  
22 Before furnishing prescription drugs to a person not known to  
23 the manufacturer or wholesale distributor, the manufacturer or  
24 wholesale distributor must affirmatively verify that the  
25 person is legally authorized to receive the prescription drugs  
26 by contacting the appropriate state licensing authorities.

1           (c) Prescription drugs furnished by a manufacturer or  
2 wholesale distributor licensed under this Act may be delivered  
3 only to the premises listed on the license, provided that the  
4 manufacturer or wholesale distributor may furnish prescription  
5 drugs to an authorized person or agent of that person at the  
6 premises of the manufacturer or wholesale distributor if:

7           (1) the identity and authorization of the recipient is  
8 properly established; and

9           (2) this method of receipt is employed only to meet the  
10 immediate needs of a particular patient of the authorized  
11 person.

12          (d) Prescription drugs may be furnished to a hospital  
13 pharmacy receiving area, provided that a pharmacist or  
14 authorized receiving personnel signs, at the time of delivery,  
15 a receipt showing the type and quantity of the prescription  
16 drug received. Any discrepancy between the receipt and the type  
17 and quantity of the prescription drug actually received shall  
18 be reported to the delivering manufacturer or wholesale  
19 distributor by the next business day after the delivery to the  
20 pharmacy receiving area.

21          (e) A manufacturer or wholesale distributor licensed under  
22 this Act may not accept payment for, or allow the use of, a  
23 person or entity's credit to establish an account for the  
24 purchase of prescription drugs from any person other than the  
25 owner of record, the chief executive officer, or the chief  
26 financial officer listed on the license of a person or entity



1 legally authorized to receive the prescription drugs. Any  
2 account established for the purchase of prescription drugs must  
3 bear the name of the licensee. This subsection (e) shall not be  
4 construed to prohibit a pharmacy or chain pharmacy warehouse  
5 from receiving prescription drugs if payment for the  
6 prescription drugs is processed through the pharmacy's or chain  
7 pharmacy warehouse's contractual drug manufacturer or  
8 wholesale distributor.

9 Section 30. Pedigree.

10 (a) Each person who is engaged in the wholesale  
11 distribution of prescription drugs, including repackagers, but  
12 excluding the original manufacturer of the finished form of the  
13 prescription drug, that leave or have ever left the normal  
14 distribution channel shall, before each wholesale distribution  
15 of the drug, provide a pedigree to the person who receives the  
16 drug.

17 A retail pharmacy or chain pharmacy warehouse must comply  
18 with the requirements of this Section only if the pharmacy or  
19 chain pharmacy warehouse engages in the wholesale distribution  
20 of prescription drugs.

21 The State Board of Pharmacy shall determine by July 1,  
22 2009, a targeted implementation date for electronic track and  
23 trace technology. This determination shall be based on  
24 consultation with manufacturers, distributors, and pharmacies  
25 responsible for the sale and distribution of prescription drug

1 products in this State. After consultation with interested  
2 stakeholders and prior to the implementation of the track and  
3 trace technology, the State Board of Pharmacy shall deem that  
4 the technology is universally available across the entire  
5 prescription pharmaceutical supply chain. The implementation  
6 date for the mandated electronic track and trace technology  
7 shall be no sooner than July 1, 2010 and may be extended by the  
8 State Board of Pharmacy in one year increments if it appears  
9 that the technology is not universally available across the  
10 entire prescription pharmaceutical supply chain.

11 (b) Each person who is engaged in the wholesale  
12 distribution of a prescription drug, including repackagers,  
13 but excluding the original manufacturer of the finished form of  
14 the prescription drug, who is provided a pedigree for a  
15 prescription drug and attempts to further distribute that  
16 prescription drug, must affirmatively verify before any  
17 distribution of a prescription drug occurs that each  
18 transaction listed on the pedigree has occurred.

19 (c) The pedigree must include all necessary identifying  
20 information concerning each sale in the chain of distribution  
21 of the product from the manufacturer or the manufacturer's  
22 third party logistics provider, co-licensed product partner,  
23 or exclusive distributor through acquisition and sale by any  
24 wholesale distributor or repackager, until final sale to a  
25 pharmacy or other person dispensing or administering the drug.  
26 This necessary chain of distribution information shall

1 include, without limitation all of the following:

2 (1) The name, address, telephone number and, if  
3 available, the e-mail address of each owner of the  
4 prescription drug and each wholesale distributor of the  
5 prescription drug.

6 (2) The name and address of each location from which  
7 the product was shipped, if different from the owner's.

8 (3) Transaction dates.

9 (4) Certification that each recipient has  
10 authenticated the pedigree.

11 (d) The pedigree must also include without limitation all  
12 of the following information concerning the prescription drug:

13 (1) The name and national drug code number of the  
14 prescription drug.

15 (2) The dosage form and strength of the prescription  
16 drug.

17 (3) The size of the container.

18 (4) The number of containers.

19 (5) The lot number of the prescription drug.

20 (6) The name of the manufacturer of the finished dosage  
21 form.

22 (e) Each pedigree or electronic file shall be maintained by  
23 the purchaser and the wholesale distributor for at least 3  
24 years from the date of sale or transfer and made available for  
25 inspection or use within 5 business days upon a request of the  
26 Department.

1           (f) The Department shall adopt rules and prescribe a form  
2 relating to the requirements of this Section no later than 90  
3 days after the effective date of this Act.

4           Section 35. Prohibited acts. It is unlawful for a person to  
5 perform or cause the performance of or aid and abet any of the  
6 following acts:

7           (1) Failure to obtain a license in accordance with this  
8 Act or operating without a valid license when a license is  
9 required by this Act.

10          (2) If the requirements of subsection (a) of Section 25  
11 are applicable and are not met, the purchasing or otherwise  
12 receiving of a prescription drug from a pharmacy.

13          (3) If licensure is required pursuant to subsection (b)  
14 of Section 25 of this Act, the sale, distribution, or  
15 transfer of a prescription drug to a person that is not  
16 authorized under the law of the jurisdiction in which the  
17 person receives the prescription drug to receive the  
18 prescription drug.

19          (4) Failure to deliver prescription drugs to specified  
20 premises, as required by subsection (c) of Section 25 of  
21 this Act.

22          (5) Accepting payment or credit for the sale of  
23 prescription drugs in violation of subsection (e) of  
24 Section 25 of this Act.

25          (6) Failure to maintain or provide pedigrees as

1 required by this Act;

2 (7) Failure to obtain, pass, or authenticate a pedigree  
3 as required by this Act.

4 (8) Providing the Department or any federal official  
5 with false or fraudulent records or making false or  
6 fraudulent statements regarding any matter within the  
7 provisions of this Act.

8 (9) Obtaining or attempting to obtain a prescription  
9 drug by fraud, deceit, or misrepresentation or engaging in  
10 misrepresentation or fraud in the distribution of a  
11 prescription drug.

12 (10) The manufacture, repacking, sale, transfer,  
13 delivery, holding, or offering for sale of any prescription  
14 drug that is adulterated, misbranded, counterfeit,  
15 suspected of being counterfeit, or that has otherwise been  
16 rendered unfit for distribution.

17 (11) The adulteration, misbranding, or counterfeiting  
18 of any prescription drug.

19 (12) The receipt of any prescription drug that is  
20 adulterated, misbranded, stolen, obtained by fraud or  
21 deceit, counterfeit, or suspected of being counterfeit and  
22 the delivery or proffered delivery of such drug for pay or  
23 otherwise.

24 (13) The alteration, mutilation, destruction,  
25 obliteration, or removal of the whole or any part of the  
26 labeling of a prescription drug or the commission of any

1 other act with respect to a prescription drug that results  
2 in the prescription drug being misbranded.

3 The acts prohibited in this Section do not include the  
4 obtaining or the attempt to obtain a prescription drug for the  
5 sole purpose of testing the prescription drug for authenticity  
6 performed by a prescription drug manufacturer or the agent of a  
7 prescription drug manufacturer.

8 Section 40. Enforcement; order to cease distribution of a  
9 drug.

10 (a) The Department shall issue an order requiring the  
11 appropriate person, including the distributors or retailers of  
12 a drug, to immediately cease distribution of the drug within  
13 this State, if the Department finds that there is a reasonable  
14 probability that:

15 (1) a wholesale distributor has (i) violated a  
16 provision in this Act or (ii) falsified a pedigree or sold,  
17 distributed, transferred, manufactured, repackaged,  
18 handled, or held a counterfeit prescription drug intended  
19 for human use;

20 (2) the prescription drug at issue, as a result of a  
21 violation in paragraph (1) of this subsection (a), could  
22 cause serious, adverse health consequences or death; and

23 (3) other procedures would result in unreasonable  
24 delay.

25 (b) An order issued under this Section shall provide the

1 person subject to the order with an opportunity for an informal  
2 hearing, to be held not later than 10 days after the date of  
3 the issuance of the order, on the actions required by the  
4 order. If, after providing an opportunity for a hearing, the  
5 Department determines that inadequate grounds exist to support  
6 the actions required by the order, the Department shall vacate  
7 the order.

8 Section 45. Penalties.

9 (a) Any person who engages in the wholesale distribution of  
10 prescription drugs in violation of this Act may be fined not  
11 more than \$10,000.

12 (b) Any person who engages in the wholesale distribution of  
13 prescription drugs in violation of this Act and does so in a  
14 grossly negligent manner may be imprisoned for not more than 15  
15 years, fined not more than \$50,000, or both.

16 (c) Any person who knowingly engages in the wholesale  
17 distribution of prescription drugs in violation of this Act may  
18 be imprisoned for any term of years, fined not more than  
19 \$500,000, or both.

20 Section 90. The Regulatory Sunset Act is amended by adding  
21 Section 4.28 as follows:

22 (5 ILCS 80/4.28 new)

23 Sec. 4.28. Act repealed on January 1, 2018. The following

1 Act is repealed on January 1, 2018:

2 The Wholesale Licensure and Prescription Medication  
3 Integrity Act.

4 Section 95. The Pharmacy Practice Act of 1987 is amended by  
5 changing Section 10 as follows:

6 (225 ILCS 85/10) (from Ch. 111, par. 4130)

7 (Section scheduled to be repealed on January 1, 2008)

8 Sec. 10. State Board of Pharmacy. There is created in the  
9 Department the State Board of Pharmacy. It shall consist of 9  
10 members, 7 of whom shall be licensed pharmacists. Each of those  
11 7 members must be a licensed pharmacist in good standing in  
12 this State, a graduate of an accredited college of pharmacy or  
13 hold a Bachelor of Science degree in Pharmacy and have at least  
14 5 years' practical experience in the practice of pharmacy  
15 subsequent to the date of his licensure as a licensed  
16 pharmacist in the State of Illinois. There shall be 2 public  
17 members, who shall be voting members, who shall not be licensed  
18 pharmacists in this State or any other state.

19 Each member shall be appointed by the Governor.

20 The terms of all members serving as of March 31, 1999 shall  
21 expire on that date. The Governor shall appoint 3 persons to  
22 serve one-year terms, 3 persons to serve 3-year terms, and 3  
23 persons to serve 5-year terms to begin April 1, 1999.  
24 Otherwise, members shall be appointed to 5 year terms. No



1 member shall be eligible to serve more than 12 consecutive  
2 years.

3 In making the appointment of members on the Board, the  
4 Governor shall give due consideration to recommendations by the  
5 members of the profession of pharmacy and by pharmaceutical  
6 organizations therein. The Governor shall notify the  
7 pharmaceutical organizations promptly of any vacancy of  
8 members on the Board and in appointing members shall give  
9 consideration to individuals engaged in all types and settings  
10 of pharmacy practice.

11 The Governor may remove any member of the Board for  
12 misconduct, incapacity or neglect of duty and he shall be the  
13 sole judge of the sufficiency of the cause for removal.

14 Every person appointed a member of the Board shall take and  
15 subscribe the constitutional oath of office and file it with  
16 the Secretary of State. Each member of the Board shall be  
17 reimbursed for such actual and legitimate expenses as he may  
18 incur in going to and from the place of meeting and remaining  
19 thereat during sessions of the Board. In addition, each member  
20 of the Board shall receive a per diem payment in an amount  
21 determined from time to time by the Director for attendance at  
22 meetings of the Board and conducting other official business of  
23 the Board.

24 The Board shall hold quarterly meetings and an annual  
25 meeting in January of each year and such other meetings at such  
26 times and places and upon such notice as the Board may

1 determine and as its business may require. Five members of the  
2 Board shall constitute a quorum for the transaction of  
3 business. The Director shall appoint a pharmacy coordinator,  
4 who shall be someone other than a member of the Board. The  
5 pharmacy coordinator shall be a registered pharmacist in good  
6 standing in this State, shall be a graduate of an accredited  
7 college of pharmacy, or hold at a minimum a Bachelor of Science  
8 degree in Pharmacy and shall have at least 5 years' experience  
9 in the practice of pharmacy immediately prior to his  
10 appointment. The pharmacy coordinator shall be the executive  
11 administrator and the chief enforcement officer of the Pharmacy  
12 Practice Act of 1987.

13 The Board shall exercise the rights, powers and duties  
14 which have been vested in the Board under this Act, and any  
15 other duties conferred upon the Board by law, including those  
16 set forth in Section 30 of the Wholesale Licensure and  
17 Prescription Medication Integrity Act.

18 The Director shall, in conformity with the Personnel Code,  
19 employ not less than 7 pharmacy investigators and 2 pharmacy  
20 supervisors. Each pharmacy investigator and each supervisor  
21 shall be a registered pharmacist in good standing in this  
22 State, and shall be a graduate of an accredited college of  
23 pharmacy and have at least 5 years of experience in the  
24 practice of pharmacy. The Department shall also employ at least  
25 one attorney who is a pharmacist to prosecute violations of  
26 this Act and its rules. The Department may, in conformity with

1 the Personnel Code, employ such clerical and other employees as  
2 are necessary to carry out the duties of the Board.

3 The duly authorized pharmacy investigators of the  
4 Department shall have the right to enter and inspect during  
5 business hours any pharmacy or any other place in the State of  
6 Illinois holding itself out to be a pharmacy where medicines or  
7 drugs or drug products or proprietary medicines are sold,  
8 offered for sale, exposed for sale, or kept for sale. The  
9 pharmacy investigators shall be the only Department  
10 investigators authorized to inspect, investigate, and monitor  
11 probation compliance of pharmacists, pharmacies, and pharmacy  
12 technicians.

13 (Source: P.A. 91-827, eff. 6-13-00; 92-651, eff. 7-11-02;  
14 92-880, eff. 1-1-04.)

15 Section 99. Effective date. This Act takes effect upon  
16 becoming law."