



## 95TH GENERAL ASSEMBLY

### State of Illinois

2007 and 2008

SB0509

Introduced 2/8/2007, by Sen. Terry Link

#### SYNOPSIS AS INTRODUCED:

New Act

5 ILCS 80/4.28 new

225 ILCS 85/10

from Ch. 111, par. 4130

Creates the Wholesale Licensure and Prescription Medication Integrity Act. Provides that every resident wholesale distributor who engages in the wholesale distribution of prescription drugs must be licensed by the Department, and every non-resident wholesale distributor must be licensed in this State if it ships prescription drugs into this State. Sets forth provisions concerning licensure, bond requirements, restrictions on transactions, a pedigree, prohibited acts, enforcement, and penalties. Amends the Regulatory Sunset Act to set a repeal date for the new Act of January 1, 2018. Amends the Pharmacy Practice Act of 1987 to make a related change. Effective immediately.

LRB095 10560 RAS 30780 b

CORRECTIONAL  
BUDGET AND  
IMPACT NOTE ACT  
MAY APPLY

FISCAL NOTE ACT  
MAY APPLY

1 AN ACT concerning regulation.

2 **Be it enacted by the People of the State of Illinois,**  
3 **represented in the General Assembly:**

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

6 Section 5. Definitions. In this Act:

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

10 "Authorized distributor of record" means a wholesale  
11 distributor with whom a manufacturer has established an ongoing  
12 relationship to distribute the manufacturer's prescription  
13 drug. An ongoing relationship is deemed to exist between a  
14 wholesale distributor and a manufacturer when the wholesale  
15 distributor, including any affiliated group of the wholesale  
16 distributor, as defined in Section 1504 of the Internal Revenue  
17 Code, complies with either of the following:

18 (1) the wholesale distributor has a written agreement  
19 currently in effect with the manufacturer evidencing the  
20 ongoing relationship; or

21 (2) the wholesale distributor is listed on the  
22 manufacturer's current list of authorized distributors of  
23 record, which is updated by the manufacturer on no less

1 than a monthly basis.

2 "Department" means the Department of Financial and  
3 Professional Regulation.

4 "Drop shipment" means the sale of a prescription drug to a  
5 wholesale distributor by the manufacturer of the prescription  
6 drug, or that manufacturer's co-licensed product partner, that  
7 manufacturer's third party logistics provider, or that  
8 manufacturer's exclusive distributor, whereby the wholesale  
9 distributor or chain pharmacy warehouse takes title but not  
10 physical possession of such prescription drug and the wholesale  
11 distributor invoices the pharmacy, chain pharmacy warehouse,  
12 or other person authorized by law to dispense or administer  
13 such drug to a patient and the pharmacy, chain pharmacy  
14 warehouse or other authorized person receives delivery of the  
15 prescription drug directly from the manufacturer, that  
16 manufacturer's third party logistics provider, or that  
17 manufacturer's exclusive distributor.

18 "Chain pharmacy warehouse" means a physical location for  
19 prescription drugs that acts as a central warehouse and  
20 performs intracompany sales or transfers of the drugs to a  
21 group of chain pharmacies that have the same common ownership  
22 and control.

23 "Co-licensed product" means a prescription drug in which 2  
24 or more parties have the right to engage in the manufacturing  
25 or marketing of such drug.

26 "Facility" means a facility of a wholesale distributor

1 where prescription drugs are stored, handled, repackaged, or  
2 offered for sale.

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

4 "Manufacturer" means a person licensed or approved by the  
5 federal Food and Drug Administration to engage in the  
6 manufacture of drugs or devices.

7 "Manufacturer's exclusive distributor" means anyone who  
8 contracts with a manufacturer to provide or coordinate  
9 warehousing, distribution, or other services on behalf of a  
10 manufacturer and who takes title to that manufacturer's  
11 prescription drug, but who does not have general responsibility  
12 to direct the sale or disposition of the manufacturer's  
13 prescription drug. A manufacturer's exclusive distributor must  
14 be licensed as a wholesale distributor under this Act and, in  
15 order to be considered part of the normal distribution channel,  
16 must also be an authorized distributor of record.

17 "Normal distribution channel" means a chain of custody for  
18 a prescription drug that goes (i) from a manufacturer of the  
19 prescription drug, (ii) from that manufacturer to that  
20 manufacturer's co-licensed partner, (iii) from that  
21 manufacturer to that manufacturer's third-party logistics  
22 provider, or (iv) from that manufacturer to that manufacturer's  
23 exclusive distributor to:

24 (1) a pharmacy to a patient or other designated persons  
25 authorized by law to dispense or administer such drug to a  
26 patient;

1           (2) a wholesale distributor to a pharmacy to a patient  
2           or other designated persons authorized by law to dispense  
3           or administer such drug to a patient;

4           (3) a wholesale distributor to a chain pharmacy  
5           warehouse to that chain pharmacy warehouse's intracompany  
6           pharmacy to a patient or other designated persons  
7           authorized by law to dispense or administer such drug to a  
8           patient; or

9           (4) a chain pharmacy warehouse to the chain pharmacy  
10          warehouse's intracompany pharmacy to a patient or other  
11          designated persons authorized by law to dispense or  
12          administer such drug to a patient.

13          "Pedigree" means a document or electronic file containing  
14          information that records each distribution of any given  
15          prescription drug.

16          "Prescription drug" means any drug, including any  
17          biological product (except for blood and blood components  
18          intended for transfusion or biological products that are also  
19          medical devices), required by federal law or regulation to be  
20          dispensed only by a prescription, including finished dosage  
21          forms and bulk drug substances subject to Section 503(b) of the  
22          federal Food, Drug and Cosmetic Act.

23          "Repackage" means repackaging or otherwise changing the  
24          container, wrapper, or labeling to further the distribution of  
25          a prescription drug, excluding that completed by the pharmacist  
26          responsible for dispensing product to a patient.

1 "Third party logistics provider" means anyone who  
2 contracts with a prescription drug manufacturer to provide or  
3 coordinate warehousing, distribution, or other services on  
4 behalf of a manufacturer, but does not take title to the  
5 prescription drug or have general responsibility to direct the  
6 prescription drug's sale or disposition. A third party  
7 logistics provider must be licensed as a wholesale distributor  
8 under this Act and, in order to be considered part of the  
9 normal distribution channel, must also be an authorized  
10 distributor of record.

11 "Wholesale distributor" means anyone engaged in the  
12 wholesale distribution of prescription drugs, including  
13 without limitation manufacturers; repackagers; own-label  
14 distributors; private-label distributors; jobbers; brokers;  
15 warehouses, including manufacturers' and distributors'  
16 warehouses; manufacturer's exclusive distributors; and  
17 authorized distributors of record; drug wholesalers or  
18 distributors; independent wholesale drug traders; specialty  
19 wholesale distributors; third party logistics providers; and  
20 retail pharmacies that conduct wholesale distribution; and  
21 chain pharmacy warehouses that conduct wholesale distribution.  
22 In order to be considered part of the normal distribution  
23 channel, a wholesale distributor must also be an authorized  
24 distributor of record.

25 "Wholesale distribution" means distribution of  
26 prescription drugs to persons other than a consumer or patient,

1 but does not include any of the following:

2 (1) Intracompany sales of prescription drugs, meaning  
3 (i) any transaction or transfer between any division,  
4 subsidiary, parent or affiliated or related company under  
5 common ownership and control of a corporate entity, or (ii)  
6 any transaction or transfer between co-licensees of a  
7 co-licensed product.

8 (2) The sale, purchase, distribution, trade, or  
9 transfer of a prescription drug or offer to sell, purchase,  
10 distribute, trade, or transfer a prescription drug for  
11 emergency medical reasons.

12 (3) The distribution of prescription drug samples by  
13 manufacturers' representatives.

14 (4) Drug returns, when conducted by a hospital, health  
15 care entity, or charitable institution in accordance with  
16 federal regulation.

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

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

23 (7) The sale, transfer, merger or consolidation of all  
24 or part of the business of a pharmacy or pharmacies from or  
25 with another pharmacy or pharmacies, whether accomplished  
26 as a purchase and sale of stock or business assets.

1           (8) The sale, purchase, distribution, trade, or  
2 transfer of a prescription drug from one authorized  
3 distributor of record to one additional authorized  
4 distributor of record when the manufacturer has stated in  
5 writing to the receiving authorized distributor of record  
6 that the manufacturer is unable to supply the prescription  
7 drug and the supplying authorized distributor of record  
8 states in writing that the prescription drug being supplied  
9 had until that time been exclusively in the normal  
10 distribution channel.

11           (9) The delivery of or the offer to deliver a  
12 prescription drug by a common carrier solely in the common  
13 carrier's usual course of business of transporting  
14 prescription drugs when the common carrier does not store,  
15 warehouse, or take legal ownership of the prescription  
16 drug.

17           (10) The sale or transfer from a retail pharmacy or  
18 chain pharmacy warehouse of expired, damaged, returned, or  
19 recalled prescription drugs to the original manufacturer  
20 or to a third party returns processor.

21           Section 10. Licensure required.

22           (a) Every resident wholesale distributor who engages in the  
23 wholesale distribution of prescription drugs must be licensed  
24 by the Department, and every non-resident wholesale  
25 distributor must be licensed in this State if it ships



1 prescription drugs into this State, in accordance with this Act  
2 before engaging in wholesale distributions of wholesale  
3 prescription drugs. The Department shall exempt manufacturers  
4 distributing their own FDA-approved drugs and devices from the  
5 requirements of this Section, to the extent not required by  
6 federal law or regulation, unless particular requirements are  
7 deemed necessary and appropriate following rulemaking.

8 (b) The Department shall require all of the following  
9 information from each applicant for licensure under this Act:

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

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

13 (3) Addresses, telephone numbers, and the names of  
14 contact persons for all facilities used by the licensee for  
15 the storage, handling, and distribution of prescription  
16 drugs.

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

19 (5) The name of the owner or operator of the wholesale  
20 distributor, including:

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

22 (B) if a partnership, the name of each partner and  
23 the name of the partnership;

24 (C) if a corporation, the name and title of each  
25 corporate officer and director, the corporate names,  
26 and the name of the state of incorporation; and

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

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

6 (7) The name of designated representative for the  
7 wholesale distributor, together with the personal  
8 information statement and fingerprints required of the  
9 person, as required under subsection (c) of this Section.

10 (8) Any additional information required by the  
11 Department.

12 (c) Each wholesale distributor must designate an  
13 individual representative who shall serve as the contact person  
14 for the Department. This representative must provide the  
15 Department with all of the following information:

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

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

19 (3) The person's occupations, positions of employment,  
20 and offices held during the past 7 years and the principal  
21 business and address of any business, corporation, or other  
22 organization in which each such office of the person was  
23 held or in which each such occupation or position of  
24 employment was carried on.

25 (4) Information concerning whether the person has  
26 been, during the past 7 years, the subject of any

1 proceeding for the revocation of any license or any  
2 criminal violation and, if so, the nature of the proceeding  
3 and the disposition of the proceeding.

4 (5) Information concerning whether, during the past 7  
5 years, the person has been enjoined, either temporarily or  
6 permanently, by a court of competent jurisdiction from  
7 violating any federal or State law regulating the  
8 possession, control, or distribution of prescription drugs  
9 or criminal violations, together with details concerning  
10 any such event.

11 (6) A description of any involvement by the person with  
12 any business, including any investments, other than the  
13 ownership of stock in a publicly traded company or mutual  
14 fund, during the past 7 years, which manufactured,  
15 administered, prescribed, distributed, or stored  
16 pharmaceutical products and any lawsuits in which such  
17 businesses were named as a party.

18 (7) A description of any felony criminal offense or  
19 offense involving moral turpitude or related to the  
20 qualifications, functions, or duties of that person in  
21 connection with the operation of the wholesale  
22 distributor, of which the person, as an adult, was found  
23 guilty, regardless of whether adjudication of guilt was  
24 withheld or whether the person pled guilty or nolo  
25 contendere. If the person indicates that a criminal  
26 conviction is under appeal and submits a copy of the notice

1 of appeal of that criminal offense, the applicant must,  
2 within 15 days after the disposition of the appeal, submit  
3 to the Department a copy of the final written order of  
4 disposition.

5 (8) A photograph of the person taken within the  
6 previous year.

7 The designated representative must also submit his or her  
8 fingerprints to the Department to be checked against the  
9 Department of State Police and Federal Bureau of Investigation  
10 criminal history record databases now and hereafter filed, in a  
11 manner prescribed by the Department and must receive and  
12 complete continuing training in applicable federal and State  
13 laws governing the wholesale distribution of prescription  
14 drugs.

15 (d) Any information required to be submitted to the  
16 Department under this Section shall be provided under oath.

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

19 (1) conducts a physical inspection of the wholesale  
20 distribution facility at the address provided by the  
21 applicant as required under item (1) of subsection (b) of  
22 this Section; and

23 (2) determines that the designated representative  
24 meets each of the following qualifications:

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

26 (B) He or she has been employed full-time for at

1 least 3 years in a pharmacy or with a wholesale  
2 distributor in a capacity related to the dispensing and  
3 distribution of, and recordkeeping relating to,  
4 prescription drugs.

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

7 (D) He or she is actively involved in and aware of  
8 the actual daily operation of the wholesale  
9 distributor.

10 (E) He or she is physically present at the facility  
11 of the applicant during regular business hours, except  
12 when the absence of the designated representative is  
13 authorized, including without limitation sick leave  
14 and vacation leave.

15 (F) He or she is serving in the capacity of a  
16 designated representative for only one applicant at a  
17 time, except where more than one licensed wholesale  
18 distributor is co-located in the same facility and such  
19 wholesale distributors are members of an affiliated  
20 group, as defined in Section 1504 of the Internal  
21 Revenue Code.

22 (G) He or she does not have any convictions under  
23 any federal, State, or local laws relating to wholesale  
24 or retail prescription drug distribution or  
25 distribution of controlled substances.

26 (H) He or she does not have any felony convictions

1 under federal, State, or local laws.

2 (h) If a wholesale distributor distributes prescription  
3 drugs from more than one facility, the wholesale distributor  
4 shall obtain a license for each facility.

5 (i) The information provided under this Section may not be  
6 disclosed to any person or entity other than the Department or  
7 another government entity in need of such information for  
8 licensing or monitoring purposes.

9 Section 15. License renewal. In accordance with each  
10 license renewal, the Department shall send to each licensee a  
11 form setting forth the information that the licensee provided  
12 to the Department in the licensee's original application for  
13 licensure under Section 10 of this Act. Within 30 days after  
14 receiving the form, the wholesale distributor must identify and  
15 state under oath to the Department any and all changes or  
16 corrections to the information originally submitted to the  
17 Department. The Department may suspend or revoke the license of  
18 a licensee if the Department determines that the licensee no  
19 longer qualifies for the license originally issued under this  
20 Act.

21 Section 20. Bond required. The Department shall require  
22 every wholesale distributor applying for a licensure under this  
23 Act to submit a bond of at least \$100,000 or another equivalent  
24 means of security acceptable to the Department, such as an

1     irrevocable letter of credit or a deposit in a trust account or  
2     financial institution, payable to a fund established by the  
3     Department. Chain pharmacy warehouses that are engaged only in  
4     intracompany transfers are exempt from the bond requirement of  
5     this Section. The purpose of the bond is to secure payment of  
6     any fines or penalties imposed by the Department and any fees  
7     and costs incurred by the Department regarding that license,  
8     which are authorized under State law and which the licensee  
9     fails to pay 30 days after the fines, penalties, or costs  
10    become final. The Department may make a claim against the bond  
11    or security until one year after the licensee's license ceases  
12    to be valid. A single bond may suffice to cover all facilities  
13    operated by an applicant in this State.

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

17           Section 25. Restrictions on transactions.

18           (a) A licensee shall receive prescription drug returns or  
19    exchanges from a pharmacy or chain pharmacy warehouse pursuant  
20    to the terms and conditions of the agreement between the  
21    wholesale distributor and the pharmacy or chain pharmacy  
22    warehouse, including the returns of expired, damaged, and  
23    recalled pharmaceutical products to either the original  
24    manufacturer or a third party returns processor, and such  
25    returns or exchanges shall not be subject to the pedigree

1 requirements of Section 30 of this Act, so long as they are  
2 exempt from the pedigree requirement of the FDA's currently  
3 applicable Prescription Drug Marketing Act guidance. Both  
4 licensees under this Act and pharmacies shall be accountable  
5 for administering their returns process and ensuring that the  
6 aspects of this operation are secure and do not permit the  
7 entry of adulterated and counterfeit product.

8 (b) A manufacturer or wholesale distributor licensed under  
9 this Act may furnish prescription drugs only to a person  
10 licensed by the appropriate state licensing authorities.  
11 Before furnishing prescription drugs to a person not known to  
12 the manufacturer or wholesale distributor, the manufacturer or  
13 wholesale distributor must affirmatively verify that the  
14 person is legally authorized to receive the prescription drugs  
15 by contacting the appropriate state licensing authorities.

16 (c) Prescription drugs furnished by a manufacturer or  
17 wholesale distributor licensed under this Act may be delivered  
18 only to the premises listed on the license, provided that the  
19 manufacturer or wholesale distributor may furnish prescription  
20 drugs to an authorized person or agent of that person at the  
21 premises of the manufacturer or wholesale distributor if:

22 (1) the identity and authorization of the recipient is  
23 properly established; and

24 (2) this method of receipt is employed only to meet the  
25 immediate needs of a particular patient of the authorized  
26 person.



1 (d) Prescription drugs may be furnished to a hospital  
2 pharmacy receiving area, provided that a pharmacist or  
3 authorized receiving personnel signs, at the time of delivery,  
4 a receipt showing the type and quantity of the prescription  
5 drug received. Any discrepancy between the receipt and the type  
6 and quantity of the prescription drug actually received shall  
7 be reported to the delivering manufacturer or wholesale  
8 distributor by the next business day after the delivery to the  
9 pharmacy receiving area.

10 (e) A manufacturer or wholesale distributor licensed under  
11 this Act may not accept payment for, or allow the use of, a  
12 person or entity's credit to establish an account for the  
13 purchase of prescription drugs from any person other than the  
14 owner of record, the chief executive officer, or the chief  
15 financial officer listed on the license of a person or entity  
16 legally authorized to receive the prescription drugs. Any  
17 account established for the purchase of prescription drugs must  
18 bear the name of the licensee.

19 Section 30. Pedigree.

20 (a) Each person who is engaged in the wholesale  
21 distribution of prescription drugs, including repackagers, but  
22 excluding the original manufacturer of the finished form of the  
23 prescription drug, who leaves or has ever left the normal  
24 distribution channel shall, before each wholesale distribution  
25 of the drug, provide a pedigree to the person who receives the

1 drug.

2 A retail pharmacy or chain pharmacy warehouse must comply  
3 with the requirements of this Section only if the pharmacy or  
4 chain pharmacy warehouse engages in the wholesale distribution  
5 of prescription drugs.

6 The State Board of Pharmacy shall determine by July 1,  
7 2009, a targeted implementation date for electronic track and  
8 trace pedigree technology. This determination shall be based on  
9 consultation with manufacturers, distributors, and pharmacies  
10 responsible for the sale and distribution of prescription drug  
11 products in this State. After consultation with interested  
12 stakeholders and prior to the implementation of the electronic  
13 pedigree, the State Board of Pharmacy shall deem that the  
14 technology is universally available across the entire  
15 prescription pharmaceutical supply chain. The implementation  
16 date for the mandated electronic track and trace pedigree  
17 technology shall be no sooner than July 1, 2010 and may be  
18 extended by the State Board of Pharmacy in one year increments  
19 if it appears that the technology is not universally available  
20 across the entire prescription pharmaceutical supply chain.

21 (b) Each person who is engaged in the wholesale  
22 distribution of a prescription drug, including repackagers,  
23 but excluding the original manufacturer of the finished form of  
24 the prescription drug, who is provided a pedigree for a  
25 prescription drug and attempts to further distribute that  
26 prescription drug, must affirmatively verify before any

1 distribution of a prescription drug occurs that each  
2 transaction listed on the pedigree has occurred.

3 (c) The pedigree must include all necessary identifying  
4 information concerning each sale in the chain of distribution  
5 of the product from the manufacturer or the manufacturer's  
6 third party logistics provider, co-licensed product partner,  
7 or exclusive distributor through acquisition and sale by any  
8 wholesale distributor or repackager, until final sale to a  
9 pharmacy or other person dispensing or administering the drug.  
10 This necessary chain of distribution information shall  
11 include, without limitation each of all of the following:

12 (1) The name, address, telephone number and, if  
13 available, the e-mail address, of each owner of the  
14 prescription drug and each wholesale distributor of the  
15 prescription drug.

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

18 (3) Transaction dates.

19 (4) Certification that each recipient has  
20 authenticated the pedigree.

21 (d) The pedigree must also include all of the following  
22 information concerning the prescription drug:

23 (1) The name of the prescription drug.

24 (2) The dosage form and strength of the prescription  
25 drug.

26 (3) The size of the container.

1 (4) The number of containers.

2 (5) The lot number and National Drug Code number of the  
3 prescription drug.

4 (6) The name of the manufacturer of the finished dosage  
5 form.

6 (e) Each pedigree or electronic file shall be maintained by  
7 the purchaser and the wholesale distributor for 3 years from  
8 the date of sale or transfer and made available for inspection  
9 or use within 5 business days upon a request of the Department.

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

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

16 (1) Failure to obtain a license in accordance with this  
17 Act or operating without a valid license when a license is  
18 required by this Act.

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

22 (3) If a licensure is required pursuant to subsection  
23 (b) of Section 25 of this Act, the sale, distribution, or  
24 transfer of a prescription drug to a person that is not  
25 authorized under the law of the jurisdiction in which the

1 person receives the prescription drug to receive the  
2 prescription drug.

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

6 (5) Accepting payment or credit for the sale of  
7 prescription drugs in violation of subsection (e) of  
8 Section of this Act.

9 (6) Failure to maintain or provide pedigrees as  
10 required by this Act;

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

13 (8) Providing the Department with false or fraudulent  
14 records or making false or fraudulent statements regarding  
15 any matter within the provisions of this Act.

16 (9) Obtaining or attempting to obtain a prescription  
17 drug by fraud, deceit, or misrepresentation or engaging in  
18 misrepresentation or fraud in the distribution of a  
19 prescription drug.

20 (10) Except for the wholesale distribution by  
21 manufacturers of a prescription drug that has been  
22 delivered into commerce pursuant to an application  
23 approved under federal law by the FDA, the manufacture,  
24 repackaging, sale, transfer, delivery, holding, or offering  
25 for sale of any prescription drug that is adulterated,  
26 misbranded, counterfeit, suspected of being counterfeit,

1 or that has otherwise been rendered unfit for distribution.

2 (11) Except for the wholesale distribution by  
3 manufacturers of a prescription drug that has been  
4 delivered into commerce pursuant to an application  
5 approved under federal law by the FDA, the adulteration,  
6 misbranding, or counterfeiting of any prescription drug.

7 (12) The receipt of any prescription drug that is  
8 adulterated, misbranded, stolen, obtained by fraud or  
9 deceit, counterfeit, or suspected of being counterfeit and  
10 the delivery or proffered delivery of such drug for pay or  
11 otherwise.

12 (13) The alteration, mutilation, destruction,  
13 obliteration, or removal of the whole or any part of the  
14 labeling of a prescription drug or the commission of any  
15 other act with respect to a prescription drug that results  
16 in the prescription drug being misbranded.

17 The acts prohibited in this Section do not include the  
18 obtaining or the attempt to obtain a prescription drug for the  
19 sole purpose of testing the prescription drug for authenticity  
20 performed by a prescription drug manufacturer or the agent of a  
21 prescription drug manufacturer.

22 Section 40. Enforcement; order to cease distribution of a  
23 drug.

24 (a) The Department shall issue an order requiring the  
25 appropriate person, including the distributors or retailers of

1 a drug, to immediately cease distribution of the drug within  
2 this State, if the Department finds that there is a reasonable  
3 probability that:

4 (1) a wholesale distributor, other than a  
5 manufacturer, has (i) violated a provision in this Act or  
6 (ii) falsified a pedigree or sold, distributed,  
7 transferred, manufactured, repackaged, handled, or held a  
8 counterfeit prescription drug intended for human use;

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

12 (3) other procedures would result in unreasonable  
13 delay.

14 (b) An order issued under this Section shall provide the  
15 person subject to the order with an opportunity for an informal  
16 hearing, to be held not later than 10 days after the date of  
17 the issuance of the order, on the actions required by the  
18 order. If, after providing an opportunity for a hearing, the  
19 Department determines that inadequate grounds exist to support  
20 the actions required by the order, the Department shall vacate  
21 the order.

22 Section 45. Penalties.

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

1 (b) Any person who knowingly engages in wholesale  
2 distribution of prescription drugs in violation of this Act may  
3 be imprisoned for any term of years, fined not more than  
4 \$500,000, or both.

5 Section 90. The Regulatory Sunset Act is amended by adding  
6 Section 4.28 as follows:

7 (5 ILCS 80/4.28 new)

8 Sec. 4.28. Act repealed on January 1, 2018. The following  
9 Act is repealed on January 1, 2018:

10 The Wholesale Licensure and Prescription Medication  
11 Integrity Act.

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

14 (225 ILCS 85/10) (from Ch. 111, par. 4130)

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

16 Sec. 10. State Board of Pharmacy. There is created in the  
17 Department the State Board of Pharmacy. It shall consist of 9  
18 members, 7 of whom shall be licensed pharmacists. Each of those  
19 7 members must be a licensed pharmacist in good standing in  
20 this State, a graduate of an accredited college of pharmacy or  
21 hold a Bachelor of Science degree in Pharmacy and have at least  
22 5 years' practical experience in the practice of pharmacy



1 subsequent to the date of his licensure as a licensed  
2 pharmacist in the State of Illinois. There shall be 2 public  
3 members, who shall be voting members, who shall not be licensed  
4 pharmacists in this State or any other state.

5 Each member shall be appointed by the Governor.

6 The terms of all members serving as of March 31, 1999 shall  
7 expire on that date. The Governor shall appoint 3 persons to  
8 serve one-year terms, 3 persons to serve 3-year terms, and 3  
9 persons to serve 5-year terms to begin April 1, 1999.  
10 Otherwise, members shall be appointed to 5 year terms. No  
11 member shall be eligible to serve more than 12 consecutive  
12 years.

13 In making the appointment of members on the Board, the  
14 Governor shall give due consideration to recommendations by the  
15 members of the profession of pharmacy and by pharmaceutical  
16 organizations therein. The Governor shall notify the  
17 pharmaceutical organizations promptly of any vacancy of  
18 members on the Board and in appointing members shall give  
19 consideration to individuals engaged in all types and settings  
20 of pharmacy practice.

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

24 Every person appointed a member of the Board shall take and  
25 subscribe the constitutional oath of office and file it with  
26 the Secretary of State. Each member of the Board shall be

1 reimbursed for such actual and legitimate expenses as he may  
2 incur in going to and from the place of meeting and remaining  
3 thereat during sessions of the Board. In addition, each member  
4 of the Board shall receive a per diem payment in an amount  
5 determined from time to time by the Director for attendance at  
6 meetings of the Board and conducting other official business of  
7 the Board.

8 The Board shall hold quarterly meetings and an annual  
9 meeting in January of each year and such other meetings at such  
10 times and places and upon such notice as the Board may  
11 determine and as its business may require. Five members of the  
12 Board shall constitute a quorum for the transaction of  
13 business. The Director shall appoint a pharmacy coordinator,  
14 who shall be someone other than a member of the Board. The  
15 pharmacy coordinator shall be a registered pharmacist in good  
16 standing in this State, shall be a graduate of an accredited  
17 college of pharmacy, or hold at a minimum a Bachelor of Science  
18 degree in Pharmacy and shall have at least 5 years' experience  
19 in the practice of pharmacy immediately prior to his  
20 appointment. The pharmacy coordinator shall be the executive  
21 administrator and the chief enforcement officer of the Pharmacy  
22 Practice Act of 1987.

23 The Board shall exercise the rights, powers and duties  
24 which have been vested in the Board under this Act, and any  
25 other duties conferred upon the Board by law, including those  
26 set forth in Section 30 of the Wholesale Licensure and

1 Prescription Medication Integrity Act.

2 The Director shall, in conformity with the Personnel Code,  
3 employ not less than 7 pharmacy investigators and 2 pharmacy  
4 supervisors. Each pharmacy investigator and each supervisor  
5 shall be a registered pharmacist in good standing in this  
6 State, and shall be a graduate of an accredited college of  
7 pharmacy and have at least 5 years of experience in the  
8 practice of pharmacy. The Department shall also employ at least  
9 one attorney who is a pharmacist to prosecute violations of  
10 this Act and its rules. The Department may, in conformity with  
11 the Personnel Code, employ such clerical and other employees as  
12 are necessary to carry out the duties of the Board.

13 The duly authorized pharmacy investigators of the  
14 Department shall have the right to enter and inspect during  
15 business hours any pharmacy or any other place in the State of  
16 Illinois holding itself out to be a pharmacy where medicines or  
17 drugs or drug products or proprietary medicines are sold,  
18 offered for sale, exposed for sale, or kept for sale. The  
19 pharmacy investigators shall be the only Department  
20 investigators authorized to inspect, investigate, and monitor  
21 probation compliance of pharmacists, pharmacies, and pharmacy  
22 technicians.

23 (Source: P.A. 91-827, eff. 6-13-00; 92-651, eff. 7-11-02;  
24 92-880, eff. 1-1-04.)

25 Section 99. Effective date. This Act takes effect upon  
26 becoming law.