



## 102ND GENERAL ASSEMBLY

### State of Illinois

2021 and 2022

**HB4664**

Introduced 1/21/2022, by Rep. Theresa Mah

#### SYNOPSIS AS INTRODUCED:

See Index

Amends the Regulatory Sunset Act. Provides that the Wholesale Drug Distribution Licensing Act is repealed on January 1, 2028 (instead of January 1, 2023). Amends the Wholesale Drug Distribution Licensing Act. Defines "address of record", "email address of record", and "suspicious order". Changes the definition of "wholesale drug distributor". Provides that applicants and licensees must provide a valid address and email address to the Department of Financial and Professional Regulation and must inform the Department of any change of these within 14 days. Provides that each licensee required to report suspicious orders shall submit such report to the Department. Provides that an individual taxpayer identification number can be included on the application for an original license, the application can be made in writing or electronically, and the application shall be accompanied by the required, nonrefundable fee. Provides that any licensee who engages in the licensed practice while the license is expired shall be considered to be practicing without a license which is grounds for discipline. Removes provisions that provide that: the Department shall present to the State Board of Pharmacy of the Department for review all appropriation requests from the Illinois State Pharmacy Disciplinary Fund; the Department shall maintain a roster of the names and addresses of all registrants and all persons whose licenses have been suspended or revoked; and rules that set detailed standards for meeting each license prerequisite requirements shall be adopted no later than September 14, 1992. Provides that the written notice of disciplinary hearing may be served by email or physical mail to the respondent's email of record or address of record. Provides that the Department may subpoena and compel the relevant documents in connection with any hearing. Provides that if the Secretary of Financial and Professional Regulation disagrees with the recommendation of the Board or hearing officer, the Secretary may issue an order in contravention of the recommendation. Provides that the sanctions imposed upon the accused by the Department shall remain in full force and effect in order to protect the public pending final resolution of the proceedings. Repeals a provision concerning references to the Department or Director of Professional Regulation. Makes corresponding and other changes. Section 5 and Section 99 take effect upon becoming law.

LRB102 24218 AMQ 33447 b

A BILL FOR

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 5. The Regulatory Sunset Act is amended by  
5 changing Sections 4.33 and 4.38 as follows:

6 (5 ILCS 80/4.33)

7 Sec. 4.33. Acts repealed on January 1, 2023. The following  
8 Acts are repealed on January 1, 2023:

9 The Dietitian Nutritionist Practice Act.

10 The Elevator Safety and Regulation Act.

11 The Fire Equipment Distributor and Employee Regulation Act  
12 of 2011.

13 The Funeral Directors and Embalmers Licensing Code.

14 The Naprapathic Practice Act.

15 The Pharmacy Practice Act.

16 The Professional Counselor and Clinical Professional  
17 Counselor Licensing and Practice Act.

18 ~~The Wholesale Drug Distribution Licensing Act.~~

19 (Source: P.A. 101-621, eff. 12-20-19.)

20 (5 ILCS 80/4.38)

21 Sec. 4.38. Acts repealed on January 1, 2028. The following  
22 Acts are repealed on January 1, 2028:

1 The Acupuncture Practice Act.

2 The Clinical Social Work and Social Work Practice Act.

3 The Home Medical Equipment and Services Provider License  
4 Act.

5 The Illinois Petroleum Education and Marketing Act.

6 The Illinois Speech-Language Pathology and Audiology  
7 Practice Act.

8 The Interpreter for the Deaf Licensure Act of 2007.

9 The Nurse Practice Act.

10 The Nursing Home Administrators Licensing and Disciplinary  
11 Act.

12 The Physician Assistant Practice Act of 1987.

13 The Podiatric Medical Practice Act of 1987.

14 The Wholesale Drug Distribution Licensing Act.

15 (Source: P.A. 100-220, eff. 8-18-17; 100-375, eff. 8-25-17;  
16 100-398, eff. 8-25-17; 100-414, eff. 8-25-17; 100-453, eff.  
17 8-25-17; 100-513, eff. 9-20-17; 100-525, eff. 9-22-17;  
18 100-530, eff. 9-22-17; 100-560, eff. 12-8-17.)

19 Section 10. The Wholesale Drug Distribution Licensing Act  
20 is amended by changing Sections 15, 27, 30, 35, 40, 50, 57, 70,  
21 75, 80, 85, 100, 105, 110, 115, 120, 125, 135, 140, 155, 165,  
22 and 200 and by adding Sections 15.5, 21, and 31 as follows:

23 (225 ILCS 120/15) (from Ch. 111, par. 8301-15)

24 (Section scheduled to be repealed on January 1, 2023)

1           Sec. 15. Definitions. As used in this Act:

2           "Address of record" means the designated address recorded  
3 by the Department in the applicant's application file or  
4 licensee's license file maintained by the Department's  
5 licensure maintenance unit.

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

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

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

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  
24 than a monthly basis.

25          "Blood" means whole blood collected from a single donor  
26 and processed either for transfusion or further manufacturing.

1 "Blood component" means that part of blood separated by  
2 physical or mechanical means.

3 "Board" means the State Board of Pharmacy of the  
4 Department of Professional Regulation.

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

12 "Co-licensed partner or product" means an instance where  
13 one or more parties have the right to engage in the  
14 manufacturing or marketing of a prescription drug, consistent  
15 with the FDA's implementation of the Prescription Drug  
16 Marketing Act.

17 "Department" means the Department of Financial and  
18 Professional Regulation.

19 "Drop shipment" means the sale of a prescription drug to a  
20 wholesale distributor by the manufacturer of the prescription  
21 drug or that manufacturer's co-licensed product partner, that  
22 manufacturer's third-party ~~third party~~ logistics provider, or  
23 that manufacturer's exclusive distributor or by an authorized  
24 distributor of record that purchased the product directly from  
25 the manufacturer or one of these entities whereby the  
26 wholesale distributor or chain pharmacy warehouse takes title

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

12 "Drug sample" means a unit of a prescription drug that is  
13 not intended to be sold and is intended to promote the sale of  
14 the drug.

15 "Email address of record" means the designated email  
16 address recorded by the Department in the applicant's  
17 application file or the licensee's license file, as maintained  
18 by the Department's licensure maintenance unit.

19 "Facility" means a facility of a wholesale distributor  
20 where prescription drugs are stored, handled, repackaged, or  
21 offered for sale, or a facility of a third-party logistics  
22 provider where prescription drugs are stored or handled.

23 "FDA" means the United States Food and Drug  
24 Administration.

25 "Manufacturer" means a person licensed or approved by the  
26 FDA to engage in the manufacture of drugs or devices,

1 consistent with the definition of "manufacturer" set forth in  
2 the FDA's regulations and guidances implementing the  
3 Prescription Drug Marketing Act. "Manufacturer" does not  
4 include anyone who is engaged in the packaging, repackaging,  
5 or labeling of drugs only to the extent permitted under the  
6 Illinois Drug Reuse Opportunity Program Act.

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  
12 responsibility to direct the sale or disposition of the  
13 manufacturer's prescription drug. A manufacturer's exclusive  
14 distributor must be licensed as a wholesale distributor under  
15 this Act and, in order to be considered part of the normal  
16 distribution channel, must also be an authorized distributor  
17 of record.

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

- 25 (1) a pharmacy or to other designated persons  
26 authorized by law to dispense or administer the drug to a

1 patient;

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

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

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

14 (5) an authorized distributor of record to one other  
15 authorized distributor of record to an office-based health  
16 care practitioner authorized by law to dispense or  
17 administer the drug to the patient; or

18 (6) an authorized distributor to a pharmacy or other  
19 persons licensed to dispense or administer the drug.

20 "Pedigree" means a document or electronic file containing  
21 information that records each wholesale distribution of any  
22 given prescription drug from the point of origin to the final  
23 wholesale distribution point of any given prescription drug.

24 "Person" means and includes a natural person, partnership,  
25 association, corporation, or any other legal business entity.

26 "Pharmacy distributor" means any pharmacy licensed in this



1 State or hospital pharmacy that is engaged in the delivery or  
2 distribution of prescription drugs either to any other  
3 pharmacy licensed in this State or to any other person or  
4 entity including, but not limited to, a wholesale drug  
5 distributor engaged in the delivery or distribution of  
6 prescription drugs who is involved in the actual,  
7 constructive, or attempted transfer of a drug in this State to  
8 other than the ultimate consumer except as otherwise provided  
9 for by law.

10 "Prescription drug" means any human drug, including any  
11 biological product (except for blood and blood components  
12 intended for transfusion or biological products that are also  
13 medical devices), required by federal law or regulation to be  
14 dispensed only by a prescription, including finished dosage  
15 forms and bulk drug substances subject to Section 503 of the  
16 Federal Food, Drug and Cosmetic Act.

17 "Repackage" means repackaging or otherwise changing the  
18 container, wrapper, or labeling to further the distribution of  
19 a prescription drug, excluding that completed by the  
20 pharmacist responsible for dispensing the product to a  
21 patient.

22 "Secretary" means the Secretary of the Department of  
23 Financial and Professional Regulation.

24 "Suspicious order" includes, but is not limited to, an  
25 order of a controlled substance of unusual size, an order of a  
26 controlled substance deviating substantially from a normal

1 pattern, and orders of controlled substances of unusual  
2 frequency as defined by 21 USC 802.

3 "Third-party logistics provider" means anyone who  
4 contracts with a prescription drug manufacturer to provide or  
5 coordinate warehousing, distribution, or other services on  
6 behalf of a manufacturer, but does not take title to the  
7 prescription drug or have general responsibility to direct the  
8 prescription drug's sale or disposition.

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

12 (1) Intracompany sales of prescription drugs, meaning

13 (i) any transaction or transfer between any division,  
14 subsidiary, parent, or affiliated or related company under  
15 the common ownership and control of a corporate entity or  
16 (ii) any transaction or transfer between co-licensees of a  
17 co-licensed product.

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

22 (3) The distribution of prescription drug samples by  
23 manufacturers' representatives.

24 (4) Drug returns, when conducted by a hospital, health  
25 care entity, or charitable institution in accordance with  
26 federal regulation.

1           (5) The sale of minimal quantities of prescription  
2 drugs by licensed pharmacies to licensed practitioners for  
3 office use or other licensed pharmacies.

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

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

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

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

1 drug.

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

7 (11) The donation of drugs to the extent permitted  
8 under the Illinois Drug Reuse Opportunity Program Act.

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

24 (Source: P.A. 101-420, eff. 8-16-19; 102-389, eff. 1-1-22.)

25 (225 ILCS 120/15.5 new)

1       Sec. 15.5. Address of record; email address of record. All  
2 applicants and licensees shall:

3           (1) provide a valid address and email address to the  
4 Department, which shall serve as the address of record and  
5 email address of record, respectively, at the time of  
6 application for licensure or renewal of a license; and

7           (2) inform the Department of any change of address of  
8 record or email address of record within 14 days after  
9 such change either through the Department's website or by  
10 contacting the Department's licensure maintenance unit.

11       (225 ILCS 120/21 new)

12       Sec. 21. Reports to Department. Each licensee that is  
13 required to report suspicious orders under 21 USC 832 shall  
14 also submit such suspicions order reports to the Department.

15       (225 ILCS 120/27)

16       (Section scheduled to be repealed on January 1, 2023)

17       Sec. 27. Social security number, individual taxpayer  
18 identification number, or unique identifying number ~~Security~~  
19 ~~Number~~ on license application. In addition to any other  
20 information required to be contained in the application, every  
21 application for an original license under this Act shall  
22 include the applicant's social security number, individual  
23 taxpayer identification number, or other unique identifying  
24 number deemed appropriate by the Department, ~~Social Security~~

1 ~~Number,~~ which shall be retained in the agency's records  
2 pertaining to the license. As soon as practical, the  
3 Department shall assign a customer's identification number to  
4 each applicant for a license.

5 Every application for a renewal or restored license shall  
6 require the applicant's customer identification number.

7 (Source: P.A. 97-400, eff. 1-1-12.)

8 (225 ILCS 120/30) (from Ch. 111, par. 8301-30)

9 (Section scheduled to be repealed on January 1, 2023)

10 Sec. 30. License applications; renewal ~~renewal application~~  
11 procedures. An application for an original license or renewal  
12 shall be made to the Department in writing or electronically  
13 on forms prescribed by the Department and shall be accompanied  
14 by the required fee, which shall not be refundable. Any such  
15 application shall require such information as in the judgment  
16 of the Department will enable the Board and Department to pass  
17 on the qualifications of the applicant for a license.  
18 ~~Application for renewal of any license required by this Act~~  
19 ~~shall be mailed or emailed to each licensee at least 60 days~~  
20 ~~before the license expires.~~ If the application for renewal  
21 with the required fee is not received by the Department before  
22 the expiration date, the existing license shall lapse and  
23 become null and void. Failure to renew before the expiration  
24 date is cause for a late payment penalty, discipline, or both.

25 (Source: P.A. 101-420, eff. 8-16-19.)

1 (225 ILCS 120/31 new)

2 Sec. 31. Expiration of license; renewal.

3 (a) The expiration date and renewal period for each  
4 license issued under this Act shall be set by rule.

5 (b) Any licensee who shall engage in the practice for  
6 which the license was issued while the license is expired or on  
7 inactive status shall be considered to be practicing without a  
8 license which shall be grounds for discipline under this Act.

9 (c) A wholesale drug distributor or third-party logistics  
10 provider whose license has been expired for one year or more  
11 may not have its license restored but must apply for a new  
12 license and meet all requirements for licensure. Any wholesale  
13 drug distributor or third-party logistics provider whose  
14 license has been expired for less than one year may apply for  
15 restoration of its license and shall have its license  
16 restored.

17 (d) Anyone operating on an expired license is engaged in  
18 unlawful practice and subject to discipline under this Act.

19 (225 ILCS 120/35) (from Ch. 111, par. 8301-35)

20 (Section scheduled to be repealed on January 1, 2023)

21 Sec. 35. Fees; Illinois State Pharmacy Disciplinary Fund.

22 (a) The Department shall provide by rule for a schedule of  
23 fees for the administration and enforcement of this Act,  
24 including but not limited to original licensure, renewal, and

1 restoration. The fees shall be nonrefundable.

2 (b) All fees collected under this Act shall be deposited  
3 into the Illinois State Pharmacy Disciplinary Fund and shall  
4 be appropriated to the Department for the ordinary and  
5 contingent expenses of the Department in the administration of  
6 this Act. Moneys in the Fund may be transferred to the  
7 Professions Indirect Cost Fund as authorized by Section  
8 2105-300 of the Department of Financial and Professional  
9 Regulation Law (20 ILCS 2105/2105-300).

10 The moneys deposited into the Illinois State Pharmacy  
11 Disciplinary Fund shall be invested to earn interest which  
12 shall accrue to the Fund.

13 ~~The Department shall present to the Board for its review~~  
14 ~~and comment all appropriation requests from the Illinois State~~  
15 ~~Pharmacy Disciplinary Fund. The Department shall give due~~  
16 ~~consideration to any comments of the Board in making~~  
17 ~~appropriation requests.~~

18 (c) Any person who delivers a check or other payment to the  
19 Department that is returned to the Department unpaid by the  
20 financial institution upon which it is drawn shall pay to the  
21 Department, in addition to the amount already owed to the  
22 Department, a fine of \$50. The fines imposed by this Section  
23 are in addition to any other discipline provided under this  
24 Act for unlicensed practice or practice on a nonrenewed  
25 license. The Department shall notify the person that payment  
26 of fees and fines shall be paid to the Department by certified



1 check or money order within 30 calendar days of the  
2 notification. If, after the expiration of 30 days from the  
3 date of the notification, the person has failed to submit the  
4 necessary remittance, the Department shall automatically  
5 terminate the license or certificate or deny the application,  
6 without hearing. If, after termination or denial, the person  
7 seeks a license or certificate, he or she shall apply to the  
8 Department for restoration or issuance of the license or  
9 certificate and pay all fees and fines due to the Department.  
10 The Department may establish a fee for the processing of an  
11 application for restoration of a license or certificate to pay  
12 all expenses of processing this application. The Secretary  
13 ~~Director~~ may waive the fines due under this Section in  
14 individual cases where the Secretary ~~Director~~ finds that the  
15 fines would be unreasonable or unnecessarily burdensome.

16 (d) (Blank). ~~The Department shall maintain a roster of the~~  
17 ~~names and addresses of all registrants and of all persons~~  
18 ~~whose licenses have been suspended or revoked. This roster~~  
19 ~~shall be available upon written request and payment of the~~  
20 ~~required fee.~~

21 (e) A manufacturer of controlled substances, wholesale  
22 distributor of controlled substances, or third-party logistics  
23 provider that is licensed under this Act and owned and  
24 operated by the State is exempt from licensure, registration,  
25 renewal, and other fees required under this Act. Nothing in  
26 this subsection (e) shall be construed to prohibit the

1 Department from imposing any fine or other penalty allowed  
2 under this Act.

3 (Source: P.A. 101-420, eff. 8-16-19.)

4 (225 ILCS 120/40) (from Ch. 111, par. 8301-40)

5 (Section scheduled to be repealed on January 1, 2023)

6 Sec. 40. Rules and regulations. The Department shall make  
7 any rules and regulations, not inconsistent with law, as may  
8 be necessary to carry out the purposes and enforce the  
9 provisions of this Act. ~~Rules and regulations that incorporate~~  
10 ~~and set detailed standards for meeting each of the license~~  
11 ~~prerequisites set forth in Section 25 of this Act shall be~~  
12 ~~adopted no later than September 14, 1992.~~ All rules and  
13 regulations promulgated under this Section shall conform to  
14 wholesale drug distributor licensing guidelines formally  
15 adopted by the FDA at 21 C.F.R. Part 205. In case of conflict  
16 between any rule or regulation adopted by the Department and  
17 any FDA wholesale drug distributor or third-party logistics  
18 provider guideline, the FDA guideline shall control.

19 (Source: P.A. 101-420, eff. 8-16-19.)

20 (225 ILCS 120/50) (from Ch. 111, par. 8301-50)

21 (Section scheduled to be repealed on January 1, 2023)

22 Sec. 50. Inspection powers; access to records.

23 (a) Any pharmacy investigator authorized by the Department  
24 has the right of entry for inspection ~~during normal business~~

1 ~~hours~~ of premises purporting or appearing to be used by a  
2 wholesale drug distributor in this State, including the  
3 business premises of a person licensed pursuant to this Act.  
4 This right of entry shall permit the authorized pharmacy  
5 investigator unfettered access to the entire business  
6 premises. Any attempt to hinder an authorized pharmacy  
7 investigator from inspecting the business premises and  
8 documenting the inspection shall be a violation of this Act.  
9 The duly authorized investigators shall be required to show  
10 appropriate identification before being given access to a  
11 wholesale drug distributor's premises and delivery vehicles.

12 (b) With the exception of the most recent 12 months of  
13 records that must be kept on the premises where the drugs are  
14 stored, wholesale drug distributors may keep records regarding  
15 purchase and sales transactions electronically at a central  
16 location apart from the principal office of the wholesale drug  
17 distributor or the location at which the drugs were stored and  
18 from which they were shipped, provided that the records shall  
19 be made readily available for inspection within 2 working days  
20 of a request by the Department. The records may be kept in any  
21 form permissible under federal law applicable to prescription  
22 drugs record keeping.

23 (c) (Blank).

24 (Source: P.A. 97-804, eff. 1-1-13.)

25 (225 ILCS 120/57)

1 (Section scheduled to be repealed on January 1, 2023)

2 Sec. 57. Pedigree.

3 (a) Each person who is engaged in the wholesale  
4 distribution of prescription drugs, including repackagers, but  
5 excluding the original manufacturer of the finished form of  
6 the prescription drug, that leave or have ever left the normal  
7 distribution channel shall, before each wholesale distribution  
8 of the drug, provide a pedigree to the person who receives the  
9 drug. A retail pharmacy, mail order pharmacy, or chain  
10 pharmacy warehouse must comply with the requirements of this  
11 Section only if the pharmacy or chain pharmacy warehouse  
12 engages in the wholesale distribution of prescription drugs.  
13 On or before July 1, 2009, the Department shall determine a  
14 targeted implementation date for electronic track and trace  
15 pedigree technology. This targeted implementation date shall  
16 not be sooner than July 1, 2010. Beginning on the date  
17 established by the Department, pedigrees may be implemented  
18 through an approved and readily available system that  
19 electronically tracks and traces the wholesale distribution of  
20 each prescription drug starting with the sale by the  
21 manufacturer through acquisition and sale by any wholesale  
22 distributor and until final sale to a pharmacy or other  
23 authorized person administering or dispensing the prescription  
24 drug. This electronic tracking system shall be deemed to be  
25 readily available only upon there being available a  
26 standardized system originating with the manufacturers and

1 capable of being used on a wide scale across the entire  
2 pharmaceutical chain, including manufacturers, wholesale  
3 distributors, third-party logistics providers, and pharmacies.  
4 Consideration must also be given to the large-scale  
5 implementation of this technology across the supply chain and  
6 the technology must be proven to have no negative impact on the  
7 safety and efficacy of the pharmaceutical product.

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

16 (c) The pedigree must include all necessary identifying  
17 information concerning each sale in the chain of distribution  
18 of the product from the manufacturer or the manufacturer's  
19 third-party ~~third-party~~ logistics provider, co-licensed  
20 product partner, or exclusive distributor through acquisition  
21 and sale by any wholesale distributor or repackager, until  
22 final sale to a pharmacy or other person dispensing or  
23 administering the drug. This necessary chain of distribution  
24 information shall include, without limitation all of the  
25 following:

26 (1) The name, address, telephone number and, if

1 available, the e-mail address of each owner of the  
2 prescription drug and each wholesale distributor of the  
3 prescription drug.

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

6 (3) Transaction dates.

7 (4) Certification that each recipient has  
8 authenticated the pedigree.

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

11 (1) The name and national drug code number of the  
12 prescription drug.

13 (2) The dosage form and strength of the prescription  
14 drug.

15 (3) The size of the container.

16 (4) The number of containers.

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

18 (6) The name of the manufacturer of the finished  
19 dosage form.

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

25 (Source: P.A. 101-420, eff. 8-16-19.)

1 (225 ILCS 120/70) (from Ch. 111, par. 8301-70)

2 (Section scheduled to be repealed on January 1, 2023)

3 Sec. 70. Immediate suspension of license or registration;  
4 hearing. The Secretary ~~Director~~ may, upon receipt of a  
5 written communication from the Secretary of Human Services or  
6 the Director of Public Health that continuation of practice of  
7 a person licensed or registered under this Act constitutes an  
8 immediate danger to the public, immediately suspend the  
9 license or registration of that person without a hearing. In  
10 instances in which the Secretary ~~Director~~ immediately suspends  
11 a license or registration under this Section, a hearing upon  
12 the person's license must be convened by the Board within 15  
13 days after the suspension and completed without appreciable  
14 delay. The hearing shall be held to determine whether to  
15 recommend to the Secretary ~~Director~~ that the person's license  
16 be revoked, suspended, placed on probationary status, or  
17 reinstated, or that the person be subject to other  
18 disciplinary action. In the hearing, the written communication  
19 and any other evidence submitted with the communication may be  
20 introduced as evidence against the person. The person or his  
21 or her counsel shall have the opportunity to discredit or  
22 impeach such evidence and submit rebuttal evidence.

23 (Source: P.A. 89-507, eff. 7-1-97.)

24 (225 ILCS 120/75) (from Ch. 111, par. 8301-75)

25 (Section scheduled to be repealed on January 1, 2023)

1           Sec. 75. Automatic suspension. The determination by a  
2 circuit court that a licensee is subject to involuntary  
3 admission or judicial admission as provided in the Mental  
4 Health and Developmental Disabilities Code operates as an  
5 automatic suspension. The suspension shall end only upon (i) a  
6 finding by a court that the patient is no longer subject to  
7 involuntary admission or judicial admission and the issuance  
8 of an order so finding and discharging the patient and (ii) the  
9 recommendation of the Board to the Secretary ~~Director~~ that the  
10 licensee be allowed to resume his or her practice.

11         (Source: P.A. 91-357, eff. 7-29-99.)

12           (225 ILCS 120/80) (from Ch. 111, par. 8301-80)

13           (Section scheduled to be repealed on January 1, 2023)

14           Sec. 80. Violations of Act.

15           (a) If any person violates the provisions of this Act, the  
16 Secretary ~~Director~~ may, in the name of the People of the State  
17 of Illinois through the Attorney General of the State of  
18 Illinois or the State's Attorney of any county in which the  
19 action is brought, petition for an order enjoining the  
20 violation or for an order enforcing compliance with this Act.  
21 Upon the filing of a verified petition in the court, the court  
22 may issue a temporary restraining order, without notice or  
23 bond, and may preliminarily and permanently enjoin the  
24 violation. If it is established that the person has violated  
25 or is violating the injunction, the Court may punish the



1 offender for contempt of court. Proceedings under this Section  
2 shall be in addition to, and not in lieu of, all other remedies  
3 and penalties provided by this Act.

4 (b) Whoever knowingly conducts business as a wholesale  
5 drug distributor or third-party logistics provider in this  
6 State without being appropriately licensed under this Act  
7 shall be guilty of a Class A misdemeanor for a first violation  
8 and for each subsequent conviction shall be guilty of a Class 4  
9 felony.

10 (c) Whenever in the opinion of the Department any person  
11 not licensed in good standing under this Act violates any  
12 provision of this Act, the Department may issue a rule to show  
13 cause why an order to cease and desist should not be entered  
14 against him. The rule shall clearly set forth the grounds  
15 relied upon by the Department and shall provide a period of 7  
16 days from the date of the rule to file an answer to the  
17 satisfaction of the Department. Failure to answer to the  
18 satisfaction of the Department shall cause an order to cease  
19 and desist to be issued immediately.

20 (Source: P.A. 101-420, eff. 8-16-19.)

21 (225 ILCS 120/85) (from Ch. 111, par. 8301-85)

22 (Section scheduled to be repealed on January 1, 2023)

23 Sec. 85. Investigations; notice of disciplinary hearing.  
24 The Department may investigate the actions of any applicant or  
25 of any person or persons holding or claiming to hold a license

1 or registration. Before suspending, revoking, placing on  
2 probationary status, or taking any other disciplinary action  
3 as the Department may deem proper with regard to any license or  
4 certificate, at least 30 days before the date set for the  
5 hearing, the Department shall (i) notify the accused in  
6 writing of any charges made and the time and place for a  
7 hearing of the charges before the Board, (ii) direct him or her  
8 to file a written answer to the charges with the Board under  
9 oath within 20 days after the service of the notice, and (iii)  
10 inform the accused that if he or she fails to file an answer  
11 default will be taken against him or her and his or her license  
12 or certificate may be suspended, revoked, placed on  
13 probationary status, or have other disciplinary action,  
14 including limiting the scope, nature or extent of business, as  
15 provided for in this Act. The written notice may be served by  
16 personal delivery, email to the respondent's email address of  
17 record, or mail to the respondent's address of record ~~or~~  
18 ~~certified or registered mail to the respondent at the address~~  
19 ~~of last notification to the Department.~~ At the time and place  
20 fixed in the notice, the Board shall proceed to hear the  
21 charges and the parties or their counsel shall be accorded  
22 ample opportunity to present any statements, testimony,  
23 evidence and argument that may be pertinent to the charges or  
24 to their defense. The hearing may be continued from time to  
25 time. In case the accused person, after receiving notice,  
26 fails to file an answer, his or her license or certificate may

1 in the discretion of the Secretary ~~Director~~, having received  
2 first the recommendation of the Board, be suspended, revoked,  
3 placed on probationary status, or the Secretary ~~Director~~ may  
4 take whatever disciplinary action as he or she may deem proper  
5 as provided in this Act, including limiting the scope, nature,  
6 or extent of the person's practice, without a hearing, if the  
7 act or acts charged constitute sufficient grounds for such  
8 action under this Act.

9 (Source: P.A. 87-594.)

10 (225 ILCS 120/100) (from Ch. 111, par. 8301-100)

11 (Section scheduled to be repealed on January 1, 2023)

12 Sec. 100. Subpoena power; administration of oaths. The  
13 Department shall have power to subpoena and bring before it  
14 any person in this State and to take testimony, either orally  
15 or by deposition or both, with the same fees and mileage and in  
16 the same manner as prescribed by law in judicial proceedings  
17 in civil cases in circuit courts of this State. The Department  
18 may subpoena and compel the production of documents, papers,  
19 files, books, and records in connection with any hearing or  
20 investigation.

21 The Secretary, hearing officer, and ~~Director~~ and any  
22 member of the Board shall each have power to administer oaths  
23 to witnesses at any hearing which the Department is authorized  
24 to conduct under this Act, and any other oaths required or  
25 authorized to be administered by the Department under this

1 Act.

2 (Source: P.A. 87-594.)

3 (225 ILCS 120/105) (from Ch. 111, par. 8301-105)

4 (Section scheduled to be repealed on January 1, 2023)

5 Sec. 105. Report of findings and recommendation. At the  
6 conclusion of the hearing, the Board shall present to the  
7 Secretary ~~Director~~ a written report of its findings of fact,  
8 conclusions of law, and recommendations. The report shall  
9 contain a finding whether or not the accused person violated  
10 this Act or failed to comply with the conditions required in  
11 this Act. The Board shall specify the nature of the violation  
12 or failure to comply and shall make its recommendations to the  
13 Secretary ~~Director~~.

14 The report of findings of fact, conclusion of law, and  
15 recommendations of the Board shall be the basis for the  
16 Department's order for refusal or for the granting of a  
17 license or registration. The finding is not admissible in  
18 evidence against the person in a criminal prosecution brought  
19 for the violation of this Act, but the hearing and finding are  
20 not a bar to a criminal prosecution brought for the violation  
21 of this Act.

22 (Source: P.A. 87-594.)

23 (225 ILCS 120/110) (from Ch. 111, par. 8301-110)

24 (Section scheduled to be repealed on January 1, 2023)

1           Sec. 110. Hearing officers; appointment. Notwithstanding  
2 any other provision of this Act, the Secretary Director shall  
3 have the authority to appoint any attorney duly licensed to  
4 practice law in the State of Illinois to serve as the hearing  
5 officer in any action before the Board for refusal to issue or  
6 renew a license, or the discipline of a licensee. ~~The Director~~  
7 ~~shall notify the Board of any such appointment. The hearing~~  
8 ~~officer shall have full authority to conduct the hearing.~~  
9 ~~There shall be present at least one member of the Board at any~~  
10 ~~such hearing.~~ The hearing officer shall report his findings of  
11 fact, conclusions of law, and recommendations to the Board and  
12 the Secretary Director. The Board shall have 60 days from  
13 receipt of the report to review the report of the hearing  
14 officer and present its findings of fact, conclusions of law,  
15 and recommendations to the Secretary Director. If the Board  
16 fails to present its report within the 60 day period, the  
17 Secretary Director may issue an order based on report of the  
18 hearing officer and the record of the proceedings or issue an  
19 order remanding the matter back to the hearing officer for  
20 additional proceedings in accordance with the order. If the  
21 Secretary disagrees with the recommendation of the Board or  
22 the hearing officer, the Secretary may issue an order in  
23 contravention of the recommendation. However, if the Board  
24 does present its report within the specified 60 days, the  
25 Director's order shall be based upon the report of the Board.

26       (Source: P.A. 87-594.)

1 (225 ILCS 120/115) (from Ch. 111, par. 8301-115)

2 (Section scheduled to be repealed on January 1, 2023)

3 Sec. 115. Motion for rehearing. In any case involving the  
4 refusal to issue, renew, or discipline of a license or  
5 registration, a copy of the Board's report shall be served  
6 upon the respondent by the Department, either personally or as  
7 provided in this Act for the service of the notice of hearing.  
8 Within 20 days after service, the respondent may present to  
9 the Department a motion in writing for a rehearing, which  
10 shall specify the particular grounds for rehearing. If no  
11 motion for rehearing is filed, then upon the expiration of the  
12 time specified for filing a motion, or if a motion for  
13 rehearing is denied, then upon denial the Secretary ~~Director~~  
14 may enter an order in accordance with recommendations of the  
15 Board. If the respondent orders from the reporting service and  
16 pays for a transcript of the record within the time for filing  
17 a motion for rehearing, the 20-day ~~20-day~~ period within which a  
18 motion may be filed shall commence upon the delivery of the  
19 transcript to the respondent.

20 (Source: P.A. 87-594.)

21 (225 ILCS 120/120) (from Ch. 111, par. 8301-120)

22 (Section scheduled to be repealed on January 1, 2023)

23 Sec. 120. Rehearing by order of Secretary ~~Director~~.  
24 Whenever the Secretary ~~Director~~ is satisfied that substantial

1 justice has not been done in the revocation, suspension, or  
2 refusal to issue or renew a license or registration, the  
3 Secretary Director may order a rehearing by the same hearing  
4 office or Board.

5 (Source: P.A. 87-594.)

6 (225 ILCS 120/125) (from Ch. 111, par. 8301-125)

7 (Section scheduled to be repealed on January 1, 2023)

8 Sec. 125. Duties of the Board ~~Board recommendations to~~  
9 ~~Director; disagreement.~~ The Board shall exercise the rights,  
10 powers, and duties which have been vested in the Board under  
11 this Act, and any other duties conferred upon the Board by law.  
12 ~~None of the disciplinary functions, powers, and duties~~  
13 ~~enumerated in this Act shall be exercised by the Department~~  
14 ~~except upon the action and report in writing of the Board,~~  
15 ~~except as otherwise provided in this Act.~~

16 ~~In all instances under this Act in which the Board has~~  
17 ~~rendered a recommendation to the Director with respect to a~~  
18 ~~particular license or certificate, the Director shall, in the~~  
19 ~~event that he or she disagrees with or takes action contrary to~~  
20 ~~the recommendation of the Board, file with the Board and~~  
21 ~~Secretary of State his or her specific written reasons for~~  
22 ~~disagreement with the Board. These reasons shall be filed~~  
23 ~~within 30 days after the Director taking the contrary~~  
24 ~~position.~~

25 ~~The action and report in writing of a majority of the Board~~

1 ~~is sufficient authority upon which the Director may act.~~

2 (Source: P.A. 87-594.)

3 (225 ILCS 120/135) (from Ch. 111, par. 8301-135)

4 (Section scheduled to be repealed on January 1, 2023)

5 Sec. 135. Disciplinary consent orders. Notwithstanding the  
6 provisions of this Act concerning the conduct of hearings and  
7 recommendations for disciplinary actions, the Secretary  
8 ~~Director~~ shall have the authority to negotiate agreements with  
9 licensees ~~and registrants~~ resulting in disciplinary consent  
10 orders. Consent orders may provide for any of the forms of  
11 discipline otherwise provided in this Act. Consent orders  
12 shall provide that they were not entered into a result of any  
13 coercion by the Department. ~~The Director shall forward copies~~  
14 ~~of all final consent orders to the Board within 30 days after~~  
15 ~~their entry.~~

16 (Source: P.A. 87-594.)

17 (225 ILCS 120/140) (from Ch. 111, par. 8301-140)

18 (Section scheduled to be repealed on January 1, 2023)

19 Sec. 140. Orders; prima facie proof. An order or a  
20 certified copy thereof, over the seal of the Department and  
21 purporting to be signed by the Secretary ~~Director~~, shall be  
22 prima facie proof that:

23 (a) the signature is the genuine signature of the

24 Secretary ~~Director~~;



1 (b) the Secretary ~~Director~~ is duly appointed and  
2 qualified; and

3 (c) the Board and its members are qualified to act.  
4 (Source: P.A. 91-357, eff. 7-29-99.)

5 (225 ILCS 120/155) (from Ch. 111, par. 8301-155)

6 (Section scheduled to be repealed on January 1, 2023)

7 Sec. 155. Temporary suspension of license; hearing. The  
8 Secretary ~~Director~~ may temporarily suspend licensure as a  
9 wholesale drug distributor or third-party logistics provider,  
10 without a hearing, simultaneously with the institution of  
11 proceedings for a hearing provided for in Section 85 of this  
12 Act, if the Secretary ~~Director~~ finds that evidence in his or  
13 her possession indicates that a continuation in business would  
14 constitute an imminent danger to the public. In the event that  
15 the Secretary ~~Director~~ temporarily suspends a license or  
16 certificate without a hearing, a hearing by the Department  
17 must be held within 10 days after the suspension has occurred  
18 and be concluded without appreciable delay.

19 (Source: P.A. 101-420, eff. 8-16-19.)

20 (225 ILCS 120/165) (from Ch. 111, par. 8301-165)

21 (Section scheduled to be repealed on January 1, 2023)

22 Sec. 165. Certification of record; ~~receipt for costs.~~ The  
23 Department shall not be required to certify any record to the  
24 court, to file an answer in court, or to otherwise appear in

1 any court in a judicial review proceeding unless and until the  
2 Department has received from the plaintiff payment of the  
3 costs of furnishing and certifying the record, which costs  
4 shall be determined by the Department. Failure on the part of  
5 the plaintiff to file a receipt in court shall be grounds for  
6 dismissal of the action. During the pendency and hearing of  
7 any and all judicial proceedings incident to the disciplinary  
8 action, the sanctions imposed upon the accused by the  
9 Department because of acts or omissions related to the  
10 delivery of direct patient care as specified in the  
11 Department's final administrative decision, shall, as a matter  
12 of public policy, remain in full force and effect in order to  
13 protect the public pending final resolution of any of the  
14 proceedings.

15 ~~The Department shall not be required to certify any record to~~  
16 ~~the court or file any answer in court or otherwise appear in~~  
17 ~~any court in a judicial review proceeding, unless there is~~  
18 ~~filed in the court, with the complaint, a receipt from the~~  
19 ~~Department acknowledging payment of the costs of furnishing~~  
20 ~~and certifying the record, which costs shall be computed at~~  
21 ~~the rate of 25 cents per page of such record. Failure on the~~  
22 ~~part of the plaintiff to file a receipt in court shall be~~  
23 ~~grounds for dismissal of the action.~~

24 (Source: P.A. 87-594.)

1 (Section scheduled to be repealed on January 1, 2023)

2 Sec. 200. Drugs in shortage.

3 (a) For the purpose of this Section, "drug in shortage"  
4 means a drug, as defined in Section 356c of the Federal Food,  
5 Drug, and Cosmetic Act, listed on the drug shortage list  
6 maintained by the U.S. Food and Drug Administration in  
7 accordance with Section 356e of the Federal Food, Drug, and  
8 Cosmetic Act.

9 (b) Any person engaged in the wholesale distribution of a  
10 drug in shortage in this State must be licensed by the  
11 Department.

12 (c) It is unlawful for any person, other than a  
13 manufacturer, a manufacturer's exclusive distributor, a  
14 third-party ~~third party~~ logistics provider, or an authorized  
15 distributor of record, to purchase or receive a drug in  
16 shortage from any person not licensed by the Department. This  
17 subsection (c) does not apply to the return of drugs or the  
18 purchase or receipt of drugs pursuant to any of the  
19 distributions that are specifically excluded from the  
20 definition of "wholesale distribution" in Section 15 of the  
21 Wholesale Drug Distribution Licensing Act.

22 (d) A person found to have violated a provision of this  
23 Section shall be subject to administrative fines, orders for  
24 restitution, and orders for disgorgement.

25 (e) The Department shall create a centralized, searchable  
26 database of those entities licensed to engage in wholesale

1 distribution, including manufacturers, wholesale  
2 distributors, and pharmacy distributors, to enable purchasers  
3 of a drug in shortage to easily verify the licensing status of  
4 an entity offering such drugs.

5 (f) The Department shall establish a system for reporting  
6 the reasonable suspicion that a violation of this Act has been  
7 committed by a distributor of a drug in shortage. Reports made  
8 through this system shall be referred to the Office of the  
9 Attorney General and the appropriate State's Attorney's office  
10 for further investigation and prosecution.

11 (g) The Department shall adopt rules to carry out the  
12 provisions of this Section.

13 (h) Nothing in this Section prohibits one hospital  
14 pharmacy from purchasing or receiving a drug in shortage from  
15 another hospital pharmacy in the event of a medical emergency.

16 (Source: P.A. 98-355, eff. 8-16-13.)

17 (225 ILCS 120/3 rep.)

18 Section 15. The Wholesale Drug Distribution Licensing Act  
19 is amended by repealing Section 3.

20 Section 99. Effective date. This Section and Section 5  
21 take effect upon becoming law.

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7	225 ILCS 120/21 new	
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- 4 225 ILCS 120/200
- 5 225 ILCS 120/3 rep.