



Sen. Thomas Cullerton

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10100SB1839sam002

LRB101 09712 AMC 59615 a

1 AMENDMENT TO SENATE BILL 1839

2 AMENDMENT NO. _____. Amend Senate Bill 1839, AS AMENDED,
3 by replacing everything after the enacting clause with the
4 following:

5 "Section 3. The Pharmacy Practice Act is amended by
6 changing Section 4 as follows:

7 (225 ILCS 85/4) (from Ch. 111, par. 4124)

8 (Section scheduled to be repealed on January 1, 2020)

9 Sec. 4. Exemptions. Nothing contained in any Section of
10 this Act shall apply to, or in any manner interfere with:

11 (a) the lawful practice of any physician licensed to
12 practice medicine in all of its branches, dentist,
13 podiatric physician, veterinarian, or therapeutically or
14 diagnostically certified optometrist within the limits of
15 his or her license, or prevent him or her from supplying to
16 his or her bona fide patients such drugs, medicines, or

1 poisons as may seem to him appropriate;

2 (b) the sale of compressed gases;

3 (c) the sale of patent or proprietary medicines and
4 household remedies when sold in original and unbroken
5 packages only, if such patent or proprietary medicines and
6 household remedies be properly and adequately labeled as to
7 content and usage and generally considered and accepted as
8 harmless and nonpoisonous when used according to the
9 directions on the label, and also do not contain opium or
10 coca leaves, or any compound, salt or derivative thereof,
11 or any drug which, according to the latest editions of the
12 following authoritative pharmaceutical treatises and
13 standards, namely, The United States
14 Pharmacopoeia/National Formulary (USP/NF), the United
15 States Dispensatory, and the Accepted Dental Remedies of
16 the Council of Dental Therapeutics of the American Dental
17 Association or any or either of them, in use on the
18 effective date of this Act, or according to the existing
19 provisions of the Federal Food, Drug, and Cosmetic Act and
20 Regulations of the Department of Health and Human Services,
21 Food and Drug Administration, promulgated thereunder now
22 in effect, is designated, described or considered as a
23 narcotic, hypnotic, habit forming, dangerous, or poisonous
24 drug;

25 (d) the sale of poultry and livestock remedies in
26 original and unbroken packages only, labeled for poultry

1 and livestock medication;

2 (e) the sale of poisonous substances or mixture of
3 poisonous substances, in unbroken packages, for
4 nonmedicinal use in the arts or industries or for
5 insecticide purposes; provided, they are properly and
6 adequately labeled as to content and such nonmedicinal
7 usage, in conformity with the provisions of all applicable
8 federal, state and local laws and regulations promulgated
9 thereunder now in effect relating thereto and governing the
10 same, and those which are required under such applicable
11 laws and regulations to be labeled with the word "Poison",
12 are also labeled with the word "Poison" printed thereon in
13 prominent type and the name of a readily obtainable
14 antidote with directions for its administration;

15 (f) the delegation of limited prescriptive authority
16 by a physician licensed to practice medicine in all its
17 branches to a physician assistant under Section 7.5 of the
18 Physician Assistant Practice Act of 1987. This delegated
19 authority under Section 7.5 of the Physician Assistant
20 Practice Act of 1987 may, but is not required to, include
21 prescription of controlled substances, as defined in
22 Article II of the Illinois Controlled Substances Act, in
23 accordance with a written supervision agreement;

24 (g) the delegation of prescriptive authority by a
25 physician licensed to practice medicine in all its branches
26 or a licensed podiatric physician to an advanced practice

1 registered nurse in accordance with a written
2 collaborative agreement under Sections 65-35 and 65-40 of
3 the Nurse Practice Act; and

4 (h) the sale or distribution of dialysate or devices
5 necessary to perform home peritoneal renal dialysis for
6 patients with end-stage renal disease, provided that all of
7 the following conditions are met:

8 (1) the dialysate, comprised of dextrose or
9 icodextrin, or devices are approved or cleared by the
10 federal Food and Drug Administration, as required by
11 federal law;

12 (2) the dialysate or devices are lawfully held by a
13 manufacturer or the manufacturer's agent, which is
14 properly registered with the Board as a manufacturer,
15 third-party logistics provider, or wholesaler;

16 (3) the dialysate or devices are held and delivered
17 to the manufacturer or the manufacturer's agent in the
18 original, sealed packaging from the manufacturing
19 facility;

20 (4) the dialysate or devices are delivered only
21 upon receipt of a physician's prescription by a
22 licensed pharmacy in which the prescription is
23 processed in accordance with provisions set forth in
24 this Act, and the transmittal of an order from the
25 licensed pharmacy to the manufacturer or the
26 manufacturer's agent; and

1 (5) the manufacturer or the manufacturer's agent
2 delivers the dialysate or devices directly to: (i) a
3 patient with end-stage renal disease, or his or her
4 designee, for the patient's self-administration of the
5 dialysis therapy or (ii) a health care provider or
6 institution for administration or delivery of the
7 dialysis therapy to a patient with end-stage renal
8 disease.

9 This paragraph (h) does not include any other drugs for
10 peritoneal dialysis, except dialysate, as described in
11 item (1) of this paragraph (h). All records of sales and
12 distribution of dialysate to patients made pursuant to this
13 paragraph (h) must be retained in accordance with Section
14 18 of this Act.

15 (Source: P.A. 100-218, eff. 8-18-17; 100-513, eff. 1-1-18;
16 100-863, eff. 8-14-18.)

17 Section 10. The Wholesale Drug Distribution Licensing Act
18 is amended by changing Sections 15, 20, 26, 30, 35, 40, 57, 80,
19 and 155 and by adding Section 25.5 as follows:

20 (225 ILCS 120/15) (from Ch. 111, par. 8301-15)

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

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

23 "Authentication" means the affirmative verification,
24 before any wholesale distribution of a prescription drug

1 occurs, that each transaction listed on the pedigree has
2 occurred.

3 "Authorized distributor of record" means a wholesale
4 distributor with whom a manufacturer has established an ongoing
5 relationship to distribute the manufacturer's prescription
6 drug. An ongoing relationship is deemed to exist between a
7 wholesale distributor and a manufacturer when the wholesale
8 distributor, including any affiliated group of the wholesale
9 distributor, as defined in Section 1504 of the Internal Revenue
10 Code, complies with the following:

11 (1) The wholesale distributor has a written agreement
12 currently in effect with the manufacturer evidencing the
13 ongoing relationship; and

14 (2) The wholesale distributor is listed on the
15 manufacturer's current list of authorized distributors of
16 record, which is updated by the manufacturer on no less
17 than a monthly basis.

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

20 "Blood component" means that part of blood separated by
21 physical or mechanical means.

22 "Board" means the State Board of Pharmacy of the Department
23 of Professional Regulation.

24 "Chain pharmacy warehouse" means a physical location for
25 prescription drugs that acts as a central warehouse and
26 performs intracompany sales or transfers of the drugs to a

1 group of chain or mail order pharmacies that have the same
2 common ownership and control. Notwithstanding any other
3 provision of this Act, a chain pharmacy warehouse shall be
4 considered part of the normal distribution channel.

5 "Co-licensed partner or product" means an instance where
6 one or more parties have the right to engage in the
7 manufacturing or marketing of a prescription drug, consistent
8 with the FDA's implementation of the Prescription Drug
9 Marketing Act.

10 "Department" means the Department of Financial and
11 Professional Regulation.

12 "Drop shipment" means the sale of a prescription drug to a
13 wholesale distributor by the manufacturer of the prescription
14 drug or that manufacturer's co-licensed product partner, that
15 manufacturer's third party logistics provider, or that
16 manufacturer's exclusive distributor or by an authorized
17 distributor of record that purchased the product directly from
18 the manufacturer or one of these entities whereby the wholesale
19 distributor or chain pharmacy warehouse takes title but not
20 physical possession of such prescription drug and the wholesale
21 distributor invoices the pharmacy, chain pharmacy warehouse,
22 or other person authorized by law to dispense or administer
23 such drug to a patient and the pharmacy, chain pharmacy
24 warehouse, or other authorized person receives delivery of the
25 prescription drug directly from the manufacturer, that
26 manufacturer's third party logistics provider, or that

1 manufacturer's exclusive distributor or from an authorized
2 distributor of record that purchased the product directly from
3 the manufacturer or one of these entities.

4 "Drug sample" means a unit of a prescription drug that is
5 not intended to be sold and is intended to promote the sale of
6 the drug.

7 "Facility" means a facility of a wholesale distributor
8 where prescription drugs are stored, handled, repackaged, or
9 offered for sale, or a facility of a third-party logistics
10 provider where prescription drugs are stored or handled.

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

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

17 "Manufacturer's exclusive distributor" means anyone who
18 contracts with a manufacturer to provide or coordinate
19 warehousing, distribution, or other services on behalf of a
20 manufacturer and who takes title to that manufacturer's
21 prescription drug, but who does not have general responsibility
22 to direct the sale or disposition of the manufacturer's
23 prescription drug. A manufacturer's exclusive distributor must
24 be licensed as a wholesale distributor under this Act and, in
25 order to be considered part of the normal distribution channel,
26 must also be an authorized distributor of record.

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

8 (1) a pharmacy or to other designated persons
9 authorized by law to dispense or administer the drug to a
10 patient;

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

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

19 (4) a chain pharmacy warehouse to the chain pharmacy
20 warehouse's intracompany pharmacy or other designated
21 persons authorized by law to dispense or administer the
22 drug to the patient;

23 (5) an authorized distributor of record to one other
24 authorized distributor of record to an office-based health
25 care practitioner authorized by law to dispense or
26 administer the drug to the patient; or

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

3 "Pedigree" means a document or electronic file containing
4 information that records each wholesale distribution of any
5 given prescription drug from the point of origin to the final
6 wholesale distribution point of any given prescription drug.

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

9 "Pharmacy distributor" means any pharmacy licensed in this
10 State or hospital pharmacy that is engaged in the delivery or
11 distribution of prescription drugs either to any other pharmacy
12 licensed in this State or to any other person or entity
13 including, but not limited to, a wholesale drug distributor
14 engaged in the delivery or distribution of prescription drugs
15 who is involved in the actual, constructive, or attempted
16 transfer of a drug in this State to other than the ultimate
17 consumer except as otherwise provided for by law.

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

25 "Repackage" means repackaging or otherwise changing the
26 container, wrapper, or labeling to further the distribution of

1 a prescription drug, excluding that completed by the pharmacist
2 responsible for dispensing the product to a patient.

3 "Secretary" means the Secretary of Financial and
4 Professional Regulation.

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

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

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

24 (2) The sale, purchase, distribution, trade, or
25 transfer of a prescription drug or offer to sell, purchase,
26 distribute, trade, or transfer a prescription drug for

1 emergency medical reasons.

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

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

7 (5) The sale of minimal quantities of prescription
8 drugs by licensed pharmacies to licensed practitioners for
9 office use or other licensed pharmacies.

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

13 (7) The sale, transfer, merger, or consolidation of all
14 or part of the business of a pharmacy or pharmacies from or
15 with another pharmacy or pharmacies, whether accomplished
16 as a purchase and sale of stock or business assets.

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

1 (9) The delivery of or the offer to deliver a
2 prescription drug by a common carrier solely in the common
3 carrier's usual course of business of transporting
4 prescription drugs when the common carrier does not store,
5 warehouse, or take legal ownership of the prescription
6 drug.

7 (10) The sale or transfer from a retail pharmacy, mail
8 order pharmacy, or chain pharmacy warehouse of expired,
9 damaged, returned, or recalled prescription drugs to the
10 original manufacturer, the originating wholesale
11 distributor, or a third party returns processor.

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

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

1 (225 ILCS 120/20) (from Ch. 111, par. 8301-20)

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

3 Sec. 20. Prohibited drug purchases or receipt. It shall be
4 unlawful for any person or entity located in this State to
5 knowingly receive any prescription drug from any source other
6 than a person or entity required by the laws of this State to
7 be licensed to ship into, out of, or within this State. A
8 person or entity licensed under the laws of this State shall
9 include, but is not limited to, a wholesale distributor,
10 manufacturer, third-party logistics provider, pharmacy
11 distributor, or pharmacy. Any person violating this Section
12 shall, upon conviction, be adjudged guilty of a Class C
13 misdemeanor. A second violation shall constitute a Class 4
14 felony.

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

16 (225 ILCS 120/25.5 new)

17 Sec. 25.5. Third-party logistics providers.

18 (a) Each resident third-party logistics provider must be
19 licensed by the Department, and every non-resident third-party
20 logistics provider must be licensed in this State, in
21 accordance with this Act, prior to shipping a prescription drug
22 into this State.

23 (b) The Department shall require, without limitation, all
24 of the following information from each applicant for licensure

1 under this Act:

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

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

5 (3) Addresses, telephone numbers, and the names of
6 contact persons for all facilities used by the licensee for
7 the storage, handling, and distribution of prescription
8 drugs.

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

11 (5) The name of the owner or operator of the
12 third-party logistics provider, including:

13 (A) if a natural person, the name of the natural
14 person;

15 (B) if a partnership, the name of each partner and
16 the name of the partnership;

17 (C) if a corporation, the name and title of each
18 corporate officer and director, the corporate names,
19 and the name of the state of incorporation; and

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

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

25 (7) The name of the designated representative for the
26 third-party logistics provider, together with the personal

1 information statement and fingerprints, as required under
2 subsection (c) of this Section.

3 (8) Minimum liability insurance and other insurance as
4 defined by rule.

5 (9) Any additional information required by the
6 Department.

7 (c) Each third-party logistics provider must designate an
8 individual representative who shall serve as the contact person
9 for the Department. This representative must provide the
10 Department with all of the following information:

11 (1) Information concerning whether the person has been
12 enjoined, either temporarily or permanently, by a court of
13 competent jurisdiction from violating any federal or State
14 law regulating the possession, control, or distribution of
15 prescription drugs or criminal violations, together with
16 details concerning any such event.

17 (2) A description of any involvement by the person with
18 any business, including any investments, other than the
19 ownership of stock in a publicly traded company or mutual
20 fund, that manufactured, administered, prescribed,
21 distributed, or stored pharmaceutical products and any
22 lawsuits in which such businesses were named as a party.

23 (3) A description of any misdemeanor or felony criminal
24 offense of which the person, as an adult, was found guilty,
25 regardless of whether adjudication of guilt was withheld or
26 whether the person pled guilty or nolo contendere. If the

1 person indicates that a criminal conviction is under appeal
2 and submits a copy of the notice of appeal of that criminal
3 offense, the applicant must, within 15 days after the
4 disposition of the appeal, submit to the Department a copy
5 of the final written order of disposition.

6 (4) The designated representative of an applicant for
7 licensure as a third-party logistics provider shall have
8 his or her fingerprints submitted to the Department of
9 State Police in an electronic format that complies with the
10 form and manner for requesting and furnishing criminal
11 history record information as prescribed by the Department
12 of State Police. These fingerprints shall be checked
13 against the Department of State Police and Federal Bureau
14 of Investigation criminal history record databases now and
15 hereafter filed. The Department of State Police shall
16 charge applicants a fee for conducting the criminal history
17 records check, which shall be deposited into the State
18 Police Services Fund and shall not exceed the actual cost
19 of the records check. The Department of State Police shall
20 furnish, pursuant to positive identification, records of
21 Illinois convictions to the Department. The Department may
22 require applicants to pay a separate fingerprinting fee,
23 either to the Department or to a vendor. The Department, in
24 its discretion, may allow an applicant who does not have
25 reasonable access to a designated vendor to provide his or
26 her fingerprints in an alternative manner. The Department

1 may adopt any rules necessary to implement this paragraph
2 (4).

3 (d) A third-party logistics provider shall not operate from
4 a place of residence.

5 (e) A third-party logistics provider facility shall be
6 located apart and separate from any retail pharmacy licensed by
7 the Department.

8 (f) The Department may not issue a third-party logistics
9 provider license to an applicant, unless the Department first:

10 (1) ensures that a physical inspection of the facility
11 satisfactory to the Department has occurred at the address
12 provided by the applicant, as required under item (1) of
13 subsection (b) of this Section; such inspection is not
14 required if the resident state of the third-party logistics
15 provider facility does not license third-party logistics
16 providers or if the resident state does not inspect
17 third-party logistics providers. If the resident state
18 does not inspect third-party logistics providers, a
19 Verified Accredited Wholesale Distributors Accreditation
20 or other inspection approved by the Department meets this
21 requirement; and

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

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

25 (B) He or she is employed by the applicant full
26 time in a managerial level position.

1 (C) He or she is actively involved in and aware of
2 the actual daily operation of third-party logistics
3 provider.

4 (g) A third-party logistics provider shall publicly
5 display all licenses and have the most recent state and federal
6 inspection reports readily available.

7 (225 ILCS 120/26)

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

9 Sec. 26. Unlicensed practice; violation; civil penalty.

10 (a) Any person who practices, offers to practice, attempts
11 to practice, or holds oneself out to practice as a wholesale
12 drug distributor, ~~or~~ pharmacy distributor, or third-party
13 logistics provider without being licensed to ship into, out of,
14 or within the State under this Act shall, in addition to any
15 other penalty provided by law, pay a civil penalty to the
16 Department in an amount not to exceed \$10,000 for each offense
17 as determined by the Department. The civil penalty shall be
18 assessed by the Department after a hearing is held in
19 accordance with the provisions set forth in this Act regarding
20 the provision of a hearing for the discipline of a licensee.

21 (b) The Department has the authority and power to
22 investigate any and all unlicensed activity.

23 (c) The civil penalty shall be paid within 60 days after
24 the effective date of the order imposing the civil penalty. The
25 order shall constitute a judgment and may be filed and

1 execution had thereon in the same manner as any judgment from
2 any court of record.

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

4 (225 ILCS 120/30) (from Ch. 111, par. 8301-30)

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

6 Sec. 30. License renewal application procedures.
7 Application ~~blanks~~ for renewal of any license required by this
8 Act shall be mailed or emailed to each licensee at least 60
9 days before the license expires. If the application for renewal
10 with the required fee is not received by the Department before
11 the expiration date, the existing license shall lapse and
12 become null and void. Failure to renew before the expiration
13 date is cause for a late payment penalty, discipline, or both.

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

15 (225 ILCS 120/35) (from Ch. 111, par. 8301-35)

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

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

18 (a) The Department shall provide by rule for a schedule of
19 fees for the administration and enforcement of this Act,
20 including but not limited to original licensure, renewal, and
21 restoration. The fees shall be nonrefundable.

22 (b) All fees collected under this Act shall be deposited
23 into the Illinois State Pharmacy Disciplinary Fund and shall be
24 appropriated to the Department for the ordinary and contingent

1 expenses of the Department in the administration of this Act.
2 Moneys in the Fund may be transferred to the Professions
3 Indirect Cost Fund as authorized by Section 2105-300 of the
4 Department of Professional Regulation Law (20 ILCS
5 2105/2105-300).

6 The moneys deposited into the Illinois State Pharmacy
7 Disciplinary Fund shall be invested to earn interest which
8 shall accrue to the Fund.

9 The Department shall present to the Board for its review
10 and comment all appropriation requests from the Illinois State
11 Pharmacy Disciplinary Fund. The Department shall give due
12 consideration to any comments of the Board in making
13 appropriation requests.

14 (c) Any person who delivers a check or other payment to the
15 Department that is returned to the Department unpaid by the
16 financial institution upon which it is drawn shall pay to the
17 Department, in addition to the amount already owed to the
18 Department, a fine of \$50. The fines imposed by this Section
19 are in addition to any other discipline provided under this Act
20 for unlicensed practice or practice on a nonrenewed license.
21 The Department shall notify the person that payment of fees and
22 fines shall be paid to the Department by certified check or
23 money order within 30 calendar days of the notification. If,
24 after the expiration of 30 days from the date of the
25 notification, the person has failed to submit the necessary
26 remittance, the Department shall automatically terminate the

1 license or certificate or deny the application, without
2 hearing. If, after termination or denial, the person seeks a
3 license or certificate, he or she shall apply to the Department
4 for restoration or issuance of the license or certificate and
5 pay all fees and fines due to the Department. The Department
6 may establish a fee for the processing of an application for
7 restoration of a license or certificate to pay all expenses of
8 processing this application. The Director may waive the fines
9 due under this Section in individual cases where the Director
10 finds that the fines would be unreasonable or unnecessarily
11 burdensome.

12 (d) The Department shall maintain a roster of the names and
13 addresses of all registrants and of all persons whose licenses
14 have been suspended or revoked. This roster shall be available
15 upon written request and payment of the required fee.

16 (e) A manufacturer of controlled substances, ~~or~~ wholesale
17 distributor of controlled substances, or third-party logistics
18 provider that is licensed under this Act and owned and operated
19 by the State is exempt from licensure, registration, renewal,
20 and other fees required under this Act. Nothing in this
21 subsection (e) shall be construed to prohibit the Department
22 from imposing any fine or other penalty allowed under this Act.

23 (Source: P.A. 95-689, eff. 10-29-07.)

24 (225 ILCS 120/40) (from Ch. 111, par. 8301-40)

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

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

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

15 (225 ILCS 120/57)

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

17 Sec. 57. Pedigree.

18 (a) Each person who is engaged in the wholesale
19 distribution of prescription drugs, including repackagers, but
20 excluding the original manufacturer of the finished form of the
21 prescription drug, that leave or have ever left the normal
22 distribution channel shall, before each wholesale distribution
23 of the drug, provide a pedigree to the person who receives the
24 drug. A retail pharmacy, mail order pharmacy, or chain pharmacy
25 warehouse must comply with the requirements of this Section

1 only if the pharmacy or chain pharmacy warehouse engages in the
2 wholesale distribution of prescription drugs. On or before July
3 1, 2009, the Department shall determine a targeted
4 implementation date for electronic track and trace pedigree
5 technology. This targeted implementation date shall not be
6 sooner than July 1, 2010. Beginning on the date established by
7 the Department, pedigrees may be implemented through an
8 approved and readily available system that electronically
9 tracks and traces the wholesale distribution of each
10 prescription drug starting with the sale by the manufacturer
11 through acquisition and sale by any wholesale distributor and
12 until final sale to a pharmacy or other authorized person
13 administering or dispensing the prescription drug. This
14 electronic tracking system shall be deemed to be readily
15 available only upon there being available a standardized system
16 originating with the manufacturers and capable of being used on
17 a wide scale across the entire pharmaceutical chain, including
18 manufacturers, wholesale distributors, third-party logistics
19 providers, and pharmacies. Consideration must also be given to
20 the large-scale implementation of this technology across the
21 supply chain and the technology must be proven to have no
22 negative impact on the safety and efficacy of the
23 pharmaceutical product.

24 (b) Each person who is engaged in the wholesale
25 distribution of a prescription drug who is provided a pedigree
26 for a prescription drug and attempts to further distribute that

1 prescription drug, including repackagers, but excluding the
2 original manufacturer of the finished form of the prescription
3 drug, must affirmatively verify before any distribution of a
4 prescription drug occurs that each transaction listed on the
5 pedigree has occurred.

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

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

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

21 (3) Transaction dates.

22 (4) Certification that each recipient has
23 authenticated the pedigree.

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

26 (1) The name and national drug code number of the

1 prescription drug.

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

4 (3) The size of the container.

5 (4) The number of containers.

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

7 (6) The name of the manufacturer of the finished dosage
8 form.

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

14 (Source: P.A. 95-689, eff. 10-29-07.)

15 (225 ILCS 120/80) (from Ch. 111, par. 8301-80)

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

17 Sec. 80. Violations of Act.

18 (a) If any person violates the provisions of this Act, the
19 Director may, in the name of the People of the State of
20 Illinois through the Attorney General of the State of Illinois
21 or the State's Attorney of any county in which the action is
22 brought, petition for an order enjoining the violation or for
23 an order enforcing compliance with this Act. Upon the filing of
24 a verified petition in the court, the court may issue a
25 temporary restraining order, without notice or bond, and may

1 preliminarily and permanently enjoin the violation. If it is
2 established that the person has violated or is violating the
3 injunction, the Court may punish the offender for contempt of
4 court. Proceedings under this Section shall be in addition to,
5 and not in lieu of, all other remedies and penalties provided
6 by this Act.

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

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

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

23 (225 ILCS 120/155) (from Ch. 111, par. 8301-155)

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

25 Sec. 155. Temporary suspension of license; hearing. The

1 Director may temporarily suspend licensure as a wholesale drug
2 distributor or third-party logistics provider, without a
3 hearing, simultaneously with the institution of proceedings
4 for a hearing provided for in Section 85 of this Act, if the
5 Director finds that evidence in his or her possession indicates
6 that a continuation in business would constitute an imminent
7 danger to the public. In the event that the Director
8 temporarily suspends a license or certificate without a
9 hearing, a hearing by the Department must be held within 10
10 days after the suspension has occurred and be concluded without
11 appreciable delay.

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

13 Section 99. Effective date. This Act takes effect upon
14 becoming law."