11

12

13

14

15

16

17

18

19

20

21

22

2.3

1 AN ACT concerning regulation.

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

- Section 3. The Pharmacy Practice Act is amended by changing

 Section 4 as follows:
- 6 (225 ILCS 85/4) (from Ch. 111, par. 4124)
- 7 (Section scheduled to be repealed on January 1, 2020)
- 8 Sec. 4. Exemptions. Nothing contained in any Section of 9 this Act shall apply to, or in any manner interfere with:
 - (a) the lawful practice of any physician licensed to practice medicine in all of its branches, dentist, podiatric physician, veterinarian, or therapeutically or diagnostically certified optometrist within the limits of his or her license, or prevent him or her from supplying to his or her bona fide patients such drugs, medicines, or poisons as may seem to him appropriate;
 - (b) the sale of compressed gases;
 - (c) the sale of patent or proprietary medicines and household remedies when sold in original and unbroken packages only, if such patent or proprietary medicines and household remedies be properly and adequately labeled as to content and usage and generally considered and accepted as harmless and nonpoisonous when used according to the

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

directions on the label, and also do not contain opium or coca leaves, or any compound, salt or derivative thereof, or any drug which, according to the latest editions of the authoritative pharmaceutical treatises following standards, namelv, The United Pharmacopoeia/National Formulary (USP/NF), the United States Dispensatory, and the Accepted Dental Remedies of the Council of Dental Therapeutics of the American Dental Association or any or either of them, in use on the effective date of this Act, or according to the existing provisions of the Federal Food, Drug, and Cosmetic Act and Regulations of the Department of Health and Human Services, Food and Drug Administration, promulgated thereunder now in effect, is designated, described or considered as a narcotic, hypnotic, habit forming, dangerous, or poisonous drug;

- (d) the sale of poultry and livestock remedies in original and unbroken packages only, labeled for poultry and livestock medication;
- (e) the sale of poisonous substances or mixture of poisonous substances, in unbroken packages, for nonmedicinal use in the arts or industries or for insecticide purposes; provided, they are properly and adequately labeled as to content and such nonmedicinal usage, in conformity with the provisions of all applicable federal, state and local laws and regulations promulgated

thereunder now in effect relating thereto and governing the same, and those which are required under such applicable laws and regulations to be labeled with the word "Poison", are also labeled with the word "Poison" printed thereon in prominent type and the name of a readily obtainable antidote with directions for its administration;

- (f) the delegation of limited prescriptive authority by a physician licensed to practice medicine in all its branches to a physician assistant under Section 7.5 of the Physician Assistant Practice Act of 1987. This delegated authority under Section 7.5 of the Physician Assistant Practice Act of 1987 may, but is not required to, include prescription of controlled substances, as defined in Article II of the Illinois Controlled Substances Act, in accordance with a written supervision agreement;
- (g) the delegation of prescriptive authority by a physician licensed to practice medicine in all its branches or a licensed podiatric physician to an advanced practice registered nurse in accordance with a written collaborative agreement under Sections 65-35 and 65-40 of the Nurse Practice Act; and
- (h) the sale or distribution of dialysate or devices necessary to perform home peritoneal renal dialysis for patients with end-stage renal disease, provided that all of the following conditions are met:
 - (1) the dialysate, comprised of dextrose or

icodextrin, or devices are approved or cleared by the
federal Food and Drug Administration, as required by
federal law;

- (2) the dialysate or devices are lawfully held by a manufacturer or the manufacturer's agent, which is properly registered with the Board as a manufacturer, third-party logistics provider, or wholesaler;
- (3) the dialysate or devices are held and delivered to the manufacturer or the manufacturer's agent in the original, sealed packaging from the manufacturing facility;
- (4) the dialysate or devices are delivered only upon receipt of a physician's prescription by a licensed pharmacy in which the prescription is processed in accordance with provisions set forth in this Act, and the transmittal of an order from the licensed pharmacy to the manufacturer or the manufacturer's agent; and
- (5) the manufacturer or the manufacturer's agent delivers the dialysate or devices directly to: (i) a patient with end-stage renal disease, or his or her designee, for the patient's self-administration of the dialysis therapy or (ii) a health care provider or institution for administration or delivery of the dialysis therapy to a patient with end-stage renal disease.

100-863, eff. 8-14-18.)

- This paragraph (h) does not include any other drugs for peritoneal dialysis, except dialysate, as described in item (1) of this paragraph (h). All records of sales and distribution of dialysate to patients made pursuant to this paragraph (h) must be retained in accordance with Section 18 of this Act.
- 7 (Source: P.A. 100-218, eff. 8-18-17; 100-513, eff. 1-1-18;
- 9 Section 10. The Wholesale Drug Distribution Licensing Act
 10 is amended by changing Sections 15, 20, 26, 30, 35, 40, 57, 80,
 11 and 155 and by adding Section 25.5 as follows:
- 12 (225 ILCS 120/15) (from Ch. 111, par. 8301-15)
- 13 (Section scheduled to be repealed on January 1, 2023)
- 14 Sec. 15. Definitions. As used in this Act:
- "Authentication" means the affirmative verification, before any wholesale distribution of a prescription drug occurs, that each transaction listed on the pedigree has
- 18 occurred.

8

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

- distributor, as defined in Section 1504 of the Internal Revenue

 Code, complies with the following:
 - (1) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and
 - (2) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.
- "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
- "Blood component" means that part of blood separated by physical or mechanical means.
- "Board" means the State Board of Pharmacy of the Department of Professional Regulation.
 - "Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of the drugs to a group of chain or mail order pharmacies that have the same common ownership and control. Notwithstanding any other provision of this Act, a chain pharmacy warehouse shall be considered part of the normal distribution channel.
 - "Co-licensed partner or product" means an instance where one or more parties have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the FDA's implementation of the Prescription Drug

1 Marketing Act.

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

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

"Drop shipment" means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug or that manufacturer's co-licensed product partner, that manufacturer's third party logistics provider, or manufacturer's exclusive distributor or by an authorized distributor of record that purchased the product directly from the manufacturer or one of these entities whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such prescription drug and the wholesale distributor invoices the pharmacy, chain pharmacy warehouse, or other person authorized by law to dispense or administer such drug to a patient and the pharmacy, chain pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from the manufacturer, that manufacturer's third party logistics provider, or manufacturer's exclusive distributor or from an authorized distributor of record that purchased the product directly from the manufacturer or one of these entities.

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

"Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or

offered for sale, or a facility of a third-party logistics

2 provider where prescription drugs are stored or handled.

Prescription Drug Marketing Act.

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

"Manufacturer" means a person licensed or approved by the FDA to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" set forth in the FDA's regulations and guidances implementing the

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

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

(1) a pharmacy or to other designated persons

authorized by law to dispense or administer the drug to a patient;

- (2) a wholesale distributor to a pharmacy or other designated persons authorized by law to dispense or administer the drug to a patient;
- (3) a wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer the drug to a patient;
- (4) a chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy or other designated persons authorized by law to dispense or administer the drug to the patient;
- (5) an authorized distributor of record to one other authorized distributor of record to an office-based health care practitioner authorized by law to dispense or administer the drug to the patient; or
- (6) an authorized distributor to a pharmacy or other persons licensed to dispense or administer the drug.

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

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

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

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

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

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

"Third-party Third party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the

1	prescription drug or have general responsibility to direct the
2	prescription drug's sale or disposition. A third party
3	logistics provider must be licensed as a wholesale distributor
4	under this Act and, in order to be considered part of the
5	normal distribution channel, must also be an authorized
6	distributor of record.

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

but does not include any of the following:

- (1) Intracompany sales of prescription drugs, meaning (i) any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity or (ii) any transaction or transfer between co-licensees of a co-licenseed product.
- (2) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons.
- (3) The distribution of prescription drug samples by manufacturers' representatives.
- (4) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with federal regulation.
- (5) The sale of minimal quantities of prescription drugs by licensed pharmacies to licensed practitioners for

office use or other licensed pharmacies.

- (6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.
- (7) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.
- (8) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel.
- (9) The delivery of or the offer to deliver a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs when the common carrier does not store, warehouse, or take legal ownership of the prescription drug.
- (10) The sale or transfer from a retail pharmacy, mail order pharmacy, or chain pharmacy warehouse of expired,

5

6

7

8

9

10

11

12

13

14

15

16

17

20

21

22

23

24

25

damaged, returned, or recalled prescription drugs to the original manufacturer, the originating wholesale

distributor, or a third party returns processor.

"Wholesale drug distributor" means anyone engaged in the wholesale distribution of prescription drugs into, out of, or within the State, including without limitation manufacturers; repackers; own label distributors; jobbers; private label distributors; brokers; warehouses, including manufacturers' distributors' warehouses: manufacturer's exclusive and distributors; and authorized distributors of record; wholesalers or distributors; independent wholesale traders; specialty wholesale distributors; third party logistics providers; and retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. In order to be considered part of the normal distribution channel, a wholesale distributor must also be an authorized distributor of record.

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

19 (225 ILCS 120/20) (from Ch. 111, par. 8301-20)

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

Sec. 20. Prohibited drug purchases or receipt. It shall be unlawful for any person or entity located in this State to knowingly receive any prescription drug from any source other than a person or entity required by the laws of this State to be licensed to ship into, out of, or within this State. A

- 1 person or entity licensed under the laws of this State shall
- 2 include, but is not limited to, a wholesale distributor,
- 3 manufacturer, third-party logistics provider, pharmacy
- 4 distributor, or pharmacy. Any person violating this Section
- 5 shall, upon conviction, be adjudged guilty of a Class C
- 6 misdemeanor. A second violation shall constitute a Class 4
- 7 felony.
- 8 (Source: P.A. 97-804, eff. 1-1-13.)
- 9 (225 ILCS 120/25.5 new)
- 10 Sec. 25.5. Third-party logistics providers.
- 11 (a) Each resident third-party logistics provider must be
- 12 licensed by the Department, and every non-resident third-party
- 13 logistics provider must be licensed in this State, in
- 14 accordance with this Act, prior to shipping a prescription drug
- 15 into this State.
- 16 (b) The Department shall require, without limitation, all
- of the following information from each applicant for licensure
- 18 under this Act:
- 19 (1) The name, full business address, and telephone
- 20 number of the licensee.
- 21 (2) All trade or business names used by the licensee.
- 22 (3) Addresses, telephone numbers, and the names of
- contact persons for all facilities used by the licensee for
- 24 <u>the storage, handling, and distribution of prescription</u>
- drugs.

25

26

Department.

1	(4) The type of ownership or operation, such as a
2	partnership, corporation, or sole proprietorship.
3	(5) The name of the owner or operator of the
4	third-party logistics provider, including:
5	(A) if a natural person, the name of the natural
6	person;
7	(B) if a partnership, the name of each partner and
8	the name of the partnership;
9	(C) if a corporation, the name and title of each
10	corporate officer and director, the corporate names,
11	and the name of the state of incorporation; and
12	(D) if a sole proprietorship, the full name of the
13	sole proprietor and the name of the business entity.
14	(6) A list of all licenses and permits issued to the
15	applicant by any other state that authorizes the applicant
16	to purchase or possess prescription drugs.
17	(7) The name of the designated representative for the
18	third-party logistics provider, together with the personal
19	information statement and fingerprints, as required under
20	subsection (c) of this Section.
21	(8) Minimum liability insurance and other insurance as
22	defined by rule.
23	(9) Any additional information required by the

(c) Each third-party logistics provider must designate an

individual representative who shall serve as the contact person

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

1	for	the I	Depart	tment	- •	Thi	s represe	entative	must	provide	the
2	D			- 1 1		±1	£-11	c			
_	рера:	rtment	Wltn	атт	ΟI	tne	following	, iniorma	tion:		

- (1) Information concerning whether the person has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or State law regulating the possession, control, or distribution of prescription drugs or criminal violations, together with details concerning any such event.
- (2) A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party.
- (3) A description of any misdemeanor or felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication of quilt was withheld or whether the person pled guilty or nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the Department a copy of the final written order of disposition.
- (4) The designated representative of an applicant for licensure as a third-party logistics provider shall have his or her fingerprints submitted to the Department of

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

State Police in an electronic format that complies with the form and manner for requesting and furnishing criminal history record information as prescribed by the Department of State Police. These fingerprints shall be checked against the Department of State Police and Federal Bureau of Investigation criminal history record databases now and hereafter filed. The Department of State Police shall charge applicants a fee for conducting the criminal history records check, which shall be deposited into the State Police Services Fund and shall not exceed the actual cost of the records check. The Department of State Police shall furnish, pursuant to positive identification, records of Illinois convictions to the Department. The Department may require applicants to pay a separate fingerprinting fee, either to the Department or to a vendor. The Department, in its discretion, may allow an applicant who does not have reasonable access to a designated vendor to provide his or her fingerprints in an alternative manner. The Department may adopt any rules necessary to implement this paragraph (4).

- (d) A third-party logistics provider shall not operate from a place of residence.
- (e) A third-party logistics provider facility shall be located apart and separate from any retail pharmacy licensed by the Department.
 - (f) The Department may not issue a third-party logistics

1	provider license to an applicant, unless the Department first:
2	(1) ensures that a physical inspection of the facility
3	satisfactory to the Department has occurred at the address
4	provided by the applicant, as required under item (1) of
5	subsection (b) of this Section; such inspection is not
6	required if the resident state of the third-party logistics
7	provider facility does not license third-party logistics
8	providers or if the resident state does not inspect
9	third-party logistics providers. If the resident state
10	does not inspect third-party logistics providers, a
11	Verified Accredited Wholesale Distributors Accreditation
12	or other inspection approved by the Department meets this
13	requirement; and
14	(2) determines that the designated representative
15	meets each of the following qualifications:
16	(A) He or she is at least 21 years of age.
17	(B) He or she is employed by the applicant full
18	time in a managerial level position.
19	(C) He or she is actively involved in and aware of
20	the actual daily operation of third-party logistics
21	provider.
22	(g) A third-party logistics provider shall publicly
23	display all licenses and have the most recent state and federal

inspection reports readily available.

24

25

- 1 (Section scheduled to be repealed on January 1, 2023)
- 2 Sec. 26. Unlicensed practice; violation; civil penalty.
- 3 (a) Any person who practices, offers to practice, attempts to practice, or holds oneself out to practice as a wholesale 4 5 drug distributor, or pharmacy distributor, or third-party <u>logistics provider</u> without being licensed to ship into, out of, 6 7 or within the State under this Act shall, in addition to any 8 other penalty provided by law, pay a civil penalty to the 9 Department in an amount not to exceed \$10,000 for each offense 10 as determined by the Department. The civil penalty shall be 11 assessed by the Department after a hearing is held in 12 accordance with the provisions set forth in this Act regarding the provision of a hearing for the discipline of a licensee. 13
- 14 (b) The Department has the authority and power to investigate any and all unlicensed activity.
- 16 (c) The civil penalty shall be paid within 60 days after
 17 the effective date of the order imposing the civil penalty. The
 18 order shall constitute a judgment and may be filed and
 19 execution had thereon in the same manner as any judgment from
 20 any court of record.
- 21 (Source: P.A. 97-804, eff. 1-1-13.)
- 22 (225 ILCS 120/30) (from Ch. 111, par. 8301-30)
- 23 (Section scheduled to be repealed on January 1, 2023)
- Sec. 30. License renewal application procedures.
- 25 Application blanks for renewal of any license required by this

- 1 Act shall be mailed <u>or emailed</u> to each licensee at least 60
- 2 days before the license expires. If the application for renewal
- 3 with the required fee is not received by the Department before
- 4 the expiration date, the existing license shall lapse and
- 5 become null and void. Failure to renew before the expiration
- 6 date is cause for a late payment penalty, discipline, or both.
- 7 (Source: P.A. 87-594.)
- 8 (225 ILCS 120/35) (from Ch. 111, par. 8301-35)
- 9 (Section scheduled to be repealed on January 1, 2023)
- 10 Sec. 35. Fees; Illinois State Pharmacy Disciplinary Fund.
- 11 (a) The Department shall provide by rule for a schedule of
- 12 fees for the administration and enforcement of this Act,
- including but not limited to original licensure, renewal, and
- restoration. The fees shall be nonrefundable.
- 15 (b) All fees collected under this Act shall be deposited
- into the Illinois State Pharmacy Disciplinary Fund and shall be
- 17 appropriated to the Department for the ordinary and contingent
- 18 expenses of the Department in the administration of this Act.
- 19 Moneys in the Fund may be transferred to the Professions
- 20 Indirect Cost Fund as authorized by Section 2105-300 of the
- 21 Department of Professional Regulation Law (20 ILCS
- 22 2105/2105-300).
- The moneys deposited into the Illinois State Pharmacy
- 24 Disciplinary Fund shall be invested to earn interest which
- 25 shall accrue to the Fund.

2

3

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

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

(c) Any person who delivers a check or other payment to the Department that is returned to the Department unpaid by the financial institution upon which it is drawn shall pay to the Department, in addition to the amount already owed to the Department, a fine of \$50. The fines imposed by this Section are in addition to any other discipline provided under this Act for unlicensed practice or practice on a nonrenewed license. The Department shall notify the person that payment of fees and fines shall be paid to the Department by certified check or money order within 30 calendar days of the notification. If, after the expiration of 30 days from the date of notification, the person has failed to submit the necessary remittance, the Department shall automatically terminate the license or certificate or deny the application, without hearing. If, after termination or denial, the person seeks a license or certificate, he or she shall apply to the Department for restoration or issuance of the license or certificate and pay all fees and fines due to the Department. The Department may establish a fee for the processing of an application for restoration of a license or certificate to pay all expenses of processing this application. The Director may waive the fines

- due under this Section in individual cases where the Director
- finds that the fines would be unreasonable or unnecessarily
- 3 burdensome.
- 4 (d) The Department shall maintain a roster of the names and
- 5 addresses of all registrants and of all persons whose licenses
- 6 have been suspended or revoked. This roster shall be available
- 7 upon written request and payment of the required fee.
- 8 (e) A manufacturer of controlled substances, or wholesale
- 9 distributor of controlled substances, or third-party logistics
- 10 provider that is licensed under this Act and owned and operated
- 11 by the State is exempt from licensure, registration, renewal,
- 12 and other fees required under this Act. Nothing in this
- 13 subsection (e) shall be construed to prohibit the Department
- from imposing any fine or other penalty allowed under this Act.
- 15 (Source: P.A. 95-689, eff. 10-29-07.)
- 16 (225 ILCS 120/40) (from Ch. 111, par. 8301-40)
- 17 (Section scheduled to be repealed on January 1, 2023)
- 18 Sec. 40. Rules and regulations. The Department shall make
- any rules and regulations, not inconsistent with law, as may be
- 20 necessary to carry out the purposes and enforce the provisions
- 21 of this Act. Rules and regulations that incorporate and set
- 22 detailed standards for meeting each of the license
- 23 prerequisites set forth in Section 25 of this Act shall be
- 24 adopted no later than September 14, 1992. All rules and
- 25 regulations promulgated under this Section shall conform to

- 1 wholesale drug distributor licensing guidelines formally
- 2 adopted by the FDA at 21 C.F.R. Part 205. In case of conflict
- 3 between any rule or regulation adopted by the Department and
- 4 any FDA wholesale drug distributor or third-party logistics
- 5 provider guideline, the FDA guideline shall control.
- 6 (Source: P.A. 87-594.)
- 7 (225 ILCS 120/57)
- 8 (Section scheduled to be repealed on January 1, 2023)
- 9 Sec. 57. Pedigree.
- 10 person who is engaged in the wholesale 11 distribution of prescription drugs, including repackagers, but 12 excluding the original manufacturer of the finished form of the prescription drug, that leave or have ever left the normal 13 distribution channel shall, before each wholesale distribution 14 15 of the drug, provide a pedigree to the person who receives the 16 drug. A retail pharmacy, mail order pharmacy, or chain pharmacy warehouse must comply with the requirements of this Section 17 only if the pharmacy or chain pharmacy warehouse engages in the 18 wholesale distribution of prescription drugs. On or before July 19 20 the 1, 2009, Department shall determine а targeted 21 implementation date for electronic track and trace pedigree 22 technology. This targeted implementation date shall not be sooner than July 1, 2010. Beginning on the date established by 23 the Department, pedigrees may be implemented through an 24 25 approved and readily available system that electronically

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

wholesale distribution tracks and traces the of each prescription drug starting with the sale by the manufacturer through acquisition and sale by any wholesale distributor and until final sale to a pharmacy or other authorized person administering or dispensing the prescription drug. electronic tracking system shall be deemed to be readily available only upon there being available a standardized system originating with the manufacturers and capable of being used on a wide scale across the entire pharmaceutical chain, including manufacturers, wholesale distributors, third-party logistics providers, and pharmacies. Consideration must also be given to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacv of the pharmaceutical product.

- (b) Each person who is engaged in the wholesale distribution of a prescription drug who is provided a pedigree for a prescription drug and attempts to further distribute that prescription drug, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, must affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.
- (c) The pedigree must include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer or the manufacturer's

- 1 third party logistics provider, co-licensed product partner,
- 2 or exclusive distributor through acquisition and sale by any
- 3 wholesale distributor or repackager, until final sale to a
- 4 pharmacy or other person dispensing or administering the drug.
- 5 This necessary chain of distribution information shall
- 6 include, without limitation all of the following:
- 7 (1) The name, address, telephone number and, if 8 available, the e-mail address of each owner of the 9 prescription drug and each wholesale distributor of the
- 10 prescription drug.
- 11 (2) The name and address of each location from which 12 the product was shipped, if different from the owner's.
- 13 (3) Transaction dates.
- 14 (4) Certification that each recipient has
 15 authenticated the pedigree.
- 16 (d) The pedigree must also include without limitation all 17 of the following information concerning the prescription drug:
- 18 (1) The name and national drug code number of the prescription drug.
- 20 (2) The dosage form and strength of the prescription 21 drug.
- 22 (3) The size of the container.
- 23 (4) The number of containers.
- 24 (5) The lot number of the prescription drug.
- 25 (6) The name of the manufacturer of the finished dosage form.

- 1 (e) Each pedigree or electronic file shall be maintained by 2 the purchaser and the wholesale distributor for at least 3
- 3 years from the date of sale or transfer and made available for
- 4 inspection or use within 5 business days upon a request of the
- 5 Department.

25

- 6 (Source: P.A. 95-689, eff. 10-29-07.)
- 7 (225 ILCS 120/80) (from Ch. 111, par. 8301-80)
- 8 (Section scheduled to be repealed on January 1, 2023)
- 9 Sec. 80. Violations of Act.
- 10 (a) If any person violates the provisions of this Act, the 11 Director may, in the name of the People of the State of 12 Illinois through the Attorney General of the State of Illinois or the State's Attorney of any county in which the action is 1.3 14 brought, petition for an order enjoining the violation or for 15 an order enforcing compliance with this Act. Upon the filing of 16 a verified petition in the court, the court may issue a temporary restraining order, without notice or bond, and may 17 18 preliminarily and permanently enjoin the violation. If it is 19 established that the person has violated or is violating the 20 injunction, the Court may punish the offender for contempt of 21 court. Proceedings under this Section shall be in addition to, 22 and not in lieu of, all other remedies and penalties provided 23 by this Act.
 - (b) Whoever knowingly conducts business as a wholesale drug distributor or third-party logistics provider in this State

without being appropriately licensed under this Act shall be guilty of a Class A misdemeanor for a first violation and for each subsequent conviction shall be guilty of a Class 4 felony.

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

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

15 (225 ILCS 120/155) (from Ch. 111, par. 8301-155)

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

Sec. 155. Temporary suspension of license; hearing. The Director may temporarily suspend licensure as a wholesale drug distributor or third-party logistics provider, without a hearing, simultaneously with the institution of proceedings for a hearing provided for in Section 85 of this Act, if the Director finds that evidence in his or her possession indicates that a continuation in business would constitute an imminent danger to the public. In the event that the Director temporarily suspends a license or certificate without a

- 28 LRB101 09712 JRG 54811 b
- hearing, a hearing by the Department must be held within 10 1
- 2 days after the suspension has occurred and be concluded without
- 3 appreciable delay.
- (Source: P.A. 87-594.)
- Section 99. Effective date. This Act takes effect upon 5
- 6 becoming law.