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1

AN ACT concerning regulation.

2 Be it enacted by the People of the State of Illinois, 3 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7 (Section scheduled to be repealed on January 1, 2020)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;

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(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 SB1839 Engrossed - 2 - LRB101 09712 JRG 54811 b

directions on the label, and also do not contain opium or 1 coca leaves, or any compound, salt or derivative thereof, 2 3 or any drug which, according to the latest editions of the authoritative pharmaceutical treatises 4 following and 5 standards, namely, The United States 6 Pharmacopoeia/National Formulary (USP/NF), the United 7 States Dispensatory, and the Accepted Dental Remedies of 8 the Council of Dental Therapeutics of the American Dental 9 Association or any or either of them, in use on the 10 effective date of this Act, or according to the existing 11 provisions of the Federal Food, Drug, and Cosmetic Act and 12 Regulations of the Department of Health and Human Services, Food and Drug Administration, promulgated thereunder now 13 14 in effect, is designated, described or considered as a 15 narcotic, hypnotic, habit forming, dangerous, or poisonous 16 druq;

17 (d) the sale of poultry and livestock remedies in 18 original and unbroken packages only, labeled for poultry 19 and livestock medication;

(e) the sale of poisonous substances or mixture of 20 21 poisonous substances, in unbroken packages, for 22 nonmedicinal use in the arts or industries or for 23 insecticide purposes; provided, they are properly and 24 adequately labeled as to content and such nonmedicinal 25 usage, in conformity with the provisions of all applicable 26 federal, state and local laws and regulations promulgated SB1839 Engrossed - 3 - LRB101 09712 JRG 54811 b

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;

7 (f) the delegation of limited prescriptive authority by a physician licensed to practice medicine in all its 8 9 branches to a physician assistant under Section 7.5 of the 10 Physician Assistant Practice Act of 1987. This delegated 11 authority under Section 7.5 of the Physician Assistant 12 Practice Act of 1987 may, but is not required to, include prescription of controlled substances, as defined in 13 14 Article II of the Illinois Controlled Substances Act, in accordance with a written supervision agreement; 15

16 (g) the delegation of prescriptive authority by a 17 physician licensed to practice medicine in all its branches or a licensed podiatric physician to an advanced practice 18 19 registered nurse in accordance with written а 20 collaborative agreement under Sections 65-35 and 65-40 of the Nurse Practice Act; and 21

(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:

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(1) the dialysate, comprised of dextrose or

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

4 (2) the dialysate or devices are lawfully held by a
5 manufacturer or the manufacturer's agent, which is
6 properly registered with the Board as a manufacturer,
7 <u>third-party logistics provider</u>, or wholesaler;

8 (3) the dialysate or devices are held and delivered 9 to the manufacturer or the manufacturer's agent in the 10 original, sealed packaging from the manufacturing 11 facility;

12 (4) the dialysate or devices are delivered only 13 upon receipt of a physician's prescription by a 14 licensed pharmacy in which the prescription is 15 processed in accordance with provisions set forth in 16 this Act, and the transmittal of an order from the 17 licensed pharmacy to the manufacturer or the 18 manufacturer's agent; and

19 (5) the manufacturer or the manufacturer's agent 20 delivers the dialysate or devices directly to: (i) a 21 patient with end-stage renal disease, or his or her 22 designee, for the patient's self-administration of the 23 dialysis therapy or (ii) a health care provider or 24 institution for administration or delivery of the 25 dialysis therapy to a patient with end-stage renal 26 disease.

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

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:

15 "Authentication" means the affirmative verification, 16 before any wholesale distribution of a prescription drug 17 occurs, that each transaction listed on the pedigree has 18 occurred.

19 "Authorized distributor of record" means a wholesale 20 distributor with whom a manufacturer has established an ongoing 21 relationship to distribute the manufacturer's prescription 22 drug. An ongoing relationship is deemed to exist between a 23 wholesale distributor and a manufacturer when the wholesale 24 distributor, including any affiliated group of the wholesale SB1839 Engrossed - 6 - LRB101 09712 JRG 54811 b

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

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

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

10 "Blood" means whole blood collected from a single donor and 11 processed either for transfusion or further manufacturing.

12 "Blood component" means that part of blood separated by 13 physical or mechanical means.

14 "Board" means the State Board of Pharmacy of the Department 15 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 SB1839 Engrossed

1 Marketing Act.

2 "Department" means the Department of Financial and3 Professional Regulation.

"Drop shipment" means the sale of a prescription drug to a 4 wholesale distributor by the manufacturer of the prescription 5 drug or that manufacturer's co-licensed product partner, that 6 7 manufacturer's third party logistics provider, or that manufacturer's exclusive distributor or by an authorized 8 9 distributor of record that purchased the product directly from 10 the manufacturer or one of these entities whereby the wholesale 11 distributor or chain pharmacy warehouse takes title but not 12 physical possession of such prescription drug and the wholesale 13 distributor invoices the pharmacy, chain pharmacy warehouse, or other person authorized by law to dispense or administer 14 15 such drug to a patient and the pharmacy, chain pharmacy 16 warehouse, or other authorized person receives delivery of the 17 prescription drug directly from the manufacturer, that manufacturer's third party logistics provider, or 18 that manufacturer's exclusive distributor or from an authorized 19 20 distributor of record that purchased the product directly from the manufacturer or one of these entities. 21

"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.

25 "Facility" means a facility of a wholesale distributor 26 where prescription drugs are stored, handled, repackaged, or SB1839 Engrossed - 8 - LRB101 09712 JRG 54811 b

offered for sale, or a facility of a third-party logistics
 provider where prescription drugs are stored or handled.

"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
Prescription Drug Marketing Act.

"Manufacturer's exclusive distributor" means anyone who 9 10 contracts with a manufacturer to provide or coordinate 11 warehousing, distribution, or other services on behalf of a 12 manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility 13 to direct the sale or disposition of the manufacturer's 14 15 prescription drug. A manufacturer's exclusive distributor must 16 be licensed as a wholesale distributor under this Act and, in 17 order to be considered part of the normal distribution channel, must also be an authorized distributor of record. 18

"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:

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(1) a pharmacy or to other designated persons

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1 authorized by law to dispense or administer the drug to a 2 patient;

3 (2) a wholesale distributor to a pharmacy or other 4 designated persons authorized by law to dispense or 5 administer the drug to a patient;

6 (3) a wholesale distributor to a chain pharmacy 7 warehouse to that chain pharmacy warehouse's intracompany 8 pharmacy to a patient or other designated persons 9 authorized by law to dispense or administer the drug to a 10 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;

15 (5) an authorized distributor of record to one other 16 authorized distributor of record to an office-based health 17 care practitioner authorized by law to dispense or 18 administer the drug to the patient; or

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

21 "Pedigree" means a document or electronic file containing 22 information that records each wholesale distribution of any 23 given prescription drug from the point of origin to the final 24 wholesale distribution point of any given prescription drug.

25 "Person" means and includes a natural person, partnership,26 association, corporation, or any other legal business entity.

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

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 pharmacist 20 responsible for dispensing the product to a patient.

21 "Secretary" means the Secretary of Financial and22 Professional Regulation.

23 "<u>Third-party</u> Third party logistics provider" means anyone 24 who contracts with a prescription drug manufacturer to provide 25 or coordinate warehousing, distribution, or other services on 26 behalf of a manufacturer, but does not take title to the SB1839 Engrossed - 11 - LRB101 09712 JRG 54811 b

prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third party logistics provider 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.

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

10 (1) Intracompany sales of prescription drugs, meaning 11 (i) any transaction or transfer between any division, 12 subsidiary, parent, or affiliated or related company under 13 the common ownership and control of a corporate entity or 14 (ii) any transaction or transfer between co-licensees of a 15 co-licensed product.

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

20 (3) The distribution of prescription drug samples by
 21 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

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office use or other licensed pharmacies.

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

5 (7) The sale, transfer, merger, or consolidation of all 6 or part of the business of a pharmacy or pharmacies from or 7 with another pharmacy or pharmacies, whether accomplished 8 as a purchase and sale of stock or business assets.

9 The sale, purchase, distribution, trade, or (8) 10 transfer of a prescription drug from one authorized 11 distributor of record to one additional authorized 12 distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record 13 14 that the manufacturer is unable to supply the prescription 15 drug and the supplying authorized distributor of record 16 states in writing that the prescription drug being supplied had until that time been exclusively in the normal 17 distribution channel. 18

(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,

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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 4 5 wholesale distribution of prescription drugs into, out of, or within the State, including without limitation manufacturers; 6 repackers; own label distributors; jobbers; private label 7 distributors; brokers; warehouses, including manufacturers' 8 9 distributors' warehouses; manufacturer's exclusive and distributors; and authorized distributors of record; 10 druq 11 wholesalers or distributors; independent wholesale druq 12 traders; specialty wholesale distributors; third party logistics providers; and retail pharmacies that conduct 13 wholesale distribution; and chain pharmacy warehouses that 14 15 conduct wholesale distribution. In order to be considered part 16 of the normal distribution channel, a wholesale distributor must also be an authorized distributor of record. 17

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

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

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(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

person or entity licensed under the laws of this State shall include, but is not limited to, a wholesale distributor, manufacturer, <u>third-party logistics provider</u>, pharmacy distributor, or pharmacy. Any person violating this Section shall, upon conviction, be adjudged guilty of a Class C misdemeanor. A second violation shall constitute a Class 4 felony.

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

9 (225 ILCS 120/25.5 new)

10 <u>Sec. 25.5. Third-party logistics providers.</u>

11 (a) Each resident third-party logistics provider must be 12 licensed by the Department, and every non-resident third-party logistics provider must be licensed in this State, in 13 accordance with this Act, prior to shipping a prescription drug 14 15 into this State. 16 (b) The Department shall require, without limitation, all of the following information from each applicant for licensure 17 18 under this Act: (1) The name, full business address, and telephone 19

20 <u>number of the licensee.</u>

21 (2) All trade or business names used by the licensee.
 22 (3) Addresses, telephone numbers, and the names of
 23 contact persons for all facilities used by the licensee for
 24 the storage, handling, and distribution of prescription
 25 drugs.

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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
24	Department.
25	(c) Each third-party logistics provider must designate an
26	individual representative who shall serve as the contact person

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

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

9 (2) A description of any involvement by the person with 10 any business, including any investments, other than the 11 ownership of stock in a publicly traded company or mutual 12 fund, that manufactured, administered, prescribed, 13 distributed, or stored pharmaceutical products and any 14 lawsuits in which such businesses were named as a party.

15 (3) A description of any misdemeanor or felony criminal 16 offense of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or 17 18 whether the person pled guilty or nolo contendere. If the 19 person indicates that a criminal conviction is under appeal 20 and submits a copy of the notice of appeal of that criminal offense, the applicant must, within 15 days after the 21 22 disposition of the appeal, submit to the Department a copy 23 of the final written order of disposition.

24(4) The designated representative of an applicant for25licensure as a third-party logistics provider shall have26his or her fingerprints submitted to the Department of

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1	State Police in an electronic format that complies with the
2	form and manner for requesting and furnishing criminal
3	history record information as prescribed by the Department
4	of State Police. These fingerprints shall be checked
5	against the Department of State Police and Federal Bureau
6	of Investigation criminal history record databases now and
7	hereafter filed. The Department of State Police shall
8	charge applicants a fee for conducting the criminal history
9	records check, which shall be deposited into the State
10	Police Services Fund and shall not exceed the actual cost
11	of the records check. The Department of State Police shall
12	furnish, pursuant to positive identification, records of
13	Illinois convictions to the Department. The Department may
14	require applicants to pay a separate fingerprinting fee,
15	either to the Department or to a vendor. The Department, in
16	its discretion, may allow an applicant who does not have
17	reasonable access to a designated vendor to provide his or
18	her fingerprints in an alternative manner. The Department
19	may adopt any rules necessary to implement this paragraph
20	(4).
21	(d) A third-party logistics provider shall not operate from
22	a place of residence.
23	(e) A third-party logistics provider facility shall be
24	located apart and separate from any retail pharmacy licensed by
25	the Department.
26	(f) The Department may not issue a third-party logistics

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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
24	inspection reports readily available.

25 (225 ILCS 120/26)

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1 2 (Section scheduled to be repealed on January 1, 2023) 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 logistics provider 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 15 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.)

(225 ILCS 120/30) (from Ch. 111, par. 8301-30)
 (Section scheduled to be repealed on January 1, 2023)
 Sec. 30. License renewal application procedures.
 Application blanks for renewal of any license required by this

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Act shall be mailed <u>or emailed</u> to each licensee at least 60 days before the license expires. If the application for renewal with the required fee is not received by the Department before the expiration date, the existing license shall lapse and become null and void. Failure to renew before the expiration date is cause for a late payment penalty, discipline, or both. (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.

(a) The Department shall provide by rule for a schedule of 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 16 into the Illinois State Pharmacy Disciplinary Fund and shall be appropriated to the Department for the ordinary and contingent 17 expenses of the Department in the administration of this Act. 18 Moneys in the Fund may be transferred to the Professions 19 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 Disciplinary Fund shall be invested to earn interest which shall accrue to the Fund. SB1839 Engrossed - 21 - LRB101 09712 JRG 54811 b

1 The Department shall present to the Board for its review 2 and comment all appropriation requests from the Illinois State 3 Pharmacy Disciplinary Fund. The Department shall give due 4 consideration to any comments of the Board in making 5 appropriation requests.

(c) Any person who delivers a check or other payment to the 6 7 Department that is returned to the Department unpaid by the 8 financial institution upon which it is drawn shall pay to the 9 Department, in addition to the amount already owed to the 10 Department, a fine of \$50. The fines imposed by this Section 11 are in addition to any other discipline provided under this Act 12 for unlicensed practice or practice on a nonrenewed license. 13 The Department shall notify the person that payment of fees and 14 fines shall be paid to the Department by certified check or 15 money order within 30 calendar days of the notification. If, 16 after the expiration of 30 days from the date of the 17 notification, the person has failed to submit the necessary remittance, the Department shall automatically terminate the 18 license or certificate or deny the application, without 19 20 hearing. If, after termination or denial, the person seeks a license or certificate, he or she shall apply to the Department 21 22 for restoration or issuance of the license or certificate and 23 pay all fees and fines due to the Department. The Department 24 may establish a fee for the processing of an application for 25 restoration of a license or certificate to pay all expenses of processing this application. The Director may waive the fines 26

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1 due under this Section in individual cases where the Director 2 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. 14 (Source: P.A. 95-689, eff. 10-29-07.) 15

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 19 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 prerequisites set forth in Section 25 of this Act shall be 23 adopted no later than September 14, 1992. All rules and 24 25 regulations promulgated under this Section shall conform to

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wholesale drug distributor licensing guidelines formally adopted by the FDA at 21 C.F.R. Part 205. In case of conflict between any rule or regulation adopted by the Department and any FDA wholesale drug distributor <u>or third-party logistics</u> <u>provider</u> 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 Each person who is engaged in the wholesale (a) 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 SB1839 Engrossed - 24 - LRB101 09712 JRG 54811 b

1 wholesale distribution tracks and traces the of each 2 prescription drug starting with the sale by the manufacturer through acquisition and sale by any wholesale distributor and 3 until final sale to a pharmacy or other authorized person 4 5 administering or dispensing the prescription drug. This electronic tracking system shall be deemed to be readily 6 available only upon there being available a standardized system 7 8 originating with the manufacturers and capable of being used on 9 a wide scale across the entire pharmaceutical chain, including 10 manufacturers, wholesale distributors, third-party logistics 11 providers, and pharmacies. Consideration must also be given to 12 the large-scale implementation of this technology across the supply chain and the technology must be proven to have no 13 14 negative impact on the safety and efficacv of the 15 pharmaceutical product.

16 (b) Each person who is engaged in the wholesale 17 distribution of a prescription drug who is provided a pedigree for a prescription drug and attempts to further distribute that 18 19 prescription drug, including repackagers, but excluding the 20 original manufacturer of the finished form of the prescription drug, must affirmatively verify before any distribution of a 21 22 prescription drug occurs that each transaction listed on the 23 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

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third party logistics provider, co-licensed product partner, or exclusive distributor through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. This necessary chain of distribution information shall 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 which12 the product was shipped, if different from the owner's.

13

(3) Transaction dates.

14 (4) Certification that each recipient has15 authenticated the pedigree.

16 (d) The pedigree must also include without limitation all17 of the following information concerning the prescription drug:

18 (1) The name and national drug code number of the19 prescription drug.

20 (2) The dosage form and strength of the prescription21 drug.

(3) The size of the container.
(4) The number of containers.
(5) The lot number of the prescription drug.
(6) The name of the manufacturer of the finished dosage form.

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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.

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 13 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 <u>or third-party logistics provider</u> in this State

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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 4 5 not licensed in good standing under this Act violates any provision of this Act, the Department may issue a rule to show 6 7 cause why an order to cease and desist should not be entered 8 against him. The rule shall clearly set forth the grounds 9 relied upon by the Department and shall provide a period of 7 10 days from the date of the rule to file an answer to the 11 satisfaction of the Department. Failure to answer to the 12 satisfaction of the Department shall cause an order to cease 13 and desist to be issued immediately.

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

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

16 (Section scheduled to be repealed on January 1, 2023) Sec. 155. Temporary suspension of license; hearing. The 17 18 Director may temporarily suspend licensure as a wholesale drug distributor or third-party logistics provider, without a 19 20 hearing, simultaneously with the institution of proceedings 21 for a hearing provided for in Section 85 of this Act, if the 22 Director finds that evidence in his or her possession indicates that a continuation in business would constitute an imminent 23 24 danger to the public. In the event that the Director 25 temporarily suspends a license or certificate without a

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hearing, a hearing by the Department must be held within 10 days after the suspension has occurred and be concluded without appreciable delay.

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

5 Section 99. Effective date. This Act takes effect upon6 becoming law.