AN ACT concerning regulation.

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

Section 5. The Wholesale Drug Distribution Licensing Act is amended by changing Sections 15, 26, 31, 40, 50, 56, 60, 80, 155, 185, and 200 and by adding Section 25.7 as follows:

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

(Section scheduled to be repealed on January 1, 2028)

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

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

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

"Authorized distributor of record" means a wholesale distributor or virtual 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 or virtual wholesale distributor and a

manufacturer when the wholesale distributor or virtual wholesale distributor, including any affiliated group of the wholesale distributor or virtual wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following:

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

(2) The wholesale distributor or virtual 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 Financial and 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 Marketing Act.

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

"Drop shipment" means the sale of a prescription drug to a wholesale distributor or virtual 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 that 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, virtual wholesale distributor, or chain pharmacy warehouse takes title but not physical possession of such prescription drug and the wholesale distributor or virtual 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 that 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.

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

"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 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" does not include anyone who is engaged in the packaging, repackaging, or labeling of drugs only to the extent permitted under the Illinois Drug Reuse Opportunity Program Act.

"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 virtual wholesale distributor ~~third-party logistics provider~~, or (iv) that manufacturer to that manufacturer's exclusive distributor or third-party logistics provider 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 the Department of Financial and Professional Regulation.

"Suspicious order" includes, but is not limited to, an order of a controlled substance of unusual size, an order of a controlled substance deviating substantially from a normal pattern, and orders of controlled substances of unusual frequency as defined by 21 U.S.C. 802.

"Third-party logistics provider" means anyone who contracts with a prescription drug manufacturer <u>or virtual wholesale distributor</u> to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer <u>or virtual wholesale distributor</u>, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

"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-licensed 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, damaged, returned, or recalled prescription drugs to the original manufacturer, the originating wholesale distributor, or a third party returns processor.

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

"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' and distributors' warehouses; manufacturer's exclusive distributors; and authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; 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.

"Virtual wholesale distributor" means any person engaged in the wholesale distribution of prescription drugs into, out of, or within the State who holds title to, but does not take physical possession of, prescription drugs.

(Source: P.A. 102-389, eff. 1-1-22; 102-879, eff. 1-1-23; 103-154, eff. 6-30-23.)

(225 ILCS 120/25.7 new)

Sec. 25.7. Virtual wholesale distributor licensing requirements.

(a) Every virtual wholesale distributor that engages in virtual drug distribution of prescription drugs shall be

licensed by the Department. A virtual wholesale distributor shall only contract with entities licensed under this Act to take physical possession of prescription drugs if the prescription drugs are being shipped into the State.

(b) Each applicant for licensure as a virtual wholesale distributor under this Act shall submit the following information to the Department:

(1) the name, full business address, and telephone number of the applicant;

(2) all trade or business names used by the applicant;

(3) addresses, email addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the storage, handling, and distribution of prescription drugs;

(4) the applicant's type of ownership or operation, such as a partnership, corporation, or sole proprietorship;

(5) the name of each person with an ownership or operation interest in the applicant, including the following:

(A) if the applicant is a natural person, the name of the person;

(B) if the applicant is a partnership, the name of each partner and the name of the partnership;

(C) if the applicant is a corporation, the name and title of each person who owns 5% or more of its

stock and each corporate officer and director and the name of the state of incorporation;

(D) if the applicant is a sole proprietorship, the full name of the sole proprietor and the name of the business entity and the state of organization;

(E) if the applicant is a limited liability company, the name and title of each member or manager and the name of the business entity and the state of organization;

(F) if the applicant is a limited liability partnership, the name and title of each partner and the name of the partnership and the state of organization; and

(G) if the applicant is a limited partnership, the name and title of each partner and the name of the partnership and the state of organization;

(6) a list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or facilitate the distribution of prescription drugs;

(7) minimum liability insurance and other insurance as defined by rule;

(8) the name and license number of the third-party logistics provider who provides warehouse and shipping services to the applicant; and

(9) any additional information required by the

Department.

(c) A virtual wholesale distributor shall ensure that any licensed entity providing distribution services to the virtual wholesale distributor complies with the following:

(1) the licensed entity is in compliance with all rules related to storage and distribution of prescription drugs;

(2) the licensed entity has designated a representative who is at least 21 years of age and who has adequate education, experience, and training to be employed by the licensed entity full time in a managerial level position and to be actively involved in and aware of the actual daily operation of the virtual wholesale distributor;

(3) the licensed entity contracts with carriers that provide adequate security to guard against in-transit losses; and

(4) the licensed entity is compliant with Title II of the federal Drug Quality and Security Act.

(d) A virtual wholesale distributor shall not operate out of a location that is a residence or personal dwelling.

(225 ILCS 120/26)

(Section scheduled to be repealed on January 1, 2028)

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

(a) Any person who practices, offers to practice, attempts

to practice, or holds oneself out to practice as a wholesale drug distributor, pharmacy distributor, virtual wholesale distributor, or third-party logistics provider without being licensed to ship into, out of, or within the State under this Act shall, in addition to any other penalty provided by law, pay a civil penalty to the Department in an amount not to exceed $10,000 for each offense as determined by the Department. The civil penalty shall be assessed by the Department after a hearing is held in accordance with the provisions set forth in this Act regarding the provision of a hearing for the discipline of a licensee.

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

(c) The civil penalty shall be paid within 60 days after the effective date of the order imposing the civil penalty. The order shall constitute a judgment and may be filed and execution had thereon in the same manner as any judgment from any court of record.

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

(225 ILCS 120/31)

(Section scheduled to be repealed on January 1, 2028)

Sec. 31. Expiration of license; renewal.

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

(b) Any licensee who shall engage in the practice for

which the license was issued while the license is expired or on inactive status shall be considered to be practicing without a license which shall be grounds for discipline under this Act.

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

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

(Source: P.A. 102-879, eff. 1-1-23.)

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

(Section scheduled to be repealed on January 1, 2028)

Sec. 40. Rules and regulations. The Department shall make any rules and regulations, not inconsistent with law, as may be necessary to carry out the purposes and enforce the provisions of this Act. All rules and regulations promulgated under this Section shall conform to 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, virtual wholesale distributor, or third-party logistics provider guideline, the FDA guideline shall control. (Source: P.A. 101-420, eff. 8-16-19; 102-879, eff. 1-1-23.)

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

(Section scheduled to be repealed on January 1, 2028)

Sec. 50. Inspection powers; access to records.

(a) Any pharmacy investigator authorized by the Department has the right of entry for inspection of premises purporting or appearing to be used by a wholesale drug distributor, virtual wholesale distributor, or third-party logistics provider in this State, including the business premises of a person licensed pursuant to this Act. This right of entry shall permit the authorized pharmacy investigator unfettered access to the entire business premises. Any attempt to hinder an authorized pharmacy investigator from inspecting the business premises and documenting the inspection shall be a violation of this Act. The duly authorized investigators shall be required to show appropriate identification before being given access to the ~~a wholesale drug distributor's~~ premises and delivery vehicles.

(b) With the exception of the most recent 12 months of records that must be kept on the premises where the drugs are stored, wholesale drug distributors, virtual wholesale distributors, and third-party logistics providers may keep records regarding purchase and sales transactions

electronically at a central location apart from the principal office of the wholesale drug distributor or the location at which the drugs were stored and from which they were shipped, provided that the records shall be made readily available for inspection within 2 working days of a request by the Department. The records may be kept in any form permissible under federal law applicable to prescription drugs record keeping.

(c) (Blank).

(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/56)

(Section scheduled to be repealed on January 1, 2028)

Sec. 56. Restrictions on transactions.

(a) A licensee shall receive prescription drug returns or exchanges from a pharmacy or other persons authorized to administer or dispense drugs or a chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor, virtual wholesale distributor, or third-party logistics provider and the pharmacy or chain pharmacy warehouse. Returns of expired, damaged, recalled, or otherwise non-saleable pharmaceutical products shall be distributed by the receiving wholesale distributor or third-party logistics provider only to either the original manufacturer or a third party returns processor. Returns or exchanges of prescription drugs, saleable or otherwise,

including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirements of Section 57 of this Act, so long as they are exempt from the pedigree requirement of the FDA's currently applicable Prescription Drug Marketing Act guidance. Both licensees under this Act and pharmacies or other persons authorized to administer or dispense drugs shall be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

(b) A manufacturer, ~~or~~ wholesale distributor, virtual wholesale distributor, or third-party logistics provider licensed under this Act may furnish prescription drugs only to a person licensed by the appropriate state licensing authorities. Before furnishing prescription drugs to a person not known to the manufacturer or licensee ~~wholesale distributor~~, the manufacturer or licensee ~~wholesale distributor~~ must affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the appropriate state licensing authorities.

(c) Prescription drugs furnished by a manufacturer, ~~or~~ wholesale distributor, virtual wholesale distributor, or third-party logistics provider licensed under this Act may be delivered only to the premises listed on the license, provided that the manufacturer or licensee ~~wholesale distributor~~ may furnish prescription drugs to an authorized person or agent of

that person at the premises of the manufacturer or licensee ~~wholesale distributor~~ if:

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

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

(d) Prescription drugs may be furnished to a hospital pharmacy receiving area, provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Any discrepancy between the receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer, ~~or~~ wholesale distributor, or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.

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

licensee. This subsection (e) shall not be construed to prohibit a pharmacy or chain pharmacy warehouse from receiving prescription drugs if payment for the prescription drugs is processed through the pharmacy's or chain pharmacy warehouse's contractual drug manufacturer or wholesale distributor.

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

(225 ILCS 120/60) (from Ch. 111, par. 8301-60)

(Section scheduled to be repealed on January 1, 2028)

Sec. 60. Wholesaler licensing; complaints. The Department may refuse to issue a license to establish a new licensed wholesale drug distributor, virtual wholesale distributor, or third-party logistics provider ~~distributorship~~, if an owner of the entity ~~wholesale drug distributorship~~ applying for a license was an owner of a wholesale drug distributor, virtual wholesale distributor, or third-party logistics provider ~~distributorship~~ that had its license revoked, unless the owner presents sufficient evidence indicating rehabilitation. Once a complaint has been filed by the Department against a wholesale drug distributor, virtual wholesale distributor, or third-party logistics provider ~~distributorship~~ the Department may refuse to issue a license to establish a new licensed wholesale drug distributor, virtual wholesale distributor, or third-party logistics provider ~~distributorship~~, until such time as the Department issues a decision on the complaint if an owner of the new wholesale drug distributor, virtual wholesale

distributor, or third-party logistics provider ~~distributorship~~ was also an owner of a wholesale drug distributor, virtual wholesale distributor, or third-party logistics provider ~~distributorship~~ against which the complaint was filed. Neither an application for change of ownership nor for a change of location for any such entity ~~wholesale drug distributorship~~ shall be acted on by the Department until such time as the Department issues a decision on the complaint. In the event that the wholesale drug distributor, virtual wholesale distributor, or third-party logistics provider ~~distributorship~~ against which the complaint has been filed ceases to be licensed by the Department, for any reason, before the Department's decision on the complaint and an owner or that wholesale drug distributor, virtual wholesale distributor, or third-party logistics provider ~~distributorship~~ applies for a license to establish a new wholesale drug distributor, virtual wholesale distributor, or third-party logistics provider ~~distributorship~~, the Department shall conduct a hearing on the complaint earlier filed, regardless of whether that wholesale drug distributor, virtual wholesale distributor, or third-party logistics provider ~~distributorship~~ is presently licensed by the Department. If the conduct for which the complaint was originally filed would have been sufficient to result in a revocation of a license to operate a licensed wholesale drug distributor, virtual wholesale distributor, or third-party logistics provider ~~distributorship~~, then the

conduct shall constitute sufficient grounds for denial of an application for a license.

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

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

(Section scheduled to be repealed on January 1, 2028)

Sec. 80. Violations of Act.

(a) If any person violates the provisions of this Act, the Secretary may, in the name of the People of the State of Illinois through the Attorney General of the State of Illinois or the State's Attorney of any county in which the action is brought, petition for an order enjoining the violation or for an order enforcing compliance with this Act. Upon the filing of a verified petition in the court, the court may issue a temporary restraining order, without notice or bond, and may preliminarily and permanently enjoin the violation. If it is established that the person has violated or is violating the injunction, the Court may punish the offender for contempt of court. Proceedings under this Section shall be in addition to, and not in lieu of, all other remedies and penalties provided by this Act.

(b) Whoever knowingly conducts business as a wholesale drug distributor, virtual wholesale 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.

(Source: P.A. 101-420, eff. 8-16-19; 102-879, eff. 1-1-23.)

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

(Section scheduled to be repealed on January 1, 2028)

Sec. 155. Temporary suspension of license; hearing. The Secretary may temporarily suspend licensure as a wholesale drug distributor, virtual wholesale 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 Secretary 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 Secretary temporarily suspends a license or certificate without a hearing, a hearing by the Department must be held within 10

days after the suspension has occurred and be concluded without appreciable delay.

(Source: P.A. 101-420, eff. 8-16-19; 102-879, eff. 1-1-23.)

(225 ILCS 120/185) (from Ch. 111, par. 8301-185)

(Section scheduled to be repealed on January 1, 2028)

Sec. 185. Home rule preemption. The regulation and licensing of wholesale drug distributors, virtual wholesale distributors, and third-party logistics providers are exclusive powers and functions of the State. A home rule unit may not regulate or license wholesale drug distributors, virtual wholesale distributors, and third-party logistics providers. This Section is a denial and limitation of home rule powers and functions under subsection (h) of Section 6 of Article VII of the Illinois Constitution.

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

(225 ILCS 120/200)

(Section scheduled to be repealed on January 1, 2028)

Sec. 200. Drugs in shortage.

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

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

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

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

(e) The Department shall create a centralized, searchable database of those entities licensed to engage in wholesale distribution, including manufacturers, wholesale distributors, virtual wholesale distributors, and pharmacy distributors, to enable purchasers of a drug in shortage to easily verify the licensing status of an entity offering such drugs.

(f) The Department shall establish a system for reporting the reasonable suspicion that a violation of this Act has been committed by a distributor of a drug in shortage. Reports made

through this system shall be referred to the Office of the Attorney General and the appropriate State's Attorney's office for further investigation and prosecution.

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

(h) Nothing in this Section prohibits one hospital pharmacy from purchasing or receiving a drug in shortage from another hospital pharmacy in the event of a medical emergency. (Source: P.A. 102-879, eff. 1-1-23.)

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