Sen. Thomas Cullerton

Filed: 3/5/2019

AMENDMENT TO SENATE BILL 1839

AMENDMENT NO. _____. Amend Senate Bill 1839 by replacing everything after the enacting clause with the following:

"Section 5. The Wholesale Drug Distribution Licensing Act is amended by changing Sections 15, 57, and 200 and adding Section 28 as follows:

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

(Section scheduled to be repealed on January 1, 2023)

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 occurred.

"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 Marketing Act.

"Department" means the Department of Financial and 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 ~~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 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 ~~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.

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

"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 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 ~~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 prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third-party ~~third party~~ logistics provider must be licensed as a third-party logistics provider ~~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~~.

"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.

"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; ~~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.

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

(225 ILCS 120/28 new)

Sec. 28. Third-party logistics providers licensing requirements.

(a) Each facility of a third-party logistics provider located within Illinois shall be licensed by the Department

prior to shipping a prescription drug:

(1) within the borders of Illinois; or

(2) to a location outside the borders of Illinois.

(b) Each facility of a third-party logistics provider located within Illinois must provide, on a form provided by the Department, information that shall include, but is not limited to:

(1) the name, business address, and social security number or federal tax identification number of each owner, officer, and stockholder owning more than 10% of the stock of the company, unless the stock of the company is publicly traded;

(2) every trade or business name used by the applicant; and

(3) any disciplinary action taken by any state or federal authority against the applicant or any other third-party logistics provider under common ownership or control, or any owner, principal, or designated representative of the applicant, in connection with the drug laws or regulations of any state or the federal government.

(c) Licenses issued under subsection (b) of this Section shall be renewed annually upon:

(1) completion of an application; and

(2) payment of a renewal fee as established by administrative rules adopted by the Department.

(d) A third-party logistics provider license shall be valid only for the name, ownership, and location listed on the license.

The Department may require a criminal history and financial background check of each principal, owner, or officer of the applicant prior to initial registration and prior to any renewal unless the applicant is publicly traded. Any such checks shall be at the applicant's expense.

Changes of name, ownership, or location shall require a new third-party logistics provider license.

Changes in information required for licensure shall be reported to the Department, in writing, within 45 days after the change.

(e) A third-party logistics provider that provides services in respect to controlled substances as defined in the Illinois Controlled Substances Act must also complete and submit the controlled substance registration form provided by the Department, with the appropriate fee.

(f) Each third-party logistics provider must designate an individual representative who shall serve as the contact person for the Department.

(g) An agent or employee of any licensed third-party logistics provider does not need a license and may lawfully possess pharmaceutical drugs when acting in the usual course of business or employment.

(h) A third-party logistics provider shall not operate from

a place of residence.

A third-party logistics provider facility shall be located apart and separate from any retail pharmacy licensed by the Department.

The Department may require a physical inspection of each facility prior to initial registration and prior to any renewal.

(i) A third-party logistics provider shall publicly display all licenses and have the most recent State and federal inspection reports readily available.

(j) The Department shall adopt rules establishing requirements for a third-party logistics provider license, licensure fees, and other relevant matters.

(k) The Department may waive any requirement of this Section if, in the Board's judgment, a waiver will further public health or safety. A waiver granted under this Section shall only be effective when issued in writing.

(l) The Department may deny, suspend, or revoke a third-party logistics provider license or otherwise discipline a third-party logistics provider for failure to meet the applicable standards or for a violation of the laws of this State, another state, or the United States or for a violation of this Act or a rule of the Department.

(225 ILCS 120/57)

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

Sec. 57. Pedigree.

(a) Each person who is engaged in the wholesale distribution of prescription drugs, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, that leave or have ever left the normal distribution channel shall, before each wholesale distribution of the drug, provide a pedigree to the person who receives the drug. A retail pharmacy, mail order pharmacy, or chain pharmacy warehouse must comply with the requirements of this Section only if the pharmacy or chain pharmacy warehouse engages in the wholesale distribution of prescription drugs. On or before July 1, 2009, the Department shall determine a targeted implementation date for electronic track and trace pedigree technology. This targeted implementation date shall not be sooner than July 1, 2010. Beginning on the date established by the Department, pedigrees may be implemented through an approved and readily available system that electronically tracks and traces the wholesale distribution 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. This 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, 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 efficacy 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 third-party ~~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:

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

prescription drug.

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

(3) Transaction dates.

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

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

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

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

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

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

(225 ILCS 120/200)

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

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 third-party ~~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,

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. 98-355, eff. 8-16-13.)

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