SB4014

LRB10224215AMQ33444b

102ND GENERAL ASSEMBLY

State of Illinois

2021 and 2022

SB4014

Introduced 1/21/2022, by Sen. Emil Jones, III

SYNOPSIS AS INTRODUCED:

See Index

Amends the Regulatory Sunset Act. Provides that the Wholesale Drug Distribution Licensing Act is repealed on January 1, 2028 (instead of January 1, 2023). Amends the Wholesale Drug Distribution Licensing Act. Defines "address of record", "email address of record", and "suspicious order". Changes the definition of "wholesale drug distributor". Provides that applicants and licensees must provide a valid address and email address to the Department of Financial and Professional Regulation and must inform the Department of any change of these within 14 days. Provides that each licensee required to report suspicious orders shall submit such report to the Department. Provides that an individual taxpayer identification number can be included on the application for an original license, the application can be made in writing or electronically, and the application shall be accompanied by the required, nonrefundable fee. Provides that any licensee who engages in the licensed practice while the license is expired shall be considered to be practicing without a license which is grounds for discipline. Removes provisions that provide that: the Department shall present to the State Board of Pharmacy of the Department for review all appropriation requests from the Illinois State Pharmacy Disciplinary Fund; the Department shall maintain a roster of the names and addresses of all registrants and all persons whose licenses have been suspended or revoked; and rules that set detailed standards for meeting each license prerequisite requirements shall be adopted no later than September 14, 1992. Provides that the written notice of disciplinary hearing may be served by email or physical mail to the respondent's email of record or address of record. Provides that the Department may subpoena and compel the relevant documents in connection with any hearing. Provides that if the Secretary of Financial and Professional Regulation disagrees with the recommendation of the Board or hearing officer, the Secretary may issue an order in contravention of the recommendation. Provides that the sanctions imposed upon the accused by the Department shall remain in full force and effect in order to protect the public pending final resolution of the proceedings. Repeals a provision concerning references to the Department or Director of Professional Regulation. Makes corresponding and other changes. Section 5 and Section 99 take effect upon becoming law.

LRB102 24215 AMQ 33444 b

A BILL FOR

AN ACT concerning regulation.

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

Section 5. The Regulatory Sunset Act is amended by changing Sections 4.33 and 4.38 as follows:

(5 ILCS 80/4.33)

Sec. 4.33. Acts repealed on January 1, 2023. The following Acts are repealed on January 1, 2023:

The Dietitian Nutritionist Practice Act.

The Elevator Safety and Regulation Act.

The Fire Equipment Distributor and Employee Regulation Act of 2011.

The Funeral Directors and Embalmers Licensing Code.

The Naprapathic Practice Act.

The Pharmacy Practice Act.

The Professional Counselor and Clinical Professional Counselor Licensing and Practice Act.

~~The Wholesale Drug Distribution Licensing Act.~~

(Source: P.A. 101-621, eff. 12-20-19.)

(5 ILCS 80/4.38)

Sec. 4.38. Acts repealed on January 1, 2028. The following Acts are repealed on January 1, 2028:

The Acupuncture Practice Act.

The Clinical Social Work and Social Work Practice Act.

The Home Medical Equipment and Services Provider License Act.

The Illinois Petroleum Education and Marketing Act.

The Illinois Speech-Language Pathology and Audiology Practice Act.

The Interpreter for the Deaf Licensure Act of 2007.

The Nurse Practice Act.

The Nursing Home Administrators Licensing and Disciplinary Act.

The Physician Assistant Practice Act of 1987.

The Podiatric Medical Practice Act of 1987.

The Wholesale Drug Distribution Licensing Act.

(Source: P.A. 100-220, eff. 8-18-17; 100-375, eff. 8-25-17; 100-398, eff. 8-25-17; 100-414, eff. 8-25-17; 100-453, eff. 8-25-17; 100-513, eff. 9-20-17; 100-525, eff. 9-22-17; 100-530, eff. 9-22-17; 100-560, eff. 12-8-17.)

Section 10. The Wholesale Drug Distribution Licensing Act is amended by changing Sections 15, 27, 30, 35, 40, 50, 57, 70, 75, 80, 85, 100, 105, 110, 115, 120, 125, 135, 140, 155, 165, and 200 and by adding Sections 15.5, 21, and 31 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:

"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 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.

"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 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 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 USC 802.

"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.

"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; <u>virtual wholesalers or virtual distributors;</u> 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; 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. 101-420, eff. 8-16-19; 102-389, eff. 1-1-22.)

(225 ILCS 120/15.5 new)

Sec. 15.5. Address of record; email address of record. All applicants and licensees shall:

(1) provide a valid address and email address to the Department, which shall serve as the address of record and email address of record, respectively, at the time of application for licensure or renewal of a license; and

(2) inform the Department of any change of address of record or email address of record within 14 days after such change either through the Department's website or by contacting the Department's licensure maintenance unit.

(225 ILCS 120/21 new)

Sec. 21. Reports to Department. Each licensee that is required to report suspicious orders under 21 USC 832 shall also submit such suspicions order reports to the Department.

(225 ILCS 120/27)

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

Sec. 27. Social security number, individual taxpayer identification number, or unique identifying number ~~Security Number~~ on license application. In addition to any other information required to be contained in the application, every application for an original license under this Act shall include the applicant's social security number, individual taxpayer identification number, or other unique identifying number deemed appropriate by the Department, ~~Social Security~~

~~Number,~~ which shall be retained in the agency's records pertaining to the license. As soon as practical, the Department shall assign a customer's identification number to each applicant for a license.

Every application for a renewal or restored license shall require the applicant's customer identification number.

(Source: P.A. 97-400, eff. 1-1-12.)

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

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

Sec. 30. License applications; renewal ~~renewal application~~ procedures. An application for an original license or renewal shall be made to the Department in writing or electronically on forms prescribed by the Department and shall be accompanied by the required fee, which shall not be refundable. Any such application shall require such information as in the judgment of the Department will enable the Board and Department to pass on the qualifications of the applicant for a license. ~~Application for renewal of any license required by this Act shall be mailed or emailed 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. 101-420, eff. 8-16-19.)

(225 ILCS 120/31 new)

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 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 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.

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

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

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.

(b) All fees collected under this Act shall be deposited into the Illinois State Pharmacy Disciplinary Fund and shall be appropriated to the Department for the ordinary and contingent expenses of the Department in the administration of this Act. Moneys in the Fund may be transferred to the Professions Indirect Cost Fund as authorized by Section 2105-300 of the Department of Financial and Professional Regulation Law (20 ILCS 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.

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

(c) Any person who delivers a check or other payment to the Department that is returned to the Department unpaid by the financial institution upon which it is drawn shall pay to the Department, in addition to the amount already owed to the Department, a fine of $50. The fines imposed by this Section are in addition to any other discipline provided under this Act for unlicensed practice or practice on a nonrenewed license. The Department shall notify the person that payment of fees and fines shall be paid to the Department by certified

check or money order within 30 calendar days of the notification. If, after the expiration of 30 days from the date of the notification, the person has failed to submit the necessary remittance, the Department shall automatically terminate the license or certificate or deny the application, without hearing. If, after termination or denial, the person seeks a license or certificate, he or she shall apply to the Department for restoration or issuance of the license or certificate and pay all fees and fines due to the Department. The Department may establish a fee for the processing of an application for restoration of a license or certificate to pay all expenses of processing this application. The Secretary ~~Director~~ may waive the fines due under this Section in individual cases where the Secretary ~~Director~~ finds that the fines would be unreasonable or unnecessarily burdensome.

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

(e) A manufacturer of controlled substances, wholesale distributor of controlled substances, or third-party logistics provider that is licensed under this Act and owned and operated by the State is exempt from licensure, registration, renewal, and other fees required under this Act. Nothing in this subsection (e) shall be construed to prohibit the

Department from imposing any fine or other penalty allowed under this Act.

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

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

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

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. ~~Rules and regulations that incorporate and set detailed standards for meeting each of the license prerequisites set forth in Section 25 of this Act shall be adopted no later than September 14, 1992.~~ 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 or third-party logistics provider guideline, the FDA guideline shall control.

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

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

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

Sec. 50. Inspection powers; access to records.

(a) Any pharmacy investigator authorized by the Department has the right of entry for inspection ~~during normal business~~

~~hours~~ of premises purporting or appearing to be used by a wholesale drug distributor 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 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 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. 97-804, eff. 1-1-13.)

(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, third-party logistics providers, and pharmacies. Consideration must also be given to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and 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. 101-420, eff. 8-16-19.)

(225 ILCS 120/70) (from Ch. 111, par. 8301-70)

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

Sec. 70. Immediate suspension of license or registration; hearing. The Secretary ~~Director~~ may, upon receipt of a written communication from the Secretary of Human Services or the Director of Public Health that continuation of practice of a person licensed or registered under this Act constitutes an immediate danger to the public, immediately suspend the license or registration of that person without a hearing. In instances in which the Secretary ~~Director~~ immediately suspends a license or registration under this Section, a hearing upon the person's license must be convened by the Board within 15 days after the suspension and completed without appreciable delay. The hearing shall be held to determine whether to recommend to the Secretary ~~Director~~ that the person's license be revoked, suspended, placed on probationary status, or reinstated, or that the person be subject to other disciplinary action. In the hearing, the written communication and any other evidence submitted with the communication may be introduced as evidence against the person. The person or his or her counsel shall have the opportunity to discredit or impeach such evidence and submit rebuttal evidence.

(Source: P.A. 89-507, eff. 7-1-97.)

(225 ILCS 120/75) (from Ch. 111, par. 8301-75)

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

Sec. 75. Automatic suspension. The determination by a circuit court that a licensee is subject to involuntary admission or judicial admission as provided in the Mental Health and Developmental Disabilities Code operates as an automatic suspension. The suspension shall end only upon (i) a finding by a court that the patient is no longer subject to involuntary admission or judicial admission and the issuance of an order so finding and discharging the patient and (ii) the recommendation of the Board to the Secretary ~~Director~~ that the licensee be allowed to resume his or her practice.

(Source: P.A. 91-357, eff. 7-29-99.)

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

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

Sec. 80. Violations of Act.

(a) If any person violates the provisions of this Act, the Secretary ~~Director~~ 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 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.)

(225 ILCS 120/85) (from Ch. 111, par. 8301-85)

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

Sec. 85. Investigations; notice of disciplinary hearing. The Department may investigate the actions of any applicant or of any person or persons holding or claiming to hold a license

or registration. Before suspending, revoking, placing on probationary status, or taking any other disciplinary action as the Department may deem proper with regard to any license or certificate, at least 30 days before the date set for the hearing, the Department shall (i) notify the accused in writing of any charges made and the time and place for a hearing of the charges before the Board, (ii) direct him or her to file a written answer to the charges with the Board under oath within 20 days after the service of the notice, and (iii) inform the accused that if he or she fails to file an answer default will be taken against him or her and his or her license or certificate may be suspended, revoked, placed on probationary status, or have other disciplinary action, including limiting the scope, nature or extent of business, as provided for in this Act. The written notice may be served by personal delivery, email to the respondent's email address of record, or mail to the respondent's address of record ~~or certified or registered mail to the respondent at the address of last notification to the Department~~. At the time and place fixed in the notice, the Board shall proceed to hear the charges and the parties or their counsel shall be accorded ample opportunity to present any statements, testimony, evidence and argument that may be pertinent to the charges or to their defense. The hearing may be continued from time to time. In case the accused person, after receiving notice, fails to file an answer, his or her license or certificate may

in the discretion of the Secretary ~~Director~~, having received first the recommendation of the Board, be suspended, revoked, placed on probationary status, or the Secretary ~~Director~~ may take whatever disciplinary action as he or she may deem proper as provided in this Act, including limiting the scope, nature, or extent of the person's practice, without a hearing, if the act or acts charged constitute sufficient grounds for such action under this Act.

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

(225 ILCS 120/100) (from Ch. 111, par. 8301-100)

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

Sec. 100. Subpoena power; administration of oaths. The Department shall have power to subpoena and bring before it any person in this State and to take testimony, either orally or by deposition or both, with the same fees and mileage and in the same manner as prescribed by law in judicial proceedings in civil cases in circuit courts of this State. The Department may subpoena and compel the production of documents, papers, files, books, and records in connection with any hearing or investigation.

The Secretary, hearing officer, and ~~Director and~~ any member of the Board shall each have power to administer oaths to witnesses at any hearing which the Department is authorized to conduct under this Act, and any other oaths required or authorized to be administered by the Department under this

Act.

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

(225 ILCS 120/105) (from Ch. 111, par. 8301-105)

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

Sec. 105. Report of findings and recommendation. At the conclusion of the hearing, the Board shall present to the Secretary ~~Director~~ a written report of its findings of fact, conclusions of law, and recommendations. The report shall contain a finding whether or not the accused person violated this Act or failed to comply with the conditions required in this Act. The Board shall specify the nature of the violation or failure to comply and shall make its recommendations to the Secretary ~~Director~~.

The report of findings of fact, conclusion of law, and recommendations of the Board shall be the basis for the Department's order for refusal or for the granting of a license or registration. The finding is not admissible in evidence against the person in a criminal prosecution brought for the violation of this Act, but the hearing and finding are not a bar to a criminal prosecution brought for the violation of this Act.

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

(225 ILCS 120/110) (from Ch. 111, par. 8301-110)

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

Sec. 110. Hearing officers; appointment. Notwithstanding any other provision of this Act, the Secretary ~~Director~~ shall have the authority to appoint any attorney duly licensed to practice law in the State of Illinois to serve as the hearing officer in any action before the Board for refusal to issue or renew a license, or the discipline of a licensee. ~~The Director shall notify the Board of any such appointment. The hearing officer shall have full authority to conduct the hearing. There shall be present at least one member of the Board at any such hearing.~~ The hearing officer shall report his findings of fact, conclusions of law, and recommendations to the Board and the Secretary ~~Director~~. The Board shall have 60 days from receipt of the report to review the report of the hearing officer and present its findings of fact, conclusions of law, and recommendations to the Secretary ~~Director~~. If the Board fails to present its report within the 60 day period, the Secretary ~~Director~~ may issue an order based on report of the hearing officer and the record of the proceedings or issue an order remanding the matter back to the hearing officer for additional proceedings in accordance with the order. If the Secretary disagrees with the recommendation of the Board or the hearing officer, the Secretary may issue an order in contravention of the recommendation. ~~However, if the Board does present its report within the specified 60 days, the Director's order shall be based upon the report of the Board.~~

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

(225 ILCS 120/115) (from Ch. 111, par. 8301-115)

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

Sec. 115. Motion for rehearing. In any case involving the refusal to issue, renew, or discipline of a license or registration, a copy of the Board's report shall be served upon the respondent by the Department, either personally or as provided in this Act for the service of the notice of hearing. Within 20 days after service, the respondent may present to the Department a motion in writing for a rehearing, which shall specify the particular grounds for rehearing. If no motion for rehearing is filed, then upon the expiration of the time specified for filing a motion, or if a motion for rehearing is denied, then upon denial the Secretary ~~Director~~ may enter an order in accordance with recommendations of the Board. If the respondent orders from the reporting service and pays for a transcript of the record within the time for filing a motion for rehearing, the 20-day ~~20 day~~ period within which a motion may be filed shall commence upon the delivery of the transcript to the respondent.

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

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

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

Sec. 120. Rehearing by order of Secretary ~~Director~~. Whenever the Secretary ~~Director~~ is satisfied that substantial

justice has not been done in the revocation, suspension, or refusal to issue or renew a license or registration, the Secretary ~~Director~~ may order a rehearing by the same hearing office or Board.

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

(225 ILCS 120/125) (from Ch. 111, par. 8301-125)

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

Sec. 125. Duties of the Board ~~Board recommendations to Director; disagreement~~. The Board shall exercise the rights, powers, and duties which have been vested in the Board under this Act, and any other duties conferred upon the Board by law. ~~None of the disciplinary functions, powers, and duties enumerated in this Act shall be exercised by the Department except upon the action and report in writing of the Board, except as otherwise provided in this Act.~~

~~In all instances under this Act in which the Board has rendered a recommendation to the Director with respect to a particular license or certificate, the Director shall, in the event that he or she disagrees with or takes action contrary to the recommendation of the Board, file with the Board and Secretary of State his or her specific written reasons for disagreement with the Board. These reasons shall be filed within 30 days after the Director taking the contrary position.~~

~~The action and report in writing of a majority of the Board~~

~~is sufficient authority upon which the Director may act.~~

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

(225 ILCS 120/135) (from Ch. 111, par. 8301-135)

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

Sec. 135. Disciplinary consent orders. Notwithstanding the provisions of this Act concerning the conduct of hearings and recommendations for disciplinary actions, the Secretary ~~Director~~ shall have the authority to negotiate agreements with licensees ~~and registrants~~ resulting in disciplinary consent orders. Consent orders may provide for any of the forms of discipline otherwise provided in this Act. Consent orders shall provide that they were not entered into a result of any coercion by the Department. ~~The Director shall forward copies of all final consent orders to the Board within 30 days after their entry.~~

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

(225 ILCS 120/140) (from Ch. 111, par. 8301-140)

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

Sec. 140. Orders; prima facie proof. An order or a certified copy thereof, over the seal of the Department and purporting to be signed by the Secretary ~~Director~~, shall be prima facie proof that:

(a) the signature is the genuine signature of the Secretary ~~Director~~;

(b) the Secretary ~~Director~~ is duly appointed and qualified; and

(c) the Board and its members are qualified to act.

(Source: P.A. 91-357, eff. 7-29-99.)

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

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

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

(225 ILCS 120/165) (from Ch. 111, par. 8301-165)

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

Sec. 165. Certification of record~~; receipt for costs~~. The Department shall not be required to certify any record to the court, to file an answer in court, or to otherwise appear in

any court in a judicial review proceeding unless and until the Department has received from the plaintiff payment of the costs of furnishing and certifying the record, which costs shall be determined by the Department. Failure on the part of the plaintiff to file a receipt in court shall be grounds for dismissal of the action. During the pendency and hearing of any and all judicial proceedings incident to the disciplinary action, the sanctions imposed upon the accused by the Department because of acts or omissions related to the delivery of direct patient care as specified in the Department's final administrative decision, shall, as a matter of public policy, remain in full force and effect in order to protect the public pending final resolution of any of the proceedings.

~~The Department shall not be required to certify any record to the court or file any answer in court or otherwise appear in any court in a judicial review proceeding, unless there is filed in the court, with the complaint, a receipt from the Department acknowledging payment of the costs of furnishing and certifying the record, which costs shall be computed at the rate of 25 cents per page of such record. Failure on the part of the plaintiff to file a receipt in court shall be grounds for dismissal of the action.~~

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

(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.)

(225 ILCS 120/3 rep.)

Section 15. The Wholesale Drug Distribution Licensing Act is amended by repealing Section 3.

Section 99. Effective date. This Section and Section 5 take effect upon becoming law.

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