SB2935

LRB09716822CELG2004b

97TH GENERAL ASSEMBLY

State of Illinois

2011 and 2012

SB2935

Introduced 2/1/2012, by Sen. Iris Y. Martinez

SYNOPSIS AS INTRODUCED:

See Index

Amends the Wholesale Drug Distribution Licensing Act. Provides that any person who practices, offers to practice, attempts to practice, or holds oneself out to practice as a wholesale drug distributor or pharmacy distributor without being licensed under the Act shall pay a civil penalty to the Department of Financial and Professional Regulation in an amount not to exceed $10,000 (instead of $5,000) per violation for each offense. Provides that any pharmacy investigator authorized by the Department has the right of entry that includes the business premises of a person licensed pursuant to the Act. Permits the authorized pharmacy investigator unfettered access to the entire business premises. Provides that the most recent 12 months of record must be kept on the premises where the drugs are stored. Allows the Department to take action, including imposing fines not to exceed $10,000 per violation, if the individual meets the requirements for grounds for disciplinary action. Provides that if any person violates the provisions of the Act, the Secretary may petition for an order enjoining the violation or for an order enforcing compliance with the Act. Provides that the Department may issue a rule to show cause why an order to cease and desist shall not be entered against that person. Makes other changes. Amends the Regulatory Sunset Act to extend the repeal of the Wholesale Drug Distribution Licensing Act from January 1, 2013 to January 1, 2023. Effective immediately.

LRB097 16822 CEL 62004 b

FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning regulation.

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

Section 1. The Regulatory Sunset Act is amended by changing Section 4.23 and by adding Section 4.33 as follows:

(5 ILCS 80/4.23)

Sec. 4.23. Acts and Sections repealed on January 1, 2013. The following Acts and Sections of Acts are repealed on January 1, 2013:

The Dietetic and Nutrition Services 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 Professional Counselor and Clinical Professional Counselor Licensing Act.

~~The Wholesale Drug Distribution Licensing Act.~~

Section 2.5 of the Illinois Plumbing License Law.

(Source: P.A. 95-331, eff. 8-21-07; 96-1499, eff. 1-18-11.)

(5 ILCS 80/4.33 new)

Sec. 4.33. Act repealed on January 1, 2023. The following

Act is repealed on January 1, 2023:

The Wholesale Drug Distribution Licensing Act.

Section 5. The Wholesale Drug Distribution Licensing Act is amended by changing Sections 15, 20, 25, 26, 50, 55, and 59 and by adding Section 173 as follows:

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

(Section scheduled to be repealed on January 1, 2013)

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 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 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 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, ~~or~~ 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 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 logistics provider must be licensed as a wholesale distributor under this Act and, in order to be considered part of the normal distribution channel, must also be an authorized distributor of record.

"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 ~~retail~~ 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 <u>into, out of, or within the State</u>, 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. 95-689, eff. 10-29-07.)

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

(Section scheduled to be repealed on January 1, 2013)

Sec. 20. Prohibited drug purchases or receipt. It shall be unlawful for any person or entity <u>located in this State</u> to knowingly purchase or receive any prescription drug from any source other than a person or entity licensed under the laws of this State ~~or the state of domicile except where otherwise provided~~. A person or entity licensed under the laws of this State shall include, but is not limited to, a wholesale distributor, manufacturer, pharmacy distributor, or pharmacy. Any person violating this Section shall, upon conviction, be adjudged guilty of a Class C misdemeanor. A second violation shall constitute a Class 4 felony.

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

(225 ILCS 120/25) (from Ch. 111, par. 8301-25)

(Section scheduled to be repealed on January 1, 2013)

Sec. 25. Wholesale drug distributor licensing requirements.

(a) Every resident wholesale distributor who engages in the wholesale distribution of prescription drugs must be licensed by the Department, and every non-resident wholesale distributor must be licensed in this State if it ships prescription drugs into this State, in accordance with this Act, before engaging in wholesale distributions of wholesale prescription drugs.

(b) The Department shall require without limitation all of the following information from each applicant for licensure under this Act:

(1) The name, full business address, and telephone number of the licensee.

(2) All trade or business names used by the licensee.

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs.

(4) The type of ownership or operation, such as a partnership, corporation, or sole proprietorship.

(5) The name of the owner or operator of the wholesale

distributor, including:

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

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

(C) if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

(D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(6) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(7) The name of the designated representative for the wholesale distributor, together with the personal information statement and fingerprints, as required under subsection (c) of this Section.

(8) Minimum liability insurance and other insurance as defined by rule.

(9) Any additional information required by the Department.

(c) Each wholesale distributor must designate an individual representative who shall serve as the contact person for the Department. This representative must provide the Department with all of the following information:

(1) Information concerning whether the person has been

enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or State law regulating the possession, control, or distribution of prescription drugs or criminal violations, together with details concerning any such event.

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

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

(4) The designated representative of an applicant for licensure as a wholesale drug distributor shall have his or her fingerprints submitted to the Department of State Police in an electronic format that complies with the form and manner for requesting and furnishing criminal history record information as prescribed by the Department of State

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

The designated representative of a licensee shall receive and complete continuing training in applicable federal and State laws governing the wholesale distribution of prescription drugs.

(d) The Department may not issue a wholesale distributor license to an applicant, unless the Department first:

(1) ensures that a physical inspection of the facility satisfactory to the Department has occurred at the address provided by the applicant, as required under item (1) of subsection (b) of this Section; and

(2) determines that the designated representative meets each of the following qualifications:

(A) He or she is at least 21 years of age.

(B) He or she has been employed full-time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs.

(C) He or she is employed by the applicant full time in a managerial level position.

(D) He or she is actively involved in and aware of the actual daily operation of the wholesale distributor.

(E) He or she is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including without limitation sick leave and vacation leave.

(F) He or she is serving in the capacity of a designated representative for only one applicant at a time, except where more than one licensed wholesale distributor is co-located in the same facility and such wholesale distributors are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code.

(e) If a wholesale distributor distributes prescription

drugs from more than one facility, the wholesale distributor shall obtain a license for each facility.

(f) The information provided under this Section may not be disclosed to any person or entity other than the Department or another government entity in need of such information for licensing or monitoring purposes.

(Source: P.A. 94-942, eff. 1-1-07; 95-689, eff. 10-29-07.)

(225 ILCS 120/26)

(Section scheduled to be repealed on January 1, 2013)

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 or pharmacy distributor without being licensed 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 ~~$5,000~~ 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. 89-474, eff. 6-18-96.)

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

(Section scheduled to be repealed on January 1, 2013)

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. ~~Any wholesale drug distributor providing adequate documentation of the most recent satisfactory inspection less than 3 years old of the distributor's wholesale drug distribution activities and facilities by either the U.S. FDA, a State agency, or any person or entity lawfully designated by a State agency to perform an inspection determined to be~~

~~comparable by the Department shall be exempt from further inspection for a period of time to be determined by the Department. The exemption shall not bar the Department from initiating an investigation of a public or governmental complaint received by the Department regarding a wholesale drug distributor. Wholesale drug distributors shall be given an opportunity to correct minor violations determined by these investigations.~~

(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 ~~Wholesale~~ drug distributors may keep records regarding purchase and sales transactions 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 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. 94-942, eff. 1-1-07.)

(225 ILCS 120/55) (from Ch. 111, par. 8301-55)

(Section scheduled to be repealed on January 1, 2013)

Sec. 55. Discipline; grounds.

(a) The Department may refuse to issue, restore, or renew,

or may revoke, suspend, place on probation, reprimand or take other disciplinary or non-disciplinary action as the Department may deem appropriate, including imposing fines not to exceed $10,000 for each violation, with regard to any applicant or licensee or any officer, director, manager, or shareholder who owns 5% or more interest in the business that holds the license ~~proper~~ for any one or a combination of the following reasons:

(1) Violation of this Act or of the ~~its~~ rules adopted under this Act.

(2) Aiding or assisting another person in violating any provision of this Act or the ~~its~~ rules adopted under this Act.

(3) Failing, within 60 days, to provide information in response ~~respond~~ to a written requirement made by the Department ~~for information~~.

(4) Engaging in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public. This includes violations of "good faith" as defined by the Illinois Controlled Substances Act and applies to all prescription drugs.

(5) Discipline by another U.S. jurisdiction or foreign nation, if at least one of the grounds for the discipline is the same or substantially equivalent to those set forth in this Act.

(6) Selling or engaging in the sale of drug samples

provided at no cost by drug manufacturers.

(7) Conviction by ~~of or entry of a~~ plea of guilty or nolo contendere, finding of guilt, jury verdict, or entry of judgment or by sentencing of any crime, including, but not limited to, convictions, preceding sentences of supervision, conditional discharge, or first offender probation, under the laws of any jurisdiction of the United States (i) ~~by the applicant or licensee, or any officer, director, manager or shareholder who owns more than 5% of stock, to any crime under the laws of the United States or any state or territory of the United States~~ that is a felony or (ii) a misdemeanor, ~~of which~~ an essential element of which is dishonesty~~,~~ or ~~any crime~~ that is directly related to the practice of this profession.

(8) Habitual or excessive use or addiction to alcohol, narcotics, stimulants, or any other chemical agent or drug by the designated representative, as provided for in item (7) of subsection (b) of Section 25 of this Act, any officer, or director that results in the inability to function with reasonable judgment, skill, or safety.

~~(b) The Department may refuse to issue, restore, or renew, or may revoke, suspend, place on probation, reprimand or take other disciplinary action as the Department may deem property including fines not to exceed $10,000 per offense for any of the following reasons:~~

(9) ~~(1)~~ Material misstatement in furnishing

information to the Department.

~~(2) Making any misrepresentation for the purpose of obtaining a license.~~

(10) ~~(3)~~ A finding by the Department that the licensee, after having his or her license placed on probationary status, has violated the terms of probation.

(11) Fraud or misrepresentation in applying for, or procuring, a license under this Act or in connection with applying for renewal of a license under this Act. ~~(4) A finding that licensure or registration has been applied for or obtained by fraudulent means.~~

(12) ~~(5)~~ Willfully making or filing false records or reports.

(13) ~~(6)~~ A finding of a substantial discrepancy in a Department audit of a prescription drug, including a controlled substance as that term is defined in this Act or in the Illinois Controlled Substances Act.

(14) Falsifying a pedigree or selling, distributing, transferring, manufacturing, repackaging, handling, or holding a counterfeit prescription drug intended for human use.

(15) Interfering with a Department investigation.

(16) Failing to adequately secure controlled substances or other prescription drugs from diversion.

(17) Acquiring or distributing prescription drugs not obtained from a licensed source.

(18) Failing to properly store drugs.

(19) Failing to maintain the licensed premises with proper storage and security controls.

(b) ~~(c)~~ The Department may refuse to issue or may suspend the license or registration of any person who fails to file a return, or to pay the tax, penalty or interest shown in a filed return, or to pay any final assessment of tax, penalty or interest, as required by any tax Act administered by the Illinois Department of Revenue, until the time the requirements of the tax Act are satisfied.

(c) ~~(d)~~ The Department shall revoke the license or certificate of registration issued under this Act or any prior Act of this State of any person who has been convicted a second time of committing any felony under the Illinois Controlled Substances Act or the Methamphetamine Control and Community Protection Act or who has been convicted a second time of committing a Class 1 felony under Sections 8A-3 and 8A-6 of the Illinois Public Aid Code. A person whose license or certificate of registration issued under this Act or any prior Act of this State is revoked under this subsection (b) ~~(c)~~ shall be prohibited from engaging in the practice of pharmacy in this State.

(Source: P.A. 94-556, eff. 9-11-05; 95-689, eff. 10-29-07; revised 11-18-11.)

(225 ILCS 120/59)

(Section scheduled to be repealed on January 1, 2013)

Sec. 59. Injunctive action; cease and desist order. ~~Enforcement; order to cease distribution of a drug.~~

(a) If any person violates the provisions of this Act, the Secretary, in the name of the People of the State of Illinois, through the Attorney General or the State's Attorney of the county where the violation is alleged to have occurred, may petition for an order enjoining the violation or for an order enforcing compliance with this Act. Upon the filing of a verified petition, the court with appropriate jurisdiction 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, then the court may punish the offender for contempt of court. Proceedings under this Section are in addition to, and not in lieu of, all other remedies and penalties provided by this Act. ~~The Department shall issue an order requiring the appropriate person, including the distributors or retailers of a drug, to immediately cease distribution of the drug within this State, if the Department finds that there is a reasonable probability that:~~

~~(1) a wholesale distributor has (i) violated a provision in this Act or (ii) falsified a pedigree or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use;~~

~~(2) the prescription drug at issue, as a result of a violation in paragraph (1) of this subsection (a), could cause serious, adverse health consequences or death; and~~

~~(3) other procedures would result in unreasonable delay.~~

(b) Whenever, in the opinion of the Department, a person violates any provision of this Act, the Department may issue a rule to show cause why an order to cease and desist shall not be entered against that person. The rule shall clearly set forth the grounds relied upon by the Department and shall allow a person at least 7 days after the date of the rule to file an answer satisfactory to the Department. Failure to answer to the satisfaction of the Department shall cause an order to cease and desist to be issued. ~~An order issued under this Section shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for a hearing, the Department determines that inadequate grounds exist to support the actions required by the order, the Department shall vacate the order.~~

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

(225 ILCS 120/173 new)

Sec. 173. Confidentiality. All information collected by the Department in the course of an examination or investigation

of a licensee or applicant, including, but not limited to, any complaint against a licensee filed with the Department and information collected to investigate any such complaint, shall be maintained for the confidential use of the Department and shall not be disclosed. The Department may not disclose the information to anyone other than law enforcement officials, other regulatory agencies that have an appropriate regulatory interest as determined by the Secretary, or a party presenting a lawful subpoena to the Department. Information and documents disclosed to a federal, State, county, or local law enforcement agency shall not be disclosed by the agency for any purpose to any other agency or person. A formal complaint filed against a licensee by the Department or any order issued by the Department against a licensee or applicant shall be a public record, except as otherwise prohibited by law.

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

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Statutes amended in order of appearance