**Rep. Mr. Jack D. Franks**

# Filed: 5/29/2007



AMENDMENT TO SENATE BILL 509

AMENDMENT NO. _____. Amend Senate Bill 509 by replacing everything after the enacting clause with the following:

"Section 5. The Wholesale Drug Distribution Licensing Act is amended by changing Sections 15, 20, and 25, and by adding Sections 3, 24, 55, 56, 57, 58, and 59 as follows:

(225 ILCS 120/3 new)

(Section scheduled to be repealed on January 1, 2013)

Sec. 3. References to Department or Director of Professional Regulation. References in this Act (i) to the Department of Professional Regulation are deemed, in appropriate contexts, to be references to the Department of Financial and Professional Regulation and (ii) to the Director of Professional Regulation are deemed, in appropriate contexts, to be references to the Secretary of Financial and Professional Regulation.

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(Section scheduled to be repealed on January 1, 2013)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

~~"Director" means the Director of 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 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.

"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;

(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; or

(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.

"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.

~~"Manufacturer" means anyone who is engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.~~

"Person" means and includes a natural person, partnership, association or corporation.

"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 ~~active ingredients~~ subject to

~~subsection (b) of~~ 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" ~~or "wholesale distributions"~~ means the distribution of prescription drugs to persons other than a consumer or patient, but does not include any of the following:

(1) ~~(a)~~ Intracompany sales of prescription drugs, meaning (i)~~, defined as~~ 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 retail pharmacies to licensed practitioners for office use.

(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 or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or to a third party returns processor. ~~(b) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of a group organization.~~

~~(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in subsection (c)(3) of Section 501 of the U.S. Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law.~~

~~(d) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control. For purposes of this Act, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise.~~

~~(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this Act, "emergency medical reasons" include transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.~~

~~(f) 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.~~

~~(g) The distribution of drug samples by manufacturers' representatives or distributors' representatives.~~

~~(h) The sale, purchase, or trade of blood and blood components intended for transfusion.~~

"Wholesale drug distributor" means anyone ~~any person or entity~~ engaged in the wholesale distribution of prescription drugs, including without limitation~~, but not limited to,~~ 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~~, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions, including, but not limited to, any pharmacy distributor as defined in this Section. A wholesale drug distributor shall not include any for hire carrier or person or entity hired solely to transport prescription drugs~~.

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

(225 ILCS 120/24 new)

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

Sec. 24. Bond required. The Department shall require every wholesale distributor applying for licensure under this Act to submit a bond not to exceed $100,000 or another equivalent means of security acceptable to the Department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to a fund established by the Department. Chain pharmacy warehouses that are not engaged in wholesale distribution are exempt from the bond requirement of

this Section. The purpose of the bond is to secure payment of any fines or penalties imposed by the Department and any fees and costs incurred by the Department regarding that license, which are authorized under State law and which the licensee fails to pay 30 days after the fines, penalties, or costs become final. The Department may make a claim against the bond or security until one year after the licensee's license ceases to be valid. A single bond may suffice to cover all facilities operated by an applicant or its affiliates in this State.

The Department shall establish a fund, separate from its other accounts, in which to deposit the wholesale distributor bonds required under this Section.

(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.

~~All wholesale distributors and pharmacy distributors, wherever located, who engage in wholesale distribution into, out of, or within the State shall be subject to the following 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. ~~No person or distribution outlet shall act as a wholesale drug distributor without first obtaining a license to do so from the Department and paying any reasonable fee required by the Department.~~

(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 person, the name of the 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. ~~may grant a temporary license when a wholesale drug distributor first applies for a license to operate within this State. A temporary license shall only be granted after the applicant meets the inspection requirements for regular licensure and shall remain valid until the Department finds that the applicant meets or fails to meet the requirements for regular licensure. Nevertheless, no temporary license shall be valid for more than 90 days from the date of issuance. Any temporary license issued under this subsection shall be renewable for a similar period of time not to exceed 90 days under policies and procedures prescribed 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. ~~No license shall be issued or renewed for a wholesale drug distributor to operate unless the wholesale drug distributor shall operate in a manner prescribed by law and according to the rules and regulations promulgated by the Department.~~

(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. ~~require a separate license for each facility directly or indirectly owned or operated by the same business entity within this State, or for a parent entity with divisions, subsidiaries, and affiliate companies within this State when operations are conducted at more than one location and there exists joint ownership and control among all the entities.~~

(e) If a wholesale distributor distributes prescription drugs from more than one facility, the wholesale distributor shall obtain a license for each facility. ~~As a condition for receiving and renewing any wholesale drug distributor license issued under this Act, each applicant shall satisfy the Department that it has and will continuously maintain:~~

~~(1) acceptable storage and handling conditions plus facilities standards;~~

~~(2) minimum liability and other insurance as may be required under any applicable federal or State law;~~

~~(3) a security system that includes after hours, central alarm or comparable entry detection capability; restricted premises access; adequate outside perimeter lighting; comprehensive employment applicant screening;~~

~~and safeguards against employee theft;~~

~~(4) an electronic, manual, or any other reasonable system of records, describing all wholesale distributor activities governed by this Act for the 2 year period following disposition of each product and reasonably accessible during regular business hours as defined by the Department's rules in any inspection authorized by the Department;~~

~~(5) officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling who must at all times demonstrate and maintain their capability of conducting business according to sound financial practices as well as State and federal law;~~

~~(6) complete, updated information, to be provided the Department as a condition for obtaining and renewing a license, about each wholesale distributor to be licensed under this Act, including all pertinent licensee ownership and other key personnel and facilities information deemed necessary for enforcement of this Act. Any changes in this information shall be submitted at the time of license renewal or within 45 days from the date of the change;~~

~~(7) written policies and procedures that assure reasonable wholesale distributor preparation for, protection against and handling of any facility security or operation problems, including, but not limited to, those caused by natural disaster or government emergency;~~

~~inventory inaccuracies or product shipping and receiving;~~ ~~outdated product or other unauthorized product control;~~ ~~appropriate disposition of returned goods; and product recalls;~~

~~(8) sufficient inspection procedures for all incoming and outgoing product shipments; and~~

~~(9) operations in compliance with all federal legal requirements applicable to wholesale drug distribution.~~

(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. ~~Department shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs in this State:~~

~~(1) any conviction of the applicant under any federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;~~

~~(2) any felony convictions of the applicant under federal, State, or local laws;~~

~~(3) the applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;~~

~~(4) the furnishing by the applicant of false or fraudulent material in any application made in connection~~

~~with drug manufacturing or distribution;~~

~~(5) suspension or revocation by federal, State, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drug, including controlled substances;~~

~~(6) compliance with licensing requirements under previously granted licenses, if any;~~

~~(7) compliance with requirements to maintain and make available to the Department or to federal, State, or local law enforcement officials those records required by this Act; and~~

~~(8) any other factors or qualifications the Department considers relevant to and consistent with the public health and safety, including whether the granting of the license would not be in the public interest.~~

~~(9) All requirements set forth in this subsection shall conform to wholesale drug distributor licensing guidelines formally adopted by the U.S. Food and Drug Administration (FDA). In case of conflict between any wholesale drug distributor licensing requirement imposed by the Department and any FDA wholesale drug distributor licensing guideline, the FDA guideline shall control.~~

~~(g) An agent or employee of any licensed wholesale drug distributor need not seek licensure under this Section and may lawfully possess pharmaceutical drugs when the agent or employee is acting in the usual course of business or~~

~~employment.~~

~~(h) The issuance of a license under this Act shall not change or affect tax liability imposed by the State on any wholesale drug distributor.~~

~~(i) A license issued under this Act shall not be sold, transferred, or assigned in any manner.~~

(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 action as the Department may deem proper for any of the following reasons:

(1) Violation of this Act or its rules.

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

(3) Failing, within 60 days, to 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 of or entry of a plea of guilty or nolo contendere by the applicant or licensee, or any officer, director, manager or shareholder who owns more than 5% of stock, to any crime that is a felony under the laws of the United States or any state or territory of the United States that is a felony or a misdemeanor, an essential element of which is dishonesty, or that is directly related to the practice of this profession ~~in State or federal court of any crime that is a felony~~.

(8) Habitual or excessive use or addiction to alcohol, narcotics, stimulants, or any other chemical agent or drug 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 ~~$1000~~ for any of the following reasons:

(1) Material misstatement in furnishing information to the Department.

(2) Making any misrepresentation for the purpose of

obtaining a license.

(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.

(4) A finding that licensure or registration has been applied for or obtained by fraudulent means.

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

(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.

(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.

(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 (c) shall be prohibited from engaging in the practice of pharmacy in this State.

(Source: P.A. 94-556, eff. 9-11-05.)

(225 ILCS 120/56 new)

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

Sec. 56. Restrictions on transactions.

(a) A licensee shall receive prescription drug returns or exchanges from a pharmacy or other persons authorized to administer or dispense drugs or a chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. Returns of expired, damaged, recalled, or otherwise non-saleable pharmaceutical products shall be distributed by the receiving wholesale distributor only to either the original manufacturer or a third party returns processor, and such returns or exchanges, including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirements of Section 57 of this Act, so long as they are exempt from the pedigree requirement of the FDA's currently applicable Prescription Drug Marketing Act guidance. Both licensees under this Act and pharmacies or other persons authorized to administer or dispense drugs shall be accountable for administering their returns process and ensuring that the

aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

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

(c) Prescription drugs furnished by a manufacturer or wholesale distributor licensed under this Act may be delivered only to the premises listed on the license, provided that the manufacturer or wholesale distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

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

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

(d) Prescription drugs may be furnished to a hospital pharmacy receiving area, provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Any discrepancy between the receipt and the type

and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesale distributor by the next business day after the delivery to the pharmacy receiving area.

(e) A manufacturer or wholesale distributor licensed under this Act may not accept payment for, or allow the use of, a person or entity's credit to establish an account for the purchase of prescription drugs from any person other than the owner of record, the chief executive officer, or the chief financial officer listed on the license of a person or entity legally authorized to receive the prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee. This subsection (e) shall not be construed to prohibit a pharmacy or chain pharmacy warehouse from receiving prescription drugs if payment for the prescription drugs is processed through the pharmacy's or chain pharmacy warehouse's contractual drug manufacturer or wholesale distributor.

(225 ILCS 120/57 new)

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

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 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. The Department shall determine by July 1, 2009, a targeted implementation date for electronic track and trace technology. This determination shall be based on consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in this State. After consultation with interested stakeholders and prior to the implementation of the track and trace technology, the Department shall deem that the technology is universally available across the entire prescription pharmaceutical supply chain. The implementation date for the mandated electronic track and trace technology shall be no sooner than July 1, 2010 and may be extended by the Department in one year increments if it appears that the technology is not universally available across the entire prescription pharmaceutical supply chain.

(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 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.

(225 ILCS 120/58 new)

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

Sec. 58. Prohibited acts. It is unlawful for a person to perform or cause the performance of or aid and abet any of the following acts:

(1) Failure to obtain a license in accordance with this Act or operating without a valid license when a license is required by this Act.

(2) If the requirements of subsection (a) of Section 56 of this Act are applicable and are not met, the purchasing or otherwise receiving of a prescription drug from a pharmacy.

(3) If licensure is required pursuant to subsection (b) of Section 56 of this Act, the sale, distribution, or transfer of a prescription drug to a person that is not

authorized under the law of the jurisdiction in which the person receives the prescription drug to receive the prescription drug.

(4) Failure to deliver prescription drugs to specified premises, as required by subsection (c) of Section 56 of this Act.

(5) Accepting payment or credit for the sale of prescription drugs in violation of subsection (e) of Section 57 of this Act.

(6) Failure to maintain or provide pedigrees as required by this Act.

(7) Failure to obtain, pass, or authenticate a pedigree as required by this Act.

(8) Providing the Department or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this Act.

(9) Obtaining or attempting to obtain a prescription drug by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug.

(10) The manufacture, repacking, sale, transfer, delivery, holding, or offering for sale of any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or that has otherwise been rendered unfit for distribution, except for the wholesale

distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the FDA.

(11) The adulteration, misbranding, or counterfeiting of any prescription drug, except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the FDA.

(12) The receipt of any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit and the delivery or proffered delivery of such drug for pay or otherwise.

(13) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded. The acts prohibited in this Section do not include the obtaining or the attempt to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity performed by a prescription drug manufacturer or the agent of a prescription drug manufacturer.

(225 ILCS 120/59 new)

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

Sec. 59. Enforcement; order to cease distribution of a drug.

(a) 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) 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.

(225 ILCS 120/45 rep.)

Section 97. The Wholesale Drug Distribution Licensing Act is amended by repealing Section 45.

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