SB1739

LRB09411222RASA1944b

94TH GENERAL ASSEMBLY

State of Illinois

2005 and 2006

SB1739

Introduced 2/25/2005, by Sen. Terry Link

SYNOPSIS AS INTRODUCED:

See Index

Amends the Freedom of Information Act to exempt the disclosure of certain information provided under the Wholesale Prescription Drug Distribution Protection and Licensing Act of 2005. Amends the Wholesale Drug Distribution Licensing Act. Changes the short title of the Act to the Wholesale Prescription Drug Distribution Protection and Licensing Act of 2005 and amends the Regulatory Sunset Act to reflect that change. Defines "authorized distributor of record", "sales unit", and "verifiable account". Sets forth separate penalties for certain acts concerning prescription drugs. Provides that the Department of Financial and Professional Regulation shall consider any findings of certain criminal background checks, civil litigation checks, and financial background checks in reviewing the qualifications of persons who engage in the wholesale distribution of prescription drugs in the State. Sets forth requirements for licensure application, drug manufacturer information, a surety bond, a designated representative, a pedigree concerning distribution, and due diligence review by wholesale drug purchasers, as they relate to the wholesale distribution of prescription drugs. Provides that the Department shall conduct a physical inspection of each in-State applicant's facility prior to issuing a license, or, for a wholesale distributor with a valid license on the effective date of this amendatory Act, prior to issuing a renewal, with regular periodic inspections conducted thereafter, no more than 3 years following the last inspection (now, 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 certain comparable entities shall be exempt from further inspection for a period of time to be determined by the Department). Provides that the Department shall make publicly available on its website the dates of the first and most recent inspections of each wholesale distributor and the license suspension, revocation, expiration, or other relevant disciplinary action. Makes other changes.

LRB094 11222 RAS 41944 b

CORRECTIONAL
BUDGET AND
IMPACT NOTE ACT
MAY APPLY

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 5. The Freedom of Information Act is amended by changing Section 7 as follows:

(5 ILCS 140/7) (from Ch. 116, par. 207)

Sec. 7. Exemptions.

(1) The following shall be exempt from inspection and copying:

(a) Information specifically prohibited from disclosure by federal or State law or rules and regulations adopted under federal or State law.

(b) Information that, if disclosed, would constitute a clearly unwarranted invasion of personal privacy, unless the disclosure is consented to in writing by the individual subjects of the information. The disclosure of information that bears on the public duties of public employees and officials shall not be considered an invasion of personal privacy. Information exempted under this subsection (b) shall include but is not limited to:

(i) files and personal information maintained with respect to clients, patients, residents, students or other individuals receiving social, medical, educational, vocational, financial, supervisory or custodial care or services directly or indirectly from federal agencies or public bodies;

(ii) personnel files and personal information maintained with respect to employees, appointees or elected officials of any public body or applicants for those positions;

(iii) files and personal information maintained with respect to any applicant, registrant or licensee

by any public body cooperating with or engaged in professional or occupational registration, licensure or discipline;

(iv) information required of any taxpayer in connection with the assessment or collection of any tax unless disclosure is otherwise required by State statute;

(v) information revealing the identity of persons who file complaints with or provide information to administrative, investigative, law enforcement or penal agencies; provided, however, that identification of witnesses to traffic accidents, traffic accident reports, and rescue reports may be provided by agencies of local government, except in a case for which a criminal investigation is ongoing, without constituting a clearly unwarranted per se invasion of personal privacy under this subsection; and

(vi) the names, addresses, or other personal information of participants and registrants in park district, forest preserve district, and conservation district programs.

(c) Records compiled by any public body for administrative enforcement proceedings and any law enforcement or correctional agency for law enforcement purposes or for internal matters of a public body, but only to the extent that disclosure would:

(i) interfere with pending or actually and reasonably contemplated law enforcement proceedings conducted by any law enforcement or correctional agency;

(ii) interfere with pending administrative enforcement proceedings conducted by any public body;

(iii) deprive a person of a fair trial or an impartial hearing;

(iv) unavoidably disclose the identity of a confidential source or confidential information

furnished only by the confidential source;

(v) disclose unique or specialized investigative techniques other than those generally used and known or disclose internal documents of correctional agencies related to detection, observation or investigation of incidents of crime or misconduct;

(vi) constitute an invasion of personal privacy under subsection (b) of this Section;

(vii) endanger the life or physical safety of law enforcement personnel or any other person; or

(viii) obstruct an ongoing criminal investigation.

(d) Criminal history record information maintained by State or local criminal justice agencies, except the following which shall be open for public inspection and copying:

(i) chronologically maintained arrest information, such as traditional arrest logs or blotters;

(ii) the name of a person in the custody of a law enforcement agency and the charges for which that person is being held;

(iii) court records that are public;

(iv) records that are otherwise available under State or local law; or

(v) records in which the requesting party is the individual identified, except as provided under part (vii) of paragraph (c) of subsection (1) of this Section.

"Criminal history record information" means data identifiable to an individual and consisting of descriptions or notations of arrests, detentions, indictments, informations, pre-trial proceedings, trials, or other formal events in the criminal justice system or descriptions or notations of criminal charges (including criminal violations of local municipal ordinances) and the nature of any disposition arising therefrom, including sentencing, court or correctional supervision,

rehabilitation and release. The term does not apply to statistical records and reports in which individuals are not identified and from which their identities are not ascertainable, or to information that is for criminal investigative or intelligence purposes.

(e) Records that relate to or affect the security of correctional institutions and detention facilities.

(f) Preliminary drafts, notes, recommendations, memoranda and other records in which opinions are expressed, or policies or actions are formulated, except that a specific record or relevant portion of a record shall not be exempt when the record is publicly cited and identified by the head of the public body. The exemption provided in this paragraph (f) extends to all those records of officers and agencies of the General Assembly that pertain to the preparation of legislative documents.

(g) Trade secrets and commercial or financial information obtained from a person or business where the trade secrets or information are proprietary, privileged or confidential, or where disclosure of the trade secrets or information may cause competitive harm, including all information determined to be confidential under Section 4002 of the Technology Advancement and Development Act. Nothing contained in this paragraph (g) shall be construed to prevent a person or business from consenting to disclosure.

(h) Proposals and bids for any contract, grant, or agreement, including information which if it were disclosed would frustrate procurement or give an advantage to any person proposing to enter into a contractor agreement with the body, until an award or final selection is made. Information prepared by or for the body in preparation of a bid solicitation shall be exempt until an award or final selection is made.

(i) Valuable formulae, computer geographic systems, designs, drawings and research data obtained or produced by

any public body when disclosure could reasonably be expected to produce private gain or public loss. The exemption for "computer geographic systems" provided in this paragraph (i) does not extend to requests made by news media as defined in Section 2 of this Act when the requested information is not otherwise exempt and the only purpose of the request is to access and disseminate information regarding the health, safety, welfare, or legal rights of the general public.

(j) Test questions, scoring keys and other examination data used to administer an academic examination or determined the qualifications of an applicant for a license or employment.

(k) Architects' plans, engineers' technical submissions, and other construction related technical documents for projects not constructed or developed in whole or in part with public funds and the same for projects constructed or developed with public funds, but only to the extent that disclosure would compromise security, including but not limited to water treatment facilities, airport facilities, sport stadiums, convention centers, and all government owned, operated, or occupied buildings.

(l) Library circulation and order records identifying library users with specific materials.

(m) Minutes of meetings of public bodies closed to the public as provided in the Open Meetings Act until the public body makes the minutes available to the public under Section 2.06 of the Open Meetings Act.

(n) Communications between a public body and an attorney or auditor representing the public body that would not be subject to discovery in litigation, and materials prepared or compiled by or for a public body in anticipation of a criminal, civil or administrative proceeding upon the request of an attorney advising the public body, and materials prepared or compiled with

respect to internal audits of public bodies.

(o) Information received by a primary or secondary school, college or university under its procedures for the evaluation of faculty members by their academic peers.

(p) Administrative or technical information associated with automated data processing operations, including but not limited to software, operating protocols, computer program abstracts, file layouts, source listings, object modules, load modules, user guides, documentation pertaining to all logical and physical design of computerized systems, employee manuals, and any other information that, if disclosed, would jeopardize the security of the system or its data or the security of materials exempt under this Section.

(q) Documents or materials relating to collective negotiating matters between public bodies and their employees or representatives, except that any final contract or agreement shall be subject to inspection and copying.

(r) Drafts, notes, recommendations and memoranda pertaining to the financing and marketing transactions of the public body. The records of ownership, registration, transfer, and exchange of municipal debt obligations, and of persons to whom payment with respect to these obligations is made.

(s) The records, documents and information relating to real estate purchase negotiations until those negotiations have been completed or otherwise terminated. With regard to a parcel involved in a pending or actually and reasonably contemplated eminent domain proceeding under Article VII of the Code of Civil Procedure, records, documents and information relating to that parcel shall be exempt except as may be allowed under discovery rules adopted by the Illinois Supreme Court. The records, documents and information relating to a real estate sale shall be exempt until a sale is consummated.

(t) Any and all proprietary information and records related to the operation of an intergovernmental risk management association or self-insurance pool or jointly self-administered health and accident cooperative or pool.

(u) Information concerning a university's adjudication of student or employee grievance or disciplinary cases, to the extent that disclosure would reveal the identity of the student or employee and information concerning any public body's adjudication of student or employee grievances or disciplinary cases, except for the final outcome of the cases.

(v) Course materials or research materials used by faculty members.

(w) Information related solely to the internal personnel rules and practices of a public body.

(x) Information contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of a public body responsible for the regulation or supervision of financial institutions or insurance companies, unless disclosure is otherwise required by State law.

(y) Information the disclosure of which is restricted under Section 5-108 of the Public Utilities Act.

(z) Manuals or instruction to staff that relate to establishment or collection of liability for any State tax or that relate to investigations by a public body to determine violation of any criminal law.

(aa) Applications, related documents, and medical records received by the Experimental Organ Transplantation Procedures Board and any and all documents or other records prepared by the Experimental Organ Transplantation Procedures Board or its staff relating to applications it has received.

(bb) Insurance or self insurance (including any intergovernmental risk management association or self insurance pool) claims, loss or risk management

information, records, data, advice or communications.

(cc) Information and records held by the Department of Public Health and its authorized representatives relating to known or suspected cases of sexually transmissible disease or any information the disclosure of which is restricted under the Illinois Sexually Transmissible Disease Control Act.

(dd) Information the disclosure of which is exempted under Section 30 of the Radon Industry Licensing Act.

(ee) Firm performance evaluations under Section 55 of the Architectural, Engineering, and Land Surveying Qualifications Based Selection Act.

(ff) Security portions of system safety program plans, investigation reports, surveys, schedules, lists, data, or information compiled, collected, or prepared by or for the Regional Transportation Authority under Section 2.11 of the Regional Transportation Authority Act or the St. Clair County Transit District under the Bi-State Transit Safety Act.

(gg) Information the disclosure of which is restricted and exempted under Section 50 of the Illinois Prepaid Tuition Act.

(hh) Information the disclosure of which is exempted under the State Officials and Employees Ethics Act.

(ii) Beginning July 1, 1999, information that would disclose or might lead to the disclosure of secret or confidential information, codes, algorithms, programs, or private keys intended to be used to create electronic or digital signatures under the Electronic Commerce Security Act.

(jj) Information contained in a local emergency energy plan submitted to a municipality in accordance with a local emergency energy plan ordinance that is adopted under Section 11-21.5-5 of the Illinois Municipal Code.

(kk) Information and data concerning the distribution of surcharge moneys collected and remitted by wireless

carriers under the Wireless Emergency Telephone Safety Act.

(ll) Vulnerability assessments, security measures, and response policies or plans that are designed to identify, prevent, or respond to potential attacks upon a community's population or systems, facilities, or installations, the destruction or contamination of which would constitute a clear and present danger to the health or safety of the community, but only to the extent that disclosure could reasonably be expected to jeopardize the effectiveness of the measures or the safety of the personnel who implement them or the public. Information exempt under this item may include such things as details pertaining to the mobilization or deployment of personnel or equipment, to the operation of communication systems or protocols, or to tactical operations.

(mm) Maps and other records regarding the location or security of a utility's generation, transmission, distribution, storage, gathering, treatment, or switching facilities.

(nn) Law enforcement officer identification information or driver identification information compiled by a law enforcement agency or the Department of Transportation under Section 11-212 of the Illinois Vehicle Code.

(oo) Records and information provided to a residential health care facility resident sexual assault and death review team or the Residential Health Care Facility Resident Sexual Assault and Death Review Teams Executive Council under the Residential Health Care Facility Resident Sexual Assault and Death Review Team Act.

<u>(pp) Information the disclosure of which is exempted under Sections 25 and 25a of the Wholesale Prescription Drug Distribution Protection and Licensing Act of 2005.</u>

(2) This Section does not authorize withholding of information or limit the availability of records to the public,

except as stated in this Section or otherwise provided in this Act.

(Source: P.A. 92-16, eff. 6-28-01; 92-241, eff. 8-3-01; 92-281, eff. 8-7-01; 92-645, eff. 7-11-02; 92-651, eff. 7-11-02; 93-43, eff. 7-1-03; 93-209, eff. 7-18-03; 93-237, eff. 7-22-03; 93-325, eff. 7-23-03, 93-422, eff. 8-5-03; 93-577, eff. 8-21-03; 93-617, eff. 12-9-03.)

Section 10. The Regulatory Sunset Act is amended by changing Section 4.23 as follows:

(5 ILCS 80/4.23)

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

The Dietetic and Nutrition Services Practice Act.

The Elevator Safety and Regulation Act.

The Funeral Directors and Embalmers Licensing Code.

The Naprapathic Practice Act.

The Professional Counselor and Clinical Professional Counselor Licensing Act.

The Wholesale Prescription Drug Distribution Protection and Licensing Act of 2005.

Section 2.5 of the Illinois Plumbing License Law.

(Source: P.A. 92-586, eff. 6-26-02; 92-641, eff. 7-11-02; 92-642, eff. 7-11-02; 92-655, eff. 7-16-02; 92-719, eff. 7-25-02; 92-778, eff. 8-6-02; 92-873, eff. 6-1-03; revised 1-18-03.)

Section 15. The Wholesale Drug Distribution Licensing Act is amended by changing Sections 1, 10, 15, 20, 25, 50, 55, and 170 and by adding Sections 25a, 25b, 25c, 25d, 25e, and 25f as follows:

(225 ILCS 120/1) (from Ch. 111, par. 8301-1)

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

Sec. 1. Short title. This Act may be cited as the Wholesale Prescription Drug Distribution Protection and Licensing Act of 2005.

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

(225 ILCS 120/10) (from Ch. 111, par. 8301-10)

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

Sec. 10. Purpose. The purpose of this Act is to implement the Federal Prescription Drug Marketing Act of 1987 (PDMA), U.S. Pub. L. 100-293, 102 Stat. 95, codified at U.S.C. Sec. 321 et seq.; and particularly PDMA requirements that no person or entity may engage in the wholesale distribution of human prescription drugs in any state unless the person or entity is licensed by that state in accordance with federally prescribed minimum standards, terms, and conditions as set forth in guidelines issued by United States Food and Drug Administration (FDA) regulations.

The purpose of this amendatory Act of the 94th General Assembly is to strengthen existing State requirements governing the distribution of prescription drugs in order to protect the drug supply and consumer safety.

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

(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:

"Authorized distributor of record" means a wholesale drug distributor with whom a manufacturer has established an ongoing relationship to distribute that manufacturer's product. An ongoing relationship is deemed to exist when a wholesale drug distributor, including any affiliated group, as defined in Section 1504 of the Internal Revenue Code, of which the wholesale distributor is a member:

(1) is listed on the manufacturer's list and the list is updated monthly;

(2) has a written agreement currently in effect with

the manufacturer; or

(3) has a verifiable account with a line of credit with the manufacturer and minimal transaction or volume requirement thresholds as follows: (i) 5,000 sales units per company within 12 months or (ii) 12 purchases or invoices from the manufacturer at the manufacturer's minimum purchasing requirements per invoice within 12 months.

"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.

"Department" means the Department of Professional Regulation.

"Director" means the Director of Professional Regulation.

"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.

"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 required by

federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to subsection (b) of Section 503 of the Federal Food, Drug and Cosmetic Act.

"Sales unit" means the unit of measure the manufacturer uses to invoice its customer for the particular product.

"Verifiable account" means:

(1) an account that the manufacturer confirms, in written or oral form, is assigned to the wholesaler; or

(2) copies of the manufacturer's invoices containing a printed account number and the name and address of the wholesaler.

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

(a) Intracompany sales, 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.

(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 <u>authorized</u> distributors' representatives.

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

<u>(i) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with Department rules.</u>

<u>(j) The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.</u>

"Wholesale drug distributor" means any person or entity engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own label distributors; jobbers; private label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, 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 120/20) (from Ch. 111, par. 8301-20)

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

Sec. 20. Prohibited acts. ~~drug purchases or receipt.~~

(a) It shall be unlawful to knowingly tamper with, counterfeit, adulterate, misbrand, or divert prescription drug products. Violation of this subsection (a) shall constitute a Class 4 felony.

(b) It shall be unlawful to knowingly purchase, transfer, sell, or distribute prescription drugs from or to persons not authorized to possess such prescription drugs. Violation of this subsection (b) shall constitute a Class 4 felony.

(c) It shall be unlawful to knowingly purchase, transfer, sell, or distribute prescription drugs that have been tampered with, counterfeited, adulterated, misbranded, or diverted. Violation of this subsection (c) shall constitute a Class 4 felony.

(d) It shall be unlawful to knowingly forge, counterfeit, or tamper with any pedigree documentation or other transactional documentation associated with the purchase, transfer, delivery, or sale of prescription drugs that is required by federal or State laws and rules. Violation of this subsection (d) shall constitute a Class 4 felony.

~~It shall be unlawful for any person or entity 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. 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) 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 may grant a temporary license when a wholesale drug distributor first applies for a license to operate within this State. A temporary license 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) 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 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) 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 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) any findings of a criminal background and civil litigation check, which the Department shall be authorized to conduct in conjunction with the Department of State Police or an independent 3rd party company or organization authorized to conduct such searches, of all company officers, key management, principals, and owners with 10% or greater interest in the company, the latter applying to non-publicly held companies only;

(7) any findings of a financial background check, including a credit history of the company and its key officers, maintained by an independent 3rd party

evaluation organization;

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

(9) ~~(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~~

(10) ~~(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; ~~.~~

(11) The information collected by the Department as part of the background checks authorized in this subsection (f) is exempt from the Freedom of Information Act; and

(12) ~~(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. 92-586, eff. 6-26-02.)

(225 ILCS 120/25a new)

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

Sec. 25a. Application requirements.

(a) An application for licensure or renewal as a wholesale distributor or an out-of-state wholesale distributor submitted to the Department must include all of the following:

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

(2) All trade or business names used by the applicant, including all affiliated businesses.

(3) The name, address, and telephone number of a contact person for each facility used by the applicant for the storage, handling, and distribution of prescription drugs. Companies with multiple facilities may designate one person to serve as the contact person for all of its facilities, including those of its affiliates.

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

(5) The names of the owner and the operator of the establishment, including the following:

(A) if an individual, the name of the individual;

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

(C) if a corporation:

(i) the name, address, and title of each corporate officer and director;

(ii) the name and address of the corporation, the name and address of the resident agent of the corporation, and the corporation's state of incorporation; and

(iii) for non-publicly held companies only, the name and address of each shareholder that owns 10% or more of the outstanding stock of the corporation;

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

(E) if a limited liability company:

(i) the name and address of each principal;

(ii) the name and address of each manager; and

(iii) the name and address of the limited liability company, the name and address of the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized.

(6) A list of all state licenses, registrations, or permits, including the license, registration, or permit numbers, issued to the applicant by any other state licensing authority that authorizes the applicant to purchase, possess, and distribute prescription drugs.

(7) A list of all disciplinary actions by state and federal agencies against the company, as well as any actions against principals, owners, directors, or officers over the last 7 years.

(8) The number of employees at each facility and screening procedures for hiring.

(9) The minimum liability insurance limits the company maintains, including general as well as product liability insurance.

(10) A full description of each facility or warehouse, including all locations utilized for prescription drug storage or distribution. The description should include the following:

(A) square footage;

(B) security and alarm system description;

(C) terms of lease or ownership;

(D) address; and

(E) temperature and humidity controls.

(11) The tax year of the applicant.

(12) A copy of the deed for the property on which the applicant's establishment is located, if the establishment is owned by the applicant, or a copy of the applicant's lease for the property on which the applicant's establishment is located that has an original term of not less than one calendar year, if the establishment is not

owned by the applicant.

(13) A description of the applicant's prescription drug import and export activities.

(14) A description of the applicant's written procedures as required under Section 25 of this Act.

(b) The portions of the information required under this Section that are personally identifiable or are a trade secret, as defined by the Freedom of Information Act, shall be maintained by the Department as a trade secret or as proprietary information and shall be exempt from public disclosure.

(225 ILCS 120/25b new)

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

Sec. 25b. Required information from drug manufacturer. Each manufacturer of a prescription drug sold in this State shall file with the Department a written list of all of the manufacturer's authorized distributors of record. A manufacturer shall notify the Department not later than 10 days after any change to the list. The Department shall publish a list of all authorized distributors of record on its website. The Department shall update this list on at least a monthly basis.

(225 ILCS 120/25c new)

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

Sec. 25c. Surety bond.

(a) An applicant for a wholesale distributor license or an applicant for the renewal of an existing wholesale distributor license must submit a surety bond of $100,000 or evidence of other equivalent means of security acceptable to the Department, such as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution. A separate surety bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies or groups when these separate locations or

affiliated companies or groups are required to apply for or renew their wholesale distributor license with the Department.

(b) The purpose of the bond or other equivalent means of security is to secure payment of any administrative penalties imposed by the Department and any fees or costs incurred by the Department regarding that license, when those penalties, fees, or costs are authorized under State law and the licensee fails to pay within 30 days after the penalty, fee, or cost becomes final.

(c) The Department may make a claim against the surety bond or other equivalent means of security until one year after the wholesale distributor's license ceases to be valid or until 60 days after any administrative or legal proceeding as authorized by law that involves the licensee is concluded, including any appeal, whichever occurs later. The surety bond or other equivalent means of security must remain in place or in effect for at least one year after the wholesale distributor's license ceases to be valid or 60 days after any administrative or legal proceeding authorized in this Act against the licensee is concluded, including any appeal, whichever occurs later.

(d) The surety bond requirement may be waived, at the discretion of the Department, if the wholesale distributor previously has obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state where the wholesale distributor possesses a valid license in good standing.

(e) The Department may accept a surety bond of $25,000 if the annual gross receipts of the previous tax year for the wholesale distributor is $10,000,000 or less.

(225 ILCS 120/25d new)

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

Sec. 25d. Wholesale distributor designated representative.

(a) Each wholesale distributor licensed by the Department must identify a designated representative who is responsible for the company's compliance with applicable State and federal

laws. A designated representative may be a corporate employee or officer, outside counsel, or outside consulting specialist with the authority to help ensure compliance and may have responsibility for multiple licensed facilities. A designated representative shall not be required to be physically present at the facility.

(b) A wholesale distributor must notify the Department within 10 business days of changing its designated representative. A wholesale distributor may not operate for more than 30 business days without a designated representative under a wholesale distributor's license without appointing another designated representative and notifying the Department of the identity of the new designated representative.

(225 ILCS 120/25e new)

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

Sec. 25e. Pedigree.

(a) Each person who is engaged in the wholesale distribution of a drug subject to this Act and who is not the manufacturer or an authorized distributor of record of the drug shall provide to each wholesale distributor of the drug, including each distribution to an authorized distributor of record or to a retail pharmacy, before the sale is made to the wholesale distributor, a statement or record that identifies by date each previous sale of the drug starting with the last authorized distributor of record or the manufacturer if the drug has not been purchased previously by an authorized distributor of record, the proprietary and established name of the drug, dosage, container size, number of containers, the lot or control number of the drug, and the business name and address of all parties identified in the statement.

(b) Notwithstanding subsection (a) of this Section, a repackager or a manufacturer that repackages a drug subject to the provisions of this Act and who is not an authorized distributor of record, shall be subject to the requirements of that subsection (a).

(c) Notwithstanding subsection (a) of this Section, each person who is engaged in the wholesale distribution of a specified drug who did not purchase the specified drug directly from the manufacturer must provide to each wholesale distributor of the specified drug, including each distribution to an authorized distributor of record or to a retail pharmacy, a statement or record that identifies by date each previous sale of the specific unit of specified drug back to the manufacturer of the specified drug, the proprietary and established name of the drug, dosage, container size, number of containers, the lot or control numbers of the specific unit of the specified drug, and the business name and address of all parties identified in the statement.

(d) For each drug specified on the list, a distributor must provide to each wholesale distributor, including each distribution to an authorized distributor of record or to a retail pharmacy, to whom it sells the specified drug a written statement on the invoice that states the following:

(1) if the establishment is not a member of an affiliated group, "This establishment purchased the specific unit of the specified drug directly from the manufacturer."; or

(2) if the establishment is a member of an affiliated group, "This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer.".

(e) As used in this Section, the term "specified drug" means a prescription drug on a national list of prescription drugs considered to be potential targets for adulteration, counterfeiting, or diversion. This national list will be created by a national drug advisory coalition in conjunction with the U.S. Food and Drug Administration and other stakeholders, including, but not limited to, wholesalers, manufacturers, pharmacy, and appropriate state government agencies responsible for regulating the sale or distribution of prescription drugs. The Department shall notify and provide

wholesale distributors with the national list of specified drugs as prescription drugs are added to or removed from the list.

(f) The Department shall allow for an effective, unique electronic product identification tracking system for drugs subject to this Act to be implemented by, among others, manufacturers, repackagers, pharmacies, and wholesale distributors of such products. The system shall be designed to deter and detect counterfeiting and to provide a means for prescription drug product manufacturers, repackagers, distributors, and pharmacies to authenticate the product. The tracking system shall be implemented by December 31, 2010 and, once implemented, shall replace the requirements of this Section. The tracking system shall be deemed to be readily available and in place only upon the availability of a standardized system capable of being used on a wide scale across the entire healthcare industry, which includes manufacturers, wholesale distributors, and pharmacies.

(225 ILCS 120/25f new)

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

Sec. 25f. Due diligence review by purchasers. Prior to purchasing any prescription drugs from another wholesale distributor, the purchasing wholesale distributor shall obtain all of the following information from the selling wholesale distributor:

(1) A listing of the states that the company is domiciled in and shipping into and copies of all current State and federal regulatory licenses and registrations that authorize the selling wholesaler to purchase, possess, and distribute prescription drugs.

(2) The company's most recent facility inspection report.

(A) A wholesale distributor may rely upon the licensure authority's most recent inspection report of the selling wholesale distributor to satisfy the

requirement of this paragraph (2). The licensure authority, when requested, shall provide to a purchasing wholesaler documentation that demonstrates that the selling wholesaler had a satisfactory inspection.

(B) If the Department has failed to conduct a physical inspection of the selling wholesaler as required under Section 25c, then the purchasing wholesaler shall, before the initial purchase of any drug from that selling wholesaler and at least once every 3 years thereafter, inspect the selling wholesale distributor's licensed establishment in order to document that it has in place policies and procedures relating to the distribution of drugs, the appropriate temperature controlled environment for drugs requiring temperature control, an alarm system, appropriate access restrictions, and procedures to ensure that records related to the wholesale distribution of prescription drugs are maintained as required by law.

(3) Information regarding the general and product liability insurance the company maintains.

(4) A list of all corporate officers.

(5) A list of all owners of greater than 10% of the company, unless it is a publicly held company.

(6) If the selling wholesale distributor claims to be an authorized distributor of record, a written statement from the company stating that it is an authorized distributor of record and the basis on which this status was given.

(7) A list of all disciplinary actions by State and federal agencies against the company, as well as principals, owners, and officers, over the last 7 years or since the company was first licensed.

(8) A description, including the address, dimensions, and other relevant information, of each facility or

warehouse that the company uses for drug storage and distribution.

(9) A description and listing of all drug import and export activities of the company.

(10) A description of the process the company uses to validate and certify its suppliers and purchases, including the supplier's status as an authorized distributor of record.

(11) A description of the company's systems and procedures for prompt reporting to appropriate State and federal authorities and manufacturers of any suspected counterfeit, stolen, or otherwise unlawful prescription drug products or buyers or sellers of the same.

(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) The Department shall conduct a physical inspection of each in-State applicant's facility prior to issuing a license or, for a wholesale distributor with a valid license on the effective date of this amendatory Act of the 94th General Assembly, prior to issuing a renewal, with regular periodic inspections conducted thereafter, no more than 3 years following the last inspection.

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. The duly authorized investigators shall be required to show appropriate identification before 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~~

At any time, the Department may initiate ~~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) 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) The Department shall employ a person whose title shall be Assistant Drug Compliance Coordinator to assist the Drug Compliance Coordinator in administering and enforcing this Act.

(d) The Department must make publicly available on its website the dates of the first and most recent inspections of each wholesale distributor.

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

(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 the applicant or licensee, or any officer, director, manager or shareholder who owns more than 5% of stock, 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 $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 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.

(e) The Department shall notify the appropriate person upon license suspension, revocation, expiration, or other relevant action and make such actions publicly available on its website within 5 working days.

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

(225 ILCS 120/170) (from Ch. 111, par. 8301-170)

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

Sec. 170. Penalties. Any person who is found to have violated any provision of this Act, except as provided in Section 20, is guilty of a Class A misdemeanor. On conviction of a second or subsequent offense, the violator shall be guilty of a Class 4 felony. All criminal fines, monies, or property

collected or received by the Department under this Section or any other State or federal statute, including, but not limited to, property forfeited to the Department under Section 505 of the Illinois Controlled Substances Act, shall be deposited into the Professional Regulation Evidence Fund.

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

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Statutes amended in order of appearance

5 ILCS 140/7	from Ch. 116, par. 207
5 ILCS 80/4.23	
225 ILCS 120/1	from Ch. 111, par. 8301-1
225 ILCS 120/10	from Ch. 111, par. 8301-10
225 ILCS 120/15	from Ch. 111, par. 8301-15
225 ILCS 120/20	from Ch. 111, par. 8301-20
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