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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2602 Session of 1992

INTRODUCED BY FEE, RICHARDSON, CAPPABIANCA, KUKOVICH, WAMBACH, DeWEESE, PESCI, HALUSKA, HARPER, PETRARCA, TRELLO, SALOOM, JAROLIN, PETRONE, KRUSZEWSKI, McGEEHAN, BATTISTO, OLASZ, MIHALICH, TIGUE, DONATUCCI, D. R. WRIGHT, COLAIZZO, CORRIGAN, PISTELLA, KOSINSKI AND JAMES, APRIL 6, 1992

SENATOR LOEPER, RULES AND EXECUTIVE NOMINATIONS, IN SENATE, RE-REPORTED AS AMENDED, NOVEMBER 17, 1992

AN ACT

Providing minimum standards, terms and conditions for the licensing of persons who engage in wholesale distributions in interstate commerce of prescription drugs; and making a repeal.

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The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Wholesale Prescription Drug Distributors License Act.

Section 2. Legislative intent.

(a) Findings.--The General Assembly finds and declares as follows:

(1) The economic interests of this Commonwealth and of its wholesale prescription drug industry will be promoted by requiring the licensure of persons who engage in the wholesale distribution of prescription drugs in interstate commerce under the Federal Prescription Drug Marketing Act of 1987 (Public Law 100-293, 102 Stat. 95).

(2) Pennsylvania consumers of prescription drugs will be better assured of safe and effective prescription drug products if the Commonwealth joins with other jurisdictions to require the licensure of all persons who operate facilities from which they engage in the wholesale distribution of prescription drugs.

(b) Intent.--It is the intent of the General Assembly that this act satisfy the requirements of the Federal Prescription

Drug Marketing Act of 1987. It is the further intent of the General Assembly to promote the safety and effectiveness of prescription drug products by requiring all persons who operate facilities within this Commonwealth from which they engage in the wholesale distribution of prescription drugs to secure a license and meet minimum quality assurance and operational standards as required by this act.

Section 3. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Blood." Whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component." That part of blood separated by physical or mechanical means.

"Common control." 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.

"Department." The Department of Health of the Commonwealth.

"Drug sample." A unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Intracompany sales." A transaction or transfer between any division, subsidiary, parent or affiliated or related company under the common ownership and control of a corporate entity.

"License." A wholesale prescription drug distributor license.

"Manufacturer." Any entity engaged in manufacturing, preparing, propagating, compounding, processing, packaging,

repackaging or labeling of a prescription drug.

"Prescription drug." Any human drug required by Federal law, the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, or regulations promulgated under either, to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 503(b)).

"Wholesale distribution of prescription drugs." Distribution in interstate commerce of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales or joining together of five or fewer pharmacies to place a direct order of medicine from the pharmaceutical manufacturer.

(2) 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 such organizations.

(3) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986 (Public Law 99-514, 26 U.S.C. § 501(c)(3)) to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

(4) 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.

(5) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons,

including transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

(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 distribution of drug samples by manufacturers' representatives or distributors' representatives.

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

(9) The sale of minimal quantities of prescription drugs by a retail pharmacy to licensed practitioners for use within their practice when the sales do not exceed 5% of that retail pharmacy's total annual prescription drug sales.

"Wholesale distributor of prescription drugs." A person who operates a facility from which a person engages in the wholesale distribution of prescription drugs, including, but not limited to, manufacturers, repackers, own-label distributors, private-label distributors or jobbers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses, independent wholesale drug traders and retail pharmacies that conduct wholesale distributions.

Section 4. License and renewal requirements.

(a) License.--After September 14, 1992, a person may not operate a facility within this Commonwealth from which a person engages in the wholesale distribution of prescription drugs without having secured from the department a license and a current renewal of that license. A person shall obtain a separate license to operate each facility.

(b) License renewal.--A licensee shall renew its license at the same time it is required to renew the registration issued to it under the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, or as otherwise required by the department, but in no case shall the period for renewing the license be longer than two years. A form for the license renewal shall be mailed to each licensee on or before the first day of the month in which the current renewal expires. If a completed license renewal is neither postmarked nor received by the department before the first day of the following month, the license shall become invalid. Failure of the licensee to receive the form by mail shall not serve as an excuse for failing to timely renew the license.

(c) Fees.--Each person who applies for a license shall submit a fee of $10 with the license application. The license renewal fee shall be $100, unless changed by regulation, and shall be submitted with the completed license renewal form. The late submission of a completed license renewal form shall be accompanied by a late payment fee of $25 for each month or portion thereof that expired after the license renewal was due. The late payment fee shall be in addition to any administrative, civil or criminal penalty that may be imposed against a licensee for continuing to engage in the wholesale distribution of prescription drugs without a current license. Fees under this section may be amended by regulation of the department.

Section 5. License application.

(a) Information on application.--An applicant for a license shall provide the following information on a license application form approved by the department:

(1) The name, full business address and telephone number

of the facility for which the applicant is seeking a license to operate.

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

(3) All trade or business names used by the applicant.

(4) Addresses, telephone numbers and the names of contact persons for all facilities used by the facility for which the license is being sought, for the storage, handling and distribution of prescription drugs.

(5) The type of ownership or operation, that is, partnership, corporation or sole proprietorship, of the facility.

(6) The name of the owner and operator of the facility as follows:

(i) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(ii) If a partnership, the name of each partner and the name of the partnership.

(iii) If a corporation, the name and title of each corporate officer and director, the corporate name and the name of the state of incorporation.

(iv) If a person other than a sole proprietorship, partnership or corporation, the name of the person and of the individual in charge of that person.

(7) Any other information required by the department, including information bearing upon whether there are grounds for refusing to grant the license under section 7.

(b) Changes in information.--A change in any information provided in the application shall be submitted to the department within 30 days after the change or as otherwise required by the

department.

Section 6. Storage, handling and recordkeeping.

(a) Minimum requirements.--Licensees and their officers, agents, representatives and employees shall satisfy the minimum requirements of this section for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(b) Facility.--The facility shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance and proper operations.

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions.

(3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated or that are in immediate or sealed, secondary containers that have been opened.

(4) Be maintained in a clean and orderly condition.

(5) Be free from infestation by insects, rodents, birds or vermin of any kind.

(c) Security.--The facility shall be secure from unauthorized entry as follows:

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lighted.

(3) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(4) The facility shall be equipped with an alarm system to detect entry after hours.

(5) The facility shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(d) Storage.--All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or with requirements in the current edition of the United States Pharmacopeia/National Formulary (USP/NF). If no storage requirements are established for a prescription drug, the drug may be held at controlled room temperature, as defined in the USP/NF, to help ensure that its identity, strength, quality and purity are not adversely affected. Appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices or logs shall be utilized to document proper storage of prescription drugs. The recordkeeping requirements under subsection (g) shall be followed for all stored drugs.

(e) Examination of materials.--Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions. The

recordkeeping requirements in subsection (g) shall be followed for all incoming and outgoing prescription drugs.

(f) Returned, damaged and outdated prescription drugs.--Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier. If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality or purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the licensee shall consider, among other things, the conditions under which the drug has been held, stored or shipped before or during its return and the condition of the drug and its container, carton or labeling as a result of storage or shipping. The recordkeeping requirements under subsection (g) shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated prescription drugs.

(g) Recordkeeping.--

(1) The licensee shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription

drugs. These records shall include the following information:

(i) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped.

(ii) The identity and quantity of the drugs received and distributed or disposed.

(iii) The dates of receipt and distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State or local law enforcement agency officials for a period of two years following disposition of the drugs.

(3) Records described in this section that are kept at the facility or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the facility and not electronically retrievable shall be made available for inspection within two working days of an authorized request by an authorized official of a Federal, State or local law enforcement agency.

(h) Written policies and procedures.--The licensee shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. The licensee shall include in its written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. The procedure shall be adequate to deal with recalls and withdrawals due to any of the following:

(i) Any action initiated at the request of the department, the United States Food and Drug Administration or other Federal, State or local law enforcement or other government agency.

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market.

(iii) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(3) A procedure to ensure that the licensee prepares for, protects against and handles any crisis that affects security or operation of the facility in the event of strike, fire, flood or other natural disaster or other situations of national, State or local emergency.

(4) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

(i) Responsible persons.--The licensee shall:

(1) Establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(2) Ensure that all personnel involved in the wholesale distribution of prescription drugs have an adequate combination of education, training and experience to perform their duties in a manner that ensures compliance with this act and applicable regulations.

(j) Salvaging and reprocessing.--The licensee shall comply with any applicable Federal, State or local law or regulation that relates to prescription drug salvaging or reprocessing.

(k) Compliance with Federal, State and local law.--The licensee shall operate in compliance with applicable Federal, State and local laws and regulations. The licensee shall permit the department and authorized Federal, State and local law enforcement officials to enter and inspect its premises and delivery vehicles and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. The licensee that deals in controlled substances shall register with the Drug Enforcement Administration (DEA) and shall comply with all applicable DEA, State and local regulations.

Section 7. Additional requirements.

The department may, BY REGULATION, establish additional requirements for the distribution, storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records. The department may also, BY REGULATION, modify the standards in section 6 if modification <—— <——

of those standards is necessary to satisfy minimum requirements contained in the United States Department of Health and Human Services regulations setting forth guidelines for state licensing of persons who engage in the wholesale distribution of prescription drugs.

Section 8. Persons without license and current renewal.

Any person who does not have a license and current renewal and who operates a facility in this Commonwealth through which it engages in the wholesale distribution of prescription drugs shall comply with the requirements of sections 6 and 7, notwithstanding the person's failure to secure a license or a current renewal.

Section 9. Refusal, revocation, suspension or limitation of license.

(a) Reasons for discipline.--The department may refuse to issue or may suspend, revoke or limit any and all licenses held by a licensee or fine a licensee for any of the following reasons:

(1) Failing to demonstrate the qualifications for a license.

(2) Violating any provision of this act.

(3) Being convicted of a felony or of a crime relating to drug samples, wholesale or retail drug distribution or any other law relating to the handling of drugs.

(4) Making misleading, deceptive, untrue or fraudulent representations in obtaining or seeking to obtain a license or registration.

(5) Having a license or equivalent authorization currently or previously held for the manufacture or distribution of any drugs denied, suspended, revoked,

restricted or subjected to any other sanction for disciplinary reasons by a Federal, State or local government agency.

(6) Violating a regulation promulgated by the department or violating a lawful order of the department entered in a disciplinary proceeding.

(7) Engaging in conduct which is harmful to the public health, safety or welfare.

(b) Notice of deficiencies.--Whenever the department shall, upon inspection, investigation or complain, preliminarily find a violation of this act or the regulations promulgated thereunder, it may, in lieu of proceeding with disciplinary action, issue a written notice to the licensee specifying the violation and directing that the violation be corrected and that a written plan of correction be filed with it by a specified date. The licensee shall respond as directed and shall either deny the alleged violation or provide a plan of correction by the date specified in the notice. If the plan of correction is accepted by the department, the licensee shall implement it as directed by the department.

(c) Reinstatement.--A person whose license has been revoked may not apply for reinstatement until five years have expired during which the license was revoked.

Section 10. Injunction against unlawful practice.

The department may maintain an action for an injunction to restrain a person from operating a facility within this Commonwealth through which it engages in the wholesale distribution of prescription drugs when that person does not have a license and a current renewal of that license as required by this act. To secure an injunction, it shall not be necessary

to show that any person has been injured by the actions complained of. The remedy of injunction is an addition to any other administrative, civil or criminal remedy authorized.

Section 11. Penalties for unlicensed practice.

(a) Civil penalty.--The department shall have authority to assess a civil penalty of up to $500 for each day that a person engages in the wholesale distribution of prescription drugs without a license as required by this act.

(b) Criminal penalty.--A person who engages in the wholesale distribution of prescription drugs without a license as required by this act commits a misdemeanor of the third degree and shall, upon conviction, be sentenced to pay a fine of not more than $2,000 and to imprisonment for not more than six months, or both, for the first violation. On the second and each subsequent conviction, the person shall be sentenced to pay a fine of not less than $5,000 nor more than $20,000 or to imprisonment for not less than six months nor more than one year, or both.

Section 12. Disciplinary proceedings.

All actions of the department taken under sections 9(a) and 11(a) shall be subject to the right of notice, hearing and adjudication and the right of appeal therefrom, in accordance with the provisions of 2 Pa.C.S. (relating to administrative law and procedure).

Section 13. Right to enter and inspect.

For the purpose of determining the suitability of an applicant for licensure and for the purpose of determining compliance with the provisions of this act and applicable regulations of any person licensed or requiring a license under this act, the department by its authorized agent may enter, visit and inspect the building, grounds and equipment and

supplies of any facility engaging or appearing to engage in the wholesale distribution of prescription drugs, shall have full and free access to the records of the facility and to the employees therein and their records and shall have full opportunity to interview employees and inspect such premises and records of the facility. Upon entering the facility, the authorized agents shall properly identify themselves to the individual on the premises then in charge of the facility.

Section 14. Rules and regulations.

The department may promulgate rules and regulations to administer and enforce this act.

Section 15. Severability.

The provisions of this act are severable. If any provision of this act or its application to any person or circumstances is held invalid, the invalidity shall not affect other provisions or applications of this act which can be given effect without the invalid provision or application.

Section 16. Repeal.

The act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, is repealed insofar as it is inconsistent with this act.

Section 17. Effective date.

This act shall take effect immediately.