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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 311 Session of 2007

INTRODUCED BY RAFFERTY, STACK, BOSCOLA, KITCHEN, FONTANA, ERICKSON, WONDERLING, ORIE, COSTA AND LOGAN, MARCH 13, 2007

REFERRED TO PUBLIC HEALTH AND WELFARE, MARCH 13, 2007

AN ACT

Requiring the licensing of secondary wholesalers and a written pedigree for use in tracking drugs through the supply chain and in identifying counterfeit prescription drugs; imposing duties and responsibilities upon the Department of Health and the State Board of Pharmacy; and prescribing penalties.

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 and Prescription Medication Integrity Act.

Section 2. 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:

"Authentication." Affirmative verification, before any wholesale distribution of a prescription drug, that each transaction listed on the pedigree has occurred.

"Authorized distributor of record." 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 such 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 of 1986 (Public Law 99-514, 26 U.S.C § 1 et seq.), complies with the following:

(1) the wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such 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.

"Chain pharmacy warehouse." 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 pharmacies having the same common ownership and control.

"Colicensed partner or product." A situation in which two or more parties have the right to engage in the manufacturing or marketing, or both, of a prescription drug, consistent with United States Food and Drug Administration's implementation of the Prescription Drug Marketing Act of 1987 (Public Law 100-293, 102 Stat. 95).

"Drop shipment." The sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug, the manufacturer's colicensed product partner, the manufacturer's third-party logistics provider or the 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 or chain pharmacy warehouse or another person authorized by law to dispense or administer such drug to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug directly from the manufacturer, the manufacturer's third-party logistics provider or the manufacturer's exclusive distributor.

"Facility." A facility of a wholesale distributor where prescription drugs are stored, handled, repackaged or offered for sale.

"FDA." The United States Food and Drug Administration.

"Manufacturer." A person licensed or approved by the United States Food and Drug Administration to engage in the manufacture of drugs or devices, consistent with its definition of "manufacturer" under its regulations and guidances implementing the Prescription Drug Marketing Act of 1987 (Public Law 100-293, 102 Stat. 95).

"Manufacturer's exclusive distributor." 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 does not have general responsibility to direct the sale or disposition of the prescription drug. The manufacturer's exclusive distributor must be licensed as a wholesale distributor under this act, and to be considered part of the normal distribution channel must also be an authorized distributor of record.

"Normal distribution channel." A chain of custody for a prescription drug that goes, directly or by drop shipment, from

a manufacturer of the prescription drug, from that manufacturer to the manufacturer's colicensed partner, from that manufacturer to the manufacturer's third-party logistics provider or from that manufacturer to the manufacturer's exclusive distributor to any of the following:

(1) a pharmacy, then to a patient or other designated persons authorized by law to dispense or administer the drug to a patient;

(2) a wholesale distributor, then to a pharmacy, then to a patient or other designated persons authorized by law to dispense or administer the drug to a patient;

(3) a wholesale distributor, then to a chain pharmacy warehouse, then to that chain pharmacy warehouse's intracompany pharmacy, then to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or

(4) a chain pharmacy warehouse, then to the chain pharmacy warehouse's intracompany pharmacy, then to a patient or other designated persons authorized by law to dispense or administer such drug to a patient.

"Pedigree." A document or electronic file containing information that records each distribution of any given prescription drug.

"Prescription drug." Any drug, including any biological product, except blood and blood components intended for transfusion or biological products that are also medical devices, required by Federal law or regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 353(b)).

"Repackage." Repackaging or otherwise changing the container, wrapper or labeling to further the distribution of a prescription drug, excluding that completed by the pharmacists responsible for dispensing product to the patient.

"Repackager." A person who repackages.

"State licensing authority." The Department of Health.

"Wholesale distribution." The term does not include:

(1) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between colicensees of a colicensed 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 21 C.F.R. § 203.23 (relating to returns).

(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 that the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply such 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 offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, and such 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.

"Wholesale distributor." Anyone engaged in the wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, and drug wholesalers or distributors; independent wholesale drug traders; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. To be considered part of the normal distribution channel the wholesale distributor must also be an authorized distributor of record.

Section 3. Wholesale drug distributor licensing requirements.

(a) Licensed required.--Every wholesale distributor who engages in the wholesale distribution of prescription drugs must be licensed by the State licensing authority in this Commonwealth, and every nonresident wholesale distributor must be licensed in this Commonwealth if it ships prescription drugs into this Commonwealth, in accordance with this act before engaging in wholesale distributions of wholesale prescription drugs. The State licensing authority shall exempt manufacturers distributing their own FDA-approved drugs and devices from any licensing and other requirements, to the extent not required by Federal law or regulation, unless particular requirements are deemed necessary and appropriate following rulemaking.

(b) Requirements.--The State licensing authority shall require the following minimum information from each wholesale distributor applying for a license under subsection (a):

(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 licensee, including:

(i) If a person, the name of the person.

(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 names and the name of the state of incorporation.

(iv) 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 applicant's designated representative for the facility, together with the personal information statement and fingerprints required pursuant to paragraph (8) for such person.

(8) Each person required by paragraph (7) to provide a personal information statement and fingerprints shall provide the following information:

(i) The person's places of residence for the past seven years.

(ii) The person's date and place of birth.

(iii) The person's occupations, positions of employment and offices held during the past seven years.

(iv) The principal business and address of any business, corporation or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on.

(v) Whether the person has been, during the past seven years, the subject of any proceeding for the revocation of any license and, if so, the nature of the proceeding and the disposition of the proceeding.

(vi) Whether, during the past seven years, 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, together with details concerning any such event.

(vii) 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 during the past seven years, which manufactured, administered, prescribed, distributed or stored pharmaceutical products and any lawsuits in which such businesses were named as a party.

(viii) A description of any 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 State a copy of the final written order of disposition.

(ix) A photograph of the person taken in the previous 30 days.

(c) Oath.--The information required pursuant to subsection (b) shall be provided under oath.

(d) Prohibitions.--The State licensing authority shall not issue a wholesale distributor license to an applicant unless the State licensing authority:

(1) Conducts a physical inspection of the facility at the required address provided by the applicant under subsection (b)(1).

(2) Determines that the designated representative meets

the following qualifications:

(i) Is 21 years of age or older.

(ii) Has been employed full time for at least three 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.

(iii) Is employed by the applicant full time in a managerial level position.

(iv) Is actively involved in and aware of the actual daily operation of the wholesale distributor.

(v) Is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave.

(vi) 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 colocated in the same facility and such wholesale distributors are members of an affiliated group, as defined in section 1504 of the Internal Revenue Code of 1986 (Public Law 99-514, 26 U.S.C. § 1 et seq.).

(vii) Does not have any convictions under any Federal, State or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances.

(viii) Does not have any felony convictions under Federal, State or local laws.

(e) Fingerprints.--The State licensing authority shall submit the fingerprints provided by a person with a license

application for a Statewide criminal record check and for forwarding to the Federal Bureau of Investigation for a national criminal record check of the person.

(f) Bond.--The State licensing authority shall require every wholesale distributor applying for a license to submit a bond of at least $100,000, or other equivalent acceptable means of security, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the restricted account established pursuant to subsection (g). Chain pharmacy warehouses that are engaged only in intracompany transfers are exempt from the bond requirement. The purpose of the bond is to secure payment of any fines or penalties and fees and costs incurred regarding that license, which are authorized by law and which the licensee fails to pay 30 days after the fines, penalties or costs become final. The Commonwealth may make a claim against such bond or security until one year after the licensee's license ceases to be valid. The bond shall cover all facilities operated by the applicant.

(g) Restricted account.--There is established within the Department of Health a restricted account, separate from other accounts, in which to deposit the wholesale distributor bonds required by subsection (f).

(h) Multiple facilities.--If a wholesale distributor distributes prescription drugs from more than one facility, the wholesale distributor shall obtain a license for each facility.

(i) Corrections.--Every calendar year, the State licensing authority shall send to each wholesale distributor licensed under this act a form setting forth the information that the wholesale distributor provided pursuant to this section. Within 30 days of receiving the form, the wholesale distributor shall

identify and state under oath all changes or corrections to the information that was provided. Changes and corrections shall be submitted as required. The State licensing authority may suspend or revoke the license of a wholesale distributor if the wholesale distributor no longer qualifies for a license.

(j) Designated representative.--The designated representative identified pursuant to subsection (b)(7) shall complete continuing education programs as required by the State licensing authority regarding Federal and State laws governing wholesale distribution of prescription drugs.

(k) Nondisclosure.--Information provided under this section shall not be disclosed to any person or entity other than the State licensing authority, a government board or a government agency.

Section 4. Restrictions on transactions.

(a) Purchases and receipts from pharmacies.--A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse, including the returns of expired, damaged and recalled pharmaceutical product to either the original manufacturer or a third-party returns processor, and such returns or exchanges shall not be subject to the pedigree requirement of this act so long as they are exempt from pedigree under FDA's currently applicable Prescription Drug Marketing Act of 1987 (Public Law 100-293, 102 Stat. 95) guidance. Wholesale distributors and pharmacies shall be held accountable for administering their returns process and ensuring that their operations are secure and do not permit entry of adulterated or counterfeit products.

(b) Sale, distribution or transfer to an unlicensed person.--A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the State licensing authority. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the State licensing authority.

(c) Delivery.--Prescription drugs furnished by a manufacturer or wholesale distributor shall be delivered only to the premises listed on the license, except 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.

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

(d) Hospital pharmacy.--Prescription drugs may be furnished to a hospital pharmacy receiving area, except that a pharmacist or authorized receiving personnel shall sign, at the time of delivery, a receipt showing the type and quantity of the prescription drug so 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) Credit.--A manufacturer or wholesale distributor shall not accept payment for or allow the use of a person's 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 prescription drugs. Any account established for the purchase of prescription drugs shall bear the name of the licensee.

Section 5. Pedigree.

(a) General rule.--Each person, including repackagers but excluding the original manufacturer of the finished form of the prescription drug, who is engaged in wholesale distribution of prescription drugs that leave or have ever left the normal distribution channel shall, before each wholesale distribution of such drug, provide a pedigree to the person who receives such drug. The following shall apply:

(1) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.

(2) The State licensing authority shall conduct a study to be completed within one year after the effective date of this section. The report shall include consultation with manufacturers, distributors and pharmacies responsible for the sale and distribution of prescription drug products in this Commonwealth. Based on the results of the study the State licensing authority shall determine a mandated implementation date for electronic pedigrees. The implementation date for the mandated electronic pedigree shall be no sooner than December 31, 2010, and may be extended by the State Board of Pharmacy in one year

increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.

(b) Authentication.--Each person who is engaged in the wholesale distribution of a prescription drug, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, and who is in possession of a pedigree for a prescription drug and attempts to further distribute that prescription drug shall affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(c) Contents.--The pedigree shall:

(1) Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer or from the manufacturer's third-party logistics provider, colicensed 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. At minimum, the necessary chain of distribution information shall include:

(i) 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.

(ii) Name and address of each location from which the product was shipped, if different from the owner's.

(iii) Transaction dates.

(iv) Certification that each recipient has authenticated the pedigree.

(2) At minimum, the:

(i) Name of the prescription drug.

(ii) Dosage form and strength of the prescription drug.

(iii) Size of the container.

(iv) Number of containers.

(v) Lot number of the prescription drug.

(vi) Name of the manufacturer of the finished dosage form.

(d) Maintenance provisions.--Each pedigree or electronic file shall be:

(1) Maintained by the purchaser and the wholesale distributor for three years from the date of sale or transfer.

(2) Available for inspection or use upon a request of an authorized officer of the law.

(e) Implementation.--The State licensing authority shall adopt rules, regulations and a form relating to the requirements of this section no later than 90 days after the effective date of this section.

Section 6. Enforcement; order to cease distribution of drug.

(a) Order to cease distribution of a prescription drug.--The State licensing authority shall issue an order requiring the appropriate person, including manufacturers, distributors or retailers of a drug, to immediately cease distribution of the drug if there is a reasonable probability that:

(1) A wholesale distributor other than a manufacturer has:

(i) violated a provision of 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 in paragraph (1) could cause serious, adverse health consequences or death.

(3) Other procedures would result in unreasonable delay.

(b) Informal hearing.--An order under subsection (a) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than ten days after the date of the issuance of the order. If after providing an opportunity for such a hearing the State licensing authority determines that inadequate grounds exist to support the actions required by the order, the order shall be vacated.

Section 7. Prohibited acts.

(a) General rule.--It is unlawful for a person to perform or cause the performance of or aid and abet any of the following acts in this Commonwealth:

(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) Purchasing or otherwise receiving a prescription drug from a pharmacy, unless the requirements of this act are met.

(3) 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 in violation of this act.

(4) Failure to deliver prescription drugs to specified premises as required by this act.

(5) Accepting payment or credit for the sale of

prescription drugs in violation 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 State licensing authority or any of its representatives 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, misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug.

(10) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved by the FDA, the manufacture, repackaging, sale, transfer, delivery, holding or offering for sale any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit or has otherwise been rendered unfit for distribution.

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

(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.

(b) Testing.--Subsection (a) does not apply to a prescription drug manufacturer, or agent of a prescription drug manufacturer, obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

Section 8. Penalties.

(a) General violations.--A person who engages in the wholesale distribution of prescription drugs in violation of this act commits a felony of the second degree and shall, upon conviction, be sentenced to pay a fine of not more than $50,000 or to imprisonment for not more than ten years, or both.

(b) Knowing violations.--A person who knowingly engages in wholesale distribution of prescription drugs in violation of this act commits a felony of the first degree and shall, upon conviction, be sentenced to pay a fine of not more than $500,000 or to imprisonment for not more than 20 years, or both.

Section 9. Effective date.

This act shall take effect immediately.