SPONSOR: Sen. Henry & Rep. Maier
Sens. Blevins, Connor, Sorenson;
Reps. Carey, Ewing, Hocker, Hudson,
Miro, Mitchell, Spence, Wagner

DELAWARE STATE SENATE
144th GENERAL ASSEMBLY

SENATE BILL NO. 38

AN ACT TO AMEND TITLE 24 OF THE DELAWARE CODE RELATING TO PHARMACY.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE (Three-fifths of all members elected to each house thereof concurring therein):

Section 1. This Act shall be known as the "Wholesale Licensure and Prescription Medication Integrity Act".

Section 2. Amend §2502(p), Title 24 of the Delaware Code by striking said subsection in its entirety and inserting in lieu thereof the following:

"'Prescription drug' means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal 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 ('FFDCA')."

Section 3. Amend §2502(t), Title 24 of the Delaware Code by striking said subsection in its entirety and inserting in lieu thereof the following:

" 'Wholesale distribution' and 'wholesale distributions' means distribution of prescription drugs to persons other than a consumer or patient, but 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 co-licenses of a co-licensed product.

(2) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons.

(3) The distribution of prescription drug samples by manufacturers' representatives.

(4) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 21 C.F.R. §203.23.

(5) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use.

(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

(7) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.

(8) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply 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."

Section 4. Amend §2502(u), Title 24 of the Delaware Code by striking said subsection in its entirety and by inserting in lieu thereof the following:

" 'Wholesale distributor' means 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; manufacturer's exclusive distributors; and authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; third party logistics providers; and retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution." To be considered part of the "normal distribution channel" such wholesale distributor must also be an "authorized distributor of record."

Section 5. Amend §2502, Title 24 of the Delaware Code by adding the following subsections by inserting them in alphabetical order and redesignating the existing subsections appropriately:

"'Authentication' means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

'Authorized distributor of record' means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between 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, complies with any one of 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' means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of such drugs to a group of chain pharmacies that have the same common ownership and control.

'Co-licensed product' means a prescription drug in which 2 or more parties have the right to engage in the manufacturing and/or marketing of such drug.

'Drop shipment' means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such prescription drug and the wholesale distributor invoices the pharmacy or chain pharmacy warehouse, and the pharmacy or chain pharmacy warehouse receives delivery of the prescription drug directly from the manufacturer, or that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor.

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

'Manufacturer' –means a person licensed or approved by the federal Food and Drug Administration to engage in the manufacture of drugs or devices

'Manufacturer's exclusive distributor' means anyone who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's

prescription drug. Such 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' means a chain of custody for a prescription drug that goes from a manufacturer of the prescription drug, (or from that manufacturer to that manufacturer's co-licensed partner), (or from that manufacturer to that manufacturer's third-party logistics provider), (or from that manufacturer to that manufacturer's exclusive distributor) to:

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

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

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

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

'Pedigree' means a document or electronic file containing information that records each distribution of any given prescription drug.

'Repackage' means 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' means a person who repackages.

'Third party logistics provider' means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. Such third party logistics provider 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."

Section 6. Amend Chapter 25, Title 24 of the Delaware Code by adding the following sections to current Subchapter IV.

§2548. Wholesale Drug Distributor Licensing Requirement/Minimum Requirements for Licensure.

(a) Every wholesale distributor who engages in the wholesale distribution of prescription drugs within this state, including resident and non-resident wholesale distributors, must be licensed by the Board of Pharmacy, in accordance with this Subchapter before engaging in wholesale distributions of wholesale prescription drugs. The Board of Pharmacy shall exempt manufacturers distributing their own FDA-approved drugs and devices from any licensing and other requirements of this section, to the extent not required by Federal law or regulation, unless particular requirements are deemed necessary and appropriate following rulemaking.

(b) The Board of Pharmacy shall require the following minimum information from each wholesale distributor applying to get 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 (i.e., partnership, corporation, or sole proprietorship).

(5) The name(s) of the owner and/or operator of the licensee, including:

(A) If a person, the name of the person;

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

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

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

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

(7) Designated Representative - 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) Personal Information Statement - Each person required by paragraph (7) to provide a personal information statement and fingerprints shall provide the following information to the Board of Pharmacy:

(A) The person's places of residence for the past 7 years;

(B) The person's date and place of birth;

(C) The person's occupations, positions of employment, and offices held during the past 7 years;

(D) 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;

(E) Whether the person has been, during the past 7 years, the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding;

(F) Whether, during the past 7 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 or criminal violations, together with details concerning any such event;

(G) 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 7 years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party;

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

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

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

(d) The Board of Pharmacy shall not issue a wholesale distributor license to an applicant, unless the Board:

(1) Conducts a physical inspection of the facility at the address provided by the applicant as required in subsection (b)(1); and

(2) Determines that the designated representative meets the following qualifications:

(A) Is at least 21 years of age;

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

(C) Is employed by the applicant full time in a managerial level position;

(D) Is actively involved in and aware of the actual daily operation of the wholesale distributor;

(E) 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;

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

(G) 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; and

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

(e) The Board of Pharmacy 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 Requirement - The Board of Pharmacy shall require every wholesale distributor applying for a license to submit a bond of at least $100,000, or other equivalent means of security acceptable to the Board, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to a fund established by the Board 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 imposed by the Board and any fees and costs incurred by the Board regarding that license, which are authorized under State law and which the licensee fails to pay 30 days after the fines, penalties, or costs become final. The Board of Pharmacy may make a claim against such bond or security until 1 year after the licensee's license ceases to be valid. The single bond may suffice to cover all facilities operated by the applicant in the state.

(g) The Board of Pharmacy shall establish a fund, separate from its other accounts, in which to deposit the wholesale distributor bonds.

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

(i) In accordance with each licensure renewal, the Board of Pharmacy shall send to each wholesale distributor licensed under this Section a form setting forth the information that the wholesale distributor provided pursuant to subsection (b) of this Section. Within 30 days of receiving such form, the wholesale distributor must identify and state under oath to the Board of Pharmacy all changes or corrections to the information that was provided pursuant to subsection (b). Changes in, or corrections to, any information in subsection (b) shall be submitted to the Board of Pharmacy as required by the Board. The Board may suspend or revoke the license of a wholesale distributor if such authority determines that the wholesale distributor no longer qualifies for the license issued under this Section.

(j) The designated representative identified pursuant to subsection (b)(7) of this Section must receive and complete continuing training in applicable Federal and State laws governing wholesale distribution of prescription drugs.

(k) Information provided under this Section shall not be disclosed to any person or entity other than the Board of Pharmacy provided the Board needs such information for licensing or monitoring purposes.

§2549. 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 and/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 §2543 of this Subchapter, so long as they are exempt from pedigree under FDA's currently applicable Prescription Drug Marketing Act guidance. Wholesale distributors and pharmacies shall be held accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

(b) Sale, Distribution, or Transfer to an Unlicensed Person - A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the Board of Pharmacy. 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 Board of Pharmacy .

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

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

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

(d) Prescription drugs may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug so received. Any discrepancy between receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesale distributor by the next business day after the delivery to the pharmacy receiving area.

(e) A manufacturer or wholesale distributor shall not accept payment for, or allow the use of, a person or entity's credit to establish an account for the purchase of prescription drugs from any person other than the owner(s) 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 must bear the name of the licensee.

§2550. Pedigree.

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

(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 Board of Pharmacy shall determine by July 1, 2009, a targeted implementation date for electronic track and trace pedigree technology. Such a determination shall be based on consultation with manufacturers, distributors, and pharmacies responsible for the sale and

distribution of prescription drug products in the State of Delaware. After consultation with interested stakeholders and prior to implementation of the electronic pedigree, the Board shall deem that the technology is universally available across the entire prescription pharmaceutical supply chain. The implementation date for the mandated electronic track and trace pedigree technology will be no sooner than July 1, 2010, and may be extended by the Board 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), who is provided 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 the manufacturer's third party logistics provider/co-licensed product partner/manufacturer's 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:

(A) 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;

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

(C) Transaction dates; and

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

(2) At minimum, the pedigree shall also include the:

(A) Name of the prescription drug;

(B) Dosage form and strength of the prescription drug;

(C) Size of the container;

(D) Number of containers;

(E) Lot number of the prescription drug; and

(F) 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 3 years from the date of sale or transfer; and

(2) Available for inspection or use within 5 business days upon a request of an authorized officer of the law.

(e) Implementation - The Board of Pharmacy shall adopt rules and a form relating to the requirements of this subchapter no later than ninety [90] days after the effective date of this Act.

§2551. Enforcement – Order to Cease Distribution of a Drug.

(a) Order to Cease Distribution of a Prescription Drug – If the Board of Pharmacy finds that there is a reasonable probability that:

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

(A) Violated a provision in this Act, or

(B) Falsified a pedigree, or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use,

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

(3) Other procedures would result in unreasonable delay, the Board of Pharmacy shall issue an order requiring the appropriate person (including the distributors, or retailers of the drug) to immediately cease distribution of the drug within the state.

(b) 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 10 days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for such a hearing, the Board of Pharmacy determines that inadequate grounds exist to support the actions required by the order, the Board shall vacate the order.

§2552. Prohibited Acts.

It is unlawful for a person to perform or cause the performance of or aid and abet any of the following acts in this State:

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

(b) If the requirements of §2542(a) of this Subchapter are applicable and are not met, the purchasing or otherwise receiving a prescription drug from a pharmacy;

(c) If a state license is required pursuant to §2542(b) of this Subchapter, the sale, distribution, or transfer of a prescription drug to a person that is not authorized by the Board of Pharmacy to receive the prescription drug;

(d) Failure to deliver prescription drugs to specified premises, as required by §2542(c) of this Subchapter;

(e) Accepting payment or credit for the sale of prescription drugs in violation of §2542(e) of this Subchapter;

(f) Failure to maintain or provide pedigrees as required by §2543 of this Subchapter;

(g) Failure to obtain, pass, or authenticate a pedigree, as required by §2543 of this Subchapter;

(h) Providing the State 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 Chapter;

(i) 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;

(j) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under Federal law by the Food and Drug Administration, the manufacture, repacking, 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;

(k) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under Federal law by the Food and Drug Administration, the adulteration, misbranding, or counterfeiting of any prescription drug;

(l) 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; and

(m) 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.

(n) The aforesaid 'prohibited acts' do not include 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.

§2553. Penalties.

(a) Unknowing Violations - A person who engages in the wholesale distribution of prescription drugs in unknowing violation of this Subchapter shall be guilty of a Class E felony. Notwithstanding any other law to the contrary, a person who engages in the wholesale distribution of prescription drugs in unknowing violation of this subchapter may be fined up to $50,000.

(b) Knowing Violations – A person engaging in wholesale distribution of prescription drugs in knowing violation of this Subchapter shall be guilty of a Class D felony. Notwithstanding any other law to the contrary, a person who engages in the wholesale distribution of prescription drugs in knowing violation of this subchapter may be fined up to $500,000.

Section 7. Amend §2547, Title 24 of the Delaware Code by deleting the words "this subchapter" where they appear in said section and inserting in lieu thereof the words: "sections 2541, 2542 or 2543".

Section 8. Amend Subchapter V, Chapter 25, Title 24 of the Delaware Code by redesignating current sections 2548 through section 2555 as sections 2555 through 2562 respectively.

Section 9. Amend Subchapter VI, Chapter 25, Title 24 of the Delaware Code by redesignating current section 2556 as section 2563 and reserving § 2564-2571; 2578-2584; 2588-2598.

SYNOPSIS

This legislation requires wholesale distributors of prescription drugs to be licensed by the Delaware Board of Pharmacy.

This bill creates a paper pedigree statement in response to the growing problem of criminal counterfeiting of prescription drugs. This bill requires verifiable documentation of drug sales as they occur outside the normal drug distribution chain in order to preserve the legitimate distribution drugs and keep suspect medicines out of circulation.

In addition to creating the pedigree requirement, the legislation would establish new penalties for those who counterfeit, adulterate, and misbrand, as well as violate pedigree requirements. To date, 14 other states have passed paper pedigree laws.

Author: Senator Henry