122nd MAINE LEGISLATURE

FIRST REGULAR SESSION-2005

Legislative Document **No. 1167**

H.P. 810 House of Representatives, March 8, 2005

An Act To Ensure the Health and Safety of All Maine Citizens by Licensing Drug Wholesalers

Reference to the Committee on Business, Research and Economic Development suggested and ordered printed.

Millicent M. MacFarland

MILLICENT M. MacFARLAND
Clerk

Presented by Representative MARRACHÉ of Waterville.
Cosponsored by Representatives: DUCHESNE of Hudson, DUDLEY of Portland, LERMAN of Augusta, PERRY of Calais, SMITH of Van Buren, Senator: COWGER of Kennebec.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 32 MRSA c. 117, sub-c. 13 is enacted to read:

SUBCHAPTER 13

WHOLESALE LICENSURE AND PRESCRIPTION MEDICATION INTEGRITY ACT

§13841. Short title

This subchapter may be known and cited as "the Wholesale Licensure and Prescription Medication Integrity Act."

§13842. Definitions

As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Authenticate. "Authenticate" means to affirmatively verify before distribution of a prescription drug that each transaction listed on the pedigree has occurred.

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

3. Normal distribution chain. "Normal distribution chain" means a chain of custody for a prescription drug that goes from a manufacturer to a wholesaler to a pharmacy to a consumer.

4. Pedigree. "Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug, from sale by a manufacturer through acquisition and sale by a drug wholesaler, distributor or repackager until final sale to a pharmacy or other person dispensing or administering the prescription drug.

5. Prescription drug. "Prescription drug" means a drug, including a biological product, required by federal law or regulation to be dispensed by a prescription, including finished dosage forms and bulk drug substances subject to the Federal Food, Drug and Cosmetic Act, 21 United States Code, Section 503(b). "Prescription drug" does not include blood or blood components intended for transfusion or biological products that are medical devices.

6. Repackage. "Repackage" means to change the container, wrapper or labeling of a prescription drug to further the distribution of the prescription drug.

7. Repackager. "Repackager" means a person who repackages.

8. Wholesale distributor. "Wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including but not limited to a manufacturer, repackager, own-label distributor, private-label distributor, jobber, broker, warehouse, independent wholesale drug trader and retail pharmacy, that conducts wholesale distribution of prescription drugs.

§13843. Wholesale distributor licensing

1. Licensing. A wholesale distributor must be licensed by the board to engage in the wholesale distribution of prescription drugs in the State. If a wholesale distributor has its principal place of business in another state, the wholesale distributor must be also licensed to distribute prescription drugs in that state. A separate license must be obtained by a wholesale distributor for each facility in the State from which the wholesale distributor distributes prescription drugs.

2. Minimum information. Upon application for an original license or renewal of a license under this section, a wholesale distributor shall provide to the board under oath the following information:

A. The name, full business address and telephone number of the applicant;

B. All trade and business names used by the applicant;

C. The name, address and telephone number of a contact person for every facility used by the applicant for the storage, handling and distribution of prescription drugs;

D. The form of organization of the business of the applicant, such as sole proprietorship, partnership or corporation;

E. The name of every person who has an ownership interest or operates the business of the applicant, including:

(1) If a sole proprietorship, the full name of the sole proprietor and name of the business entity;

(2) If a partnership, the name of the partnership as well as the name of every partner; or

(3) If a corporation, the name and title of each corporate officer and director, all corporate names and the state of incorporation;

F. A list of all licenses and permits issued to the applicant by any other state that authorize the applicant to purchase or possess prescription drugs;

G. The name of the manager and the next 4 highest ranking employees responsible for prescription drug wholesale operations of the facility for which the applicant is applying for a license or renewal under this section;

H. The name of the applicant's designated representative for the facility for which the applicant is applying for a license or renewal under this section; and

I. A set of fingerprints and a personal information statement for every person listed under paragraphs G and H including:

(1) Every place of residence for the person for the previous 7 years;

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

(3) Every occupation, position of employment or office held for the previous 7 years;

(4) The principal business and address of every organization in which the person held a position of employment or office under subparagraph 3;

(5) Whether in the previous 7 years the person has been subject to a proceeding for the revocation of a license and for every proceeding listed the nature and disposition of the proceeding;

(6) Whether in the previous 7 years the person has been temporarily or permanently enjoined by a court of competent jurisdiction from violating state or federal law regulating the possession, control or distribution of prescription drugs and the details for every injunction listed;

(7) A description of the involvement of the person with every business or investment that manufactured, administered, prescribed, distributed or stored

pharmaceutical products, except for the ownership of stock in a publicly traded company or mutual fund;

(8) Every lawsuit in which a business or investment listed in subparagraph 7 was named as a party;

(9) A description of every felony of which the person as an adult was convicted, regardless of whether adjudication of guilt was withheld or the person pled guilty nolo contendere. If a conviction listed under this subparagraph is under appeal, then the applicant must attach a copy of the notice of appeal for that conviction; and

(10) A photograph of the person taken within the previous 30 days.

If a change in the information required under this subsection occurs, the applicant shall provide the board with the updated information within the time required by the board by rule.

3. Designated representative qualifications. The board may not issue or renew a wholesale distributor license under this section unless the board determines that the designated representative under subsection 2, paragraph H 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, distribution or record keeping of prescription drugs;

C. Has received a score of 75% or higher on an examination given by the board regarding state and federal laws governing the wholesale distribution of prescription drugs. A designated representative must take the examination required in this paragraph for every application for license or renewal filed under this section that names the designated representative under subsection 2, paragraph H;

D. Is employed full time in a managerial position by the applicant;

E. Is actively involved in and aware of the daily operation of the applicant;

F. Is physically present at the facility of the applicant during regular business hours, except when the absence of

the designated representative is authorized for reasons such as sick leave or vacation leave;

G. Is serving in the capacity of designated representative for only one applicant at a time;

H. Has no convictions under any local, state or federal law relating to wholesale or retail prescription drug or controlled substance distribution; and

I. Has no felony convictions under any local, state or federal law.

4. Fingerprints. The board shall submit the fingerprints required under subsection 2, paragraph I to the Department of Public Safety, Bureau of Identification for a state criminal history record check and the Federal Bureau of Investigation for a national criminal history record check.

5. Bond requirement. An applicant under this section must submit to the board a bond or other equivalent means of security such as a letter of credit or a deposit in a trust account payable to the Wholesale Distributor Application Fund, established in subsection 6. The bond must secure payment of any fine or fee imposed by or cost incurred by the State regarding the license applied for under this section that the applicant fails to pay within 30 days after the fine, fee or cost is final. The State may make a claim on the bond or security required under this subsection within 1 year after the license for which the bond or security is filed ceases to be valid.

6. Wholesale Distributor Application Fund. The Wholesale Distributor Application Fund, a nonlapsing fund administered by the board, is established. Assets are received into the fund pursuant to the bonds and securities required under subsection 5. The purpose of the fund is to secure the payment of a fine, fee or cost levied against a licensee under this subchapter by the State pursuant to subsection 5.

§13844. Minimum restrictions on transactions

1. Ninety-five percent rule. In any calendar month, a wholesale distributor must sell, distribute, transfer or otherwise furnish at least 95% of the prescription drugs possessed by the wholesale distributor to a pharmacy or other person dispensing or administering prescription drugs.

2. Purchases and receipts from pharmacies. A wholesale distributor may not purchase or otherwise receive a prescription drug from a pharmacy, except if the prescription drug was

originally purchased by the pharmacy from the wholesale distributor. In a transaction excepted under this subsection, a wholesale distributor may not receive from a pharmacy an amount or quantity greater than was originally sold to the pharmacy by the wholesale distributor or pay the pharmacy an amount in cash or credit more than the pharmacy originally paid the wholesale distributor for the prescription drugs.

3. Sale, distribution or transfer to unlicensed person. A wholesale distributor may furnish prescription drugs in the State only to a person licensed by the board to receive prescription drugs under this subchapter. A wholesale distributor shall verify that a person is licensed by the board to receive prescription drugs under this subchapter by contacting the board before the wholesale distributor distributes prescription drugs to the person.

4. Premises listed on license. A wholesale distributor may deliver prescription drugs only to the premises listed on the license of the person receiving the prescription drugs, except that the wholesale distributor may deliver prescription drugs to an authorized agent of the person licensed to receive drugs by the board under this subchapter at the premises of the wholesale distributor if:

A. The identity and license of the recipient is properly established; and

B. The method of receipt is necessary for the immediate needs of a patient of the licensed recipient.

5. Hospital pharmacy. A wholesale distributor may deliver prescription drugs to a hospital pharmacy receiving area if at the time of delivery a pharmacist or person authorized to receive the prescription drugs signs a receipt showing the type and quantity of the prescription drugs received. A discrepancy between the receipt and the type and quantity of the prescription drugs actually received must be reported to the wholesale distributor by the next business day after the delivery of the prescription drugs.

6. Credit. A wholesale distributor may not accept payment for or allow the use of a person's or entity's credit to establish an account to purchase prescription drugs from a person other that an owner of record, chief executive officer of chief financial officer listed on the person's or entity's license from the board to receive prescription drugs under this subchapter. An account established for the purchase of prescription drugs must bear the name of the licensee licensed by the board to receive prescription drugs under this subchapter.

§13845. Pedigree

1. Pedigree. A person engaged in the wholesale distribution of a prescription drug, excluding the original manufacturer of the finished form of the prescription drug, shall provide a pedigree identifying each sale, trade or transfer of the prescription drug when the prescription drug leaves the normal distribution channel and is sold, traded or transferred to another person. If a pharmacy sells a drug to a person who is not the final consumer, the pharmacy shall provide to the person acquiring the prescription drug a pedigree. This subsection does not include a sale, trade or transfer of a prescription drug between licensees with a common ownership of the prescription drug to meet emergency needs.

2. Authentication. A person who is engaged in the wholesale distribution of a prescription drug, excluding the original manufacturer, who possesses a pedigree for a prescription drug may not distribute that prescription drug until the person verifies that each transaction listed on the pedigree has occurred.

3. Contents. A pedigree must include all necessary identifying information concerning each sale in the chain of distribution of the prescription drug from the manufacturer through acquisition and sale by a wholesale distributor or repackager until final sale to a pharmacy or other person dispensing or administering the drug, including:

A. The name of the prescription drug;

B. The dosage form and strength of the prescription drug;

C. The size of the container;

D. The number of containers;

E. The lot number of the prescription drug;

F. The name of the manufacturer of the finished dosage form; and

G. The information in the chain of distribution, including:

(1) The name, address, telephone number and e-mail address if available of each owner of the prescription drug and each wholesale distributor who does not take title to the prescription drug;

(2) The signature of each owner of the prescription drug and each wholesale distributor who does not take title to the prescription drug;

(3) The name and address of each location from which the prescription drug was shipped, if different from the owner's name and address;

(4) The transaction dates; and

(5) Certification that each recipient in the chain of distribution has authenticated the pedigree.

4. Records. A purchaser or wholesale distributor of a prescription drug must maintain the pedigree for that drug for 3 years and make the pedigree available for inspection or removal upon request of an authorized law enforcement officer.

§13846. Enforcement

1. Order to cease distribution of prescription drug. The board may order a manufacturer, wholesale distributor or retailer to immediately cease distribution of a prescription drug if the board finds that there is a reasonable probability that:

A. A wholesale distributor of the prescription drug has:

(1) Knowingly violated a provision of this subchapter; or

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

B. The prescription drug could cause serious, adverse health consequences or death; and

C. Other measures to protect the public health, safety or welfare would result in unreasonable delay.

2. Hearing. An order under subsection 1 must provide to the person subject to the order an opportunity for an informal hearing on the actions required by the order no later than 10 days after the date of the order. After a hearing held under this subsection, if the board determines that inadequate grounds exist to support the actions required by the order, the board must vacate the order.

§13847. Prohibited acts

1. Prohibited acts. A person may not perform, cause to be performed, aid or abet any violation of this subchapter, including the following acts:

A. Providing the board, another official of the State or a federal official with false or fraudulent records or making false or fraudulent statements regarding a matter within the provisions of this subchapter;

B. Obtaining or attempting to obtain a prescription drug by fraud, deceit or misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug;

C. Adulterating, misbranding or counterfeiting a prescription drug;

D. Manufacturing, repackaging, selling, transferring, delivering, holding or offering for sale a prescription drug that is adulterated, misbranded, counterfeited, suspected of being counterfeited or otherwise unfit for distribution;

E. Receiving a prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeited or suspected of being counterfeited and delivering or offering to deliver the prescription drug; and

F. Altering, mutilating, destroying, obliterating or removing the whole or part of the label of a prescription drug or any other act that misbrands a prescription drug.

2. Penalties. Notwithstanding the provisions of Title 17-A, section 1301, a violation of this subchapter is a Class B offense for which a fine of up to $50,000 may be adjudged, unless the State proves that the person in violation of this subchapter knowingly violated this subchapter, in which case the violation is a Class A offense for which a penalty of no more that $500,000 may be adjudged.

§13848. Examination

The board shall develop an examination regarding state and federal laws governing the wholesale distribution of prescription drugs that is to be taken by a designated representative pursuant to section 13843, subsection 3, paragraph C.

§13849. Rules

The board shall adopt rules to carry out the purposes of this subchapter no later than 90 days after the effective date of this subchapter. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

SUMMARY

This bill creates a licensing structure for wholesale distributors of prescription drugs to be regulated by the Maine Board of Pharmacy. Provisions of this licensing structure include:

1. Definitions;

2. Licensing requirements for wholesale distributors of prescription drugs;

3. Restrictions on transactions for wholesale distributors of prescription drugs;

4. Requirements for pedigrees for prescription drugs;

5. Enforcement and authority for the Maine Board of Pharmacy to issue an order to cease distribution of a prescription drug; and

6. Prohibited acts and penalties for violations of the provisions of this bill.