FIRST REGULAR SESSION

HOUSE BILL NO. 471

93RD GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE HUNTER.

Read 1st time February 7, 2005 and copies ordered printed.

STEPHEN S. DAVIS, Chief Clerk

1215L.01I

AN ACT

To amend chapter 338, RSMo, by adding thereto six new sections relating to wholesale distributors of prescription drugs, with penalty provisions.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Chapter 338, RSMo, is amended by adding thereto six new sections, to be known as sections 338.410, 338.413, 338.416, 338.419, 338.422, and 338.425, to read as follows:

338.410. As used in sections 338.410 to 338.425, the following terms mean:

(1) "Authentication", to affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred;

(2) "Facility", a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale;

(3) "Immediate family", a person's spouse, children, parents, siblings, the spouses of a person's children, and the spouses of a person's siblings;

(4) "Normal distribution chain", a chain of custody for a medication that goes from a manufacturer to a wholesaler to a pharmacy to a patient;

(5) "Pedigree", a document or electronic file containing information that records each distribution of any given prescription drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the prescription drug;

(6) "Prescription drug", any drug, including biological product except for blood

EXPLANATION — Matter enclosed in bold-faced brackets **[**thus**]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

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 502(b) of the Federal Food, Drug and Cosmetic Act;

(7) "Repackage", repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug;

(8) "Repackager", a person who repackages;

(9) "Wholesale distributor", any person or entity engaged in the wholesale distribution of prescription drugs, including but not limited to manufacturers (unless otherwise specified); repackagers; own-label distributors, private-label distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct whole distribution.

338.413. 1. Every wholesale distributor who engages in the wholesale distribution of prescription drugs in the state of Missouri shall be licensed by the board of pharmacy before engaging in wholesale distributions of wholesale prescription drugs in this state.

2. The board of pharmacy shall require the following minimum information to be provided under oath from each whole distributor seeking licensure or renewal of licensure under sections 338.410 to 338.425:

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

(2) All trade or business names used by the applicant;

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the storage, handling, and distribution of prescription drugs;

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

(5) The name or names of the owner or owners and/or operator or operators of the applicant, 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 authorized the applicant to purchase or possess prescription drugs;

(7) The name of the manager of the facility that is applying for the initial license or to renew a license, the next four highest ranking employees responsible for prescription

drug wholesale operations for the facility, and the name of all affiliated parties for the facility, together with the personal information statement and fingerprints required under subdivision (9) of this subsection for such person;

(8) The name of the applicant's designated representative for the facility, together with the personal information statement and fingerprints required under subdivision (9) of this subsection for such person;

(9) The following information shall be provided by each person required under subdivisions (7) and (8) of this subsection to provide a personal statement and fingerprints:

(a) The person's places of residence for the past seven years;

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

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

(d) The principle 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, during the last seven years, the person has been 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;

(f) Whether, during the last 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;

(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 seven 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 felony criminal offenses of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty of nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant shall within fifteen days after disposition of the appeal submit to the board of pharmacy a copy of the final written order of disposition;

(i) A photograph of the person taken within the previous thirty days.

3. The board of pharmacy shall not issue or renew a wholesale distributor license of an applicant unless the board determines that the designated representative meets the

following qualifications:

(1) Is at least twenty-one years of age;

(2) 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 record keeping relating to, prescription drugs;

(3) Has received a score of seventy-five percent or more on an examination given by the board of pharmacy regarding federal and state laws governing wholesale distribution of prescription drugs. A designated representative who has previously served in such capacity shall retake the board of pharmacy examination each time an applicant lists the person as the designated representative in an application for license renewal;

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

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

(6) 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;

(7) Is serving in the capacity of a designated representative for only one applicant at a time;

(8) 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

(9) Does not have any felony convictions under federal, state, or local laws.

4. The board of pharmacy shall submit the fingerprints provided by an applicant with an initial application or a renewal of licensure application for a statewide criminal record check and for forwarding to the Federal Bureau of Investigation for a national criminal record check of the applicant.

5. The board of pharmacy shall require every wholesale distributor applying for a license or renewing a license to submit a bond of at least, or the 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 of pharmacy under subsection 6 of this section. 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 such license which are authorized under state law and which the licensee fails to pay thirty days after the fines, penalties, or costs become final. The board of pharmacy may make a claim against such bond or security until one year after the licensee's license ceases to be valid.

6. The board of pharmacy shall establish a fund, separate from any other accounts held by the board, in which to deposit the wholesale distributor bonds.

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

8. Any changes to any information provided under subsection 2 of this section shall be submitted to the board of pharmacy as required by the board.

338.416. 1. In any calendar month, a wholesale distributor shall sell, distribute, transfer, or otherwise sell at least ninety-five percent of its total amount of prescription drugs to a pharmacy or other person dispensing or administering the drug.

2. (1) A wholesale distributor shall not purchase or otherwise receive a prescription drug from a pharmacy, except that a wholesale distributor may receive a prescription drug from a pharmacy if the prescription drug was originally purchased by the pharmacy from the wholesale distributor.

(2) A wholesale distributor who meets the exception in subdivision (1) of this subsection shall not:

(a) Receive from a pharmacy an amount or quantity of a prescription drug larger than the amount or quantity that was originally sold by the wholesale distributor to the pharmacy; or

(b) Pay the pharmacy an amount, either in cash or on credit, more than the pharmacy originally paid the wholesale distributor for the prescription drug.

3. 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 affirmative verify that the person is legally authorized to receive the prescription drugs by contacting the board of pharmacy.

4. 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 such person at the premises of the manufacturer or wholesale distributor if:

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

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

5. 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.

6. 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 or owners 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.

338.419. 1. Any 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, shall provide a pedigree or electronic file identifying each sale, trade, or transfer of a prescription drug when a prescription drug leaves the normal distribution channel and is sold, traded, or transferred to any other person. If a pharmacy sells a prescription drug to any person that is not the final consumer, the pharmacy shall provide such person acquiring the prescription drug with a pedigree identifying each sale, trade, or transfer of the prescription drug. Sale, trade, or transfer of a prescription drug between licensees with a common ownership or to meet emergency needs are not subject to this section.

2. Any 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 such prescription drug shall affirmatively verify that each transaction listed on the pedigree has occurred before any distribution of a prescription drug occurs.

3. The pedigree shall:

(1) Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, 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 a minimum, the necessary chain of distribution shall include:

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

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

(c) The name and address of each location from which the product is shipped, if

different from the owner's address;

(d) Transaction dates; and

(e) Certification that each recipient has authenticated the pedigree;

(2) At a minimum, include:

(a) The name of the prescription drug;

(b) The dosage 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; and

(f) The name of the manufacturer of the finished dosage form.

4. Each statement shall be:

(1) Maintained by the purchaser and the wholesale distributor for three years; and

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

5. The board of pharmacy shall promulgate rules and a form relating to the requirements of this section no later December 1, 2005. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, RSMo, and, if applicable, section 536.028, RSMo. This section and chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2005, shall be invalid and void.

338.422. 1. The board of pharmacy shall issue an order requiring the appropriate person, including the manufacturers, distributors, or retailers of a prescription drug, to immediately cease distribution of a prescription drug if the board of pharmacy determines that there is reasonable cause to believe that:

(1) A wholesale distributor has:

(a) Knowingly violated a provision of sections 338.410 to 338.425; or

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

(2) The prescription drug could cause serious adverse health consequences or death; and

(3) Other procedures would result in unreasonable delay.

2. An order issued under subsection 1 of this section shall provide the person

subject to the order with an opportunity to be heard regarding the actions required by the order not more than ten days after the date of issuance of the order. If, after providing an opportunity to be heard, the board of pharmacy determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

338.425. 1. No person shall perform or cause the performance of or aid and abet any of the following acts in this state:

(1) Failure to obtain a license in accordance with sections 338.410 to 338.425, or operating without a valid license when a license is required under sections 338.410 to 338.425;

(2) Selling, distributing, transferring, or otherwise providing prescription drugs in violation of subsection 1 of section 338.416;

(3) Purchasing or otherwise receiving a prescription drug from a pharmacy unless the requirements of subsection 2 of section 338.416 have been met;

(4) The sale, distribution, or transfer of a prescription drug to a person that is not authorized by law to receive the prescription drug in violation of subsection 3 of section 338.416;

(5) Failure to deliver prescription drugs to specified premises as required in subsection 4 of section 338.416;

(6) Accepting payment or credit for the sale of prescription drugs in violation of subsection 5 of section 338.416;

(7) Failure to maintain or provide a pedigree, or failure to obtain, pass, or authenticate a pedigree as required in sections 338.410 to 338.425;

(8) Providing the board of pharmacy 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 sections 338.410 to 338.425;

(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) 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) 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 prescription drug for remuneration or otherwise; or

(13) The alteration, mutilation, destruction, obliteration, or removal of the whole

or any portion 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.

2. Any person who engages in the wholesale distribution of prescription drugs in violation of sections 338.410 to 338.425 shall be imprisoned for not more than fifteen years and fined not more than fifty thousand dollars.

3. Any person who knowingly engages in the wholesale distribution of prescription drugs in violation of sections 338.410 to 338.425 shall be imprisoned for term of up to life and fined not more than five hundred thousand dollars.