Stricken language would be deleted from and underlined language would be added to the law as it existed prior to this session of the General Assembly.

State of Arkansas
85th General Assembly
Regular Session, 2005

A Bill

HOUSE BILL 2446

By: Representative Mahony

For An Act To Be Entitled

THE WHOLESALE LICENSURE AND PRESCRIPTION MEDICATION INTEGRITY ACT.

Subtitle

THE WHOLESALE LICENSURE AND PRESCRIPTION MEDICATION INTEGRITY ACT.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code Title 17, Chapter 92 is amended to add an additional subchapter to read as follows:

17-92-1201. Definitions.

As used in this subchapter:

(1) "Authentication" means to affirmatively verify before any prescription drug is distributed that each transaction listed on the pedigree has occurred;

(2)(A) "Chain pharmacy warehouse" means a physical location for drugs or devices, or both, that acts as a central warehouse and performs intracompany sales or transfers of the drugs or devices, or both, to a group of chain pharmacies that have common ownership and control.

(B) Chain pharmacy warehouses shall be licensed by the Arkansas State Board of Pharmacy as chain pharmacy warehouses;

(3) "Facility" means the place of business of a wholesale distributor at which prescription drugs are stored, handled, repackaged, or offered for sale;

(4) "Intracompany sales" means any transaction or transfer between any division, subsidiary, parent, or affiliated or related company

under common ownership and control of a corporate entity;

(5) "Normal distribution channel" means a chain of custody for a medication that is transferred from a manufacturer to a wholesale distributor, from a wholesale distributor to a pharmacy, and from a pharmacy to a patient;

(6) "Pedigree" means 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;

(7) "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 or regulation, or both, to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to § 503(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. as it existed on January 1, 2005;

(8)(A) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling of a prescription drug to further the distribution of the drug.

(B) "Repackage" does not include repackaging or otherwise changing the container, wrapper, or labeling of a prescription drug completed by the pharmacist responsible for dispensing the drug to the patient;

(9) "Repackager" means a person who repackages; and

(10)(A) "Wholesale distributor" means anyone engaged in the wholesale distribution of prescription drugs, including, but not limited to:

(i) Manufacturers, unless exempted by law;

(ii) Repackagers;

(iii) Own-label distributors;

(iv) Private-label distributors;

(v) Jobbers;

(vi) Brokers;

(vii) Warehouses, including, but not limited to:

(a) Manufacturers' warehouses; and

(b) Distributors' warehouses;

(viii) Drug wholesalers or distributors;

(ix) Independent wholesale drug traders;

(x) Retail pharmacies that conduct wholesale distribution; and

(xi) Chain pharmacy warehouses that conduct wholesale distribution.

(B) "Wholesale distributor" does not include:

(i) Intracompany sales of prescription drugs;

(ii) A 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;

(iii) A distribution of prescription drug samples by a manufacturer's representative;

(iv) Drug returns, if the returns are conducted by a hospital, health care entity, retail pharmacy, or charitable institution in accordance with 21 C.F.R. § 203.23 as it existed on January 1, 2005;

(v) A sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use; or

(vi) Delivery by a retail pharmacy of prescription drugs to a patient or patient's agent under the order of a person licensed to prescribe prescription drugs.

17-92-1202. Wholesale drug distributor licensing -- Minimum requirements for licensure.

(a)(1) A wholesale distributor that engages in the wholesale distribution of prescription drugs shall be licensed by the state licensing authority in the state in which it resides.

(2) If a wholesale distributor that is not a resident of the State of Arkansas ships prescription drugs into Arkansas in accordance with this subchapter, the wholesale distributor shall be licensed by the Arkansas State Board of Pharmacy before engaging in wholesale distribution of needed prescription drugs in Arkansas.

(b) The board shall promulgate rules to require at least the following information from each wholesale distributor applying for a license under subsection (a) of this section, including, but not limited to:

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

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

(3) The addresses, telephone numbers, and 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, whether a partnership, corporation, sole proprietorship, or other business entity;

(5) The name of the owner or operator, or both, of the applicant, including:

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

(B) If a partnership, the name of each partner and 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) For the applicant's designated representative for the facility, the designated representative's:

(A) Name;

(B) Fingerprints;

(C) Places of residence for the past seven (7) years;

(D) Date and place of birth;

(E)(i) Occupations, positions of employment, and offices held during the past seven (7) years.

(ii) The information required under subdivision (b)(7)(E)(i) of this section shall be accompanied by the name and address of any business, corporation, or other organization for which the designated representative worked during the past seven (7) years;

(F) Background information regarding any proceeding against the designated representative for the revocation of any license, the nature of the proceeding, and the disposition of the proceeding;

(G) For the past seven (7) years, background information regarding whether the designated representative 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;

(H)(i) For the past seven (7) years, a description of any involvement by the designated representative with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund that manufactured, administered, prescribed, distributed, or stored pharmaceutical products.

(ii) The description shall include any lawsuits in which any of the businesses were named as a party;

(I)(i) Description of any felony criminal offense committed by the designated representative as an adult for which the designated representative was convicted, regardless of whether adjudication of guilt was withheld or whether the person pleaded guilty or nolo contendere.

(ii) If the designated representative indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant shall submit to the board within fifteen (15) days after the disposition of the appeal a copy of the final written order of disposition; and

(J) A photograph taken within the previous thirty (30) days.

(c) The information required under subsection (b) of this section shall be provided under oath.

(d) The board shall not issue a wholesale distributor license to an applicant unless the board determines that the designated representative meets the following qualifications:

(1) Is at least twenty-one (21) years of age;

(2) Has been employed full time for at least three (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;

(3) Has received a score of seventy-five percent (75%) or higher on an examination given by the Arkansas State Board of Pharmacy regarding federal and state laws governing wholesale distribution of

prescription drugs;

(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 applicant;

(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 (1) 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 the distribution of controlled substances; and

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

(e) The board 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) The board shall require every wholesale distributor applying for a license to submit a bond of at least one hundred thousand dollars ($100,000) or another equivalent means of security acceptable to the board, including, but not limited to:

(1) An irrevocable letter of credit; or

(2)(A) A deposit in a trust account or financial institution, payable to a fund established by the board under subsection (g) of this section.

(B)(i) 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 the licensee that are authorized under state law and that the licensee fails to pay thirty (30) days after the fines, penalties, or costs become final.

(ii) The board may make a claim against the bond or security until one (1) year after the licensee's license ceases to be valid.

(iii) The bond shall cover all facilities operated

by the applicant in the state.

(g) The board 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 (1) facility, the wholesale distributor shall obtain a license for each facility.

(i)(1) Each calendar year, the board shall send to each wholesale distributor licensed under this section a form setting forth the information that the wholesale distributor provided under subsection (b) of this section.

(2) Within thirty (30) days of receiving the form, the wholesale distributor shall identify and state under oath to the board all changes or corrections to the information that was provided under subsection (b) of this section.

(3) Changes in or corrections to any information in subsection (b) of this section shall be submitted to the board.

(4) The board may suspend or revoke the license of a wholesale distributor if the board determines that the wholesale distributor no longer qualifies for the license issued under this section.

(j) The designated representative identified under subdivision (b)(7) of this section shall complete continuing education programs as required by the board regarding federal and state laws governing wholesale distribution of prescription drugs.

(k) Information provided under this section may not be disclosed to any person or entity other than a state licensing authority, government board, or government agency if the licensing authority, government board, or government agency needs the information for licensing or monitoring purposes.

17-92-1203. Restrictions on transactions.

(a)(1)(A) Returns of prescription drugs and exchanges from a pharmacy or chain pharmacy warehouse received by a wholesale distributor under the terms and conditions of an agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse shall not be subject to the pedigree requirement of § 17-92-1204.

(B) A wholesale distributor shall be held accountable for policing its returns process and ensuring that its operations are secure and do not permit the entry of adulterated and counterfeit products.

(2) A wholesale distributor who meets the exception in this subsection (a) shall not receive from a pharmacy or chain pharmacy warehouse 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 chain pharmacy warehouse.

(b)(1) A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the appropriate state licensing authority.

(2) 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 authorized to receive the prescription drugs by contacting the appropriate state licensing authorities.

(c)(1) Prescription drugs furnished by a manufacturer or wholesale distributor shall be delivered only to the premises listed on the license.

(2) However, 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:

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

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

(d)(1) Prescription drugs may be furnished to a hospital pharmacy receiving area if a pharmacist or authorized receiving person signs at the time of delivery a receipt showing the type and quantity of the prescription drug received.

(2) Any discrepancy between a 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)(1) 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 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.

(2) Any account established for the purchase of prescription drugs shall bear the name of the licensee.

17-92-1204. Pedigree.

(a)(1) Each person who is engaged in wholesale distribution of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs.

(2) The records shall include, but not be limited to:

(A) Pedigrees for all prescription drugs that leave the normal distribution channel; and

(B) Pedigrees for all prescription drugs that are included on the Specified List of Susceptible Products of the National Association of Boards of Pharmacy as the list existed on January 1, 2005.

(3) Effective December 31, 2007, all wholesale distributors whether located in or out of this state shall provide to the Arkansas State Board of Pharmacy and maintain an electronic pedigree developed in accordance with standards and requirements of the board for all prescription drugs received and distributed.

(b) 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.

(c) 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 in possession of a pedigree for a prescription drug and attempts to further distribute that prescription drug shall affirmatively verify before any prescription drug is distributed that each transaction listed on the pedigree has occurred.

(d) The pedigree shall 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.

(e) The necessary chain of distribution information shall include, but not be limited to:

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

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

(3) Transaction dates; and

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

(f) The pedigree shall also include, but not be limited to:

(1) The name of the prescription drug;

(2) The dosage form and strength of the prescription drug;

(3) The size of the container;

(4) The number of containers;

(5) The lot number of the prescription drug; and

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

(g) Each pedigree or electronic file shall be:

(1) Maintained by the purchaser and the wholesale distributor for three (3) years from the date of sale or transfer; and

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

(h) The board shall adopt rules and a form relating to the requirements of this section no later than ninety (90) days after the effective date of this subchapter.

17-92-1205. Enforcement — Order to cease distribution of a drug.

(a) The Arkansas State Board of Pharmacy shall issue an order requiring the appropriate person including the manufacturers, distributors, or retailers of the drug to immediately cease distribution of the drug if the Arkansas State Board of Pharmacy finds that there is a reasonable probability that:

(1) A wholesale distributor has:

(A) Violated a provision in this subchapter; 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 in subdivision (a)(1) of this

section could cause serious adverse health consequences or death; and

(3) Other procedures would result in unreasonable delay.

(b)(1) An order under subsection (a) of this section shall provide the person subject to the order with an opportunity for an informal hearing on the actions required by the order to be held not later than ten (10) days after the date of the issuance of the order.

(2) If after providing an opportunity for a hearing the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

17-92-1206. 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:

(1) Failing to obtain a license in accordance with this subchapter;

(2) Operating without a valid license if a license is required by this subchapter;

(3) Purchasing or otherwise receiving a prescription drug from a pharmacy unless the requirements in § 17-92-1203 are met;

(4) Selling, distributing, or transferring a prescription drug to a person who is not authorized under the laws of the state in which the person receives the prescription drug in violation of § 17-92-1203;

(5) Failing to deliver prescription drugs to specified premises as required by § 17-92-1203;

(6) Accepting payment or credit for the sale of prescription drugs in violation of § 17-92-1203;

(7) Failing to maintain or provide pedigrees as required by this subchapter;

(8) Failing to obtain, pass, or authenticate a pedigree as required by this subchapter;

(9) 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 subchapter;

(10) 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;

(11) Manufacturing, repacking, selling, transferring, delivering, 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;

(12) Adulterating, misbranding, or counterfeiting any prescription drug;

(13) Receiving any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit coupled with delivering or proffering delivery of the drug for pay or otherwise; and

(14) Altering, mutilating, destroying, obliterating, or removing 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's being misbranded.

17-92-1207. Penalties.

(a) If a person engages in the wholesale distribution of prescription drugs in violation of this subchapter, the person shall be imprisoned for not more than fifteen (15) years or fined not more than fifty thousand dollars ($50,000), or both.

(b) If a person knowingly engages in wholesale distribution of prescription drugs in violation of this subchapter, the person shall be imprisoned for any term of years or fined not more than five hundred thousand dollars ($500,000), or both.