MISSISSIPPI LEGISLATURE REGULAR SESSION 2006

By: Senator(s) Nunnelee

To: Public Health and Welfare

SENATE BILL NO. 2889

AN ACT TO PROVIDE THAT WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS SHALL BE LICENSED BY THE STATE BOARD OF PHARMACY; TO PROVIDE DEFINITIONS; TO PRESCRIBE QUALIFICATIONS AND CONDITIONS FOR THE ISSUANCE OF A LICENSE; TO PROVIDE RESTRICTIONS ON TRANSACTIONS BETWEEN DISTRIBUTORS AND PHARMACIES; TO REQUIRE DOCUMENTATION OR ELECTRONIC FILES ON PRESCRIPTION DRUGS WHICH RECORDS EACH TRANSACTION IN THE TRANSACTION PROCESS; TO AUTHORIZE THE STATE BOARD OF PHARMACY TO ISSUE ORDERS TO ENFORCE THE PROVISIONS OF THIS ACT; TO PRESCRIBE PROHIBITED ACTS AND CRIMINAL PENALTIES FOR VIOLATIONS OF THIS ACT; AND FOR RELATED PURPOSES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

SECTION 1. When used in this act, the following words shall have the meanings ascribed herein unless the context clearly requires otherwise.

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

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

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

(d) "Normal distribution channel" means a chain of custody for a medication that goes from a manufacturer to a wholesale distributor to a pharmacy to a patient or a chain of custody for medication that goes from a manufacturer to a wholesale distributor to a chain pharmacy warehouse to their intracompany pharmacy to a patient.

(e) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug within the distribution channel.

(f) "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).

(g) "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.

(h) "Repackager" means a person who repackages.

(i) "Wholesale Distributor" means anyone engaged in the wholesale distribution of prescription drugs, including, but not limited to, repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses; including manufacturers' and distributors warehouses, and drug wholesalers or distributors; independent wholesale drug traders; and retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

(j) "Wholesale distribution" does not include:

(i) 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;

(ii) 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;

(iii) The distribution of prescription drug samples by manufacturers' representatives;

(iv) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR Section 203.23;

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

(vi) Retail pharmacies' delivery of prescription drugs to a patient or patient's agent pursuant to the lawful order of a licensed practitioner; or

(vii) 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.

(k) "Wholesaler" means a person engaged in the wholesale distribution of prescription drugs.

(l) "Board" means State Board of Pharmacy created under Section 73-21-75.

SECTION 2. (1) Every wholesale distributor who engages in the wholesale distribution of prescription drugs shall be licensed by the State Board of Pharmacy and every nonresident wholesale distributor shall be licensed in the state in which it resides, if it ships prescription drugs into Mississippi, in accordance with this act before engaging in wholesale distributions of wholesale prescription drugs. The State Board of Pharmacy shall exempt manufacturers 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.

(2) The State Board of Pharmacy shall require the following minimum information from each wholesale distributor applying to get a license under subsection (1):

(a) The name, full business address and telephone number of the licensee.

(b) All trade or business names used by the licensee.

(c) 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.

(d) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship).

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

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

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

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

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

(f) 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.

(g) 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 (h) for such person.

(h) Personal information Statement - Each person required by paragraph (g) to provide a personal information statement and fingerprints shall provide the following information to the state:

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

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

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

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

(v) Whether the person has been, during the past seven (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;

(vi) Whether during the past seven (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;

(vii) A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven (7) years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party;

(viii) A description of any 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 fifteen (15) days after the disposition of the appeal, submit to the state a copy of the final written order of disposition; and

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

(3) The information required pursuant to subsection (2) shall be provided under oath.

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

(a) Conducts a physical inspection of the facility at the address provided by the applicant as required in Section 2(2)(a) of this act.

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

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

(ii) 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 record keeping relating to, prescription drugs;

(iii) He received a score of seventy-five percent (75%) or more on an examination given by the state licensing authority regarding federal and state laws governing wholesale distribution of prescription drugs;

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

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

(vi) 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;

(vii) Is serving in the capacity of a designated representative for only one (1) applicant at a time;

(viii) 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

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

(5) The State 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.

(6) The State Board of Pharmacy shall require every wholesale distributor applying for a license to submit a bond of at least One Hundred Thousand Dollars ($100,000.00) or other equivalent means of security acceptable to the state, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to a fund established by the State Board of Pharmacy pursuant to subsection (7). The purpose of the bond is to secure payment of any fines or penalties imposed by the State Board of Pharmacy and any fees and costs incurred by the state regarding that license, which are authorized under state law and which the licensee fails to pay thirty (30) days after the fines, penalties, or costs become final. The State Board of Pharmacy may make a claim against such bond or security until one (1) year after the licensee's license ceases to be valid. The bond shall cover all facilities operated by the applicant in the state.

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

(8) If a wholesale distributor distributes prescription drugs from more than one (1) facility, the wholesale distributor shall obtain a license for each facility.

(9) Every calendar year the State 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 paragraph (b)(ii) of this section. Within thirty (30) days of receiving such form, the wholesale distributor must identify and state under oath to the State Board of Pharmacy all changes or corrections to the information that was provided pursuant to paragraph (b)(ii). Changes in, or corrections to, any information in paragraph (b)(ii) shall be submitted to the State Board of Pharmacy as required by such authority. The State Board of Pharmacy 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.

(10) The designated representative identified pursuant to subsection (2)(g) of this section must complete continuing education programs as required by the State Board of Pharmacy regarding federal and state laws governing wholesale distribution of prescription drugs.

(11) Information provided under this section shall not be disclosed to any person or entity other than a state licensor authority, government board, or government agency provided such licensing authority, government board or agency needs such information for licensing or monitoring purposes.

SECTION 3. (1) 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, and such returns or exchanges shall not be subject to the pedigree requirement of Section 4 of this act. Wholesale distributors shall be held accountable for policing their returns process and insuring that this is of their operations, are secure and do not permit the entry of adulterated and counterfeit product.

(2) A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the State Board of Pharmacy or state licensing authorities. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the State Board of Pharmacy or the appropriate state licensing authorities.

(3) 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:

(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.

(4) 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.

(5) 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.

SECTION 4. (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. These records shall include pedigrees for all prescription drugs that leave the normal distribution channel.

(a) 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.

(b) The State Board of Pharmacy shall conduct a study to be completed by January 1, 2007. Such report shall include consultation with manufacturers, distributors and pharmacies responsible for the sale and distribution of prescription drug products in the state. Based on the results of the study the Board will determine a mandated implementation date for electronic pedigrees. The implementation date for the mandated electronic pedigree will be no sooner than December 31, 2007.

(2) 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 distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(3) The pedigree shall:

(a) 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 minimum, the necessary chain of distribution information shall include:

(i) Name, address, telephone number, and if available, the email address, of each owner of the prescription drug and each wholesale distributor of the prescription drug;

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

(iii) Transaction dates; and

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

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

(i) Name of the prescription drug;

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

(iii) Size of the container;

(iv) Number of containers;

(v) Lot number of the prescription drug; and

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

(4) Each pedigree or electronic file shall be:

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

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

(5) The State Board of Pharmacy shall adopt rules and a form relating to the requirements of this paragraph no later than ninety (90) days after the effective date of this act.

SECTION 5. (1) If the State Board of Pharmacy finds that there is a reasonable probability that:

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

(i) Violated a provision of this act, or

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

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

(c) Other procedures would result in unreasonable delay, the State 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 this state.

(2) An order under subsection (1) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than ten (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 State Board of Pharmacy determines that inadequate grounds exist to support the actions required by the order, the State Board of Pharmacy shall vacate the order.

SECTION 6. 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) Purchasing or otherwise receiving a prescription drug from a pharmacy, unless the requirements in Section 3(1) of this act are met;

(c) The sale, distribution or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug in violation of Section 3(2) of this act;

(d) Failure to deliver prescription drugs to specified premises, as required by Section 3(4) of this act;

(e) Accepting payment or credit for the sale of prescription drugs in violation of Section 3(5) of this act;

(f) Failure to maintain or provide pedigrees as required by this act;

(g) Failure to obtain, pass or authenticate a pedigree, as required by this act;

(h) Providing the State 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 this act;

(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;

(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; and

(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.

SECTION 7. (1) If a person engages in the wholesale distribution of prescription drugs in violation of this act, the person may, upon conviction, be imprisoned in the State Penitentiary for not more than fifteen (15) years and fined not more than Fifty Thousand Dollars ($50,000.00), or both.

(2) If a person knowingly engages in wholesale distribution of prescription drugs in violation of this act, the person shall, upon conviction, be imprisoned in the State Penitentiary for any term of years or fined not more than Five Hundred Thousand Dollars ($500,000.00), or both.

SECTION 8. This act shall take effect and be in force from and after July 1, 2006.