House Bill 907

By: Representative Reece of the 27th

A BILL TO BE ENTITLED

AN ACT

To amend Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, so as to enact the "Wholesale Licensure and Prescription Medication Integrity Act"; to provide for a short title; to provide for definitions; to provide for license requirements and procedures for wholesale distributors of prescription drugs; to provide for restrictions on transactions involving prescription drugs; to provide for pedigrees for prescription drugs; to provide for enforcement; to provide for prohibited acts; to provide for penalties; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, is amended by inserting a new article at the end of such chapter to read as follows:

"ARTICLE 11

26-4-190.

This article shall be known and may be cited as the 'Wholesale Licensure and Prescription Medication Integrity Act.'

26-4-191.

As used in this article, the term:

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

(2) 'Board' means the State Board of Pharmacy.

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

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

(5) 'Normal distribution channel' means a chain of custody for a prescription drug that goes from a manufacturer to a wholesale distributor to a pharmacy to a patient.

(6) 'Pedigree' means a document or electronic file containing information that records each transaction of a prescription drug from sale by a pharmaceutical manufacturer, to acquisition and sale by any wholesale distributor or repackager, to final sale to a pharmacy or other person dispensing or administering the prescription drug.

(7) 'Prescription drug' means a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with either of the following statements: 'Caution: federal law prohibits dispensing without prescription' or 'Caution: federal law restricts this drug to use by, or on the order of, a licensed veterinarian'; or a drug which is required by any applicable federal or state law or rule to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only; or a controlled substance as defined in paragraph (6) of Code Section 26-4-5 or a dangerous drug as defined in paragraph (7) of Code Section 26-4-5.

(8) 'Repackage' means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug; provided, however, that this shall not apply to pharmacists in the dispensing of prescription drugs to the patient.

(9) 'Repackager' means a person who repackages.

(10) 'Wholesale distributor' means any person engaged in wholesale distribution of drugs, including but not limited to repackagers; own label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers´ and distributors´ warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail and hospital pharmacies and chain pharmacy warehouses that conduct wholesale distributions. This terms shall not include manufacturers.

(11) 'Wholesale distribution' shall not include:

(A) Intracompany sales of prescription drugs by a chain pharmacy warehouse, meaning any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under common ownership and control of a corporate entity;

(B) 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;

(C) The distribution of prescription drug samples by manufacturers´ representatives;

(D) Prescription drug returns when conducted by a hospital, health care entity, retail pharmacy, or charitable institution in accordance with 21 C.F.R. Section 203.23;

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

(F) Retail pharmacies´ delivery of prescription drugs to a patient or patient´s agent pursuant to the lawful order of a licensed practitioner.

26-4-192.

(a) Every wholesale distributor who engages in wholesale distribution of prescription drugs in this state shall be licensed by the board pursuant to Article 6 of this chapter.

(b) In addition to any other requirements as provided by law or regulation, the board shall require the following minimum information from each wholesale distributor applying for a license pursuant to Article 6 of this chapter:

(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 of the applicant, including, but not limited to, corporation or sole proprietorship;

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

(A) If an individual, the name of such individual;

(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, distribute, or possess prescription drugs; and

(7) The name and fingerprints of the applicant´s designated representative for the facility and the following information relative to such designated representative:

(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 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 seven years, 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 past 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 any of such businesses was named as a party;

(H) A description of any 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) of this Code section shall be provided under oath.

(d) The board shall not issue a license to a wholesale distributor pursuant to Article 6 of this chapter to an applicant unless the board:

(1) Conducts a physical inspection of the facility at the address provided by the applicant pursuant to paragraph (1) of subsection (b) of this Code section if such facility is in this state; 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 three 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) Has received a score of 75 percent or more on an examination given by the board regarding federal and state laws governing wholesale distribution of prescription drugs;

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

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

(F) 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;

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

(H) 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

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

(e) The board shall submit the fingerprints provided by an applicant pursuant to paragraph (7) of subsection (b) for a state-wide criminal records check and for forwarding to the Federal Bureau of Investigation for a national criminal records check of the applicant.

(f) The board shall require every wholesale distributor applying for a license to submit a bond of at least $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 the state. The purpose of the bond shall be to cover payment of any fines or penalties imposed by the board and any fees and costs incurred by the board in processing such 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 may make a claim against such bond or security until one year after the licensee´s license ceases to be valid. The bond shall cover all facilities operated by the applicant in this state.

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

(h) Every calendar year, the board shall send to each wholesale distributor licensed under Article 6 of this chapter a form setting forth the information that the wholesale distributor provided pursuant to subsection (b) of this Code section. Within 30 days of receiving such form, the wholesale distributor must identify and state under oath to the board all changes or corrections to such information. Changes in, or corrections to, any such information shall be submitted to the board in a manner designated by the board. 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 pursuant to Article 6 of this chapter.

(i) The designated representative identified pursuant to paragraph (7) of subsection (b) of this Code section must complete continuing education programs as required by the board regarding federal and state laws governing wholesale distribution of prescription drugs.

(j) Except as otherwise required under Article 4 of Chapter 18 of Title 50, information provided pursuant to this Code section shall not be disclosed to any person or entity other than the board.

26-4-193.

(a)(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 or chain pharmacy warehouse, and such returns or exchanges shall not be subject to the pedigree requirement of Code Section 26-4-194. Wholesale distributors shall be held accountable for policing their returns process and ensuring that their operations are secure and do not permit the entry of adulterated or counterfeit prescription drugs.

(2) A wholesale distributor who meets the exception in paragraph (1) of this subsection shall not receive from a pharmacy or chain pharmacy warehouse an amount or quantity of a prescription drug, excluding returns processed in accordance with the pharmaceutical product manufacturer´s return goods policy or return of expired prescription drug product policy, larger than the amount or quantity that was originally sold by the wholesale distributor to the pharmacy or chain pharmacy warehouse.

(b) A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the board. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall contact the board to affirmatively verify that the person is legally authorized to receive the prescription drugs.

(c) Prescription drugs furnished by a manufacturer or wholesale distributor shall be delivered only to the premises listed on the license; provided, however, 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 employee signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug so received. Any discrepancy between the 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 delivery.

(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 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 must bear the name of the licensee.

26-4-194.

(a) 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.

(1) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this Code section only if the retail pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.

(2) The board shall conduct a study to be completed no later than January 1, 2007, which shall include consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in this state. Based on the results of the study, the board shall establish a mandated implementation date for electronic pedigrees which shall be no sooner than December 31, 2007.

(b) Each person in possession of a pedigree for a prescription drug 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 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) The pedigree shall include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, to acquisition and sale by any wholesale distributor or repackager, and to final sale to a pharmacy or other person dispensing or administering the prescription drug. At a minimum, the pedigree shall include:

(1) The name, address, telephone number, and, if available, e-mail address of each owner of the prescription drug and each wholesale distributor of the prescription drug;

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

(3) Transaction dates;

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

(5) The name of the prescription drug;

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

(7) Size of the container;

(8) Number of containers;

(9) Lot number of the prescription drug; and

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

(d) Each pedigree shall be:

(1) Maintained by the dispensing pharmacy or individual and the wholesale distributor for three years from the date of sale or transfer; and

(2) Available for inspection or use upon a request by the board.

(e) The board shall adopt rules and regulations, including a standard form, relating to the requirements of this article no later than 90 days after the effective date of this article.

26-4-195.

(a) If the board finds that there is a reasonable probability that:

(1) A wholesale distributor has:

(A) Violated a provision of this article; 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 subparagraph (1)(B) of this subsection could cause serious, adverse health consequences or death; and

(3) Other procedures would result in unreasonable delay,

the board shall issue an order requiring the appropriate person, including the manufacturers, distributors, or retailers of the prescription drug, to immediately cease distribution of the prescription drug in or to this state.

(b) An order under subsection (a) of this Code section shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than ten days after the date of the issuance of the order, on the actions required by the order. If, after such a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

26-4-196.

It shall be 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 article or operating without a valid license when a license is required by this article;

(2) Receiving prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse, unless the requirements in subsection (a) of Code Section 26-4-193 are met;

(3) Selling, distributing, or transferring a prescription drug to a person that is not authorized to receive the prescription drug under the law of the jurisdiction in which the person receives the prescription drug in violation of subsection (b) of Code Section 26-4-193;

(4) Failing to deliver prescription drugs to specified premises as required in subsection (c) of Code Section 26-4-193;

(5) Accepting payment or credit for the sale of prescription drugs in violation of subsection (e) of Code Section 26-4-193;

(6) Failing to maintain or provide pedigrees as required by this article;

(7) Failing to obtain, transfer, or authenticate a pedigree as required by this article;

(8) Providing the board 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 article;

(9) 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;

(10) 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 manufacturing, repacking, selling, transferring, delivering, holding, or offering for sale of any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution;

(11) 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;

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

(13) 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.

26-4-197.

(a) Notwithstanding Code Section 26-4-115, any person who engages in the wholesale distribution of prescription drugs in violation of this article shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not more than 15 years, by fine not to exceed $50,000.00, or both.

(b) Notwithstanding Code Section 26-4-115, any person who knowingly engages in wholesale distribution of prescription drugs in violation of this article shall be gulity of a felony and, upon conviction thereof, shall be punished by imprisonment for not more than 25 years, by fine not to exceed $500,000.00, or both.″

SECTION 2.

All laws and parts of laws in conflict with this Act are repealed.