Session of 2005

HOUSE BILL No. 2397

By Committee on Appropriations

2-9

AN ACT concerning distribution of certain prescription drugs; enacting the wholesale licensure and prescription medication integrity act.

Be it enacted by the Legislature of the State of Kansas:

Section 1. Sections 1 through 7, and amendments thereto, shall be known and may be cited as the "wholesale licensure and prescription medication integrity act".

Sec. 2. As used in the wholesale licensure and prescription integrity act:

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

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

(c) "Immediate family" shall include a person's spouse, children, parents, siblings, the spouses of a person's children and the spouses of a person's siblings.

(d) "Normal distribution channel" means a chain of custody for a medication that goes from a manufacturer to a wholesaler to a pharmacy to a patient.

(e) "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.

(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 or regulations, 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.

(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, manufacturers unless specified otherwise; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; chain drug warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distribution.

Sec. 3. (a) Every wholesale distributor which engages in the wholesale distribution of prescription drugs in the state shall be licensed by the state licensing authority in the state in which it resides and every nonresident wholesale distributor shall be licensed in the state if it ships prescription drugs into the state in accordance with the wholesale licensure and prescription medication integrity act before engaging in wholesale distribution of wholesale prescription drugs in the state.

(b) In addition to any other requirement prescribed by law, the state board of pharmacy shall require the following minimum information from each wholesale distributor applying for a license under this section and as a part of any renewal of such license:

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

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

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

(4) The type of ownership or operation, including, but not limited to, partnership, corporation or sole proprietorship;

(5) The name or names of the owner or operator of the licensee or applicant and related information, including:

(A) If an individual, the name of the 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 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 or licensee by any other state that authorizes the applicant or licensee 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 the 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 required pursuant to subsection

(b)(9) of this section and fingerprints for each of such persons;

(8) the name of the designated representative of the applicant or licensee for the facility and the personal information statement required pursuant to subsection (b)(9) of this section and fingerprints for such person; and

(9) the following information for each person described in paragraph (b)(7) or (b)(8) of this section required to provide a personal information statement and fingerprints shall provide the following information to the state:

(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 held;

(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 such businesses were 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 or licensee 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 section shall be provided under oath.

(d) The board of pharmacy shall not issue or renew a wholesale distributor license of an applicant or licensee unless the state board of pharmacy determines that the designated representative meets the following qualifications:

(1) Is at least 21 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 recordkeeping relating to prescription drugs;

(3) has received a score of 75% or more on an examination given by the state 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 state examination each time a licensee 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 or licensee 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.

(e) The state board of pharmacy shall submit the fingerprints provided by a person with an initial or a renewal license application for a statewide criminal history record check and for forwarding to the federal bureau of investigation for a national criminal history record check of the person.

(f) The state board of pharmacy shall require every wholesale distributor applying for a new license or the renewal of a license to submit a bond in an amount determined by the state board of pharmacy or other equivalent means of security acceptable to the state board of pharmacy, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the drug wholesaler trust fund established pursuant to subsection (g). 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 board of pharmacy regarding that license which are authorized under the wholesale licensure and prescription medication integrity act and which the licensee fails to pay 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 year after the licensee's license ceases to be valid.

(g) There is hereby created in the state treasury the drug wholesaler trust fund. The executive secretary of the state board of pharmacy shall administer the fund. Proceeds from the bond prescribed by subsection (f) of this section shall be remitted to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon receipt of each such remittance the state treasurer shall deposit the entire amount in the state treasury to the credit of the drug wholesaler trust fund. Moneys in the drug wholesaler trust fund may be expended for the purposes prescribed in subsection (h) of this section. All expenditures from the drug wholesaler trust fund shall be made in accordance with appropriation acts upon warrants of the director of accounts and reports issued pursuant to vouchers approved by the executive secretary of the state board of pharmacy.

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

(i) Changes in any information in subsection (b) shall be submitted to the board of pharmacy as required by such board.

Sec. 4. (a) On and after the effective date of this act, in any calendar month, a wholesale distributor shall sell, distribute, transfer or otherwise sell at least 95% of its total amount of prescription drugs to a pharmacy or other person dispensing or administering the drug.

(b) 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.

(c) A wholesale distributor which meets the exception in subsection (b) shall not:

(1) 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

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

(d) A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the appropriate 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 the person is legally authorized to receive the prescription drugs by contacting the appropriate state licensing authorities.

(e) 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:

(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.

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 stating the type and quantity of such prescription drug, or drugs 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 on or before the next business day after the delivery to the pharmacy receiving area.

(f) 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 or record, the chief executive officer or the chief financial officer listed on 1he 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.

Sec. 5. (a) 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, 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 drug to any person who is not the final consumer, the pharmacy shall provide to the person acquiring the prescription drug a pedigree identifying each sale, trade or transfer of a 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 the provisions of this section.

(b) Each person who is engaged in the wholesale distribution of a prescription drug, including repackagers, but excluding the original manufacture of the finished form of the prescription drug, who is in possession of a pedigree for a prescription drug and attempts to further distribute such 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:

(1) Include all necessary identifying information concerning each sale

in the chain of distribution of the product from the manufacture, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. The necessary chain of distribution information shall include, but shall not be limited to:

(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 does 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 was shipped, if different from the owner's;

(D) the transaction dates; and

(E) certification that each recipient has authenticated the pedigree.

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

(A) The name of the prescription drug;

(B) dosage form and strength of the prescription drug;

(C) size of the container;

(D) number of containers;

(E) lot number of the prescription drug; and

(F) name of the manufacturer of the finished dosage form.

(d) 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.

(e) The state board of pharmacy administering this act shall adopt rules and a form relating to the requirements of this section on or before 90 days after the effective date of this act.

Sec. 6. (a) If the state finds that there is a reasonable probability that:

(1) A wholesale distributor has:

(A) Knowingly violated a provision of this act; or

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

(2) The prescription drug which is alleged to be in violation of paragraph (1) of subsection (a) of this section could cause serious adverse health consequences or death; and

(3) other procedures would result in unreasonable delay, the state shall issue an order requiring the appropriate person, including the manufacturers, distributors or retailers of the drug, to immediately cease distribution of the drug.

(b) An order issued under paragraph (3) of subsection (a) of this sec-

tion shall provide the person subject to the order with an opportunity for an informal hearing, to be held on or before 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 determines that inadequate grounds exist to support the actions required by the order, the state shall vacate the order.

Sec. 7. (a) 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) Failure to obtain a license in accordance with this act, or operating without a valid license when a license is required by this act;

(2) selling, distributing, transferring or otherwise providing prescription drugs in violation of the 5% rule established in subsection (a) of section 4;

(3) purchasing or otherwise receiving a prescription drug from a pharmacy, unless the requirements in subsection (a) of section 3 are met;

(4) 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 to receive the prescription drug, in violation of subsection (c) of section 3;

(5) failure to deliver prescription drugs to specified premises, as required by subsection (d) of section 3;

(6) accepting payment or credit for the sale of prescription drugs in violation of subsection (e) of section 3;

(7) failure to maintain or provide pedigrees as required by this act;

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

(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 under the provisions of this act;

(10) 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;

(11) the manufacture, repacking, sale, transfer, delivery, holding or offering or sale any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit or has otherwise been rendered unfit for distribution;

(12) the adulteration, misbranding or counterfeiting of any prescription drug;

(13) 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; and

(14) 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.

(b) A person convicted of violating subsection (a) shall be guilty of a severity level 1 felony.

(c) This section shall be part of and supplemental to the Kansas criminal code.

Sec. 8. This act shall take effect and be in force from and after its publication in the statute book.