

STATE OF OKLAHOMA

1st Session of the 50th Legislature (2005)

COMMITTEE SUBSTITUTE  
FOR  
SENATE BILL 640

By: Shurden

COMMITTEE SUBSTITUTE

[ professions and occupations - Wholesale Licensure  
and Prescription Medication Integrity Act -  
codification - effective date ]

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified  
in the Oklahoma Statutes as Section 353.18A of Title 59, unless  
there is created a duplication in numbering, reads as follows:

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

SECTION 2. NEW LAW A new section of law to be codified  
in the Oklahoma Statutes as Section 353.18B of Title 59, unless  
there is created a duplication in numbering, reads as follows:

As used in the Wholesale Licensure and Prescription Medication  
Integrity Act:

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

2. "Chain pharmacy warehouse" means a physical location for  
drugs and/or devices that acts as a central warehouse and performs  
intra-company sales or transfers of the drugs or devices to a group  
of chain pharmacies that must have the same common ownership and  
control. Chain pharmacy warehouses must be licensed as such;

3. "Facility" means a wholesale distributor where prescription  
drugs are stored, handled, repackaged or offered for sale;

4. "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;

5. "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;

6. "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 the provisions of Section 503(b) of the Federal Food, Drug and Cosmetic Act (FFDCA);

7. "Repackage" means repackaging or otherwise changing the container, wrapper or labeling to further the distribution of a prescription drug excluding that completed by the pharmacist responsible for dispensing product to the patient;

8. "Repackager" means a person who repackages prescription drugs;

9. "Wholesale distributor" means anyone engaged in the wholesale distribution of prescription drugs including, but not limited to:

- a. manufacturers, unless specified otherwise
- b. repackagers,
- c. own-label distributors,
- d. private-label distributors,
- e. jobbers,
- f. brokers,

- g. warehouses, including manufacturers' and distributors' warehouses, and drug wholesalers or distributors,
  - h. independent wholesale drug traders,
  - i. retail pharmacies that conduct wholesale distribution, and
  - j. chain pharmacy warehouses that conduct wholesale distribution; and
10. Wholesale distribution does not include:
- a. intra-company 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,
  - 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. 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 to a patient or patient's agent pursuant to the lawful order of a licensed practitioner.

SECTION 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.18C of Title 59, unless there is created a duplication in numbering, reads as follows:

A. Every wholesale distributor who engages in the wholesale distribution of prescription drugs in this state shall be licensed by the Board of Pharmacy, and every nonresident wholesale distributor shall be licensed in a state, if it ships prescription

drugs into that state, in accordance with the provisions of this act before engaging in wholesale distributions of wholesale prescription drugs.

B. 1. The Board shall require the following minimum information from each wholesale distributor applying for a license under the provisions of subsection A of this section, and as part of any renewal process for such license:

- 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, such as a partnership, corporation or sole proprietorship,
- e. the name(s) of the owner and/or operator of the licensee including:
  - (1) if a person, the name of the person,
  - (2) if a partnership, the name of each partner and the name of the partnership,
  - (3) 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
  - (4) 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, and

- g. the name of the applicant's designated representative for the facility, together with the personal information statement and fingerprints, required pursuant to the provisions of paragraph 2 of this subsection;

2. Each person required by the provisions of subparagraphs f and g of paragraph 1 of this subsection 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 (7) 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 (7) 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 (7) years, the subject of any proceeding for the revocation of any license and, if so, the nature and disposition of the proceeding,
- f. 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 or 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 (7) 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 such 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,
- i. a photograph of the person taken in the previous thirty (30) days, and
- j. a set of fingerprints for the person on a form and under procedures specified by the state, together with payment of an amount equal to the costs incurred by the state for the criminal record check of the person. Once the person has submitted a set of fingerprints for the initial license, the person need not submit a second set of fingerprints for the renewal; and

C. The information required pursuant to the provisions of subsection B of this section shall be provided under oath.

D. The Board 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 (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 more on an examination given by the Board 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 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.

E. The Board shall submit the fingerprints provided by a person with an initial or a renewal license application to the Oklahoma State Bureau of Investigation for a statewide criminal history record check and for forwarding to the Federal Bureau of Investigation for a national criminal history record check.

F. The Board shall require every wholesale distributor applying for a new license or a renewal 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 pursuant to the provisions of subsection G 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 that

license, which are authorized under state law and which the licensee fails to pay within thirty (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. 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 facility, the wholesale distributor shall obtain a license for each facility.

I. Changes in any information in subsection B of this section shall be submitted to the Board pursuant to rules promulgated 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 under this section.

J. The designated representative identified pursuant to subparagraph h of paragraph 2 of subsection B of this section shall complete continuing education programs as required by the Board regarding federal and state laws governing the wholesale distribution of prescription drugs.

K. Information provided under this section shall not be disclosed to any person or entity other than a Board authority, government board, or government agency provided that the Board authority, government board, or government agency needs such information for licensing or monitoring purposes.

L. Every calendar year, the Board shall send to each wholesale distributor licensed under this act a form setting forth the information that the wholesale distributor provided pursuant to subsection B of this 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 the information that was provided pursuant to subsection B.

SECTION 4. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.18D of Title 59, unless there is created a duplication in numbering, reads as follows:

A. 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 requirements of Section 5 of this act. 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 and counterfeit products.

B. A wholesale distributor who meets the exception in subsection A of this section 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.

C. 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 that the person is legally authorized to receive the prescription drugs by contacting the appropriate state licensing authorities.

D. 1. 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.

2. Prescription drugs may be furnished to a hospital pharmacy receiving area, provided that a pharmacist or authorized receiving personnel signs a receipt at the time of delivery 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 the delivery to the pharmacy receiving area.

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.

SECTION 5. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.18E of Title 59, unless there is created a duplication in numbering, reads as follows:

A. Each person who is engaged in the 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:

1. Pedigrees for all prescription drugs that leave the normal distribution channel;

2. Pedigrees for all prescription drugs that are included on the Specified List of Susceptible Products; and

3. Effective December 31, 2007, all wholesale distributors, whether located in or out of state, must provide and maintain an electronic pedigree developed in accordance with standards and requirements of the Board for all prescription drugs received and distributed by the wholesale distributor.

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

D. 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 information 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 does not take title to the prescription drug,
- b. the name and address of each location from which the product was shipped, if different from the owner's,
- c. transaction dates, and

d. certification that each recipient has authenticated the pedigree;

2. At a minimum, the pedigree shall also include the:

- a. 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.

E. Each pedigree or electronic file shall be:

1. Maintained by the purchaser and the wholesale distributor for three (3) years; and

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

F. The Board of Pharmacy shall promulgate rules and develop a form relating to the requirements of this section not later than ninety (90) days after the effective date of this act.

SECTION 6. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.18F of Title 59, unless there is created a duplication in numbering, reads as follows:

A. If the state finds that there is a reasonable probability that:

1. A wholesale distributor has:

- a. violated a provision of this act, 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 paragraph 1 of this subsection could cause serious, adverse health consequences or death; and

3. Other procedures would result in unreasonable delay,

the Board of Pharmacy shall issue an order requiring the appropriate persons, including the manufacturers, distributors or retailers of the drug, to immediately cease distribution of the drug.

B. An order pursuant to the provisions of subsection A of this section 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 action required by the order. If, after providing an opportunity for such a hearing, the Board determines that inadequate grounds exist to support the actions required by the order, the Board shall vacate the order.

SECTION 7. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.18G of Title 59, unless there is created a duplication in numbering, reads as follows:

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 the provisions of the this act, or to operate without a valid license when a license is required by the Wholesale Licensure and Prescription Medication Integrity Act;

2. Purchasing or otherwise receiving a prescription drug from a pharmacy unless the requirements of subsection B of Section 4 of this act are met;

3. The sale, distribution or transfer of a prescription drug to a person who 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 the provisions of subsection C of Section 4 of this act;

4 Failure to deliver prescription drugs to specified premises, as required by subsection D of Section 4 of this act;

5. Accepting payment or credit for the sale of prescription drugs in violation of the provisions of subsection E of Section 4 of this act;

6. Failure to maintain or provide a pedigree as required by Section 5 of this act;

7. Failure to obtain, pass or authenticate a pedigree as required by this act;

8. Providing the Board of Pharmacy, 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;

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. 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 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's being misbranded.

SECTION 8. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.18H of Title 59, unless there is created a duplication in numbering, reads as follows:

A. Any person who engages in the wholesale distribution of prescription drugs in violation of the provisions of the Wholesale Licensure and Prescription Medication Integrity Act shall be guilty of a felony, punishable by imprisonment in the state penitentiary for not more than fifteen (15) years, a fine of not more than Fifty Thousand Dollars (\$50,000.00), or by both.

B. Any person who knowingly engages in the wholesale distribution of prescription drugs in violation of the provisions of this act shall be guilty of a felony punishable by imprisonment in the state penitentiary for twenty-five (25) years, or a fine of not more than Five Hundred Thousand Dollars (\$500,000.00), or by both.

SECTION 9. This act shall become effective November 1, 2005.

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CJ

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