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H.B. 354

LICENSURE OF WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS

2005 GENERAL SESSION

STATE OF UTAH

Sponsor: Bradley G. Last

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act to increase the regulation of pharmaceutical wholesalers and distributors.

Highlighted Provisions:

This bill:

- defines terms;
- establishes licensing requirements;
- establishes restriction on pharmaceutical transactions;
- requires the use of drug pedigrees;
- establishes enforcement mechanisms;
- describes prohibited acts; and
- imposes penalties.

Monies Appropriated in this Bill:

None

Other Special Clauses:

This bill takes effect on July 1, 2005.

Utah Code Sections Affected:

AMENDS:

58-17b-503, as enacted by Chapter 280, Laws of Utah 2004

58-17b-505, as enacted by Chapter 280, Laws of Utah 2004

ENACTS:

58-17b-801, Utah Code Annotated 1953

58-17b-802, Utah Code Annotated 1953

58-17b-803, Utah Code Annotated 1953

58-17b-804, Utah Code Annotated 1953

58-17b-805, Utah Code Annotated 1953

58-17b-806, Utah Code Annotated 1953

58-17b-807, Utah Code Annotated 1953

58-17b-808, Utah Code Annotated 1953

REPEALS:

58-17b-617, as enacted by Chapter 280, Laws of Utah 2004

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **58-17b-503** is amended to read:

58-17b-503. Exception to unprofessional conduct.

(1) For purposes of this section:

(a) "ICFMR" means an intermediate care facility for the mentally retarded licensed as a nursing care facility or a small health care facility under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

(b) "Nursing care facility" has the same definition as in Section 26-21-2.

(c) "Unit pack" means a single dose-single drug package which identification indicates the lot number and expiration date for the drug.

(2) Notwithstanding the provisions of Subsection 58-17b-502(5) and Part 8, Pharmaceutical Wholesaler and Distributor Regulation Act, a pharmacist may accept back and redistribute any unused drug, or a part of it, after it has left the premises of the pharmacy if:

(a) the drug was prescribed to a patient in a nursing care facility, an ICFMR, or state prison facility, county jail, or state hospital;

(b) the drug was stored under the supervision of a licensed health care provider according to manufacturer recommendations;

(c) the drug is in a unit pack or in the manufacturer's sealed container;

(d) the drug was returned to the original dispensing pharmacy;

(e) the drug was initially dispensed by a licensed pharmacist or licensed pharmacy intern; and

(f) accepting back and redistribution of the drug complies with Federal Food and Drug Administration and Drug Enforcement Administration regulations.

Section 2. Section **58-17b-505** is amended to read:

58-17b-505. Educational and enforcement fund.

(1) The director may use the money collected pursuant to [~~Section~~] Sections 58-17b-504 and 58-17b-808 for the following purposes:

(a) education and training of licensees under this chapter;

(b) enforcement of this chapter by:

(i) investigating unprofessional or unlawful conduct;

(ii) providing legal representation to the division when legal action is taken against a person engaging in unprofessional or unlawful conduct;

(iii) monitoring compliance of renewal requirement; and

(iv) education and training of division staff and board members.

(2) All funding for the purposes listed in Subsection (1) is nonlapsing.

(3) Any penalty which is not paid may be collected by the director by either referring the matter to a collection agency or bringing an action in the district court of the county in which the person against whom the penalty is imposed resides or in the county where the office of the director is located.

(4) Any county attorney or the attorney general of the state is to provide legal assistance and advice to the director in any action to collect the penalty. In any action brought to enforce the provisions of this section, reasonable attorney's fees and costs shall be awarded in which the person against whom the penalty is imposed resides or in the county where the office of the director is located.

Section 3. Section **58-17b-801** is enacted to read:

Part 8. Pharmaceutical Wholesaler and Distributor Regulation Act

58-17b-801. Title.

This part is known as the "Pharmaceutical Wholesaler and Distributor Regulation Act."

Section 4. Section **58-17b-802** is enacted to read:

58-17b-802. Definitions.

In addition to the definitions in Section 58-17b-102, for purposes of this part:

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

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

(3) "Immediate family" includes a person's spouse, children, parents, siblings, the spouses of a person's children, and the spouses of a person's siblings.

(4) "Normal distribution channel" means a chain of custody for a prescription drug that goes from a manufacturer, to a pharmaceutical wholesaler and 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 pharmaceutical wholesaler and distributor or repackager, until final sale to a pharmacy, or other person dispensing or administering the prescription drug.

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

Section 5. Section **58-17b-803** is enacted to read:

58-17b-803. Pharmaceutical wholesaler and distributor licensing requirement.

(1) Every pharmaceutical wholesaler and distributor who engages in the wholesale distribution of prescription drugs into this state must be licensed by the state in which it resides, before engaging in wholesale distributions of wholesale prescription drugs into this state.

(2) The division shall require the following minimum information from each pharmaceutical wholesaler or distributer applying to get a license under Subsection (1) and as part of any renewal of any 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;

(e) the name of the owner and 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 proprietor, 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 licensee by any other state that authorizes the licensee to purchase or possess prescription drugs;

(g) 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 and fingerprints required pursuant to Subsection (2)(i) for each such persons;

(h) the name of the licensee's designated representative for the facility in accordance with Subsection (4), together with the personal information statement and fingerprints, required pursuant to Subsection (2)(i) for the designated representative; and

(i) each person required by Subsections (2)(g) and (h) to provide a personal information statement and fingerprints shall provide the following information to the division:

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

(iv) the principal business and address of any business, corporation, or other organization in which the person held a position or was employed under Subsection (2)(h)(iii);

(v) 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;

(vi) 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;

(vii) (A) a description of any involvement or investments by the person during the past seven years with any business:

(I) that manufactured, administered, prescribed, distributed, or stored pharmaceutical products; or

(II) that was named as a party in a lawsuit during the past seven years; and

(B) Subsection (2)(i)(vii)(A) does not include any ownership of stock in a publicly traded company or mutual fund;

(viii) (A) a description of any felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication or guilt was withheld or whether the person pled guilty or nolo contendere; and

(B) 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 division a copy of the final written order of disposition; and

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

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

(4) The division shall not issue or renew a pharmaceutical wholesaler and distributor license of a licensee, unless the division determines that the designated representative required under Subsection (2)(h) 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 pharmaceutical wholesaler and distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs;

(c) has received a score of 75% or more on an examination given by the division regarding federal and state laws governing wholesale distribution of prescription drugs, which test shall be retaken each time the licensee lists the person as the designated representative in an application for license or renewal of a license;

(d) is employed by the licensee full time in a managerial level position;

(e) is actively involved in and aware of the actual daily operation of the pharmaceutical wholesaler and distributor;

(f) is physically present at the facility of the licensee during regular business hours, except when the absence of the designated representative is authorized, including sick leave and vacation leave;

(g) is serving in the capacity of a designated representative for only one licensee at a time;

(h) does not have any convictions under any federal, state, or local laws relating to wholesale or retail prescription drug distribution of controlled substances; and

(i) does not have any felony convictions under federal, state, or local laws.

(5) The division shall submit the fingerprints provided by a person with an initial or a renewal license application for a statewide and national criminal background check.

(6) (a) The division shall:

(i) require every pharmaceutical wholesaler and distributor applying for a new license or the renewal of a license to submit a bond to the division in an amount established by the division by administrative rule; or

(ii) other equivalent means of security acceptable to the division including an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to a fund established by the division pursuant to Subsection (7).

(b) (i) The purpose of the bond required by this Subsection (6) is to secure payment of:

(A) any fines or penalties lawfully imposed by the division against a licensee for violating this part;

(B) any fees and costs incurred by the division enforcing this part; and

(C) any costs incurred by the state as a result of the licensee's violation of this part.

(ii) The bond may be used by the state if the licensee fails to pay any fines, penalties, or costs imposed under Subsection (6)(b)(i) within 30 days after the imposition of the fine is final.

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

(7) The division shall establish a fund, separate from its other accounts, in which to deposit the pharmaceutical wholesaler and distributor bonds.

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

(9) Changes in any information in Subsection (2) shall be submitted to the division as required by the division by administrative rule adopted in accordance with Title 63, Chapter 46a, Utah Administrative Rulemaking Act.

Section 6. Section **58-17b-804** is enacted to read:

58-17b-804. Minimum restrictions on transactions.

(1) In any calendar month, a pharmaceutical wholesaler and distributor shall sell, distribute, or otherwise transfer at least 95% of its total amount of prescription drugs to a pharmacy or other person dispensing or administering the drug.

(2) (a) A pharmaceutical wholesaler and distributor shall not purchase or otherwise receive a prescription drug from a pharmacy, except that a pharmaceutical wholesaler and distributor may receive a prescription drug from a pharmacy if the prescription drug was originally purchased by the pharmacy from the pharmaceutical wholesaler and distributor.

(b) A pharmaceutical wholesaler and distributor who meets the exception in Subsection (2)(a) shall not:

(i) receive from a pharmacy an amount or quantity of a prescription drug larger than the amount or quantity that was originally sold by the pharmaceutical wholesaler and distributor to the pharmacy; or

(ii) pay the pharmacy an amount, either in cash or credit, more than the pharmacy originally paid the pharmaceutical wholesaler and distributor for the prescription drug.

(3) A manufacturer or pharmaceutical wholesaler and 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 pharmaceutical wholesaler and distributor, the manufacturer or pharmaceutical wholesaler and distributor shall affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the appropriate state licensing authorities.

(4) (a) Prescription drugs furnished by a manufacturer or pharmaceutical wholesaler and distributor shall be delivered only to the premises listed on the license, provided that the manufacturer or pharmaceutical wholesaler and distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or pharmaceutical wholesaler and distributor if:

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

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

(b) 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 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 pharmaceutical wholesaler and distributor by the next business day after the delivery to the pharmacy receiving area.

(5) A manufacturer or pharmaceutical wholesaler and distributor shall not accept payment for, or allow the use of, a person or entity's credit to establish an account for the purchase of prescription drugs from any person other than the owner of record, the chief executive officer, or the chief financial officer listed on the license of a person or entity legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee.

Section 7. Section **58-17b-805** is enacted to read:

58-17b-805. Pedigree.

(1) (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.

(b) If a pharmacy sells a drug to any person that 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 the prescription drug.

(c) Sale, trade, or transfer of a prescription drug between licensees with a common ownership, or to meet emergency needs are not subject to this Subsection (1).

(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) (a) The pedigree required by this section shall include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, through acquisition and sale by any pharmaceutical wholesaler and distributor, or repackager, until final sale to a pharmacy or other person dispensing or administering the drug.

(b) At minimum, the necessary chain of distribution information required by Subsection (3)(a) shall include the:

(i) name, address, telephone number, and if available, the email address, of each owner of the prescription drug, and each pharmaceutical wholesaler and distributor who does not take title to the prescription drug;

(ii) signature of each owner of the prescription drug and each pharmaceutical wholesaler and distributor who does not take title to the prescription drug;

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

(iv) transaction dates; and

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

(c) 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 statement required by this section shall be:

(a) maintained by the purchaser and the pharmaceutical wholesaler and distributor for three years; and

(b) available for inspection or removal upon a request of an authorized officer of the law.

(5) The division shall adopt administrative rules and a form in accordance with Title 63, Chapter 46a, Utah Administrative Rulemaking Act, relating to the requirements of this part no later than 90 days after the effective date of this part.

Section 8. Section **58-17b-806** is enacted to read:

58-17b-806. Enforcement -- Order to cease distribution of a drug.

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

(a) a pharmaceutical wholesaler and distributor has:

(i) knowingly violated a provision of this part or a rule adopted in accordance with this part; or

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

(b) the prescription drug at issue in Subsection (1)(a) could cause serious, adverse health consequences or death; and

(c) other procedures would result in unreasonable delay, the division shall issue an order in accordance with Title 63, Chapter 46b, Administrative Procedures Act, requiring the appropriate person, including manufacturers, pharmaceutical wholesalers and distributors, or retailers of the drug, to immediately cease distribution of the drug.

(2) An order under Subsection (1) is subject to review in accordance with Title 63, Chapter 46b, Administrative Procedures Act.

Section 9. Section **58-17b-807** is enacted to read:

58-17b-807. Prohibited acts.

It is unlawful for a person to perform, or cause the performance of, or aid and abet any of the following acts in this state:

(1) failure to obtain a license in accordance with this part or operating without a valid license when a license is required by this part;

(2) selling, distributing, transferring, or otherwise providing prescription drugs in violation of the 5% rule established in Subsection 58-17b-804(1);

(3) purchasing or otherwise receiving a prescription drug from a pharmacy, unless the requirements in Subsection 58-17b-804(2) 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 58-17b-804(3);

(5) failure to deliver prescription drugs to specified premises, as required by Subsection 58-17b-804(4);

(6) accepting payment or credit for the sale of prescription drugs in violation of Subsection 58-17b-804(5);

(7) failure to maintain or provide a drug pedigree as required by this part;

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

(9) providing the state or any of its representatives or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this part;

(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 for 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; or

(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.

Section 10. Section **58-17b-808** is enacted to read:

58-17b-808. Penalties.

(1) Notwithstanding the provisions of Section 58-17b-504, a person is guilty of a second degree felony and is subject to imprisonment under Section 76-3-203 and a fine of not more than $50,000 per violation if that person knowingly engages in the wholesale distribution of a prescription drug in violation of this part or any rule or order adopted under this part.

(2) If a person is an organization, it shall, upon conviction of violating this part, be subject to a fine of not more than $500,000.

(3) Circumstantial evidence may be used to prove that a defendant possessed actual knowledge, including evidence that the defendant took affirmative steps to be shielded from receiving relevant information.

(4) Penalties and fines imposed under this part shall be deposited into the education and enforcement fund created in Section 58-17b-505.

Section 11. **Repealer.**

This bill repeals:

Section **58-17b-617, Limitations on distribution of prescription drugs by pharmaceutical manufacturers or wholesalers.**

Section 12. **Effective date.**

This bill takes effect on July 1, 2005.

Legislative Review Note
as of 2-14-05 4:05 PM

Based on a limited legal review, this legislation has not been determined to have a high probability of being held unconstitutional.

Office of Legislative Research and General Counsel