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H.B. 354
1st Sub. (Buff)

Representative Bradley G. Last proposes the following substitute bill:

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:

- requires the use of drug pedigrees in certain circumstances;
- requires the Division of Occupational and Professional Licensing to develop, by administrative rule, a list of drug products that should be subject to pedigrees due to susceptibility to counterfeit and misbranding; and
- establishes enforcement mechanisms.

Monies Appropriated in this Bill:

None

Other Special Clauses:

This bill takes effect on July 1, 2005.

Utah Code Sections Affected:

AMENDS:

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

ENACTS:

58-17b-617.1, Utah Code Annotated 1953

58-17b-617.2, Utah Code Annotated 1953

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

Section 1. Section **58-17b-617** is amended to read:

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

(1) A pharmaceutical manufacturer or pharmaceutical wholesaler may not provide a prescription drug to any person, except as defined by rule.

(2) (a) Prescription drugs that are not controlled substances may be:

(i) distributed or provided as drug samples to a person licensed within the state to sell, prescribe, administer, or conduct research with legend drugs; and

(ii) supplied in connection with a manufacturer's patient assistance program to be distributed to qualifying patients enrolled in the program.

(b) Controlled substance prescription drugs may be sold or provided only:

(i) upon the issuance of an order or request by a person appropriately licensed under state and federal law to sell, prescribe, administer, or conduct research with prescription drugs; and

(ii) upon the establishment of documents in the possession of the manufacturer or distributor recording the purchaser, type of drug, quantity of drug, date of shipment, and date of delivery.

(3) Purchasers or those in receipt of drugs under this section shall maintain records in accordance with Section 58-17b-617.1, federal, and state laws regarding controlled substances.

Section 2. Section **58-17b-617.1** is enacted to read:

58-17b-617.1. Pedigree.

(1) (a) Each person who is engaged in the wholesale distribution of a prescription drug, as defined in Subsection 58-17b-102(48) shall establish and maintain inventories and records, in accordance with Subsection (3), of all transactions regarding the receipt and distribution or other disposition of the prescription drug.

(b) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this section if the retail pharmacy or chain pharmacy warehouse is a

pharmaceutical wholesaler or distributor as defined in Subsection 58-17b-102(48).

(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 comply with the provisions of this section.

(3) (a) Pedigrees required by Subsections (3)(b) and (c) shall be maintained for:

(i) all prescription drugs that leave the normal distribution channel; and

(ii) prescription drugs that are included on a list of prescription drugs that the division determines by administrative rule are susceptible to counterfeit, misbranding, or mislabeling.

(b) 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.

(c) At minimum, the necessary chain of distribution information required by Subsection (3)(b) 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) name and address of each location from which the product was shipped, if different from the owner's;

(iii) transaction dates; and

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

(d) 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;

(b) by December 31, 2007, maintained in an electronic format approved by the division by administrative rule; and

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

(5) (a) If the division receives a complaint or suspects a violation of this section or Section 58-17b-617, the division may require a person subject to this section and Section 58-17b-617 to provide documentation to the division verifying compliance with this chapter and division rules.

(b) The division shall adopt administrative rules in accordance with Title 63, Chapter 46a, Utah Administrative Rulemaking Act, relating to:

(i) the list of susceptible products required in Subsection (3)(a)(ii); and

(ii) by July 1, 2006, the electronic format required by Subsection (4)(b).

Section 3. Section **58-17b-617.2** is enacted to read:

58-17b-617.2. 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 chapter or a rule adopted in accordance with this chapter; 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 4. **Effective date.**

This bill takes effect on July 1, 2005.