

SUBJECT: Licensing and regulation of wholesale drug distributors

COMMITTEE: Public Health — favorable, without amendment

VOTE: 7 ayes — Delisi, Coleman, Dawson, Jackson, McReynolds, Truitt, Zedler
0 nays
2 absent — Laubenberg, Solis

SENATE VOTE: On final passage, May 12 — 31-0 on Local and Uncontested calendar

WITNESSES: *(On House companion, HB 3174 by Truitt:)*
For — Jim Caldwell, Texas Silver Haired Legislators; David Gonzales, Healthcare Distribution Management Association; David Searle, Pfizer, Inc.

Against — None

On — Susan Tennyson, Texas Department of State Health Services – Environmental and Consumer Safety Section

BACKGROUND: The Department of State Health Services (DSHS) is responsible for the regulation of wholesale drug distributors. DSHS routinely inspects drug distributors to determine compliance with state and federal laws governing the distribution of drugs. Examples of wholesale drug distributors include warehouses that supply over-the-counter (OTC) and prescription drugs to hospitals, clinics, pharmacies, retail stores, and other licensed wholesalers.

The Health and Safety Code requires all businesses that distribute drugs to anyone other than the consumer or patient to submit a license statement with DSHS annually. The license statement must contain the names under which the business is conducted, the address of each place of business, and the name and residence address of the proprietor, partners, or principals, depending on the classification of the business.

DIGEST: CSHB 3174 would amend provisions in the Health and Safety Code

concerning wholesale drug distribution. The bill would expand the definition of nonprescription wholesale distribution to include distribution by a repackager, broker, or warehouse and of prescription drug wholesale distribution to include distribution by a manufacturer, repackager, own-label distributor, broker, jobber, warehouse, retail pharmacy that conducts wholesale distribution, or wholesaler. Wholesale distribution would not include intracompany sales or transfers, the sale of drugs for emergency medical reasons, distribution of samples, return of drugs, the sale of limited quantities of drugs for doctor's office use, or retail dispensing.

With certain exemptions, the bill would require any person engaging in wholesale distribution of drugs, or drug distribution as a chain pharmacy warehouse location, to obtain a license biennially. The license application would include additional personal information under oath from proprietors, partners, principals, and managers of the business, including past occupations, employment positions, and any history of involvement in license revocation proceedings, lawsuits, or injunction by a court from violating federal or state laws regulating prescription drugs. These individuals would also have to submit information concerning their criminal histories, including any felony offenses and criminal convictions.

To qualify for a wholesale distributor license, the designated representative would be required to have been employed full-time for at least three years by a pharmacy or a wholesale distributor in a capacity related to the dispensing and distributing of prescription drugs, be currently employed by the applicant in a full-time managerial position, and be physically present at the place of business. The representative could not be a convicted felon or have been convicted of a violation of any laws relating to wholesale or retail prescription drug distribution or the distribution of controlled substances. DSHS would have the authority to assess and collect an inspection fee to cover the costs of an investigation and business and criminal background checks on the applicant. Distributors also would be required to keep current the information about the place of business in a timely manner.

SB 1685 would authorize DSHS to submit to the Department of Public Safety (DPS) fingerprints provided by an applicant for a wholesale distributor license in order to obtain the applicant's criminal history record

information. The fingerprints also could be forwarded to the Federal Bureau of Investigation for a federal criminal history check.

The distributor would secure a \$100,000 bond payable to the state or an equivalent security that could be used to pay any fines or fees assessed against the distributor.

Wholesale distributors' activities would be limited, including by what returned prescription drugs they could purchase, to whom they could distribute prescription drugs, and where they could deliver the prescription drugs. A distributor that was not the original manufacturer and labeler would be required to maintain on all transactions a record of pedigree — a file that states each step in the chain of possession of a drug.

The bill would require DSHS to conduct a study on electronic pedigrees. The executive commissioner of HHSC would have rulemaking authority to implement the required electronic pedigree program based on the results of the study.

Under the bill, the executive commissioner could refuse to license or renew a license because of certain offenses and could issue an order requiring a person, including a manufacturer, distributor, or retailer of a prescription drug, immediately to cease distribution if a violation occurred.

SB 1685 would create an offense and provide for penalties against a person engaging in the wholesale distribution of prescription drugs in violation of prohibited acts. It would be punishable by a \$50,000 maximum fine or a jail sentence of 15 years or less and a possible fine of up to \$500,000, depending on the violation.

The executive commissioner of HHSC would adopt rules necessary to implement the changes in law made by the bill to the Health and Safety Code by January 1, 2006. HHSC would set fees at a level to pay for administration and oversight of the licensing.

The bill would take effect on September 1, 2005, but the substantial changes would take effect on March 1, 2006.

**SUPPORTERS
SAY:**

SB 1685 would strengthen state law governing drug manufacturers and wholesalers, especially secondary wholesalers. The vast majority of prescription drugs in the United States are distributed by three major

wholesalers that purchase products from manufacturers and sell them to pharmacies or consumers. A significant amount, however, is sold through smaller, local wholesalers known as secondary wholesalers. Texas has an estimated 2,200 secondary wholesalers. Secondary wholesalers buy and sell prescription drugs horizontally — that is, from wholesaler to wholesaler, or pharmacy to pharmacy. When products move horizontally, the existing supervisory mechanisms are compromised and the ability adequately to protect the public is lost.

An environment with thousands of distributors requires a better mechanism of licensing and regulation. Current law provides only for a lax application process with little or no regulation, enforcement, or penalty mechanisms. SB 1685 would enhance the regulation of wholesalers by requiring that applicants meet strict qualifications.

Counterfeiting of prescription drugs has rapidly increased in the past few years and is a growing problem. Counterfeit drugs pose a threat to the health and safety of Texans, and existing regulations are ineffective in preventing counterfeit drugs from crossing the state's borders. The electronic pedigree program would make future counterfeiting efforts much more difficult than they are today. More than 30 states are considering this type of legislation to ensure a safer drug supply.

The increased regulation would not be a cost to the state. Licensure fees would be increased and collected from wholesalers in order to pay for the regulation increased by the bill. It also would not result in less oversight, as suggested by a fiscal note attached to an earlier version of the bill, because it would not change DSHS' existing authority to inspect or license distributors.

OPPONENTS
SAY:

No apparent opposition.

NOTES:

The fiscal note estimates no cost to the state.

The House companion bill, HB 3174 by Truitt, was placed on the General State Calendar for May 12 and was postponed.