

- SUBJECT:** Licensing and regulation of wholesale drug distributors
- COMMITTEE:** Public Health — committee substitute recommended
- VOTE:** 8 ayes — Delisi, Laubenberg, Dawson, Jackson, McReynolds, Solis, Truitt, Zedler
- 0 nays
- 1 absent — Coleman
- WITNESSES:** 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 wholesale distribution to include distribution by a repackager, private-label distributor, broker, warehouse, independent wholesale drug trader, retail pharmacy that conducted wholesale distribution. 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.

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 annually. 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 enjoinderment by a court from violating federal or state laws regulating prescription drugs. These individuals would also have to submit information concerning their criminal history, including any felony offenses and criminal convictions.

To qualify for a wholesale distributor license, the designated representative would have to meet a number of requirements, including full-time employment for at least three years by a pharmacy or a wholesale distributor in a capacity related to the dispensing and distributing of prescription drugs, currently be 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 or a private contractor 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.

CSHB 3174 would authorize DSHS to submit to the Department of Public Safety (DPS) fingerprints provided by an applicant for a wholesale distributor license to obtain the applicant's criminal history record information. The fingerprints could also be forwarded to the FBI 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.

The bill would require DSHS to conduct a study on electronic pedigrees – a file that states each step in the chain of possession of a drug – and the implementation of a program to require wholesale distributors to offer a pedigree on the drugs they distribute. The executive commissioner of HHSC would have rulemaking authority to implement the required electronic pedigree program based on the results of the study. Implementation could take place no earlier than December 31, 2007.

Under the bill, the executive commissioner 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 or if the prescription drug could cause serious adverse health consequences or death.

CSHB 3174 would create an offense and provide for criminal penalties against a person engaging in the wholesale distribution of prescription drugs in violation of prohibited acts.

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, except that Health and Safety Code, sec. 431.2077, would take effect on March 1, 2006, and would apply only to an offense committed on or after March 1, 2006.

**SUPPORTERS
SAY:**

CSHB 3174 would strengthen state law governing drug manufacturers and wholesalers, especially secondary wholesalers. The vast majority of prescription drugs in the U.S. are distributed by three major wholesalers that purchase the 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 by horizontal movement, which 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 and penalty mechanisms. CSHB 3174 would enhance the regulation of wholesalers by requiring strict qualifications to be met by applicants.

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 entering our borders. The electronic pedigree program would make future counterfeiting efforts much more difficult than 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.

**OPPONENTS
SAY:**

CSHB 3174 would actually make state oversight more lax for some drug manufacturers and distributors. The definitions in the bill would not permit DSHS to inspect an estimated 1,350 over-the-counter drug manufacturers and distributors and would make 1,060 distributors of certain medical equipment unable to renew their licenses and pay license fees.

NOTES:

The substitute would apply only to offenses committed on or after March 1, 2006, instead of the effective date of the bill.

The fiscal note states that the changes in DSHS' authority to license and inspect certain manufacturers and distributors would result in lost revenue of \$964,000 per year. Any changes in DSHS administrative costs would be covered by additional fees.