

BILL ANALYSIS

Senate Research Center
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S.B. 1685
By: Janek
Health & Human Services
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As Filed

AUTHOR'S/SPONSOR'S STATEMENT OF INTENT

As proposed, S.B. 1685 protects the public from adulterated, misbranded, or counterfeit prescription drugs by increasing the regulation of wholesale distributors. S.B. 1685 revises the wholesale drug distributors section of the Health and Safety Code to include a wholesale license application and issuance of a license by the Department of State Health Services. The bill also establishes a tracking mechanism for prescription drugs distributed outside the usual scheme.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 6 (Section 431.2067, Health and Safety Code) of this bill.

Rulemaking authority previously granted to the Texas Board of Health is transferred to the executive commissioner of the Health and Human Services Commission in SECTION 5 (Section 431.204, Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

[While statutory reference in this bill is to the Texas Department of Health (TDH), the following amendments affect the Department of State Health Services, as the successor agency to TDH.]

SECTION 1. Amends Section 431.201, Health and Safety Code, to define "authentication," "chain pharmacy warehouse," "normal distribution chain," "pedigree," "place of business," "prescription drug," "repackage," "repackager," and "wholesale distributor." Redefines "wholesale distribution." Deletes existing definition of "place of business."

SECTION 2. Amends Sections 431.202 and 431.203, Health and Safety Code, as follows:

Sec. 431.202. New heading: LICENSE REQUIRED. (a) Prohibits a person from engaging in wholesale distribution of drugs in this state unless the person holds a wholesale drug distribution license under this subchapter for each place of business. Deletes existing text requiring a person to file with the commissioner of health (commissioner) a signed and verified license statement.

(a-1) Prohibits a person from engaging in wholesale distribution of drugs as a chain pharmacy warehouse location unless the person holds a chain pharmacy license under this chapter.

(b) Provides that a license issued under this subchapter expires on the first anniversary of the date of issuance. Deletes existing text requiring a license statement to be filed annually.

Sec. 431.203. New heading: LICENSE APPLICATION. (a) Requires an applicant for a license under this subchapter to submit an application to the Texas Department of Health (TDH) on the form prescribed by TDH. Requires the application, rather than the license statement, to contain certain modified information.

(b) Requires each person listed in Subsections (a)(6) (designated representative) and (a)(9) (manager and affiliated parties for the business) to provide certain information to TDH.

(c) Requires the information submitted under Subsection (b) to be attested to under oath.

(d) Requires an applicant or license holder to file with the Texas Board of Health (board) a written notice of any change in the information required under this section.

SECTION 3. Amends Subchapter I, Chapter 431, Health and Safety Code, by adding Section 431.2030, as follows:

Sec. 431.2030. QUALIFICATIONS FOR LICENSE. (a) Sets forth requirements for a designated representative of an applicant or license holder to qualify for the issuance or renewal of a wholesale distributor license under this subchapter.

(b) Authorizes TDH or a nationally recognized accreditation program selected by TDH to assess and collect an inspection fee to cover the costs of determining whether an applicant is qualified for a license under this subchapter, including costs to conduct physical inspections, business and criminal background checks, activities related to bonding requirements, and any other necessary activity.

SECTION 4. Amends Subchapter I, Chapter 431, Health and Safety Code, by adding Sections 431.2035 and 431.2036, as follows:

Sec. 431.2035. CRIMINAL HISTORY RECORD INFORMATION. Requires TDH to submit to the Department of Public Safety the fingerprints provided by a person with an initial or a renewal license application to obtain the person's criminal history record information and authorizes TDH to forward the fingerprints to the Federal Bureau of Investigation for a federal criminal history check.

Sec. 431.2036. BOND. (a) Requires a wholesale distributor applying for or renewing a license to submit payable to this state a bond or other equivalent security acceptable to TDH in the amount of \$100,000, including an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to this state.

(b) Requires the bond submitted under Subsection (a) to secure payment of any fines or penalties imposed by TDH and any fees and costs incurred by this state related to that license holder, that are authorized under the laws of this state and that the license holder fails to pay before the 30th day after the date a fine, penalty, or cost is assessed.

(c) Authorizes TDH or this state to make a claim against a bond or security submitted under Subsection (a) before the first anniversary of the date a license expires or is revoked under this chapter.

(d) Requires TDH to deposit the bonds received under this section in a separate account.

SECTION 5. Amends Section 431.204(c), Health and Safety Code, to require the executive commissioner of the Health and Human Services Commission (executive commissioner), rather than the board, by rule, to set the fees in amounts that are reasonable and necessary and allow TDH to recover the annual expenditures, rather than 50 percent of expenditures, of state funds by TDH in administering licenses under this chapter.

SECTION 6. Amends Subchapter I, Chapter 431, Health and Safety Code, by adding Sections 431.2065-431.2067, as follows:

Sec. 431.2065. MINIMUM RESTRICTIONS ON TRANSACTIONS. (a) Prohibits a wholesale distributor, except as otherwise provided by this subsection, from purchasing or otherwise receiving a prescription drug from a pharmacy. Authorizes a wholesale distributor to receive a prescription drug from a pharmacy if the prescription drug was originally purchased by the pharmacy from the wholesale distributor.

(b) Prohibits a wholesale distributor who receives a prescription drug from a pharmacy from receiving an amount or quantity of a prescription drug greater than the amount or quantity originally sold by the wholesale distributor to the pharmacy or paying the pharmacy an amount, either in cash or credit, that exceeds the amount the pharmacy originally paid the wholesale distributor for the prescription drug.

(c) Authorizes a manufacturer or wholesale distributor to distribute prescription drugs only to a person licensed by the appropriate state licensing authorities. Requires the manufacturer or wholesale distributor, before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, to verify that the person is legally authorized to receive the prescription drugs by contacting the appropriate state licensing authority.

(d) Authorizes prescription drugs distributed by a manufacturer or wholesale distributor, except as otherwise provided by this subsection, to be delivered only to the premises listed on the license. Authorizes a manufacturer or wholesale distributor to distribute prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if certain requirements are met.

(e) Authorizes prescription drugs to be distributed to a hospital pharmacy receiving area if a pharmacist or an authorized receiving person signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Requires any discrepancy between the receipt and the type and quantity of the prescription drug actually received to be reported to the delivering manufacturer or wholesale distributor not later than the next business day after the date of delivery to the pharmacy receiving area.

(f) Prohibits a manufacturer or wholesale distributor from accepting payment for, or allowing the use of, a person's credit to establish an account to purchase 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 legally authorized to receive prescription drugs. Requires an account established to purchase prescription drugs to bear the name of the license holder.

Sec. 431.2066. PEDIGREE REQUIRED. (a) Requires a person who is engaged in the wholesale distribution of a prescription drug, including a repackager but excluding the original manufacturer of the finished form of a prescription drug, to provide a pedigree for each prescription drug that is not distributed through the normal distribution chain and is sold, traded, or transferred to any other person.

(b) Requires a pharmacy that sells a drug to a person other than the final consumer to provide a pedigree to the person acquiring the prescription drug.

(c) Provides that the sale, trade, or transfer of a prescription drug between license holders with common ownership or for an emergency is not subject to this section.

(d) Requires a person who is engaged in the wholesale distribution of a prescription drug, including a repackager but excluding the original manufacturer of the finished form of the prescription drug, and who is in possession of a pedigree for a prescription drug to verify before distributing the prescription drug that each transaction listed on the pedigree has occurred.

Sec. 431.2067. PEDIGREE CONTENTS. (a) Requires a pedigree to include all necessary identifying information concerning each sale in the product's chain of distribution from the manufacturer, through acquisition and sale by a wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. Sets forth minimum requirements to be included in the chain of distribution information.

(b) Sets forth minimum requirements for information to be included in the pedigree.

(c) Requires each pedigree statement to be maintained by the purchaser and the wholesale distributor for at least three years and be available for inspection or removal on a request by TDH or a peace officer of this state.

(d) Requires the executive commissioner to adopt rules to implement this section.

(e) Sets forth requirements for TDH regarding a study to be conducted on the implementation of electronic pedigrees.

(f) Provides that Subsection (e) and this subsection expire January 1, 2009.

SECTION 7. Amends Subchapter I, Chapter 431, Health and Safety Code, by adding Sections 431.2075-431.2077, as follows:

Sec. 431.2075. ORDER TO CEASE DISTRIBUTION. (a) Requires the commissioner of state health services to issue an order requiring a person, including a manufacturer, distributor, or retailer of a prescription drug, to immediately cease distribution of the drug if the commissioner determines there is a reasonable probability that certain circumstances apply.

(b) Requires an order under Subsection (a) to provide the person subject to the order with an opportunity for an informal hearing on the actions required by the order to be held not later than the 10th day after the date of issuance of the order.

(c) Requires the commissioner of state health services, if, after providing an opportunity for a hearing, the commissioner determines that inadequate grounds exist to support the actions required by the order, to vacate the order.

Sec. 431.2076. PROHIBITED ACTS. (a) Provides that a person violates this subchapter if the person performs, causes the performance of, or aids and abets the performance of an act listed under Subsection (b).

(b) Sets forth actions that constitute violations of this chapter.

Sec. 431.2077. CRIMINAL PENALTIES. (a) Provides that a person commits an offense if the person engages in the wholesale distribution of prescription drugs in violation of this subchapter. Provides that an offense under this subsection is punishable by imprisonment for not more than 15 years, a fine not to exceed \$50,000, or both imprisonment and a fine.

(b) Provides that a person commits an offense if the person knowingly engages in the wholesale distribution of prescription drugs in violation of this subchapter. Provides that an offense under this subsection is punishable by imprisonment, a fine not to exceed \$500,000, or both imprisonment and a fine.

SECTION 8. Amends Section 411.110, Government Code, as follows:

Sec. 411.110. New heading: ACCESS TO CRIMINAL HISTORY RECORD INFORMATION: DEPARTMENT OF STATE HEALTH SERVICES. (a) Entitles the Department of State Health Services (DSHS) to obtain from the Department of Public Safety of the State of Texas (DPS) criminal history record information maintained by

DPS that relates to certain persons or to an applicant for a license or an applicant for a license or a license holder under Subchapter I, Chapter 431, Health and Safety Code. Makes nonsubstantive changes.

(b)-(e) Make conforming changes.

SECTION 9. (a) Requires the executive commissioner of the Health and Human Services Commission to adopt the rules necessary to implement the changes in law made by this Act to Subchapter I, Chapter 431, Health and Safety Code, not later than January 1, 2006.

(b) Provides that a wholesale drug manufacturer is not required to comply with and is not subject to penalties for a violation of Subchapter I, Chapter 431, Health and Safety Code, as amended by this Act, before March 1, 2006.

SECTION 10. Makes application of this Act prospective.

SECTION 11. Effective date: September 1, 2005, except that Section 431.2077, Health and Safety Code, as added by this Act, takes effect March 1, 2006.