

## BILL ANALYSIS

Senate Research Center  
79R14331 YDB-F

C.S.S.B. 1685  
By: Janek  
Health & Human Services  
5/4/2005  
Committee Report (Substituted)

### AUTHOR'S/SPONSOR'S STATEMENT OF INTENT

C.S.S.B. 1685 protects the public from adulterated, misbranded, or counterfeit prescription drugs by increasing the regulation of wholesale distributors. C.S.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 7 (Sections 431.409, 431.413, and 431.414, 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.

Rulemaking authority previously granted to the commissioner of health is transferred to the executive commissioner of the Health and Human Services Commission in SECTION 6 (Section 431.207, 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 the heading to Subchapter I, Chapter 431, Health and Safety Code, to read as follows:

#### SUBCHAPTER I. WHOLESALE DISTRIBUTORS OF NONPRESCRIPTION DRUGS

SECTION 2. Amends Section 431.201, Health and Safety Code, to define "nonprescription drug" and "place of business." Redefines "wholesale distribution." Deletes existing definition of "place of business."

SECTION 3. Amends Subchapter I, Chapter 431, Health and Safety Code, by adding Section 431.2011, as follows:

431.2011. APPLICABILITY OF SUBCHAPTER. Provides that this subchapter applies only to the wholesale distribution of nonprescription drugs.

SECTION 4. Amends section 431.202, Health and Safety Code, as follows:

Sec. 431.202. New heading: LICENSE REQUIRED. (a) Prohibits a person from engaging in wholesale distribution of nonprescription drugs in this state unless the person holds a wholesale drug distribution license issued by the Texas Department of Health (TDH) under this subchapter or Subchapter N. Deletes existing text requiring a person to file with the commissioner of health (commissioner) a signed and verified license statement.

(b) Requires an applicant for license under this subchapter to submit an application to TDH on the form prescribed by TDH or electronically on the TexasOnline Internet website. Deletes existing text requiring the license statement to be filed annually.

(c) Provides that a license issued under this subchapter expires on the second anniversary of the date of issuance.

SECTION 5. Amends Section 431.204, Health and Safety Code, as follows:

Sec. 431.204. FEES. (a) Requires TDH, rather than the Texas Board of Health (board), to collect fees for certain licenses and inspections.

(b) Requires the executive commissioner of the Health and Human Services Commission (HHSC), rather than the board, by rule, to set the fees in amounts that allow TDH to recover certain biennial, rather than annual, expenditures of state funds by TDH. Deletes existing text authorizing the board to charge an annual fee.

(c) Redesignated text of existing Subsection (d). Makes nonsubstantive changes.

SECTION 6. Amends Sections 431.206 and 431.207, Health and Safety Code, as follows:

Sec. 431.206. CHANGE OF LOCATION OF PLACE OF BUSINESS. (a) Creates subsection from existing text. Requires the licensee, not fewer than 30 days in advance of the change, to notify TDH, rather than the commissioner or the commissioner's designee, in writing of the licensee's intent to change the location of a licensed place of business.

(b) Creates subsection from existing text.

(c) Creates subsection from existing text. Requires the licensee, not more than 10 days after the completion of the change of location, to notify TDH in writing to confirm the completion of the change of location and provide verification of the information previously provided or correct and confirm any information that has changed since providing the notice of intent. Deletes existing text requiring written verification of certain information.

(d) Creates subsection from existing text. Provides that the notice and confirmation required by this section are deemed adequate if the licensee sends the notices by certified mail, return receipt requested, to the central office of TDH or submits them electronically through the TexasOnline Internet website. Makes conforming changes.

Sec. 431.207. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION OF LICENSE. (a) Authorizes the commissioner of state health services to refuse an application for a license or to suspend or revoke a license if the applicant or licensee meets certain modified requirements.

(b) Requires the executive commissioner of HHSC, by rule, to establish minimum standards required for the issuance or renewal of a license under this subchapter. Deletes existing text relating to refusing an application for a license.

(c) Makes conforming changes.

SECTION 7. Amends Chapter 431, Health and Safety Code, by adding Subchapter N, as follows:

SUBCHAPTER N. WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS

Sec. 431.401. DEFINITIONS. Defines "authentication," "authorized distributor of record," "chain pharmacy warehouse," "logistics provider," "normal distribution chain," "pedigree," "place of business," "prescription drug," "repackage," "repackager," and "wholesale distribution."

Sec. 431.4011. ONGOING RELATIONSHIP. Defines "ongoing relationship." Requires an agreement, if the distributor is not authorized to distribute the manufacturer's entire product line, to identify the specific drug products that the distributor is authorized to distribute.

Sec. 431.4012. APPLICABILITY OF SUBCHAPTER. Provides that this subchapter applies only to the wholesale distribution of prescription drugs.

Sec. 431.402. LICENSE REQUIRED. (a) Prohibits a person from engaging in wholesale distribution of prescription drugs in this state unless the person holds a wholesale drug distribution license under this subchapter for each place of business.

(b) Provides that a license issued under this subchapter expires on the second anniversary of the date of issuance.

Sec. 431.403. EXEMPTION FROM LICENSING. (a) Sets forth conditions under which a person who engages in wholesale distribution of prescription drugs in this state for use in humans is exempt from this subchapter.

(b) Provides that an exemption from the licensing requirements under this section does not constitute an exemption from the other provisions of this chapter or the rules adopted under this chapter to administer and enforce the other provisions of this chapter.

Sec. 431.4031. EXEMPTION FROM CERTAIN PROVISIONS FOR CERTAIN WHOLESAL DISTRIBUTORS. Provides that a wholesale distributor that distributes prescription drugs that are medical gases or a wholesale distributor that is a logistics provider on behalf of a manufacturer is exempt from Sections 431.404(b) and (c), 431.405, 431.407, 431.408, 431.412, and 431.413.

Sec. 431.404. LICENSE APPLICATION. (a) Requires an applicant for a license under this subchapter to submit an application to TDH on the form prescribed by TDH. Requires the application to contain certain information.

(b) Requires each person listed in Subsections (a)(6) and (a)(9) to provide certain information relating to each place of business to TDH.

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

(c) Requires an applicant or license holder to file with TDH a written notice of any change in the information required under this section.

Sec. 431.405. QUALIFICATIONS FOR LICENSE. 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.

Sec. 431.406. EFFECT OF OPERATION IN OTHER JURISDICTIONS; REPORTS. (a) Authorizes a person who engages in the wholesale distribution of drugs outside this state to engage in wholesale distribution of drugs in this state if the person holds a license issued by TDH.

(b) Authorizes TDH to accept reports from authorities in other jurisdictions to determine the extent of compliance with this subchapter and the minimum standards adopted under this subchapter.

(c) Authorizes TDH to issue a license to a person who engages in the wholesale distribution of drugs outside this state to engage in the wholesale distribution of drugs in this state if, after an examination of the reports of the person's compliance history and current compliance record, TDH determines that the person is in compliance with this subchapter and the rules adopted under this subchapter.

(d) Requires TDH to consider each license application and any related documents or reports filed by or in connection with a person who wishes to engage in wholesale distribution of drugs in this state on an individual basis.

Sec. 431.407. **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. 431.408. **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 or equivalent security submitted under Subsection (a) to secure payment of any fines or penalties imposed by TDH or imposed in connection with an enforcement action by the attorney generally, any fees or other enforcement costs, including attorney's fees payable to the attorney general, 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 and equivalent securities received under this section in a separate account.

Sec. 431.409. **FEEES.** (a) Requires the department to collect certain fees.

(b) Requires the executive commissioner of HHSC, by rule, to set the fees in amounts that are reasonable and necessary and allow TDH to recover the biennial expenditures of certain state funds by TDH.

(c) Requires fees collected under this section to be deposited to the credit of the food and drug registration fee account of the general revenue fund and appropriated to TDH to carry out this chapter.

Sec. 431.410. **CHANGE OF LOCATION OF PLACE OF BUSINESS.** (a) Requires the license holder, not fewer than 30 days in advance of the change, to notify TDH in writing of the license holder's intent to change the location of a licensed place of business.

(b) Requires the notice to include the address of the new location and the name and residence address of the individual in charge of the business at the new location.

(c) Requires the license holder, not more than 10 days after the completion of the change of location, to notify TDH in writing to confirm the completion of the change of location and provide verification of the information previously provided or correct and confirm any information that has changed since providing the notice of intent.

(d) Provides that the notice and confirmation required by this section are deemed adequate if the licensee sends the notices by certified mail, return receipt requested, to the central office of TDH or submits them electronically through the TexasOnline Internet website.

Sec. 431.411. MINIMUM RESTRICTIONS ON TRANSACTIONS. (a) Requires a wholesale distributor to receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse in accordance with the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. Provides that the returns or exchanges received by the wholesale distributor as provided by this subsection are not subject to the pedigree requirement under Section 431.412. Provides that wholesale distributors are responsible for policing the returns process and ensuring the operations are secure and do not allow the entry of an adulterated or counterfeit product into distribution.

(b) Authorizes a manufacturer or wholesale distributor to distribute prescription drugs only to a person licensed by the appropriate state licensing authorities or authorized by federal law to receive the drug. 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 by the appropriate state licensing authority to receive the prescription drugs or authorized by federal law to receive the drugs.

(c) 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.

(d) 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.

Sec. 431.412. 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 and the original labeler 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, 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. 431.413. 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 of HHSC 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.

Sec. 431.414. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION OF LICENSE. (a) Authorizes the commissioner of state health services to refuse an application for a license or to suspend or revoke a license of certain applicants or licensees.

(b) Requires the executive commissioner of HHSC, by rule, to establish minimum standards required for the issuance or renewal of a license under this subchapter.

(c) Requires TDH to deny a license application that is incomplete, contains false, misleading, or incorrect information, or contains information that cannot be verified by TDH.

(d) Provides that the refusal to license an applicant or the suspension or revocation of a license by TDH and the appeal from that action are governed by the procedures for a contested case hearing under Chapter 2001 (Administrative Procedure), Government Code.

Sec. 431.415. 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.

SECTION 8. Amends Section 431.059, Health and Safety Code, by amending Subsection (a) and adding Subsections (a-1) and (a-2), as follows:

(a) Makes a conforming change.

(a-1) Provides that a person commits an offense, punishable by a fine not to exceed \$50,000, if the person engages in the wholesale distribution of prescription drugs in violation of Subchapter N.

(a-2) Provides that a person commits an offense, punishable by imprisonment for not more than 15 years, a fine not to exceed \$500,000, or both imprisonment and a fine, if the

person knowingly engages in the wholesale distribution of prescription drugs in violation of Subchapter N.

SECTION 9. Amends Section 431.021, Health and Safety Code, to set forth a modified list of acts and the causing of acts which are unlawful and prohibited within this state.

SECTION 10. 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 (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 11. Repealer: Sections 431.2021 (Exemption from Licensing) and 431.205 (Expiration Date), Health and Safety Code.

SECTION 12. 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, and adding Subchapter N, Chapter 431, Health and Safety Code, not later than January 1, 2006.

SECTION 13. Requires the Department of State Health Services, not later than January 1, 2006, to prescribe the forms required to implement the changes in law made by this Act by the amendment of Subchapter I, Chapter 431, Health and Safety Code, and the addition of Subchapter N, Chapter 431, Health and Safety Code.

SECTION 14. Makes application of this Act prospective to March 1, 2006.

SECTION 15. Effective date: September 1, 2005, except that Sections 1-9 of this Act, take effect March 1, 2006.