

BILL ANALYSIS

S.B. 1685
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Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

The World Customs Organization estimates counterfeiting of prescription drugs accounts for 5% to 7% of global merchandise trade and is a growing global problem. Seizures of counterfeit prescription drugs by U.S. Customs jumped by 46% in 2004 as counterfeiters boosted exports to Western markets. According to a 2004 FDA Report, the counterfeit pharmaceutical trade is largely operated by "well-organized criminal operations" producing look-alike products that contain only inactive ingredients, incorrect ingredients, improper or contaminated dosages. In the U.S., over 18 million counterfeit Lipitor tablets were seized in 2003 in the largest domestic counterfeit case to date. This growing crisis will only worsen and our state's drug supply will continue to come under an increasing counterfeit threat if Texas does not strengthen its licensure and oversight of the wholesale drug distribution system. S.B. 1685 protects the public from adulterated, misbranded, or counterfeit prescription drugs by increasing the regulation of wholesale distributors.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 5, SECTION 6, SECTION 7, and SECTION 12 of this bill.

ANALYSIS

The bill defines "nonprescription drug," redefines "wholesale distribution" and moves the definition of "place of business" to come after "nonprescription drug."

The bill limits the applicability of the bill only to the wholesale distribution of nonprescription drugs.

The bill 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 department. The bill deletes existing text requiring a person to file with the commissioner of health (commissioner) a signed and verified license statement. The bill requires an applicant for license under this subchapter to submit an application to the department on the form prescribed by the department or electronically on the TexasOnline Internet website. The bill also deletes existing text requiring the license statement to be filed annually and provides that a license issued under this subchapter expires on the second anniversary of the date of issuance.

The bill requires the department to collect fees for certain licenses and inspections and the executive commissioner of the Health and Human Services Commission (HHSC) by rule, to set the fees in amounts that allow the department to recover certain biennial expenditures of state funds by the department. The bill deletes existing text authorizing the board to recover at least 50 percent of the annual expenditures of state funds by the department and redesignates the text of an existing Subsection and makes nonsubstantive changes as well as specifying that fees collected shall be used to carry out the administration and enforcement of this chapter.

The bill requires the licensee, not fewer than 30 days in advance of the change, to notify the department, 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. The bill requires the licensee, not more than 10 days after the completion of the change of location, to notify the department 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. The bill deletes existing text requiring written verification of certain information and also 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 the department or submits them electronically through the TexasOnline Internet website and makes conforming changes.

The bill 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 has not violated: statutes relating to counterfeiting of a drug; the Texas Controlled Substance Act or the Texas Dangerous Drug Act; the rules of the director of the Texas Department of Public Safety; or fails to complete or submits an incorrect license application. The bill requires the executive commissioner of HHSC, by rule, to establish minimum standards required for the issuance or renewal of a license under this subchapter and deletes existing text relating to refusing an application for a license, as well as making conforming changes.

The bill creates a new Subchapter titled "Wholesale Distributors of Prescription Drugs" and 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."

The bill defines "ongoing relationship" and 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.

The bill provides that Subchapter N applies only to the wholesale distribution of prescription drugs. The bill 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 and provides that a license issued under this subchapter expires on the second anniversary of the date of issuance.

The bill 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 and 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.

The bill 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 certain Sections.

The bill requires an applicant for a license under this subchapter to submit an application to the department on the form prescribed by the department and requires the application to contain certain information. The bill also requires a person subject to a criminal history record check or manager for each place of business to provide certain background information to the department and that the information submitted to be attested to under oath and requires an applicant or license holder to file with the department a written notice of any change in the information required under this section.

The bill sets forth requirements for the issuance or renewal of a wholesale distributor license under this subchapter that the designated representative of an applicant or license holder must meet.

The bill 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 the department. The bill authorizes the department 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 as well as 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, the department determines that the person is in compliance with this

subchapter and the rules adopted under this subchapter. The bill requires the department 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.

The bill requires the department 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 the department to forward the fingerprints to the Federal Bureau of Investigation for a federal criminal history check.

The bill requires a wholesale distributor applying for or renewing a license to submit payable to this state a bond or other equivalent security acceptable to the department 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. The bill requires the bond or equivalent security submitted to secure payment of any fines or penalties imposed by the department or imposed in connection with an enforcement action by the attorney general, 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. The bill authorizes the department or this state to make a claim against a bond or security submitted before the first anniversary of the date a license expires or is revoked under this chapter and requires the department to deposit the bonds and equivalent securities received under this section in a separate account.

The bill requires the department to collect certain fees and requires the executive commissioner of HHSC, by rule, to set the fees in amounts that are reasonable and necessary and allow the department to recover the biennial expenditures of certain state funds by the department. The bill 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 the department to carry out this chapter.

The bill requires the license holder, not fewer than 30 days in advance of the change, to notify the department in writing of the license holder's intent to change the location of a licensed place of business and 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. The bill also requires the license holder, not more than 10 days after the completion of the change of location, to notify the department 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. The bill provides that the notice and confirmation required by this section are considered adequate if the licensee sends the notices by certified mail, return receipt requested, to the central office of the department or submits them electronically through the TexasOnline Internet website.

The bill 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 and provides that the returns or exchanges received by the wholesale distributor as provided by this subsection are not subject to the pedigree requirement. The bill also 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. The bill 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. The bill 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. The bill 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 and 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. The bill also 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 and 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.

The bill 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. The bill 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 and 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. The bill 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.

The bill 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. The bill sets forth minimum requirements to be included in the chain of distribution information and the minimum requirements for information to be included in the pedigree and 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 the department or a peace officer of this state. The bill requires the executive commissioner of HHSC to adopt rules to implement this section and sets forth requirements for the department regarding a study to be conducted on the implementation of electronic pedigrees and provides that the section requiring the study and this subsection expire January 1, 2009.

The bill 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 and requires the executive commissioner of HHSC, by rule, to establish minimum standards required for the issuance or renewal of a license under this subchapter. The bill requires the department to deny a license application that is incomplete, contains false, misleading, or incorrect information, or contains information that cannot be verified by the department and provides that the refusal to license an applicant or the suspension or revocation of a license by the department and the appeal from that action are governed by the procedures for a contested case hearing.

The bill 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 a wholesale distributor violated this subchapter, falsified a pedigree or has been involved with counterfeit drugs or other procedures would result in unreasonable delay. The bill requires an order 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 and 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.

The bill makes a conforming change and 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 and 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.

The bill sets forth a modified list of acts and the causing of acts which are unlawful and prohibited within this state regarding prescription drugs.

The bill designate the 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 N, Chapter 431, Health and Safety Code. Makes nonsubstantive and conforming changes.

The bill repeals Sections 431.2021 and 431.205 of the Health and Safety Code.

The bill requires the executive commissioner of the HHSC 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.

The bill requires the DSHS, 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.

The bill makes application of this Act prospective to March 1, 2006.

While statutory reference in this bill is to the Texas Department of Health (department), HB 2292 from the 78th regular called session changed the name of the Texas Department of Health to the Department of State Health Services.

EFFECTIVE DATE

September 1, 2005.

Sections 1 through 9 of this Act, take effect March 1, 2006.