BILL ANALYSIS

Senate Research Center

S.B. 943
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Health & Human Services
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Enrolled

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Texas has made changes in law to address new challenges to the integrity of the prescription drug distribution system as a result of the threat of counterfeit and adulterated drugs by requiring more stringent wholesaler and pedigree licensing. Current law requires wholesaler licensing and drug pedigree documentation only in certain instances. Texas law requires further change to conform state law with newly clarified Food and Drug Administration (FDA) requirements.

S.B. 943 conforms state law to FDA requirements by providing certain definitions and prohibiting certain acts.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission SECTION 15 of this bill.

SECTION BY SECTION ANALYSIS

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

SECTION 1. Amends Section 431.021, Health and Safety Code, to provide that the receipt of a prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such a drug for payment or otherwise, or the alteration, mutilation, destruction, obliteration, or removal of all or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded are unlawful and prohibited within this state.

SECTION 2. Amends Subchapter B, Chapter 431, Health and Safety Code, by adding Section 431.0211, as follows:

> Sec. 431.0211. EXCEPTION. Provides that any provision of Section 431.021 that relates to a prescription drug does not apply to a prescription drug manufacturer, or an agent of a prescription drug manufacturer, who is obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

SECTION 3. Amends Section 431.401, Health and Safety Code, by amending Subdivisions (3), (5), and (11) and adding Subdivisions (3-a), (3-b), (4-a), (4-b), (10-a), and (12), as follows:

(3) Defines “pharmacy warehouse,” rather than “chain pharmacy warehouse.”

(3-a) Defines "co-licensed product partner."

(3-b) Defines "drop shipment."

(4-a) Defines "manufacturer."

(4-b) Defines "manufacturer's exclusive distributor."

(5) Defines "normal distribution channel," rather than "normal distribution chain."

(10-a) Defines "third-party logistics provider."

(11) Redefines "wholesale distribution."

(12) Defines "wholesale distributor."

SECTION 4. Amends Section 431.4031, Health and Safety Code, as follows:

Sec. 431.4031. EXEMPTION FROM CERTAIN PROVISIONS FOR CERTAIN WHOLESALE DISTRIBUTORS. Exempts a wholesale distributor that distributes prescription drugs that are medical gases or a wholesale distributor that is a manufacturer or a third party logistics provider on behalf of a manufacturer from Sections 431.404(a)(5) and (6), (b), and (c), 431.4045(2), 431.405, 431.407, and 431.408, rather than 431.404(b) and (c), 431.405, 431.407, 431.412, and 431.413.

SECTION 5. Amends Sections 431.404(a), (b), and (d), Health and Safety Code, as follows:

(a) Requires an application for a license to contain certain information.

(b) Requires each person listed in Subsection (a)(5) to provide certain information to the Texas Department of Health (TDH). Deletes existing text requiring each person listed in Subsections (a)(6) and (a)(9) to provide certain information to TDH.

(d) Requires an applicant or license holder to submit to TDH any change in or correction to the information required under this section in the form and manner prescribed by TDH. Deletes existing text requiring an applicant or license holder to file with TDH a written notice of any change in the information required under this section.

SECTION 6. Amends Subchapter N, Chapter 431, Health and Safety Code, by adding Section 431.4045, as follows:

Sec. 431.4045. INSPECTION REQUIRED. Prohibits TDH from issuing a wholesale distributor license to an applicant under this subchapter unless TDH takes certain action to determine that certain qualifications are met.

SECTION 7. Amends Section 431.405, Health and Safety Code, as follows:

Sec. 431.405. QUALIFICATIONS FOR LICENSE. (a) Prohibits TDH from issuing a wholesale distributor license to an applicant without considering the minimum federal information and related qualification requirements published in federal regulations at 21 C.F.R. Part 205, including certain factors set forth in this subsection.

(b) Requires the designated representative of an applicant or license holder to serve as a designated representative for only one applicant at any one time, except in a circumstance, as DHS determines reasonable, in which more than one licensed wholesale distributor is colocated in the same place of business and the wholesale distributors are members of an affiliated group, as defined by Section 1504, Internal Revenue Code of 1986, to qualify for the issuance or renewal of a wholesale distributor license under this subchapter.

SECTION 8. Amends Section 431.408, Health and Safety Code, by adding Subsections (a-1) and (c-1), as follows:

(a-1) Provides an exemption from the bond requirement under Subsection (a) for a pharmacy warehouse that is not engaged in wholesale distribution.

(c-1) Provides that a single bond is sufficient to cover all places of business operated by a wholesale distributor in this state.

SECTION 9. Amends Subchapter N, Chapter 431, Health and Safety Code, by adding Section 431.4095, as follows:

Sec. 431.4095. RENEWAL NOTIFICATION; CHANGE OR RENEWAL. (a) Requires TDH to send to each licensed wholesale distributor a form containing a copy of the information the distributor before the expiration of a license issued under this subchapter.

(b) Requires the wholesale distributor to identify and state under oath to TDH any change in or correction to the information not later than the 30th day after the date the wholesale distributor receives the form under Subsection (a).

SECTION 10. Amends Section 431.411(a), Health and Safety Code, by amending Subsection (a) and adding Subsections (a-1) and (a-2), as follows:

(a) Authorizes an expired, damaged, recalled, or otherwise nonsalable prescription drug that is returned to the wholesale distributor to be distributed by the wholesale distributor only to either the original manufacturer or a third-party returns processor. Provides that the returns or exchanges, salable or otherwise, received by the wholesale distributor as provided by this subsection, including any redistribution of returns or exchanges by the wholesale distributor, are not subject to the pedigree requirement under Section 431.412 if the returns or exchanges are exempt from pedigree under certain federal laws, regulations, and interpretations.

(a-1) Requires each wholesale distributor and pharmacy to administer the process of drug returns and exchanges to ensure that the process is secure and does not permit the entry of adulterated or counterfeit drugs into the distribution channel. Deletes existing text providing that a wholesale distributor should establish appropriate business practices and exercise due diligence designed to prevent the entry of adulterated or counterfeit drugs into the distribution channel in connection with the returned goods process.

(a-2) Provides that a person that has not otherwise been required to obtain a wholesale license under this subchapter and that is a pharmacy engaging in the sale or transfer of expired, damaged, returned, or recalled prescription drugs to the originating wholesale distributor or manufacturer and pursuant to federal statute, rules, and regulations, including the United States Food and Drug Administration's applicable guidances implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293), is exempt from wholesale licensure requirements under this subchapter, notwithstanding any provision of state or federal law to the contrary.

SECTION 11. Amends Section 431.412, Health and Safety Code, by amending Subsections (a) and (d) and adding Subsection (b-1), as follows:

(a) Requires a person who is engaged in the wholesale distribution of a prescription drug, including a repackager but excluding the original manufacturer, to provide a pedigree for each prescription drug that is not distributed through the normal distribution channel and is sold, traded, or transferred to any other person. Deletes existing text requiring the original labeler of a prescription drug to provide a pedigree for each prescription drug that is not distributed through the normal distribution channel and is sold, traded, or transferred to any other person. Makes a conforming change.

(b-1) Provides that a retail pharmacy or chain pharmacy warehouse is required to comply with this section only if the pharmacy or warehouse engages in the wholesale distribution of a prescription drug.

(d) Excludes the original manufacturer of the finished form of a prescription drug from the requirement to verify before distributing the prescription drug that each transaction listed on the pedigree has occurred.

SECTION 12. Amends Section 431.413, Health and Safety Code, by amending Subsections (a), (c), and (e) and adding Subsection (e-1), as follows:

(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. Requires the chain of distribution information to include certain information, at a minimum.

(c) Requires each pedigree statement to be available for inspection and photocopying not later than the second business day after the date a request is submitted by TDH or a peace officer in this state. Makes a nonsubstantive change.

(e) Deletes existing text requiring TDH to establish an implementation date, which may not be earlier than December 31, 2007, for electronic pedigrees based on the results of the study on the implementation of electronic pedigrees.

(e-1) Requires TDH to establish a targeted implementation date for electronic track and trace pedigree technology if after consulting with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drugs in this state, TDH determines that track and trace pedigree technology is universally available across the entire prescription pharmaceutical supply chain. Authorizes TDH to revise the date after it has been established. Prohibits the date from being earlier than July 1, 2010.

SECTION 13. Amends Section 431.414, Health and Safety Code, by adding Subsection (a-1), as follows:

(a-1) Authorizes the commissioner of state health services to suspend or revoke a license if the license holder no longer meets the qualifications for obtaining a license under Section 431.405.

SECTION 14. Repealer: Sections 431.059(a-1) (providing a criminal offense) and (a-2) (providing a criminal offense), and 431.412(b) (pharmacy sale of drugs) and (c) (transfer of drugs between license holders), Health and Safety Code.

SECTION 15. 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 not later than May 1, 2008.

SECTION 16. Makes application of this Act prospective.

SECTION 17. Effective date: September 1, 2007.