

## **BILL ANALYSIS**

Senate Research Center  
80R4203 YDB-F

S.B. 943  
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Health & Human Services  
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### **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.

As proposed, 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 18 of this bill.

Rulemaking authority is expressly granted to the Texas Department of Health in SECTION 10 (Section 431.4104, Health and Safety Code) 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 431.401, Health and Safety Code, by amending Subdivisions (2), (5), (7), and (11) and adding Subdivisions (3-a), (3-b), (4-a), (4-b), (10-a), and (12), as follows:

- (2) Redefines "authorized distributor of record."
- (3-a) Defines "co-licensed product."
- (3-b) Defines "drop shipment."
- (4-a) Defines "manufacturer."
- (4-b) Defines "manufacturer's exclusive distributor."
- (5) Redesignates "normal distribution chain" as "normal distribution channel." Defines "Normal distribution channel."
- (7) Redefines "place of business."
- (10-a) Defines "third-party logistics provider."
- (11) Redefines "wholesale distribution."
- (12) Defines "wholesale distributor."

SECTION 2. Amends Section 431.4011, Health and Safety Code, to redefine "ongoing relationship."

SECTION 3. Amends Section 431.402(a), Health and Safety Code, to prohibit 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 (General Provisions) for each separate place of business.

SECTION 4. Amends Section 431.403, Health and Safety Code, as follows:

Sec. 431.403. EXEMPTION FROM LICENSING. (a) Provides an exemption from this subchapter for a person who engages in wholesale distribution of prescription drugs in this state for use in humans if the person is distributing the person's own drugs and devices that have been approved by the United States Food and Drug Administration (U.S. FDA) and the person is not required to obtain a license under federal law. Deletes existing exemptions under specific federal laws and regulations.

(b) Provides that an exemption from the licensing requirements under this section does not constitute an exemption from compliance with any other requirement under this subchapter that the Texas Department of Health (TDH) by rule considers necessary and appropriate to protect the public health or safety. Deletes existing text providing 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.

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 determines certain qualifications are met.

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

Sec. 431.405. QUALIFICATIONS FOR LICENSE. 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 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 chain pharmacy warehouse that engages only in intracompany transfers.

(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 Subchapter N, Chapter 431, Health and Safety Code, by adding Sections 431.4101 and 431.4102, as follows:

Sec. 431.4101. CONTINUING EDUCATION. Requires certain designated representatives identified to successfully complete continuing education training regarding applicable federal and state laws governing the wholesale distribution of prescription drugs as required by TDH rule.

Sec. 431.4102. CONFIDENTIALITY. Prohibits information provided under Section 431.404 (License Application) from being disclosed to any person other than TDH for licensing or monitoring purposes.

SECTION 11. Amends Section 431.411(a), Health and Safety Code, by amending Subsection (a) and adding Subsections (a-1) and (e), as follows:

(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, including the return of an expired, damaged, or recalled prescription drug to either the original manufacturer or a third-party returns processor. 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 if the returns or exchanges are exempt from pedigree under certain federal laws and regulations.

(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.

(e) Prohibits a manufacturer or wholesale distributor from accepting payment for, or allowing the use of a person's credit to establish an account for the purchase of, prescription drugs from any person other than certain persons listed on the license of a person legally authorized to receive prescription drugs. Requires any account for the purchase of prescription drugs to be established in the name of the license holder.

SECTION 12. 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 13. 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, or from the manufacturer's third-party logistics provider, co-licensed product partner, or exclusive distributor, 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 fifth 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 an implementation date, which may not be earlier than July 1, 2010, for electronic pedigrees 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 technology to implement electronic pedigrees is universally available across the entire prescription pharmaceutical supply chain.

SECTION 14. 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 15. Amends Section 431.415, Health and Safety Code, by amending Subsection (a) and adding Subsection (a-1), as follows:

(a) Deletes existing text requiring the commissioner of state health services to issue an order including a manufacturer of a prescription drug, to immediately cease distribution of the drug if the commissioner determines there is a reasonable probability that a wholesale distributor has committed certain actions.

(a-1) Provides that this section does not authorize the commissioner of state health services to issue a cease and desist order against a manufacturer.

SECTION 16. Amends Subchapter N, Chapter 431, Health and Safety Code, by adding Sections 431.416 and 431.417, as follows:

Sec. 431.416. PROHIBITED ACTS. (a) Sets forth certain acts and the aiding and abetting of said acts that are unlawful and prohibited.

(b) Provides that Subsection (a) 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.

(c) Provides that Subsections (a)(13) and (14) do not apply to a manufacturer's wholesale distribution of a prescription drug approved by the U.S. FDA.

Sec. 431.417. 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 section is a felony punishable by imprisonment for a term not to exceed 15 years, a fine not to exceed \$50,000, or both imprisonment and a fine. Provides that an offense is a felony punishable by imprisonment for a term of not more than 99 years or less than 15 years, a fine not to exceed \$500,000, or both imprisonment and a fine if it is shown on the trial of an offense under this section that the person knowingly engaged in the wholesale distribution of prescription drugs in violation of this subchapter.

(b) Authorizes an actor to be prosecuted under this section, the other law, or both if an actor's conduct constituting an offense under this section also constitutes an offense under any other law.

SECTION 17. 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 18. 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 December 1, 2007.

SECTION 19. Makes application of this Act prospective.

SECTION 20. Effective date: September 1, 2007.