BILL ANALYSIS

S.B. 943
By: Janek
Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

In 2005, Texas made important changes to its Health & Safety Code to address new and growing challenges to the integrity of the prescription drug distribution system, from the threat of counterfeit and adulterated drugs. Those amendments address these threats through more stringent wholesaler licensing and pedigree requirements. SB 943 refines Texas law regarding wholesale licensing requirements, ensures compliance with federal law, and closes loopholes in order to better protect Texas drug consumers.

RULEMAKING AUTHORITY

It is the opinion of the committee that additional rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 16 of this bill. It is the opinion of the committee that the rulemaking authority of the executive commissioner of the Health and Human Services Commission is referenced in SECTION 3, SECTION 8, and SECTION 12 of the bill.

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.]

SB 943 amends definitions for "pharmacy warehouse," “normal distribution channel,” “wholesale distribution,” and adds definitions for "drop shipment," “co-licensed product partner,” “manufacturer,” “manufacturer’s exclusive distributor,” “third-party logistics provider,” and "wholesale distributor."

SB 943 exempts 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, 431.405, 431.407, and 431.408, Health and Safety Code. A wholesale distributor that distributes prescription drugs that are medical gases is exempt from Sections 431.404(a)(5) and (6), (b), and (c), 431.4045, 431.405, 431.407, and 431.408, and deletes references to 431.412 and 431.413, Health and Safety Code.

SB 943 modifies the requirements for the contents of an application for a wholesale license in the State of Texas, and requires an applicant or license holder to submit to the Texas Department of Health (department) any change in or correction to the information in the form and manner prescribed by the department.

SB 943 prohibits the department from issuing a wholesale distributor license to an applicant under Subchapter N unless the department conducts a physical inspection of the place of business at the address provided by the applicant under Section 431.404, and determines that the designated representative of the place of business meets the certain qualifications.

SB 943 allows an individual to serve as a designated representative for more than one applicant if more than one licensed wholesale distributor is colocated in the same place of business and the wholesale distributors are members of certain affiliated groups.

SB 943 provides a specific exemption to the surety bond requirements and provides that a single bond is sufficient to cover all places of business operated by a wholesale distributor in this state.

SB 943 requires the department, before the expiration of an issued license, to send to each licensed wholesale distributor a form containing a copy of certain information provided by the distributor, and requires the wholesale distributor, not later than the 30th day after the date the received by the wholesale, to identify and state under oath to the department any change in or correction to the information.

SB 943 requires designated representatives to complete continuing training regarding certain laws as required by the department by rule, and provides for the confidentiality of information provided as part of the application process for a wholesale distributor license.

SB 943 provides that an expired, damaged, recalled, or otherwise nonsalable prescription drug that is returned to the wholesale distributor may be distributed by the wholesale distributor only to either the original manufacturer or a third-party returns processor. The returns or exchanges, salable or otherwise, received by the wholesale distributor, including any redistribution of returns or exchanges by the wholesale distributor, are not subject to certain pedigree requirements if the returns or exchanges are exempt from pedigree under specified federal laws and regulations.

SB 943 sets standards for the administration of the process of drug returns and exchanges. SB 943 provides an exemption from wholesale licensure for certain entities not covered by SB 943. SB 943 specifies from whom a manufacturer or wholesale distributor may accept payment for, or allow the use of a person's credit to establish an account for the purchase of, prescription drugs. SB 943 further specifies who may establish an account for the purchase of prescription drugs. A Pharmacy or pharmacy warehouse is not prohibited from receiving prescription drugs where the payment for the prescription drugs is processed through the pharmacy's or pharmacy warehouse's contractual wholesale distributor.

SB 943 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 leaves or at any time has left the normal distribution channel and is sold, traded, or transferred to any other person. A retail pharmacy or pharmacy warehouse is required to comply with this section only if the pharmacy or warehouse engages in the wholesale distribution of a prescription drug. The bill deletes the exclusion for an original labeler of a prescription drug regarding providing a pedigree for certain prescription drugs. The bill excludes the original manufacturer of the finished form of a prescription drug, from the provision that certain persons engaged in the wholesale distribution of a prescription drug must verify before distributing the prescription drug that each transaction listed on the pedigree has occurred.

SB 943 provides that a pedigree must include certain identifying information from the manufacturer's third-party logistics provider, co-licensed product partner, or exclusive distributor and modifies the minimum distribution information that must be included. The bill provides that if after consulting with certain manufacturers, distributors, and pharmacies the department determines that electronic track and trace pedigree technology (technology) is available, the department is required to establish a targeted implementation date for the technology. The department is authorized to revise the established implementation date, but it may not be earlier than July 1, 2010.

SB 943 authorizes the commissioner of state health services (commissioner) to revoke or suspend a license if the holder no longer meets certain qualifications for obtaining a license, and it prohibits the commissioner from issuing a cease and desist order against a pharmaceutical manufacturer.

SB 943 creates new prohibited acts regarding prescription drugs, provides that it is an offense for a person to knowingly or with criminal negligence engages in certain wholesale distribution of prescription drugs, and provides penalties.

SB 943 repeals Sections (a-1) and (a-2), Section 431.059, and Subsections (b) and (c), Section 431.412, Health and Safety Code.

SB 943 directs the executive commissioner of the Health and Human Services Commission to adopt rules necessary implement the changes in law made by SB 943.

SB 943 makes conforming and other non-substantive changes.

EFFECTIVE DATE

This Act takes effect on September 1, 2007.