BILL ANALYSIS

C.S.H.B. 1504
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Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

The distribution channel of pharmaceutical products in Texas has several sources of wholesale supply, one of which is through licensed secondary wholesale distributors. As a result of S.B. 943, 80th Legislature, Regular Session, 2007, secondary wholesale distribution and drug pedigree documentation in Texas came under increased oversight by the Department of State Health Services (DSHS) through more stringent wholesaler licensing and drug pedigree documentation as stated under Chapter 431, Health and Safety Code. One of the intended purposes of S.B. 943 was to conform state law to proposed Food and Drug Administration requirements that were then not yet implemented.

The changes in the drug pedigree documentation required by S.B. 943 created unintended consequences for the market of professionals and patients being served by these licensed secondary wholesale distributors of pharmaceutical products, such as the increase in pharmaceutical costs for Medicaid and Medicare patients because of increased costs to the medical clinics or offices where they were treated. The non-pharmacy secondary wholesale distributors primarily serve communities where small medical clinics, including outpatient clinics and veterinary clinics, and physicians' offices need pharmaceutical supplies. In some instances, they serve the pharmaceutical needs of state mental health and mental retardation facilities. Small distributors are the main suppliers of prescription products to physicians' offices, nursing homes, clinics, and hospitals in major cities and rural communities in Texas, but purchase and delivery of pharmaceuticals to these locations through larger wholesale distribution outlets is either not available or is more costly and slower in delivery.

S.B. 943 also exempted larger wholesale distributors from the requirement of providing pedigreed prescription products because these distributors remained in the normal distribution channel. This increased the pharmaceutical costs for clinics, physicians, and patients not being served by the large annual access fees charged by the larger, primary national wholesale pharmaceutical distributors to the secondary distributors.

This bill seeks to enable licensed small wholesale distributors who contract with larger wholesalers for supply or pharmaceutical products to contract for such products within the normal distribution channel and resell the products in their original form to the health care providers they customarily serve by placing secondary wholesale distributors in the ordinary or normal channel of distribution. The bill maintains DSHS licensure and oversight of non-pharmacy secondary wholesale distributors.

C.S.H.B. 1504 revises the definition of "normal distribution channel." The bill exempts a state agency or political subdivision of the state from certain requirements if the agency or political subdivision distributes prescription drugs under certain circumstances.

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 3 of this bill.

ANALYSIS

C.S.H.B. 1504 amends the Health and Safety Code to revise the definition for "normal distribution channel" to include a chain of custody for a prescription drug, either directly or by drop shipment, from the manufacturer of a prescription drug, the manufacturer to the manufacturer's co-licensed product partner, the manufacturer to the manufacturer's third-party logistics provider, or the manufacturer to the manufacturer's exclusive distributor, to an authorized distributor of record to a wholesale distributor licensed under the Texas Food, Drug, and Cosmetic Act to another designated person authorized by law to dispense or administer the drug to a patient.

C.S.H.B. 1504 exempts a state agency or political subdivision of the state that distributes prescription drugs using federal or state funding to nonprofit health care facilities or local mental health or mental retardation authorities for distribution to a pharmacy, practitioner, or patient from certain provisions relating to wholesale distributor license requirements, criminal history record information, bond requirements, and pedigree requirements for prescription drugs provided.

C.S.H.B. 1504 requires the executive commissioner of the Health and Human Services Commission to adopt, modify, or repeal rules as necessary to implement the bill's provisions as soon as practicable after the effective date of the bill.

EFFECTIVE DATE

On passage, or, if the act does not receive the necessary vote, the act takes effect September 1, 2009.

COMPARISON OF ORIGINAL AND SUBSTITUTE

C.S.H.B. 1504 differs from the original by omitting from the revised definition of "normal distribution channel" the chain of custody for a prescription drug from an authorized distributor of record to a licensed wholesale distributor to a pharmacy to a patient and from an authorized distributor of record to one other licensed wholesale distributor to a licensed practitioner for office use.

C.S.H.B. 1504 adds a provision not included in the original exempting from certain requirements relating to wholesale distributors a state agency or political subdivision of the state that distributes prescription drugs using federal or state funding to nonprofit health care facilities or local mental health or mental retardation authorities.