BILL ANALYSIS

C.S.H.B. 1457
By: Delisi
Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

Many physicians and veterinarians depend upon pharmacies to prepare medications which are unavailable from pharmaceutical companies. The medications are used for treatment in the office or other medical facilities on patients requiring immediate treatment. A reason for doing this is to save hospitals money by allowing the consolidation of compounding into one primary location and avoiding duplication. This legislation would allow compounded medications produced at a primary compounding pharmacy to be used at other facilities under common ownership.

RULEMAKING AUTHORITY

It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

ANALYSIS

This bill amends Section 551 of the Occupations Code by adding to the definition of compounding to specify prescription drug orders that are based on the practitioner-patient-pharmacist relationship and are for administration to a patient by a practitioner. Conforming changes, renumbers accordingly.

The bill also authorizes the Texas State Board of Pharmacy to inspect and inventory a facility relative to components used in compounding, finished and unfinished products, containers, and labeling items. The person authorized to conduct a search may inspect any components and finished and unfinished products used in compounding within reasonable limits. Renumbers accordingly.

The bill also amends Chapter 562 of the Occupations Code by adding Subchapter D on compounded and repackaged drugs. "Office use" refers to the provision of drugs by a practitioner. "Prepackaging" means the act of repackaging and relabeling drug products from a manufacturer into dose packaging for distribution. "Reasonable quantity" means amount of a drug that may be reasonably used by the expiration date, is proper given the intended use, and the amount a pharmacy is capable of compounding. A pharmacy is authorized to deliver and dispense reasonable quantities of a compounded drug to a practitioner for office use.

To dispense and deliver a compounded drug, a pharmacy must verify the source of raw materials, comply with United States Pharmacopoeia guidelines, and comply with competency standards and board rules.

Class A and Class C pharmacies licensed under Chapter 560 are not required to register under Chapter 431 to distribute compounded and repackaged products to Class C licensed pharmacies. The definition of manufacture is expanded to include repacking that is done in accordance with this act.

Adds exemption for the wholesale distribution of drugs if exempt under new Section 562.154, Distribution of Compounded and Prepackaged Products to Certain Pharmacies.

EFFECTIVE DATE

September 1, 2005.

COMPARISON OF ORIGINAL TO SUBSTITUTE

CSHB 1457 modifies the original bill by adding a section authorizing the board to inspect and perform an inventory of a facility relative to components used in compounding, finished and unfinished products, containers, and labeling items. It also adds a definition of prepackaging. The committee substitute eliminates the section requiring a pharmacy and a physician to enter in to a written agreement and adds other requirements for office use compounding.