BILL ANALYSIS

S.B. 492
By: Van de Putte
Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

In recent years, a growing number of medications have been unavailable from the manufacturer for various reasons, sometimes these shortages can last months or longer. The result is that some critical products are unavailable for essential patient care demands in hospitals, clinics, and surgical centers. Such medications required compounding and the challenge is to ensure that the process occurs in the most controlled and safe pharmacy environment. Compounding pharmacists do not compound if the drug is commercially available and pharmacies do not compound, dispense, sell, or distribute without a physician's order or prescription.

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 adds 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.

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.

The bill provides that "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 are not required to register 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 for distribution of compounded and prepackaged products to certain pharmacies.

The bill makes conforming and technical changes.

EFFECTIVE DATE

September 1, 2005.