

SUBJECT: Authorizing office and hospital preparations of compounded drugs

COMMITTEE: Public Health — committee substitute recommended

VOTE: 8 ayes — Delisi, Laubenberg, Coleman, Dawson, Jackson, McReynolds,  
Truitt, Zedler

0 nays

1 absent — Solis

WITNESSES: For — Michael Brimberry, Seton Healthcare Network; Pat Downing and Travis Leeah, Texas Pharmacy Association Academy of Compounding Pharmacists; (*Registered, but did not testify*: Jennifer Banda, Texas Hospital Association; Richard Beck, American Pharmacies; Ed Berger Seton Healthcare Network; Cristen Wohlgemuth, Texas Pharmacy Association, Academy of Independent Pharmacists; Kristie Zamrazil, Texas Pharmacy Association)

Against — None

On — Gay Dodson, Texas State Board of Pharmacy; (*Registered, but did not testify*: Karen Tannert, Department of State Health Services)

BACKGROUND: Compounded drugs are preparations of active pharmaceutical ingredients that are prepared in smaller batches by compounding pharmacists. Compounding involves the creation of a new pharmaceutical product through a range of activities from crushing a pill to combining elements. Some common compounded drugs include intravenous solutions and other alternate delivery methods for prescription drugs.

The compounding of drugs is regulated both by the federal pharmacy compounding law, administered by the Food and Drug Administration, and state law. Occupations Code, ch. 562 governs pharmacy practices, including compounding, which are regulated and enforced by the Texas State Board of Pharmacy.

Ch. 560 defines the types of licenses a pharmacy may hold: class A, community pharmacies; class B, nuclear pharmacies; class C, institutional

or hospital pharmacies; class D, a pharmacy that dispenses a limited type of drug or device under a prescription drug order; and class E, an out-of-state pharmacy that dispenses drugs in Texas. Health and Safety Code, ch. 431, requires wholesale drug manufacturers to be licensed, unless exempt under federal law.

**DIGEST:**

CSHB 1457 would authorize a pharmacy to dispense a limited quantity of a compounded drug for office use if the source of materials had been verified and the dispensing was in compliance with all state and federal guidelines and regulations.

The bill would exempt class A (community) pharmacies from the licensing requirements under Health and Safety Code, ch. 431, when distributing compounded products to a class C (institutional) pharmacy. It also would exempt class C pharmacies from those requirements when distributing compounded products to other institutional pharmacies under common ownership.

CSHB 1457 would add elements used in compounding to the items the Texas State Board of Pharmacy could inspect as a part of the board's inspection and enforcement actions.

The bill would take effect September 1, 2005.

**SUPPORTERS  
SAY:**

CSHB 1457 would fix a problem for doctor's offices. Outpatient procedures often require the use of compounded drugs, such as some topical anesthetics, pediatric dosing, or other compounds not available from manufacturers, yet they are available only with a prescription. To administer these under current law, doctors must write the prescription, have the patient collect the compounded drug, then perform the procedure, resulting in additional office visits and hassle. This bill would allow the provider to keep a limited supply of commonly used compounds in the office.

This bill also would benefit veterinarians who frequently use compounded medications to administer an appropriate dose or delivery method to their animal patients. Pharmacists often make up compounds of human drugs with a different flavoring or for administration to animals.

Allowing hospitals (class C pharmacies) to distribute compounded products to other institutional pharmacies under common ownership

would save them a significant amount of money and ensure consistency of compounded products. A health care network could have a single compounding pharmacy supply all of the hospitals in the network, saving the hospital the expense of duplicate equipment and staff. It also would ensure that all compounding was performed by specialized staff whose primary job was to prepare compounds, rather than general staff who perform the broad range of pharmacy activities.

OPPONENTS  
SAY:

No apparent opposition.

NOTES:

The bill as filed did not include the board inspection provisions and would have required a written agreement between the provider and pharmacist for compounding for office use.

The companion bill, SB 492 by Van de Putte, passed the Senate on the Local and Uncontested Calendar on April 7 and was reported favorably, without amendment, by the House Public Health Committee on April 20, making it eligible to be considered in lieu of HB 1457.