

BILL ANALYSIS

Senate Research Center

C.S.S.B. 492
By: Van de Putte
Health and Human Services
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Committee Report (Substituted)

AUTHOR'S/SPONSOR'S STATEMENT OF INTENT

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.

C.S.S.B. 492 amends the Occupations Code to allow for dispensing, sale, or distribution of compounded drugs to state-licensed physicians for in-house administration and the distribution of compounded and prepackaged products to and from pharmacies under common ownership.

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to a state officer, institution, or agency.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 551.003(9), Occupations Code, to redefine "compounding."

SECTION 2. Amends Section 556.051, Occupations Code, as follows:

Sec. 556.051. AUTHORIZATION TO ENTER AND INSPECT. Authorizes the Texas State Board of Pharmacy (board) or a representative of the board to enter and inspect a facility relative to components used in compounding, finished and unfinished products, containers, and labeling of any item.

SECTION 3. Amends Section 556.053, Occupations Code, as follows:

Sec. 556.053. EXTENT OF INSPECTION. Authorizes the person authorized to represent the board, except as otherwise provided in an inspection warrant, to inspect, within reasonable limits and in a reasonable manner, a facility's storage, equipment, security, prescription drugs or devices, components used in compounding, finished and unfinished products, or records or perform an inventory of any stock of prescription drugs or devices, components used in compounding, or finished and unfinished products in a facility and obtain samples of these substances.

SECTION 4. Amends Subchapter D, Chapter 562, Occupations Code, as follows:

SUBCHAPTER D. New heading: COMPOUNDED AND REPACKAGED DRUGS

Sec. 562.151. New heading: DEFINITIONS. Defines "office use," "prepackaging," and "reasonable quantity."

Sec. 562.152. COMPOUNDING FOR OFFICE USE. Authorizes a pharmacy to dispense and deliver a reasonable quantity of a compounded drug to a practitioner for office use by the practitioner in accordance with this chapter.

Sec. 562.153. **REQUIREMENTS FOR OFFICE USE COMPOUNDING.** Requires a pharmacy, to dispense and deliver a compounded drug under Section 562.152 of this Act, to comply with certain procedures, guidelines, standards, and board rules.

Sec. 562.154. **DISTRIBUTION OF COMPOUNDED AND PREPACKAGED PRODUCTS TO CERTAIN PHARMACIES.** Provides that a Class A pharmacy licensed under Chapter 560 (Licensing of Pharmacies), Occupations Code, is not required to register or be licensed under Chapter 431 (Texas Food, Drug, and Cosmetic Act), Health and Safety Code, to distribute compounded pharmaceutical products to a Class C pharmacy licensed under Chapter 560, Occupations Code. Provides that a Class C pharmacy licensed under Chapter 560, Occupations Code, is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute compounded and prepackaged pharmaceutical products to other Class C pharmacies licensed under Chapter 560, Occupations Code, and under common ownership.

Sec. 562.155. **COMPOUNDING SERVICE AND COMPOUNDED DRUG PRODUCTS.** Redesignated from existing Section 562.151.

SECTION 5. Amends Section 431.002(23), Health and Safety Code, to redefine "manufacture."

SECTION 6. Amends Section 431.2021(a), Health and Safety Code, to provide that a person who engages in wholesale distribution of prescription drugs in this state for use in humans is exempt from this subchapter if, in addition to exemptions under existing law, that person is exempt under Section 562.154, Occupations Code.

SECTION 7. Effective date: September 1, 2005.