

BILL ANALYSIS

Senate Research Center
79R4456 YDB-F

S.B. 492
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Health & Human Services
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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.

As proposed, 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 repacked 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 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" 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 and guidelines.

Sec. 562.154. WRITTEN AGREEMENT. Sets forth requirements for a written agreement required by Section 562.153(3).

Sec. 562.155. DISTRIBUTION OF COMPOUNDED AND REPACKAGED 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 and prepackaged 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 repackaged pharmaceutical products to other Class C pharmacies licensed under Chapter 560, Occupations Code, and under common ownership.

Sec. 562.156. COMPOUNDING SERVICE AND COMPOUNDED DRUG PRODUCTS. Redesignated from existing Section 562.151.

SECTION 3. Amends Section 431.002(23), Health and Safety Code, to redefine "manufacture."

SECTION 4. 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 562.155, Occupations Code.

SECTION 5. Effective date: September 1, 2005.