By: Van de Putte S.B. No. 492

A BILL TO BE ENTITLED

AN ACT

relating to drug compounding by a pharmacy for a practitioner's office use and to distribution of compounded and repackaged drugs to pharmacies under common ownership.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 551.003(9), Occupations Code, is amended to read as follows:

(9) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner's prescription drug order <u>based on the practitioner-patient-pharmacist relationship in the course of professional practice;</u>

<u>(B) for administration to a patient by a practitioner as the result of a</u> [~~or the~~] practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

<u>(C)</u> [~~(B)~~] in anticipation of a prescription drug order based on a routine, regularly observed prescribing pattern; or

<u>(D)</u> [~~(C)~~] for or as an incident to research, teaching, or chemical analysis and not for selling or dispensing<u>, except as allowed under Section 562.155</u>.

SECTION 2. Subchapter D, Chapter 562, Occupations Code, is

amended to read as follows:

SUBCHAPTER D. COMPOUNDED AND REPACKAGED DRUGS [~~ADVERTISING OR PROMOTING BY PHARMACIST OR PHARMACY~~]

Sec. 562.151. DEFINITIONS. In this subchapter:

(1) "Office use" means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy.

(2) "Reasonable quantity" with reference to drug compounding means an amount of a drug that:

(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration date of the drug;

(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and

(C) for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

Sec. 562.152. COMPOUNDING FOR OFFICE USE. A pharmacy may 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. To dispense and deliver a compounded drug under Section 562.152, a pharmacy must:

(1) verify the source of the raw materials to be used in a compounded drug;

(2) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);

(3) enter into a written agreement with a practitioner for the practitioner's office use of a compounded drug;

(4) comply with all applicable competency and accrediting standards as determined by the board; and

(5) comply with the procedures established by the board.

Sec. 562.154. WRITTEN AGREEMENT. An agreement required by Section 562.153(3) must:

(1) address acceptable standards of practice for a compounding pharmacy and a practitioner that enter into an agreement under this section;

(2) require the practitioner to include on a patient's chart the lot number and expiration date of a compounded drug administered by the practitioner to a patient under this subchapter;

(3) include the name and address of each party to the agreement and the location of the compounding pharmacy and practitioner's office;

(4) describe the scope of services to be performed by the pharmacy and practitioner, including a statement of the process for:

(A) the practitioner to administer a compounded drug;

(B) the practitioner administering a compounded drug to counsel patients;

(C) a patient to report an adverse reaction or submit a complaint;

(D) the pharmacy to recall batches of compounded drugs; and

(E) the pharmacy to access a patient's name and medical information if necessary;

(5) include a description of the procedure for a practitioner to request a compounded drug, which must include a written statement of the product's commercial unavailability; and

(6) include indemnity and liability clauses.

Sec. 562.155. DISTRIBUTION OF COMPOUNDED AND REPACKAGED PRODUCTS TO CERTAIN PHARMACIES. (a) A Class A pharmacy licensed under Chapter 560 is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute compounded and prepackaged pharmaceutical products to a Class C pharmacy licensed under Chapter 560.

(b) A Class C pharmacy licensed under Chapter 560 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 and under common ownership.

Sec. 562.156. COMPOUNDING SERVICE AND COMPOUNDED DRUG PRODUCTS. A compounding pharmacist or pharmacy may advertise or promote:

(1) nonsterile prescription compounding services provided by the pharmacist or pharmacy; and

(2) specific compounded drug products that the pharmacy or pharmacist dispenses or delivers.

SECTION 3. Section 431.002(23), Health and Safety Code, is amended to read as follows:

(23) "Manufacture" means:

(A) the process of combining or purifying food or packaging food for sale to a person at wholesale or retail, and includes repackaging, labeling, or relabeling of any food;

(B) the process of preparing, propagating, compounding, processing, packaging, repackaging, labeling, testing, or quality control of a drug or drug product, but does not include compounding that is done within the practice of pharmacy and pursuant to a prescription drug order or initiative from a practitioner for a patient or repackaging that is done in accordance with Section 562.155, Occupations Code;

(C) the process of preparing, fabricating, assembling, processing, packing, repacking, labeling, or relabeling a device; or

(D) the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to

the product.

SECTION 4. Section 431.2021(a), Health and Safety Code, is amended to read as follows:

(a) A person who engages in wholesale distribution of prescription drugs in this state for use in humans is exempt from this subchapter if the person is exempt under:

(1) the Prescription Drug Marketing Act of 1987, as amended (21 U.S.C. Section 353(c)(3)(B));

(2) the regulations adopted by the secretary to administer and enforce that Act; [~~or~~]

(3) the interpretations of that Act set out in the compliance policy manual of the United States Food and Drug Administration; or

(4) Section 562.155, Occupations Code.

SECTION 5. This Act takes effect September 1, 2005.