By: Delisi H.B. No. 1457

Substitute the following for H.B. No. 1457:

By: Truitt C.S.H.B. No. 1457

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 prepackaged 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 562.154 or Chapter 563</u>.

SECTION 2. Section 556.051, Occupations Code, is amended to

read as follows:

Sec. 556.051. AUTHORIZATION TO ENTER AND INSPECT. The board or a representative of the board may enter and inspect a facility relative to the following:

(1) drug storage and security;

(2) equipment;

(3) components used in compounding, finished and unfinished products, containers, and labeling of any item;

(4) sanitary conditions; or

(5) [~~(4)~~] records, reports, or other documents required to be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws.

SECTION 3. Section 556.053, Occupations Code, is amended to read as follows:

Sec. 556.053. EXTENT OF INSPECTION. Except as otherwise provided in an inspection warrant, the person authorized to represent the board may:

(1) inspect and copy documents, including records or reports, required to be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws;

(2) 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

(3) 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 those substances.

SECTION 4. Subchapter D, Chapter 562, Occupations Code, is amended to read as follows:

SUBCHAPTER D. COMPOUNDED AND PREPACKAGED 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 in accordance with Chapter 563.

(2) "Prepackaging" means the act of repackaging and relabeling quantities of drug products from a manufacturer's original container into unit dose packaging or a multiple dose container for distribution within a facility licensed as a Class C pharmacy or to other pharmacies under common ownership for distribution within those facilities. The term as defined does not prohibit the prepackaging of drug products for use within other pharmacy classes.

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

(4) comply with board rules, including rules regarding the reporting of adverse events by practitioners and recall

procedures for compounded products.

Sec. 562.154. DISTRIBUTION OF COMPOUNDED AND PREPACKAGED 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 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 prepackaged pharmaceutical products that the Class C pharmacy has compounded or prepackaged to other Class C pharmacies licensed under Chapter 560 and under common ownership.

Sec. 562.155. 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 5. 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 prepackaging that is done in accordance with Section 562.154, 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 6. 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 562.154, Occupations Code.

SECTION 7. This Act takes effect September 1, 2005.