

By: Delisi

H.B. No. 1457

A BILL TO BE ENTITLED

1 AN ACT

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

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

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

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

10 (A) as the result of a practitioner's
11 prescription drug order based on the
12 practitioner-patient-pharmacist relationship in the course of
13 professional practice;

14 (B) for administration to a patient by a
15 practitioner as the result of a [or the] practitioner's initiative
16 based on the practitioner-patient-pharmacist relationship in the
17 course of professional practice;

18 (C) [~~(B)~~] in anticipation of a prescription drug
19 order based on a routine, regularly observed prescribing pattern;
20 or

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

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

1 amended to read as follows:

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

4 Sec. 562.151. DEFINITIONS. In this subchapter:

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

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

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

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

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

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

1 Sec. 562.153. REQUIREMENTS FOR OFFICE USE COMPOUNDING. To
2 dispense and deliver a compounded drug under Section 562.152, a
3 pharmacy must:

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

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

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

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

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

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

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

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

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

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

4 (A) the practitioner to administer a compounded
5 drug;

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

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

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

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

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

17 (6) include indemnity and liability clauses.

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

24 (b) A Class C pharmacy licensed under Chapter 560 is not
25 required to register or be licensed under Chapter 431, Health and
26 Safety Code, to distribute compounded and repackaged
27 pharmaceutical products to other Class C pharmacies licensed under

1 Chapter 560 and under common ownership.

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

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

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

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

11 (23) "Manufacture" means:

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

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

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

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

1 the product.

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

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

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

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

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

14 (4) Section 562.155, Occupations Code.

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