By: Gervin-Hawkins H.B. No. 3785

A BILL TO BE ENTITLED

AN ACT

relating to labeling requirements for compounded drug products.

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

SECTION 1. Subchapter D, Chapter 562, Occupations Code, is amended by adding Section 562.157 to read as follows:

Sec. 562.157. LABELING OF COMPOUNDED DRUG PRODUCTS. (a) This section applies to:

(1) a pharmacy that compounds a sterile or non-sterile preparation; and

(2) a manufacturer or other entity that compounds a drug intended to be distributed:

(A) through a telepharmacy service;

(B) by over-the-counter sale; or

(C) directly from a pharmacist to a patient.

(b) A pharmacist may not furnish or dispense a compounded drug to a patient unless the drug is labeled with the following information:

(1) the patient's name;

(2) the name, address, telephone number, and license number of:

(A) the pharmacy furnishing or dispensing the compounded drug; or

(B) the pharmacy that prepared the compounded drug, if that is not the same pharmacy described by Paragraph (A);

(3) the statement "Compounded Drug, Substitute for (insert name of drug applicable to the compound)";

(4) all active ingredients used to prepare the compounded drug;

(5) the compounded drug's beyond-use date, as determined by the pharmacist using appropriate documented criteria;

(6) the quantity or amount of the compounded drug in the container dispensed to the patient;

(7) appropriate ancillary instructions, including:

(A) storage instructions; and

(B) cautionary instructions or statements, including any hazardous drug warning;

(8) directions for use, including all appropriate:

(A) dosage directions; and

(B) other administration directions, including as applicable, the appropriate dosage level per time interval;

(9) any side effects noted from trials, research, and other appropriate information sources;

(10) whether the compounded drug was prepared in a sterile facility or a non-sterile facility; and

(11) whether the compounded drug was prepared in a location outside of the pharmacy that furnishes the drug to the patient.

(c) The board shall adopt rules regarding the labeling requirements of Subsection (b) in accordance with other existing labeling requirements.

SECTION 2. Not later than December 1, 2025, the Texas State Board of Pharmacy shall adopt the rules required by Section 562.157, Occupations Code, as added by this Act.

SECTION 3. This Act takes effect September 1, 2025.