

BILL ANALYSIS

Senate Research Center
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S.B. 1100
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Health & Human Services
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AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Pharmaceutical compounding refers to the creation of a pharmaceutical product tailored to the needs of specific clients, through the combination of medically appropriate ingredients. For example, changing the form of the medication from a solid pill to an ingestible or injectable liquid, to avoid a non-essential ingredient that the patient is allergic to or to obtain the exact doses needed of particular active pharmaceutical ingredients.

In October 2012, there was a widespread outbreak of fungal meningitis, caused by tainted injections prepared by the New England Compounding Center in Framingham, Massachusetts. Nearly 14,000 people in 23 states were exposed to the contaminated drugs produced by the now-shuttered compounding pharmacy, and so far 48 people have been killed and over 720 people in 20 states have fallen ill due to the tainted medicine.

Compounding pharmacies in Texas are subject to some of the most responsible and precautionary regulations in the country. However, out-of-state compounding pharmacies like the one responsible for the meningitis outbreak can easily sell and ship their products to patients and health care providers in Texas without having to adhere to the same requirements as the in-state compounders. In order to prevent a potentially deadly outbreak in Texas, this bill requires that any out-of-state compounding pharmacies wishing to ship their products into Texas must be inspected by a Texas State Board of Pharmacy inspector, and additionally must reimburse the board for the costs associated with this inspection.

As proposed, S.B. 1100 amends current law relating to the licensing and inspection of certain out-of-state pharmacies by the Texas State Board of Pharmacy, and authorizes fees.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTION 1 (Section 556.0551, Occupations Code), SECTION 2 (Section 560.052, Occupations Code), and SECTION 3 of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subchapter B, Chapter 556, Occupations Code, by adding Section 556.0551, as follows:

Sec. 556.0551. INSPECTION OF LICENSED OUT-OF-STATE PHARMACY. (a) Authorizes the Texas State Board of Pharmacy (TSBP) to conduct a random inspection of a pharmacy that holds a Class E pharmacy license and that compounds sterile prescription drugs for delivery to patients in this state as necessary to ensure compliance with the safety standards and other requirements of this subtitle and TSBP rules.

(b) Requires TSBP by rule to set fees in amounts reasonable and necessary to cover the costs incurred by the board in inspecting a pharmacy as provided by Subsection (a).

SECTION 2. Amends Section 560.052, Occupations Code, by amending Subsection (c) and adding Subsection (g), as follows:

(c) Requires an applicant, in addition to satisfying the other requirements of this chapter, to qualify for a Class E pharmacy license, to provide to TSBP certain evidence, including, except as provided by Subsection (f) (relating to authorizing a Class E pharmacy submitting an inspection report issued by an entity other than the pharmacy licensing board of the state in which the pharmacy is physically located under certain circumstances) or (g), an inspection report issued under certain circumstances, including by the pharmacy licensing board in the state of the pharmacy's physical location, rather than except as provided by Subsection (f).

(g) Prohibits a Class E pharmacy license from being issued to a pharmacy that compounds sterile prescription drugs for delivery to patients in this state unless the pharmacy has been inspected by TSBP to ensure the pharmacy meets the safety standards and other requirements of this subtitle and TSBP rules. Requires TSBP by rule to set fees in amounts reasonable and necessary to cover the costs incurred by TSBP in inspecting an applicant as required by this subsection.

SECTION 3. Requires TSBP, not later than November 1, 2013, to adopt rules as required by Section 556.0551, Occupations Code, as added by this Act, and Section 560.052, Occupations Code, as amended by this Act.

SECTION 4. Makes application of Section 560.052, Occupations Code, as amended by this Act, prospective.

SECTION 4. Effective date: September 1, 2013.