

BILL ANALYSIS

Senate Research Center

C.S.S.B. 1100
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Health & Human Services
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Committee Report (Substituted)

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 the Texas State Board of Pharmacy (TSBP), and additionally must reimburse TSBP for the costs associated with this inspection.

C.S.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 (TSBP) in SECTION 1 (Section 556.0551, Occupations Code), SECTION 3 (Section 560.052, Occupations Code), SECTION 4 (Section 561.0032, Occupations Code), SECTION 6 (Section 562.156, Occupations Code), and SECTION 11 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 NONRESIDENT PHARMACY. (a) Authorizes the Texas State Board of Pharmacy (TSBP) to inspect a nonresident pharmacy licensed by TSBP that compounds sterile preparations as necessary to ensure compliance with the safety standards and other requirements of this subtitle and TSBP rules.

(b) Requires a nonresident pharmacy to reimburse TSBP for all expenses, including travel, incurred by TSBP in inspecting the pharmacy as provided by Subsection (a).

SECTION 2. Amends Section 560.001(b), Occupations Code, as follows:

(b) Prohibits a pharmacy located in another state from shipping, mailing, or delivering to this state a prescription drug or device dispensed under a prescription drug order, or dispensed or delivered as authorized by Subchapter D (Compounded and Prepackaged Drugs), Chapter 562 (Practice by License Holder), rather than shipping, mailing, or delivering to a resident of this state, unless the pharmacy is licensed by TSBP or is exempt under Section 560.004.

SECTION 3. Amends Section 560.052, Occupations Code, by amending Subsections (b) and (c) and adding Subsections (g) and (h), as follows:

(b) Requires an applicant, to qualify for a pharmacy license, to submit to TSBP:

(1) Makes no change to this subdivision; and

(2) a completed application that:

(A)-(B) Makes no change to these paragraphs; and

(C) includes a statement of certain information, including the license number of each pharmacist who is employed by the pharmacy, if the pharmacy is located in this state, or who is licensed to practice pharmacy in this state, if the pharmacy is located in another state, rather than if the pharmacy is a Class E pharmacy.

(c) Requires a pharmacy located in another state that applies for a license, rather than requiring an applicant, to qualify for a Class E pharmacy license, in addition to satisfying the other requirements of this chapter, to provide to TSBP certain evidence, including:

(1)-(2) Makes no change to this subdivision;

(3) evidence of the applicant's ability to provide to TSBP a record of a prescription drug order dispensed or delivered as authorized by Subchapter D, Chapter 562, by the applicant to a resident of or practitioner in this state not later than 72 hours after the time TSBP requests the record;

(4) an affidavit by the pharmacist-in-charge that states that the pharmacist has read and understands the laws and rules relating to the applicable license, rather than rules relating to a Class E pharmacy;

(5) Makes no change to this subdivision;

(6) an inspection report issued not more than two years before the date the license application is received by the pharmacy licensing board in the state of the pharmacy's physical location, except as provided by Subsection (f) (relating to authorizing a Class E pharmacy to submit 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); and

(7) any other information TSBP determines necessary.

(g) Prohibits a license from being issued to a pharmacy that compounds sterile preparations 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.

(h) Authorizes TSBP to accept, as satisfying the inspection requirement in Subsection (g) for a pharmacy located in another state, an inspection report issued by the pharmacy licensing board in the state in which the pharmacy is located if:

(1) TSBP determines that the other state has comparable standards and regulations applicable to pharmacies, including standards and regulations related to health and safety;

(2) the pharmacy provides to TSBP any requested documentation related to the inspection.

SECTION 4. Amends Chapter 561, Occupations Code, by adding Section 561.0032, as follows:

Sec. 561.0032. **ADDITIONAL RENEWAL REQUIREMENT FOR COMPOUNDING PHARMACY.** (a) Prohibits a pharmacy that compounds sterile preparations, in addition to the renewal requirements under Section 561.003 (Requirements for Renewal), from renewing a pharmacy license unless the pharmacy has been inspected as provided by TSBP rule, and if the pharmacy is located in another state, has reimbursed TSBP for all expenses, including travel, incurred by TSBP in inspecting the pharmacy during the term of the expiring license.

(b) Authorizes TSBP to accept, as satisfying the inspection requirement in Subsection (a) for a pharmacy located in another state, an inspection report issued by the pharmacy licensing board in the state in which the pharmacy is located if TSBP determines that the other state has comparable standards and regulations applicable to pharmacies, including standards and regulations related to health and safety, and the pharmacy provides to TSBP any requested documentation related to the inspection.

SECTION 5. Amends Section 562.106(a), Occupations Code, as follows:

(a) Requires a pharmacy to report in writing to TSBP not later than the 10th day after the date of:

(1)-(7) Makes no change to these subdivision;

(8) a final order against the pharmacy license holder by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state, rather than is a Class E pharmacy; or

(9) a final order against a pharmacist who is designated as the pharmacist-in-charge of the pharmacy by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state, rather than is a Class E pharmacy.

SECTION 6. Amends Subchapter D, Chapter 562, Occupations Code, by adding Section 562.156, as follows:

Sec. 562.156. **COMPOUNDED STERILE PREPARATION; NOTICE TO BOARD.** (a) Prohibits a pharmacy from compounding and dispensing a sterile preparation unless the pharmacy holds a license as required by TSBP rule.

(b) Requires a pharmacy that compounds a sterile preparation to notify TSBP immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy, and not later than 24 hours after the pharmacy issues a recall for a sterile preparation compounded by the pharmacy.

SECTION 7. Amends Section 565.003, Occupations Code, as follows:

Sec. 565.003. **New heading: ADDITIONAL GROUNDS FOR DISCIPLINE REGARDING APPLICANT FOR OR HOLDER OF NONRESIDENT PHARMACY LICENSE.** Deletes existing Subsection (b) designation. Authorizes TSBP, unless compliance would violate the pharmacy or drug statutes or rules in the state in which the

pharmacy is located, to discipline an applicant for or the holder of a nonresident pharmacy license, rather than the holder of a Class E pharmacy license, if TSBP finds that the applicant or license holder has failed to comply with certain requirements and rules.

SECTION 8. Amends Section 565.053, Occupations Code, as follows:

Sec. 565.053. New heading: DISCIPLINE OF NONRESIDENT PHARMACY; NOTICE TO RESIDENT STATE. Requires TSBP to give notice of a disciplinary action by TSBP against a license holder located in another state, rather than against the holder of a Class E pharmacy license, to the regulatory or licensing agency of the state in which the pharmacy is located.

SECTION 9. Amends the heading to Section 565.054, Occupations Code, to read as follows:

Sec. 565.054. SERVICE OF PROCESS ON NONRESIDENT PHARMACY.

SECTION 10. Amends Section 565.054(a), Occupations Code, to require that service of process on a nonresident pharmacy, rather than a Class E pharmacy, under Section 565.058 (Subpoena Authority) or 565.061 (Administrative Procedure) or for disciplinary action taken by TSBP under Section 565.061 be on the owner and pharmacist-in-charge of the pharmacy, as designated on the pharmacy's license application.

SECTION 11. Requires TSBP, not later than March 1, 2014, to adopt rules necessary to implement the changes in law made by this Act.

SECTION 12. Makes application of Section 560.052, Occupations Code, as amended by this Act, prospective.

SECTION 13. Makes application of Section 561.0032, Occupations Code, as added by this Act, prospective.

SECTION 14. Effective date: September 1, 2013.