

BILL ANALYSIS

S.B. 1100
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Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

Pharmaceutical compounding refers to the creation of a pharmaceutical product by mixing chemical ingredients. Interested parties assert that this process is often done to tailor medications to the needs of specific clients, such as changing the form of a medication from a solid pill to an ingestible or injectable liquid, to avoid a nonessential ingredient to which the patient has an allergy or to obtain an exact dosage of particular active pharmaceutical ingredients.

After a recent outbreak of fungal meningitis caused by tainted injections prepared by a compounding center in Massachusetts that exposed thousands of people in many different states to contaminated drugs, concerned parties observe that out-of-state compounding pharmacies can currently sell and ship their products to patients and health care providers in Texas without having to adhere to the same requirements as in-state compounders. S.B. 1100 seeks to prevent a potentially deadly outbreak in Texas by amending current law relating to the licensing and inspection of certain out-of-state pharmacies by the Texas State Board of Pharmacy.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTION 11 of this bill.

ANALYSIS

S.B. 1100 amends the Occupations Code to prohibit a pharmacy from compounding and dispensing a sterile preparation unless the pharmacy holds a license as required by Texas State Board of Pharmacy rule. The bill requires a pharmacy that compounds a sterile preparation to notify the board 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 to notify the board not later than 24 hours after the pharmacy issues a recall for a sterile preparation compounded by the pharmacy.

S.B. 1100 authorizes the board to inspect a nonresident pharmacy licensed by the board that compounds sterile preparations as necessary to ensure compliance with safety standards and other requirements of the Texas Pharmacy Act and board rules. The bill requires a nonresident pharmacy to reimburse the board for all expenses, including travel, incurred by the board in inspecting the pharmacy. The bill prohibits a pharmacy located in another state from shipping, mailing, or delivering to Texas a prescription drug or device dispensed or delivered as authorized by statutory provisions relating to compounded and prepackaged drugs unless the pharmacy is licensed by the board or is exempt from licensing requirements because the state in which the pharmacy is located restricts the pharmacy's dispensing of a prescription drug or device to a Texas resident.

S.B. 1100 makes a requirement that the application of an applicant for a pharmacy license include the license number of each pharmacist who is licensed to practice pharmacy in Texas applicable to a pharmacy that is located in another state, rather than a Class E pharmacy. The bill

requires a pharmacy located in another state that applies for a license, rather than an applicant for a Class E pharmacy license, to provide certain additional information to the board. The bill includes among the additional required information evidence of the applicant's ability to provide to the board a record of a prescription drug order delivered as authorized by statutory provisions relating to compounded and prepackaged drugs by the applicant and any other information the board determines necessary. The bill includes a practitioner in Texas, in addition to a Texas resident, among the recipients of such a drug order to which evidence of the applicant's ability to provide record of the order applies. The bill prohibits the issuance of a license to a pharmacy that compounds sterile preparations unless the pharmacy has been inspected by the board to ensure the pharmacy meets the safety standards and other requirements of the Texas Pharmacy Act and board rules. The bill authorizes the board to accept, as satisfying the inspection requirement for issuing a license to 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 the board determines that the other state has comparable standards and regulations applicable to pharmacies, including standards and regulations related to health and safety, and if the pharmacy provides to the board any requested documentation related to the inspection.

S.B. 1100 prohibits a pharmacy that compounds sterile preparations from renewing a pharmacy license unless the pharmacy has been inspected as provided by board rule and, if the pharmacy is located in another state, has reimbursed the board for all expenses, including travel, incurred by the board in inspecting the pharmacy during the term of the expiring license. The bill authorizes the board to accept, as satisfying the inspection requirement for renewing a license of 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 the board determines that the other state has comparable standards and regulations applicable to pharmacies, including standards and regulations related to health and safety, and if the pharmacy provides to the board any requested documentation related to the inspection.

S.B. 1100 makes a requirement that a pharmacy report to the board a final order against the pharmacy license holder by the regulatory or licensing agency of the state in which the pharmacy is located and a final order against a pharmacist who is designated as the pharmacist-in-charge of the pharmacy by such a regulatory or licensing agency applicable to a pharmacy located in another state, rather than a Class E pharmacy.

S.B. 1100 replaces references to a Class E pharmacy license holder with references to a nonresident pharmacy in certain statutory provisions relating to disciplining such a license holder. The bill requires the board to adopt rules necessary to implement the bill's provisions not later than March 1, 2014.

EFFECTIVE DATE

September 1, 2013.