### **BILL ANALYSIS**

C.S.S.B. 2316 By: Hinojosa Public Health Committee Report (Substituted)

#### **BACKGROUND AND PURPOSE**

It has been suggested that current requirements relating to the Prescription Monitoring Program are too onerous. C.S.S.B. 2316 seeks to provide regulatory relief both to the Texas State Board of Pharmacy and to pharmacy practitioners.

### **CRIMINAL JUSTICE IMPACT**

It is the committee's opinion that this bill expressly does one or more of the following: creates a criminal offense, increases the punishment for an existing criminal offense or category of offenses, or changes the eligibility of a person for community supervision, parole, or mandatory supervision.

### **RULEMAKING AUTHORITY**

It is the committee's opinion that rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTIONS 1, 2, and 4 of this bill.

# **ANALYSIS**

C.S.S.B. 2316 amends the Health and Safety Code to establish that a prescriber or dispenser of a controlled substance is not liable in a civil action for damages arising from the failure to access prescription drug information before prescribing or dispensing certain controlled substances or from the failure to submit the information to the Texas State Board of Pharmacy (TSBP), unless the failure constitutes gross negligence or wilful misconduct and the prescriber or dispenser would be liable to the claimant under other law. The bill establishes that these provisions do not establish a standard of care.

C.S.S.B. 2316 requires the TSBP to establish an advisory committee to make recommendations regarding information submitted to the TSBP concerning controlled substance prescriptions and authorized access to that information. The bill provides for the composition and administration of the advisory committee and establishes that the advisory committee is abolished and these provisions expire on September 1, 2023.

C.S.S.B. 2316 creates a Class A misdemeanor offense for a person authorized to receive official prescription information who discloses or uses the information in a manner that is not authorized. The bill creates a Class C misdemeanor offense for a person requesting information under the bill's provisions if the person makes a material misrepresentation or fails to disclose a material fact in the request for information. The bill requires a regulatory agency that issues a license, certification, or registration to a prescriber or dispenser to periodically update the administrative penalties, or any applicable disciplinary guidelines concerning the penalties, assessed by that agency for conduct constituting an offense. The bill requires the regulatory agency to set the penalties in an amount sufficient to deter the conduct. The bill requires the regulatory agency, not later than September 1, 2020, to evaluate and update any applicable administrative penalties and guidelines.

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C.S.S.B. 2316 excepts a patient or patient's authorized representative inquiring about the patient's prescription record, including persons who have accessed that record, from the prohibition against the TSBP permitting any person to have access to certain controlled substance prescription information. The bill entitles a patient or the patient's authorized representative to a copy of the patient's prescription record, including a list of persons who have accessed that record, if the patient or representative submits to the TSBP a completed patient data request form and any supporting documentation required by the TSBP. The bill authorizes the TSBP to charge a reasonable fee for providing the copy. The bill requires the TSBP to adopt rules to implement these provisions, including rules prescribing the patient data request form, listing the documentation required for receiving a copy of the prescription record, and setting the fee.

C.S.S.B. 2316 amends the Occupations Code to authorize the TSBP to adopt rules to administer the bill's provisions relating to the limitation of liability of a prescriber or dispenser of controlled substances, criminal offenses related to prescription information, and an administrative penalty a regulatory agency is required to update. The bill authorizes the TSBP to discipline an applicant for or the holder of a nonresident pharmacy license if the TSBP finds that the applicant or license holder has failed to comply with those provisions and provisions relating to the communication of prescriptions by an agent, duties of the TSBP with regard to official prescription information, contracting and rulemaking authority of the TSBP, monitoring by a regulatory agency, registration by a regulatory agency, duties of certain health care practitioners, exceptions to those duties, and reports of wholesale distributors. The bill adds a temporary provision, set to expire September 1, 2023, authorizing the TSBP to adopt rules to administer the bill's provisions relating to the advisory committee.

C.S.S.B. 2316 requires the State Auditor's Office to audit the TSBP with respect to the information submitted to the TSBP and access to that information. The bill requires the audit to consider the economy and efficiency and the effectiveness of the systems for submission of and access to the information, including vendor performance and contract management and to be completed not later than December 1, 2024.

C.S.S.B. 2316 establishes that certain provisions of a previously enacted law apply only to a prescriber, other than a veterinarian, who issues a prescription for a controlled substance on or after March 1, 2020, or to a person authorized by law to dispense a controlled substance, other than a veterinarian, who dispenses a controlled substance on or after March 1, 2020.

### **EFFECTIVE DATE**

September 1, 2019.

# COMPARISON OF SENATE ENGROSSED AND SUBSTITUTE

While C.S.S.B. 2316 may differ from the engrossed in minor or nonsubstantive ways, the following summarizes the substantial differences between the engrossed and committee substitute versions of the bill.

The substitute revises the composition of the advisory committee by including a representative of a company whose primary line of business is electronic medical records. The bill does not include a veterinarian and an electronic records consultant as members of the committee.

The substitute includes a provision establishing that, to the extent of any conflict, the bill's provisions prevail over another Act of the 86th Legislature, Regular Session, 2019, relating to nonsubstantive additions to and corrections in enacted codes.

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