

BILL ANALYSIS

Senate Research Center
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C.S.S.B. 2316
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Health & Human Services
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Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

In 2015, the 84th Legislature voted to transfer the Prescription Monitoring Program (PMP) from the Department of Public Safety of the State of Texas (DPS) to the Texas State Board of Pharmacy (TSBP). TSBP launched a new and more user-friendly system on September 1, 2016.

Prior to the 85th Legislative Session, statute required pharmacists to enter data on controlled substances within seven days of filling the prescription but did not require them to search the PMP database prior to dispensing. Due to lack of PMP usage by pharmacists, the 85th Legislature passed legislation requiring pharmacists or their delegates to enter dispensing information in the PMP database within one business day of dispensing controlled substances. That legislation also required all prescribers and dispensers (except veterinarians) to search the PMP database before prescribing or dispensing opioids, benzodiazepines, barbiturates, or carisoprodol beginning September 1, 2019.

S.B. 2316 delays the mandate until March 1, 2020, to give TSBP more time to purchase computer software capable of integrating electronic patient records and PMP data. This software will eliminate workflow interruption concerns by stakeholders and improve patient care service.

S.B. 2316 seeks to relieve pharmacists or their delegates from liability in a civil action for damages arising from the failure to access prescription drug information due to PMP system access problems. However, providers are not relieved from liability if their actions constitute gross negligence or willful misconduct.

Additionally, S.B. 2316 protects patient medical records by criminalizing the disclosure of PMP information or prescriptions in a manner not authorized by law. Any violations of this section would result in a Class A misdemeanor and administrative penalty by licensing boards. (Original Author's/Sponsor's Statement of Intent)

C.S.S.B. 2316 amends current law relating to controlled substance prescriptions under the Texas Controlled Substances Act and creates a criminal offense.

RULEMAKING AUTHORITY

Rulemaking authority previously granted to the director of the Department of Public Safety of the State of Texas is modified in SECTION 1 (Section 481.003, Health and Safety Code) of this bill.

Rulemaking authority previously granted to the Texas State Board of Pharmacy is modified in SECTION 1 (Section 481.003, Health and Safety Code) and SECTION 3 (Section 554.051, Occupations Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 481.003(a), Health and Safety Code, as follows:

- (a) Authorizes the director of the Department of Public Safety of the State of Texas to adopt rules to administer and enforce this chapter (Texas Controlled Substances Act), other than Sections 481.07655, 481.0767, 481.0768, 481.0769 and certain other sections.

Authorizes the Texas State Board of Pharmacy (TSBP) to adopt rules to administer Sections 481.07655, 481.0767, 481.0768, 481.0769 and certain other sections.

SECTION 2. Amends Subchapter C, Chapter 481, Health and Safety Code, by adding Sections 481.07655, 481.0767, 481.0768, and 481.0769, as follows:

Sec. 481.07655. **LIMITATION OF LIABILITY.** (a) Provides that a prescriber or dispenser is not liable in a civil action for damages arising from the failure to access prescription drug information as required or authorized by Section 481.0764 (Duties of Prescribers, Pharmacists, and Related Health Care Practitioners) or failure to submit the information to TSBP as required under Section 481.074(q) (relating to requiring each dispensing pharmacist to send all required information to TSBP by certain means approved by TSBP not later than a certain date) or 481.075 (Official Prescription Program), unless the failure constitutes gross negligence or wilful misconduct and the prescriber or dispenser would be liable to the claimant under other law.

(b) Provides that this section does not establish a standard of care.

Sec. 481.0767. **ADVISORY COMMITTEE.** (a) Requires TSBP to establish an advisory committee to make recommendations regarding information submitted to TSBP and access to that information under Sections 481.074 (Prescriptions), 481.075, 481.076 (Official Prescription Information; Duties of Texas State Board of Pharmacy), and 481.0761 (Rules; Authority to Contract).

(b) Requires TSBP to appoint certain members to the advisory committee and sets forth the required TSBP-appointed members of the advisory committee.

(c) Provides that members of the advisory committee serve three-year terms. Requires each member to serve until the member's replacement has been appointed.

(d) Requires the advisory committee to annually elect a presiding officer from its members.

(e) Requires the advisory committee to meet at least two times a year and at the call of the presiding officer or TSBP.

(f) Provides that a member of the advisory committee serves without compensation but is authorized to be reimbursed by TSBP for actual expenses incurred in performing the duties of the advisory committee.

(g) Provides that the advisory committee is abolished and this section expires on September 1, 2023.

Sec. 481.0768. **CRIMINAL OFFENSE: DISCLOSURE OR USE OF INFORMATION.** (a) Provides that a person authorized to receive information under Section 481.076(a) (relating to prohibiting TSBP from permitting any person to have access to certain information submitted to TSBP, with certain exceptions) commits an offense if the person discloses or uses the information in a manner not authorized by this subchapter (Regulation of Manufacture, Distribution, and Dispensation of Controlled Substances, Chemical Precursors, and Chemical Laboratory Apparatus) or other law.

(b) Provides that an offense under this section is a Class A misdemeanor.

Sec. 481.0769. **ADMINISTRATIVE PENALTY: DISCLOSURE OR USE OF INFORMATION.** (a) 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 under Section 481.0768(a).

(b) Requires the agency to set the penalties in an amount sufficient to deter the conduct.

SECTION 3. Amends Section 554.051, Occupations Code, by amending Subsection (a-1) and adding Subsection (a-2), as follows:

(a-1) Authorizes TSBP to adopt rules to administer certain sections, including Sections 481.07655, 481.0768, and 481.0769, Health and Safety Code.

(a-2) Authorizes TSBP to adopt rules to administer Section 481.0767, Health and Safety Code. Provides that this subsection expires September 1, 2023.

SECTION 4. Amends Section 565.003, Occupations Code, to authorize TSBP, unless compliance would violate certain statutes or rules, to discipline an applicant for or the holder of a nonresident pharmacy license if TSBP finds that the applicant or license holder has failed to comply with certain requirements, TSBP rules, or provisions, including Sections 481.073 (Communication of Prescriptions by Agent), 481.076, 481.0761, 481.0762 (Monitoring by Regulatory Agency), 481.0763 (Registration by Regulatory Agency), 481.0764, 481.0765 (Exceptions), 481.07655, 481.0766 (Reports of Wholesale Distributors), 481.0767, 481.0768, or 481.0769, Health and Safety Code, and to make nonsubstantive changes.

SECTION 5. Requires each regulatory agency that issues a license, certification, or registration to a prescriber or dispenser, not later than September 1, 2020, to evaluate and update any administrative penalties and guidelines as provided by Section 481.0769, Health and Safety Code, as added by this Act.

SECTION 6. Provides that, notwithstanding Section 24 (relating to the applicability of Section 481.0764(a), Health and Safety Code), Chapter 485 (H.B. 2561), Acts of the 85th Legislature, Regular Session, 2017, Section 481.0764(a), Health and Safety Code, as added by that Act, applies only to:

(1) a prescriber, other than a veterinarian, who issues a prescription for a controlled substance on or after March 1, 2020; or

(2) 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.

SECTION 7. Effective date: September 1, 2019.