

BILL ANALYSIS

Senate Research Center
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C.S.H.B. 3284
By: Sheffield et al. (Nelson)
Health & Human Services
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Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Calls have been made to do more to address the current opioid crisis. H.B. 3284 seeks to answer those calls by providing for better prescription monitoring and increasing the use of technology. (Original Author's/Sponsor's Statement of Intent)

C.S.H.B. 3284 amends current law relating to prescribing and dispensing controlled substances and monitoring the prescribing and dispensing of controlled substances under the Texas Controlled Substances Act; authorizes a fee; provides for administrative penalties; and creates criminal offenses.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the Texas State Board of Pharmacy (TSBP) in SECTION 1 (Section 481.0755, Health and Safety Code) and SECTION 2 (Section 481.076, Health and Safety Code) of this bill.

Rulemaking authority is expressly granted to the State Board of Veterinary Medical Examiners in SECTION 5 (Section 801.307, Occupations Code) of this bill.

Rulemaking authority previously granted to the director of the Department of Public Safety of the State of Texas is modified in SECTION 6 (Section 481.003, Health and Safety Code) of this bill.

Rulemaking authority previously granted to TSBP is modified in SECTION 6 (Section 481.003, Health and Safety Code) and SECTION 9 (Section 554.051, Occupations Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subchapter C, Chapter 481, Health and Safety Code, by adding Section 481.0755, as follows:

Sec. 481.0755. WRITTEN, ORAL, AND TELEPHONICALLY COMMUNICATED PRESCRIPTIONS. (a) Requires a person prescribing or dispensing a controlled substance, notwithstanding Sections 481.073 (Communication of Prescriptions by Agent), 481.074 (Prescriptions), and 481.075 (Official Prescription Program), to use the electronic prescription record and prohibits the person from using a written, oral, or telephonically communicated prescription.

(b) Authorizes a prescriber to issue a written, oral, or telephonically communicated prescription for a controlled substance as authorized under this subchapter only if the prescription is issued:

(1) by a veterinarian;

(2) in circumstances in which electronic prescribing is not available due to temporary technological or electronic failure, as prescribed by Texas State Board of Pharmacy (TSBP) rule;

- (3) by a practitioner to be dispensed by a pharmacy located outside this state, as prescribed by TSBP rule;
- (4) when the prescriber and dispenser are the same entity;
- (5) in circumstances in which necessary elements are not supported by the most recent electronic prescription drug software;
- (6) for a drug for which the United States Food and Drug Administration requires additional information in the prescription that is not possible with electronic prescribing;
- (7) for a non-patient-specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative drug management, or comprehensive medication management, in response to a public health emergency or in other circumstances in which the practitioner may issue a non-patient-specific prescription;
- (8) for a drug under a research protocol;
- (9) by a prescriber who is employed by or is practicing a health care profession at a health-related institution, as defined by Section 62.161 (Definitions), Education Code, as added by Chapter 448 (H.B. 7), Acts of the 84th Legislature, 2015;
- (10) by a practitioner who has received a waiver under Subsection (c) from the requirement to use electronic prescribing; or
- (11) under circumstances in which the practitioner has the present ability to submit an electronic prescription but reasonably determines that it would be impractical for the patient to obtain the drugs prescribed under the electronic prescription in a timely manner and that a delay would adversely impact the patient's medical condition.

(c) Requires TSBP to adopt rules establishing a process by which a practitioner may request and receive a waiver under Subsection (b)(10), not to exceed one year, from the requirement to use electronic prescribing. Requires TSBP to adopt rules establishing the eligibility for a waiver, including:

- (1) economic hardship;
- (2) technological limitations not reasonably within the control of the practitioner; or
- (3) other exceptional circumstances demonstrated by the practitioner.

(d) Requires that a written, oral, or telephonically communicated prescription comply with the applicable requirements prescribed by Sections 481.074 and 481.075.

(e) Provides that a dispensing pharmacist who receives a controlled substance prescription in a manner other than electronically is not required to verify that the prescription is exempt from the requirement that it be submitted electronically.

(f) Requires TSBP enforce this section.

SECTION 2. Amends Sections 481.076, Health and Safety Code, by amending Subsections (a), (f), (g), and (h) and adding Subsection (a-6), Health and Safety Code, as follows:

(a) Prohibits TSBP from permitting any person to have access to information submitted to TSBP under Section 481.074(q) (relating to each dispensing pharmacy sending certain information to TSBP) or 481.075 except:

(1) includes the Texas Department of Licensing and Regulation, with respect to the regulation of podiatrists, and removes the State Board of Podiatric Medical Examiners;

(2) an authorized employee of TSBP, rather than an authorized officer or member of the Department of Public Safety of the State of Texas (DPS) or authorized employee of TSBP, engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

(3) DPS or other law enforcement or prosecutorial official engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state, if TSBP is provided a warrant, subpoena, or other court order compelling the disclosure, rather than DPS on behalf of a law enforcement or prosecutorial official engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

(4) and (5) makes no changes to these subdivisions;

(6) and (7) makes nonsubstantive changes to these subdivisions;

(8) a health care facility certified by the federal Centers for Medicare and Medicaid Services; or

(9) the patient, the patient's parent or legal guardian, if the patient is a minor, or the patient's legal guardian, if the patient is an incapacitated person, as defined by Section 1002.017(2) (relating to defining "incapacitated person" to mean an adult who is substantially unable to perform certain tasks because of a physical or mental condition), Estates Code, inquiring about the patient's prescription record, including persons who have accessed that record.

(a-6) Entitles a patient, the patient's parent or legal guardian, if the patient is a minor, or the patient's legal guardian, if the patient is an incapacitated person, as defined by Section 1002.017(2), Estates Code, to a copy of the patient's prescription record as provided by Subsection (a)(9), including a list of persons who accessed that record, if a completed patient data request form and any supporting documentation required by TSBP is submitted to TSBP. Authorizes TSBP to charge a reasonable fee for providing the copy. Requires TSBP to adopt rules to implement this subsection, including rules prescribing the patient data request form, listing the documentation required for receiving a copy of the prescription record, and setting the fee.

(f) Requires TSBP, if TSBP accesses information under Subsection (a)(2) relating to a person licensed or regulated by an agency listed in Subsection (a)(1), to notify and cooperate with that agency regarding the disposition of the matter before taking action against the person, unless TSBP determines that notification is reasonably likely to interfere with an administrative or criminal investigation or prosecution, rather than requiring the director of DPS (director), if the director permits access to information under Subsection (a)(2) relating to a person licensed or regulated by an agency listed in Subsection (a)(1), to notify and cooperate with that agency regarding the disposition of the matter before taking action against the person, unless the director determines that notification is reasonably likely to interfere with an administrative or criminal investigation or prosecution.

(g) Makes conforming changes to this subsection.

(h) Makes conforming changes to this subsection.

SECTION 3. Amends Section 481.0766, Health and Safety Code, as follows:

(c) Requires TSBP to make the information reported under Subsection (a) (relating to wholesale distributors reporting certain information to TSBP in a prescribed manner) available to the State Board of Veterinary Medical Examiners for the purpose of routine inspections and investigations.

SECTION 4. Amends Subchapter C, Chapter 481, Health and Safety Code, by adding Sections 481.0767, 481.0768, and 481.0769, as follows:

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, 481.075, 481.076, and 481.0761 (Rules; Authority to Contract), including recommendations for:

- (1) operational improvements to the electronic system that stores the information, including implementing best practices and improvements that address system weaknesses and workflow challenges;
- (2) resolutions to identified data concerns;
- (3) methods to improve data accuracy, integrity, and security and to reduce technical difficulties; and
- (4) the addition of any new data set or service to the information submitted to the TSBP or the access to that information.

(b) Requires TSBP to appoint the certain members to 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 may be reimbursed by TSBP for actual expenses incurred in performing the duties of the advisory committee.

Sec. 481.0768. **ADMINISTRATIVE PENALTY: DISCLOSURE OR USE OF INFORMATION.** (a) Prohibits a person authorized to receive information under Section 481.076(a) from disclosing or using the information in a manner not authorized by this subchapter or other law.

(b) 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 that violates Subsection (a).

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

Sec. 481.0769. **CRIMINAL OFFENSES RELATED TO PRESCRIPTION INFORMATION.** (a) Provides that a person authorized to receive information under

Section 481.076(a) commits an offense if the person discloses or uses the information in a manner not authorized by this subchapter or other law.

(b) Provides that a person requesting information under Section 481.076(a-6) commits an offense if the person makes a material misrepresentation or fails to disclose a material fact in the request for information under that subsection.

(c) Provides that an offense under Subsection (a) is a Class A misdemeanor.

(d) Provides that an offense under Subsection (b) is a Class C misdemeanor.

SECTION 5. Amends Section 801.307, Occupations Code, by adding Subsection (a-1) to require TSBP to require a veterinarian to complete two hours of continuing education related to opioid abuse and controlled substance diversion, inventory, and security every two years to renew a license to practice veterinary medicine.

SECTION 6. Amends Section 481.003(a), Health and Safety Code, as follows:

(a) Authorizes the director to adopt rules to administer and enforce this chapter, other than certain sections, including Sections 481.0755, 481.0767, 481.0768, and 481.0769. Authorizes TSBP to adopt rules to administer certain sections, including Sections 481.0755, 481.0767, 481.0768, and 481.0769.

SECTION 7. Amends Section 481.128(a), Health and Safety Code, to provide that a registrant or dispenser commits an offense if the registrant or dispenser knowingly commits certain acts, including distributes, delivers, administers, or dispenses a controlled substance in violation of Subchapter C (Regulation of Manufacture, Distribution, and Dispensation of Controlled Substances, Chemical Precursors, and Chemical Laboratory Apparatus), rather than Sections 481.070–481.075.

SECTION 8. Amends Section 481.129(a), Health and Safety Code, to provide that a person commits an offense if the person knowingly commits certain acts, including possesses, obtains, or attempts to possess or obtain a controlled substance or an increased quantity of a controlled substance through the use of a fraudulent electronic prescription.

SECTION 9. Amends Section 554.051(a-1), Occupations Code, to authorize TSBP to adopt rules to administer certain sections of the Health and Safety Code, including Sections 481.0755, 481.0767, 481.0768, and 481.0769.

SECTION 10. Amends Section 565.003, Occupations Code, to authorize 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 if TSBP finds that the applicant or license holder has failed to comply with Subchapter C, Chapter 481, Health and Safety Code, rather than Section 481.074 or 481.075, Health and Safety Code.

SECTION 11. Repealer: Section 481.076(a-3) (relating to TSBP ensuring DPS has access to certain information at all times through an electronic portal), Health and Safety Code.

Repealer: Section 481.076(a-4) (relating to authorizing certain law enforcements agents or prosecutorial official to obtain certain information by submitting an official request), Health and Safety Code.

Repealer: Section 481.076(a-5) (relating to certain records relating to the access of information being confidential), Health and Safety Code.

SECTION 12. Provides that, to the extent of any conflict, this Act prevails over another Act of the 86th Legislature, Regular Session, 2019, relating to nonsubstantive additions to and corrections in enacted codes.

SECTION 13. Provides that Section 481.0764(a), Health and Safety Code, notwithstanding Section 24, Chapter 485 (H.B.2561), Acts of the 85th Legislature, Regular Session, 2017, applies only to a prescriber, other than a veterinarian, who issues a prescription for a controlled substance on or after March 1, 2020, or 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 14. Makes application of Section 481.0755, Health and Safety Code, as added by this Act, prospective.

SECTION 15. Makes application of Section 481.0768(a), Health and Safety Code, as added by this Act, prospective.

SECTION 16. Makes application of Section 801.307(a-1), Occupations Code, as added by this Act, prospective to September 1, 2020.

SECTION 17. Effective date: September 1, 2019.