

## **BILL ANALYSIS**

C.S.H.B. 3284  
By: Sheffield  
Public Health  
Committee Report (Substituted)

### **BACKGROUND AND PURPOSE**

Calls have been made to do more to address the current opioid crisis. C.S.H.B. 3284 seeks to answer those calls by providing for better prescription monitoring and increasing the use of technology.

### **CRIMINAL JUSTICE IMPACT**

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change 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 1,6, and 9 of this bill and to the State Board of Veterinary Medical Examiners in SECTION 5 of this bill.

### **ANALYSIS**

C.S.H.B. 3284 amends the Health and Safety Code to require a person prescribing or dispensing a controlled substance to use the electronic prescription record and prohibits such a person from using a written, oral, or telephonically communicated prescription unless the prescription is issued as follows:

- by a veterinarian;
- 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;
- by a practitioner to be dispensed by a pharmacy located outside of Texas, as prescribed by TSBP rule;
- when the prescriber and dispenser are the same entity;
- in circumstances in which necessary elements are not supported by the most recent electronic prescription drug software;
- for a drug for which the U.S. Food and Drug Administration requires additional information in the prescription that is not possible with electronic prescribing;
- 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;
- for a drug under a research protocol;
- by a prescriber who is employed by or is practicing a health care profession at a

health-related institution, as defined by reference;

- by a practitioner who has received a waiver from the requirement to use electronic prescribing; or
- 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.

The bill requires the TSBP to adopt rules establishing a process by which a practitioner may request and receive such a waiver, not to exceed one year, from the requirement to use electronic prescribing and rules establishing the eligibility for a waiver, including economic hardship, technological limitations not reasonably within the control of the practitioner, or other exceptional circumstances demonstrated by the practitioner. The bill requires a written, oral, or telephonically communicated prescription to comply with the applicable requirements for prescriptions under the Texas Controlled Substances Act and the official prescription program. The bill expressly does not require a dispensing pharmacist who receives a controlled substance prescription in a manner other than electronically to verify that the prescription is exempt from the requirement that it be submitted electronically. The bill requires the TSBP to enforce these provisions relating to written, oral, and telephonically communicated prescriptions.

C.S.H.B. 3284 revises the conditions under which the TSBP may permit access to certain information submitted to the TSBP relating to prescriptions for controlled substances, including by making the condition with regard to permitting access for the Department of Public Safety or certain other law enforcement or prosecutorial officials dependent on the TSBP being provided a warrant, subpoena, or other court order compelling the disclosure. The bill authorizes the TSBP to permit access to that information to a health care facility certified by the federal Centers for Medicare and Medicaid Services.

C.S.H.B. 3284 requires the TSBP to make available to the State Board of Veterinary Medical Examiners (TBVME) for purposes of routine inspections and investigations certain information reported to the Automation of Reports and Consolidated Orders System (ARCOS) of the Federal Drug Enforcement Administration and made available to the TSBP by a wholesale distributor regarding the distribution of a controlled substance by the distributor to a person in Texas.

C.S.H.B. 3284 requires the TSBP to establish an advisory committee to make recommendations regarding information submitted to the TSBP and access to that information under Texas Controlled Substances Act provisions relating to prescriptions, the official prescription program, official prescription information and duties of the TSBP, and rules and the authority to contract, including recommendations for:

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

The bill sets out the advisory committee's membership and provides for the terms of its members and the election of its presiding officer and requires the advisory committee to meet at least two times a year at the call of the presiding officer or the TSBP. The bill establishes that a member of the advisory committee serves without compensation but may be reimbursed by the TSBP for actual expenses incurred in performing advisory committee duties.

C.S.H.B. 3284 prohibits a person authorized to receive prescription history information from disclosing or using the information in a manner not authorized by statutory provisions relating to the regulation of controlled substances, chemical precursors, and chemical laboratory apparatus or other law. 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 that violates such a prohibition. The bill requires an applicable regulatory agency to set the penalties in an amount sufficient to deter the conduct. The bill expands the conduct that constitutes fraud under the Texas Controlled Substances Act to include possessing, obtaining, or attempting to possess or obtain a controlled substance or an increased quantity of a controlled substance through the use of a fraudulent electronic prescription.

C.S.H.B. 3284 amends the Occupations Code to expand the grounds on which the TSBP may discipline an applicant or the holder of a nonresident pharmacy license to include the TSBP finding that the applicant or license holder has failed to comply with provisions under the Texas Controlled Substances Act relating to the regulation of the manufacture, distribution, and dispensation of controlled substances, chemical precursors, and chemical laboratory apparatus.

C.S.H.B. 3284 requires the TBVME by rule 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. This requirement applies only to the renewal of a license to practice veterinary medicine on or after September 1, 2020.

C.S.H.B. 3284 repeals Sections 481.076(a-3), (a-4), and (a-5), Health and Safety Code.

#### **EFFECTIVE DATE**

September 1, 2019.

#### **COMPARISON OF ORIGINAL AND SUBSTITUTE**

While C.S.H.B. 3284 may differ from the original in minor or nonsubstantive ways, the following summarizes the substantial differences between the introduced and committee substitute versions of the bill.

The substitute does not include the following provisions:

- a requirement for dispensing veterinarians to submit and retain certain information to the TSBP and a provision relating to disciplinary action for a failure to comply with that requirement;
- a certain limitation on a prescription for an opioid for the initial treatment of acute pain; and
- a limitation of liability for a prescriber or dispenser that failed to access certain prescription drug information or failed to submit certain information to the TSBP.

The substitute includes the following provisions:

- an authorization for a prescriber to issue a written, oral, or telephonically communicated prescription for a controlled substance for a prescription issued by a prescriber who is employed by or is practicing a health care profession at a health-related institution;
- a requirement for the TSBP to make certain information reported to ARCOS available to the TBVME;
- provisions establishing an advisory committee to make recommendations regarding

certain information submitted to the TSBP; and

- a provision requiring certain continuing education for a veterinarian to renew a license to practice veterinary medicine.

The substitute changes the grounds on which the TSBP may discipline an applicant or the holder of a nonresident pharmacy license regarding a finding of noncompliance from a finding the applicant or license holder has failed to comply with the applicable bill provisions and certain provisions under the Texas Controlled Substances Act to a finding the applicant or license holder has failed to comply with provisions under the act relating to the regulation of the manufacture, distribution, and dispensation of controlled substances, chemical precursors, and chemical laboratory apparatus.