

## **BILL ANALYSIS**

Senate Research Center  
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C.S.S.B. 316  
By: Hinojosa et al.  
Health & Human Services  
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Committee Report (Substituted)

### **AUTHOR'S / SPONSOR'S STATEMENT OF INTENT**

C.S.S.B. 316 makes several changes:

Delays implementation to give time for practitioners to adjust to new requirements:

- For prescribers and pharmacists, delays the scope and effective date of the requirement to search the database before prescribing or dispensing certain drugs. Beginning September 1, 2018, practitioners would only be required to search the database before prescribing or dispensing schedule II controlled substances. Then, on September 1, 2019, practitioners would begin checking the database before prescribing or dispensing any schedule of all four classes of controlled substances listed in the bill (opioids, benzodiazepines, barbiturates, and carisoprodol.)
- For veterinarians that dispense controlled substances, phases in the new data entry requirement over three years. Beginning September 1, 2018, veterinarians would enter dispensing data within 30 days of dispensing. Then, on September 1, 2019, veterinarians would enter data within seven days. Finally, by September 1, 2020, veterinarians would enter data within one business day.

Clarifies the responsibility of licensing boards to monitor prescribing and dispensing:

- Expressly authorizes the Texas State Board of Pharmacy (TSBP) to identify patterns that may indicate a patient is doctor shopping and send electronic alerts to practitioners.
- Requires TSBP to copy licensing boards on electronic alerts sent to their licensees about potentially dangerous prescribing or dispensing patterns.
- Requires each prescriber licensing board to develop guidelines to educate licensees on potentially dangerous prescribing practices for the four classes of controlled substances listed in the bill (opioids, benzodiazepines, barbiturates, and carisoprodol.)
- Requires each practitioner licensing board to provide information to the TSBP to enable automatic registration of licensees and easier access to the database.
- Reduces the fiscal impact of the bill by deleting two unnecessary requirements for veterinary prescription data entry. (These two data fields—directions for use and intended use of the prescription—would not help identify potential drug abuse or diversion and would require costly reprogramming of the database to capture.
- Clarifies that the bill does not expand any practitioner's authority to prescribe controlled substances.

Requires a study on program impacts:

- Requires the Senate Health and Human Services Committee to complete an interim study on effects of changes to the Prescription Monitoring Program and the extent of veterinary drug diversion by January 1, 2019, to understand the impacts of the database on controlled substance abuse and guide potential future changes.

Exempts practitioner requirements in certain instances:

- Exempts practitioners from the requirement to search the Prescription Monitoring Program before prescribing or dispensing certain drugs in circumstances beyond the practitioner's control, such as technical problems or system down time.

Technical change:

- Fixes a printing error by breaking Subsection (b), beginning on line 26 of page 10 of the introduced version of the bill, into a new Subsection (c), and makes conforming changes to the numbering of the rest of the section.

C.S.S.B. 316 amends current law relating to powers and duties of certain prescribers and dispensers of controlled substances and the regulatory agencies that issue a license, certification, or registration to the prescriber or dispenser; and follows the recommendations of the Sunset Advisory Commission.

### **RULEMAKING AUTHORITY**

Rulemaking authority previously granted to the Texas State Board of Pharmacy (TSBP) is modified in SECTION 4 (Section 481.076, Health and Safety Code) and SECTION 5 (Section 481.0761, Health and Safety Code) of this bill.

Rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTION 5 (Section 481.0761, Health and Safety Code) of this bill.

### **SECTION BY SECTION ANALYSIS**

SECTION 1. Amends Sections 481.074(k) and (q), Health and Safety Code, as follows:

(k) Requires a prescription for a controlled substance to show among certain other information, if the controlled substance is prescribed for an animal, the name, species, gender, and actual or estimated date of birth of the animal and the name and address of the animal's, rather than its, owner.

(q) Requires each dispensing pharmacist to send certain required information to the Texas State Board of Pharmacy (TSBP) not later than the next business day, rather than the seventh day, after the date the prescription is completely filled.

SECTION 2. Amends Section 481.075(i), Health and Safety Code, to require each dispensing pharmacist to, among certain recordkeeping requirements, send certain required information to TSBP not later than the next business day, rather than the seventh day, after the date the prescription is completely filled.

SECTION 3. Amends Subchapter C, Chapter 481, Health and Safety Code, by adding Section 481.0751, as follows:

Sec. 481.0751. DISPENSING VETERINARIANS. (a) Provides that this section applies to a veterinarian who holds a registration issued by the Federal Drug Enforcement Administration and dispenses Schedule II, III, IV, or V controlled substances directly to the owner or handler of an animal.

(b) Requires the veterinarian to, not later than the next business day after the date the veterinarian dispenses a controlled substance, submit to TSBP certain information.

(c) Requires a veterinarian to retain a record of the information submitted to TSBP under Subsection (b) for a period of not less than two years after the date the substance is dispensed.

(d) Provides that failure to comply with this section is grounds for disciplinary action by the Texas Board of Veterinary Medical Examiners (TBVME).

SECTION 4. Amends Sections 481.076(a), (a-3), (a-4), (c), (d), (i), and (j), Health and Safety Code, as follows:

(a) Prohibits TSBP from permitting any person to have access to information submitted to TSBP under certain sections, including Section 481.0751, except:

(1) TSBP, rather than an investigator for TSBP, and certain other governmental entities for the purpose of investigating a specific license holder or monitoring for potentially harmful prescribing or dispensing patterns or practices under Section 481.0762;

(2) to (4) Makes no changes to these subdivisions;

(5) certain pharmacists, pharmacy technicians, and practitioners, provided that accessing the information is authorized under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and regulations adopted under that Act. Deletes existing text providing that the person accessing the information be authorized to do so under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and rules adopted under that Act. Makes nonsubstantive changes;

(6) and (7) makes no changes to these subdivisions.

(a-3) Requires TSBP to ensure that the Texas Department of Public Safety (DPS) has unrestricted access at all times to information submitted to TSBP under Sections 481.074(q), 481.075 (Official Prescription Program), or 481.0751, rather than Sections 481.074(q) and 481.075.

(a-4) Makes conforming changes.

(c) Requires TSBP, by rule, to design and implement a system for submission of information to TSBP by certain means and for retrieval of submitted information under this section and Sections 481.074 (Prescriptions), 481.075, and 481.0751.

(d) Authorizes information submitted to TSBP under this section to be used only for:

(1) makes no changes to this subdivision;

(2) certain investigatory, evidentiary, or monitoring purposes, rather than certain investigatory or evidentiary purposes;

(3) the prescribing and dispensing of controlled substances by a person listed in Subsection (a)(5); or

(4) redesignates existing Subdivision (3) as Subdivision (4) and makes no further changes to this subdivision.

(i) Establishes the confidentiality of information submitted to TSBP under Section 481.074(q), 481.075, or 481.0751.

(j) Authorizes TSBP to, pursuant to an interoperability agreement, authorize the prescription monitoring program of one or more or an association of states to access information submitted to TSBP under Sections 481.074(q), 481.075, and 481.0751.

SECTION 5. Amends Section 481.0761, Health and Safety Code, by amending Subsections (a) and (c) and adding Subsections (h), (i), and (j), and (k) as follows:

(a) Requires TSBP to, by rule, establish and revise as necessary a standardized database format that may be used by a pharmacy to transmit information required by Sections 481.074(q), 481.075(i), and 481.0751.

(c) Authorizes TSBP to, by rule, among certain other measures, establish a procedure to control the release of information under Sections 481.074, 481.075, 481.0751, and 481.076 (Official Prescription Information; Duties of Texas State Board of Pharmacy).

(h) Requires TSBP, in consultation with DPS and the regulatory agencies listed in Section 481.076(a)(1), to identify potentially harmful prescribing or dispensing patterns or practices that may suggest drug diversion or abuse. Requires TSBP to develop indicators for levels of prescriber or patient activity that suggest that a potentially harmful prescribing or dispensing pattern or practice may be occurring or that drug diversion or drug abuse may be occurring.

(i) Authorizes TSBP to, based on the indicators developed under Subsection (h), send a prescriber or dispenser an electronic notification if the information submitted under Sections 481.074(q), 481.075, and 481.0751 indicates that a potentially harmful prescribing or dispensing pattern or practice or drug diversion or drug abuse may be occurring.

(j) Authorizes TSBP, by rule, to develop guidelines identifying patterns that may indicate that a particular patient to whom a controlled substance is prescribed or dispensed is engaging in drug abuse or drug diversion. Authorizes these guidelines to be based on the frequency of prescriptions issued to and filled by the patient, the types of controlled substances prescribed, and the number of prescribers who prescribe controlled substances to the patient. Authorizes TSBP to, based on the guidelines developed under this subsection, send a prescriber or dispenser an electronic notification if there is reason to believe that a particular patient is engaging in drug abuse or drug diversion.

(k) Authorizes TSBP to, by rule, develop guidelines identifying additional behavior that would suggest that drug diversion or drug abuse is occurring. Requires a person described by Section 481.076(a)(5)(a) who observes that behavior by a person to whom a controlled substance is to be dispensed to access the information under Section 481.076(a)(5) regarding the patient for whom the prescription for the controlled substance was issued.

SECTION 6. Amends Subchapter C, Chapter 481, Health and Safety Code, by adding Sections 481.0762, 481.0763, and 481.0764, and 481.0765, as follows:

Sec. 481.0762. **MONITORING BY REGULATORY AGENCY.** (a) Requires each regulatory agency that issues a license, certification, or registration to a prescriber to promulgate specific guidelines for prescribers regulated by that agency for the responsible prescribing of opioids, benzodiazepines, barbiturates, or carisoprodol.

(b) Requires a regulatory agency that issues a license, certification, or registration to a prescriber to periodically access the information submitted to TSBP under Sections 481.074(q), 481.075, and 481.0751 to determine whether a prescriber is engaging in potentially harmful prescribing patterns or practices.

(c) Requires TBVME to periodically access the information submitted to TSBP under Sections 481.074(q), 481.075, and 481.0751 to determine whether a veterinarian is engaging in potentially harmful prescribing or dispensing patterns or practices.

(d) Requires TSBP, if the board sends a prescriber or dispensing veterinarian an electronic notification authorized under Section 481.0761(i), to simultaneously send an electronic notification to the appropriate regulatory agency.

(e) Requires the appropriate regulatory agency, in determining whether a potentially harmful prescribing or dispensing pattern or practice is occurring, at a minimum, to consider:

(1) the number of times a prescriber prescribes or a veterinarian dispenses opioids, benzodiazepines, barbiturates, or carisoprodol; and

(2) for prescriptions and dispensations described by Subdivision (1), patterns of prescribing or dispensing combinations of those drugs and other dangerous combinations of drugs identified by TSBP.

(f) Authorizes the regulatory agency, if, during a periodic check under this section, the regulatory agency finds evidence that a prescriber may be engaging in potentially harmful prescribing or dispensing patterns or practices, to notify that prescriber.

(g) Authorizes a regulatory agency to open a complaint against a prescriber if the agency finds evidence during a periodic check under this section that the prescriber is engaging in conduct that violates this subchapter or any other statute or rule.

**Sec. 481.0763. REGISTRATION BY REGULATORY AGENCY.** Requires a regulatory agency that issues a license, certification, or registration to a prescriber or dispenser to provide TSBP with any necessary information for each prescriber or dispenser, including contact information for the notifications described by Sections 481.0761(i) and (j), to register the prescriber or dispenser with the system by which the prescriber or dispenser receives information as authorized under Section 481.076(a)(5).

**Sec. 481.0764. DUTIES OF PRESCRIBERS, PHARMACISTS, AND RELATED HEALTH CARE PRACTITIONERS.** (a) Requires a person authorized to receive information under Section 481.076(a)(5) to access that information with respect to the patient before prescribing or dispensing opioids, benzodiazepines, barbiturates, or carisoprodol.

(b) Authorizes a person authorized to receive information under Section 481.076(a)(5) to access that information with respect to the patient before prescribing or dispensing any controlled substance.

(c) Provides that a veterinarian subject to this section is required to access the information for prescriptions dispensed only for the animals of an owner and prohibits a veterinarian subject to this section from considering the personal prescription history of the owner.

(d) Provides that a violation of Subsection (a) is grounds for disciplinary action by the regulatory agency that issued a license, certification, or registration to the person who committed a violation.

(e) Provides that this section does not grant a person the authority to issue prescriptions for or dispense controlled substances.

**Sec. 481.0765. EXCEPTIONS.** (a) Provides that a prescriber is not subject to the requirements of Section 481.0764(a) if the patient has been diagnosed with cancer or the patient is receiving hospice care; and the prescriber clearly notes in the prescription record that the patient was diagnosed with cancer or is receiving hospice care, as applicable.

(b) Provides that a dispenser is not subject to the requirements of Section 481.0764(a) if it is clearly noted in the prescription record that the patient has been diagnosed with cancer or is receiving hospice care.

(c) Provides that a prescriber or dispenser is not subject to the requirements of Section 481.0764(a) and a dispenser is not subject to a rule adopted under Section 481.0761(k) if the prescriber or dispenser makes a good faith attempt to comply but is unable to access the information under Section 481.076(a)(5) because of circumstances outside the control of the prescriber or dispenser.

SECTION 7. (a) Requires the Senate Committee on Health and Human Services (committee) to conduct an interim study on the monitoring of the prescribing and dispensing of controlled substances in this state.

(b) Requires the interim study to:

(1) include the number of prescribers and dispensers registered to receive information electronically under Section 481.076, Health and Safety Code, as amended by this Act;

(2) evaluate the accessing of information under Section 481.076, Health and Safety Code, as amended by this Act, by regulatory agencies to monitor persons issued a license, certification, or registration by those agencies;

(3) address any complaints, technical difficulties, or other issues with electronically accessing and receiving information under Section 481.076, Health and Safety Code, as amended by this Act;

(4) examine controlled substance prescribing and dispensing trends that may be affected by the passage and implementation of this Act;

(5) evaluate the integration of any new data elements required to be reported under this Act, including certain information from veterinarians;

(6) evaluate the existence and scope of diversion of controlled substances by animal owners to whom the substances are dispensed by veterinarians;

(7) explore the best methods for preventing the diversion of controlled substances by animal owners, including veterinary reporting under Section 481.0751, Health and Safety Code, as added by this Act; and

(8) determine how mandated reporting by veterinarians under Section 481.0751, Health and Safety Code, as added by this Act, might best be tailored to fit the practice of veterinary medicine.

(c) Requires the committee to solicit feedback from regulatory agencies, prescribers, dispensers, and patients affected by the passage of this Act.

(d) Requires the committee to submit a report to the legislature on the results of the interim study, including any legislative recommendations for improvements to information access and controlled substance prescription monitoring, not later than January 1, 2019.

SECTION 8. (a) Provides that, notwithstanding Section 481.0751(b), Health and Safety Code, as added by this Act:

(1) a veterinarian who dispenses a controlled substance before September 1, 2018, is not required to submit the information under that subsection to TSBP;

(2) a veterinarian who dispenses a controlled substance on or after September 1, 2018, but before September 1, 2019, is required to submit the information under that subsection to TSBP not later than the 30th day after the date the veterinarian dispenses the controlled substance; and

(3) a veterinarian who dispenses a controlled substance on or after September 1, 2019, but before September 1, 2020, is required to submit the information under that subsection to TSBP not later than the seventh day after the date the veterinarian dispenses the controlled substance.

(b) Provides that a veterinarian who dispenses a controlled substance on or after September 1, 2020, is required to comply with Section 481.0751(b), Health and Safety Code, as added by this Act.

SECTION 9. Provides that a person is not required to comply with Section 481.0761(k), Health and Safety Code, as added by this Act, before September 1, 2018.

SECTION 10. Provides that Section 481.0764(a), Health and Safety Code, as added by this Act, applies only to:

(1) a prescriber who issues a prescription for a Schedule II controlled substance on or after September 1, 2018;

(2) a prescriber who issues a prescription for a controlled substance on any schedule on or after September 1, 2019;

(3) a person authorized by law to dispense a controlled substance who dispenses a Schedule II controlled substance on or after September 1, 2018; or

(4) a person authorized by law to dispense a controlled substance who dispenses a controlled substance on any schedule on or after September 1, 2019.

SECTION 11. Effective date: September 1, 2017.