

## **BILL ANALYSIS**

Senate Research Center  
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S.B. 316  
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### **AUTHOR'S / SPONSOR'S STATEMENT OF INTENT**

- The prescription drug abuse epidemic facing the country claims tens of thousands of lives each year, a constant backdrop to the Sunset Advisory Commission's (Sunset) reviews of the agencies responsible for licensing health practitioners who prescribe and dispense controlled substances. Texas' Prescription Monitoring Program (PMP) is a database collecting statewide information on controlled substances dispensed in Texas. In 2015, the legislature transferred operation of the database to the Texas State Board of Pharmacy (TSBP), and the TSBP began operating the PMP on September 1, 2016. The PMP allows prescribers, pharmacists, and related regulatory agencies to check for information on a patient's controlled substance prescription history to inform responsible prescribing and dispensing practices. Regulatory agencies also rely on the database to investigate potentially improper prescribing and dispensing patterns.
- Texas' PMP lags behind national best practices, lacking basic tools needed to maximize its effectiveness. Sunset reviewed TSBP and regulatory agencies responsible for licensing prescribers and made several recommendations to improve the effectiveness of the PMP. These recommendations are reflected in this bill.
- Major Provisions in S.B. 316:
- Requires regulatory agencies overseeing prescribers and dispensers of controlled substances to query the PMP to evaluate practitioner prescribing and dispensing patterns.
- Requires the dental, medical, nursing, optometry, podiatry, and veterinary boards to monitor the PMP to identify potentially harmful prescribing and dispensing patterns. Authorizes these boards to open a complaint on the basis of information obtained from the database.
- Authorizes TSBP to highlight potentially dangerous prescribing and dispensing patterns through proactive electronic notifications to system users.
- Increases use and effectiveness of the PMP by requiring practitioners or their delegates to query the database before prescribing or dispensing especially dangerous controlled substances.
- Requires practitioners to search the PMP database before prescribing or dispensing especially addictive and dangerous controlled substances. Pharmacists would be required to search the database before dispensing beginning January 1, 2018, and prescribers would be required to search the database beginning September 1, 2018.
- Subjects practitioners failing to search the PMP database before prescribing or dispensing these drugs to disciplinary action by the appropriate licensing board.
- Exempts practitioners from searching the PMP before prescribing or dispensing controlled substances if the patient is diagnosed with cancer or is receiving hospice treatment, if the prescriber notes the diagnosis or hospice setting on the prescription.

- Requires pharmacists or their delegates to enter dispensing information in the PMP database within one business day of dispensing controlled substances, rather than the current one week, to ensure timely, complete data.
- Requires veterinarians to enter controlled substance dispensing information in the PMP database to close an important gap in tracking distribution of highly addictive drugs in Texas.
- Requires veterinarians to enter controlled substance dispensing information in the database within one business day of dispensing controlled substances.
- Requires veterinarians to include standard data elements for veterinary prescriptions and for dispensing information entered into the PMP to facilitate accurate data entry of animal-related prescriptions.
- Subjects veterinarians failing to enter dispensing information in the PMP to disciplinary action by the Texas Board of Veterinary Medical Examiners.

As proposed, 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; following 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.

(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 investigatory or evidentiary purposes only;

(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), as follows:

(a) Requires TSBP, by rule, to 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 practice or drug diversion or 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(g) (relating to certain restrictions on prescriptions for controlled substances), 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 to by rule develop guidelines identifying behavior that would suggest that drug diversion or 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, as follows:

Sec. 481.0762. MONITORING BY REGULATORY AGENCY. (a) 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(g), 481.075, and 481.0751 to determine whether a prescriber is engaging in potentially harmful prescribing patterns or practices.

(b) Requires TBVME to periodically access the information submitted to TSBP under Sections 481.074(g), 481.075, and 481.0751 to determine whether a veterinarian is engaging in potentially harmful prescribing or dispensing patterns or practices. Requires the appropriate regulatory agency, in determining whether a potentially harmful prescribing or dispensing pattern or practice is occurring, to at a minimum 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.

(c) Authorizes the regulatory agency to notify the prescriber 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.

(d) 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. 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.

Sec. 481.0764. EXCEPTIONS. (a) Provides that a prescriber is not subject to the requirements of Section 481.0763(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 481.0763(a) if it is clearly noted in the prescription record that the patient has been diagnosed with cancer or is receiving hospice care.

SECTION 7. Provides that a person is not required to comply with a rule adopted under Section 481.0761(j), Health and Safety Code, as added by this Act, before January 1, 2018.

SECTION 8. Provides that Section 481.0763, Health and Safety Code, as added by this Act, applies only to a prescriber who issues a prescription on or after September 1, 2018; a veterinarian who dispenses a controlled substance on or after September 1, 2018; or a person other than a veterinarian authorized by law to dispense a controlled substance who dispenses the substance on or after January 1, 2018.

SECTION 9. Effective date: September 1, 2017.