By: Hinojosa, et al. S.B. No. 316
(Gonzales of Williamson, Coleman)

Substitute the following for S.B. No. 316:

By: Price C.S.S.B. No. 316

A BILL TO BE ENTITLED

AN ACT

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.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 481.003(a), Health and Safety Code, is amended to read as follows:

(a) The director may adopt rules to administer and enforce this chapter, other than Sections 481.073, 481.074, 481.075, 481.0751, 481.076, [~~and~~] 481.0761, 481.0762, 481.0763, 481.0764, and 481.0765. The board may adopt rules to administer Sections 481.073, 481.074, 481.075, 481.0751, 481.076, [~~and~~] 481.0761, 481.0762, 481.0763, 481.0764, and 481.0765.

SECTION 2. Sections 481.074(k) and (q), Health and Safety Code, are amended to read as follows:

(k) A prescription for a controlled substance must show:

(1) the quantity of the substance prescribed:

(A) numerically, followed by the number written as a word, if the prescription is written;

(B) numerically, if the prescription is electronic; or

(C) if the prescription is communicated orally or

telephonically, as transcribed by the receiving pharmacist;

(2) the date of issue;

(2-a) if the prescription is issued for a Schedule II controlled substance to be filled at a later date under Subsection (d-1), the earliest date on which a pharmacy may fill the prescription;

(3) the name, address, and date of birth or age of the patient or:

(A) [~~,~~] if the controlled substance is prescribed for an individual animal:

(i) [~~,~~] the name, species, and actual or estimated date of birth of the animal; and

(ii) the name and address of the animal's [~~its~~] owner; or

(B) if the controlled substance is prescribed for a group or herd of animals:

(i) an identifier for the group or herd and the species of the group or herd; and

(ii) the name and address of the owner of the group or herd or, if the group or herd is not owned by a person, the name and address of the client to whom the controlled substance is to be dispensed;

(4) the name and strength of the controlled substance prescribed;

(5) the directions for use of the controlled substance;

(6) the intended use of the substance prescribed

unless the practitioner determines the furnishing of this information is not in the best interest of the patient;

(7) the name, address, Federal Drug Enforcement Administration number, and telephone number of the practitioner at the practitioner's usual place of business, which must be legibly printed or stamped on a written prescription; and

(8) if the prescription is handwritten, the signature of the prescribing practitioner.

(q) Each dispensing pharmacist shall send all required information, including any information required to complete the Schedule III through V prescription forms, to the board by electronic transfer or another form approved by the board not later than the next business [~~seventh~~] day after the date the prescription is completely filled.

SECTION 3. Section 481.075(i), Health and Safety Code, is amended to read as follows:

(i) Each dispensing pharmacist shall:

(1) fill in on the official prescription form or note in the electronic prescription record each item of information given orally to the dispensing pharmacy under Subsection (h) and the date the prescription is filled, and:

(A) for a written prescription, fill in the dispensing pharmacist's signature; or

(B) for an electronic prescription, appropriately record the identity of the dispensing pharmacist in the electronic prescription record;

(2) retain with the records of the pharmacy for at

least two years:

(A) the official prescription form or the electronic prescription record, as applicable; and

(B) the name or other patient identification required by Section 481.074(m) or (n); and

(3) send all required information, including any information required to complete an official prescription form or electronic prescription record, to the board by electronic transfer or another form approved by the board not later than the next business [~~seventh~~] day after the date the prescription is completely filled.

SECTION 4. Subchapter C, Chapter 481, Health and Safety Code, is amended by adding Section 481.0751 to read as follows:

Sec. 481.0751. DISPENSING VETERINARIANS. (a) 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) Not later than the seventh day after the date the veterinarian dispenses a controlled substance, the veterinarian shall submit to the board:

(1) the name, strength, and quantity of the substance dispensed;

(2) the date the substance was dispensed;

(3) the name of the individual animal or if the substance is dispensed for a group or herd of animals, an identifier for the group or herd;

(4) the species of the animal or group or herd of animals;

(5) if the controlled substance is dispensed for an individual animal, the actual or estimated date of birth of the animal;

(6) as applicable, the name and address of:

(A) the owner of the individual animal;

(B) the owner of the group or herd; or

(C) if the controlled substance is dispensed for a group or herd that is not owned by a person, the name and address of the client to whom the controlled substance is dispensed; and

(7) the name, address, Federal Drug Enforcement Administration number, and telephone number of the veterinarian at the veterinarian's usual place of business.

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

(d) Failure to comply with this section is grounds for disciplinary action by the State Board of Veterinary Medical Examiners.

SECTION 5. Sections 481.076(a), (a-3), (a-4), (c), (d), (i), and (j), Health and Safety Code, are amended to read as follows:

(a) The board may not permit any person to have access to information submitted to the board under Section 481.074(q), [~~or~~] 481.075, or 481.0751 except:

(1) [~~an investigator for~~] the board, the Texas Medical

Board, the Texas State Board of Podiatric Medical Examiners, the State Board of Dental Examiners, the State Board of Veterinary Medical Examiners, the Texas Board of Nursing, or the Texas Optometry Board for the purpose of:

(A) investigating a specific license holder; or

(B) monitoring for potentially harmful prescribing or dispensing patterns or practices under Section 481.0762;

(2) an authorized officer or member of the department or authorized employee of the board engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

(3) the department 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) a medical examiner conducting an investigation;

(5) 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:

(A) a pharmacist or a pharmacy technician, as defined by Section 551.003, Occupations Code, acting at the direction of a pharmacist; or

(B) a practitioner who:

(i) is a physician, dentist, veterinarian, podiatrist, optometrist, or advanced practice nurse or is a

physician assistant described by Section 481.002(39)(D) or an employee or other agent of a practitioner acting at the direction of a practitioner; and

(ii) is inquiring about a recent Schedule II, III, IV, or V prescription history of a particular patient of the practitioner[~~, provided that the person accessing the information is 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~~];

(6) a pharmacist or practitioner who is inquiring about the person's own dispensing or prescribing activity; or

(7) one or more states or an association of states with which the board has an interoperability agreement, as provided by Subsection (j).

(a-3) The board shall ensure that the department has unrestricted access at all times to information submitted to the board under Sections 481.074(q), [~~and~~] 481.075, and 481.0751. The department's access to the information shall be provided through a secure electronic portal under the exclusive control of the department. The department shall pay all expenses associated with the electronic portal.

(a-4) A law enforcement or prosecutorial official described by Subsection (a)(3) may obtain information submitted to the board under Section 481.074(q), [~~or~~] 481.075, or 481.0751 only if the official submits a request to the department. If the department finds that the official has shown proper need for the information, the department shall provide access to the relevant information.

(c) The board by rule shall design and implement a system for submission of information to the board by electronic or other means and for retrieval of information submitted to the board under this section and Sections 481.074, [~~and~~] 481.075, and 481.0751. The board shall use automated information security techniques and devices to preclude improper access to the information. The board shall submit the system design to the director and the Texas Medical Board for review and comment a reasonable time before implementation of the system and shall comply with the comments of those agencies unless it is unreasonable to do so.

(d) Information submitted to the board under this section may be used only for:

(1) the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

(2) investigatory, [~~or~~] evidentiary, or monitoring purposes in connection with the functions of an agency listed in Subsection (a)(1);

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

(4) [~~(3)~~] dissemination by the board to the public in the form of a statistical tabulation or report if all information reasonably likely to reveal the identity of each patient, practitioner, or other person who is a subject of the information has been removed.

(i) Information submitted to the board under Section 481.074(q), [~~or~~] 481.075, or 481.0751 is confidential and remains

confidential regardless of whether the board permits access to the information under this section.

(j) The board may enter into an interoperability agreement with one or more states or an association of states authorizing the board to access prescription monitoring information maintained or collected by the other state or states or the association, including information maintained on a central database such as the National Association of Boards of Pharmacy Prescription Monitoring Program InterConnect. Pursuant to an interoperability agreement, the board may authorize the prescription monitoring program of one or more states or an association of states to access information submitted to the board under Sections 481.074(q), [~~and~~] 481.075, and 481.0751, including by submitting or sharing information through a central database such as the National Association of Boards of Pharmacy Prescription Monitoring Program InterConnect.

SECTION 6. Section 481.0761, Health and Safety Code, is amended by amending Subsections (a) and (c) and adding Subsections (h), (i), (j), (k), and (l) to read as follows:

(a) The board shall by rule establish and revise as necessary a standardized database format that may be used by a pharmacy to transmit the information required by Sections 481.074(q), [~~and~~] 481.075(i), and 481.0751 to the board electronically or to deliver the information on storage media, including disks, tapes, and cassettes.

(c) The board by rule may:

(1) permit more than one prescription to be administered or dispensed and recorded on one prescription form for

a Schedule III through V controlled substance;

(1-a) establish a procedure for the issuance of multiple prescriptions of a Schedule II controlled substance under Section 481.074(d-1);

(2) remove from or return to the official prescription program any aspect of a practitioner's or pharmacist's hospital practice, including administering or dispensing;

(3) waive or delay any requirement relating to the time or manner of reporting;

(4) establish compatibility protocols for electronic data transfer hardware, software, or format, including any necessary modifications for participation in a database described by Section 481.076(j);

(5) establish a procedure to control the release of information under Sections 481.074, 481.075, 481.0751, and 481.076; and

(6) establish a minimum level of prescription activity below which a reporting activity may be modified or deleted.

(h) The board, in consultation with the department and the regulatory agencies listed in Section 481.076(a)(1) shall identify potentially harmful prescribing or dispensing patterns or practices that may suggest drug diversion or drug abuse. The board shall 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) The board may, 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 may be occurring or that drug diversion or drug abuse may be occurring.

(j) The board by rule may develop guidelines identifying patterns that may indicate that a particular patient to whom a controlled substance is prescribed or dispensed is engaging in drug diversion or drug abuse. These guidelines may 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. The board may, 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 diversion or drug abuse.

(k) The board by rule may develop guidelines identifying additional behavior that would suggest that drug diversion or drug abuse is occurring. 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 shall access the information under Section 481.076(a)(5) regarding the patient for whom the prescription for the controlled substance was issued.

(l) If the board finds that the electronic system used by the board in maintaining the information under Section 481.076 requires data elements that cannot be provided for a prescription or dispensation of a controlled substance to a group or herd of

animals, the board, in consultation with the State Board of Veterinary Medical Examiners, shall adopt rules relating to the specific format in which a person may enter or submit those data elements with respect to the group or herd.

SECTION 7. Subchapter C, Chapter 481, Health and Safety Code, is amended by adding Sections 481.0762, 481.0763, 481.0764, and 481.0765 to read as follows:

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

(b) A regulatory agency that issues a license, certification, or registration to a prescriber shall periodically access the information submitted to the board 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) The State Board of Veterinary Medical Examiners shall periodically access the information submitted to the board 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) If the board sends a prescriber or dispensing veterinarian an electronic notification authorized under Section 481.0761(i), the board shall immediately send an electronic

notification to the appropriate regulatory agency.

(e) In determining whether a potentially harmful prescribing or dispensing pattern or practice is occurring, the appropriate regulatory agency, at a minimum, shall 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 the board.

(f) 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, the regulatory agency may notify that prescriber.

(g) A regulatory agency may 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. A regulatory agency that issues a license, certification, or registration to a prescriber or dispenser shall provide the board 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) A person authorized to receive information under Section 481.076(a)(5) shall access that information with respect to the patient before prescribing or dispensing opioids, benzodiazepines, barbiturates, or carisoprodol.

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

(c) A veterinarian subject to this section is required to access the information for prescriptions dispensed only for the animals of an owner and may not consider the personal prescription history of the owner.

(d) 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 the violation.

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

Sec. 481.0765. EXCEPTIONS. (a) A prescriber is not subject to the requirements of Section 481.0764(a) if:

(1) the patient has been diagnosed with cancer or the patient is receiving hospice care; and

(2) the prescriber clearly notes in the prescription record that the patient was diagnosed with cancer or is receiving hospice care, as applicable.

(b) 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) A prescriber is not subject to the requirements of Section 481.0764(a) if:

(1) the prescription is for a controlled substance in a quantity not to exceed a five-day supply;

(2) the prescription does not authorize any refills;

(3) the prescription is issued:

(A) pursuant to a patient's emergency medical condition; or

(B) following the patient's surgical procedure; and

(4) the prescriber clearly notes in the prescription record that the prescription was issued pursuant to the patient's emergency medical condition or following the patient's surgical procedure, as applicable.

(d) A dispenser is not subject to the requirements of Section 481.0764(a) if:

(1) the prescription is for a controlled substance in a quantity not to exceed a five-day supply;

(2) the prescription does not authorize any refills; and

(3) it is clearly noted in the prescription record that the prescription was issued pursuant to a patient's emergency medical condition or following a patient's surgical procedure, as

applied.

(e) 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 8. Section 481.127(a), Health and Safety Code, is amended to read as follows:

(a) A person commits an offense if the person knowingly gives, permits, or obtains unauthorized access to information submitted to the board under Section 481.074(q), [~~or~~] 481.075, or 481.0751.

SECTION 9. Section 554.051(a-1), Occupations Code, is amended to read as follows:

(a-1) The board may adopt rules to administer Sections 481.073, 481.074, 481.075, 481.0751, 481.076, [~~and~~] 481.0761, 481.0762, 481.0763, 481.0764, and 481.0765, Health and Safety Code.

SECTION 10. (a) A joint interim committee is created to conduct an interim study on the monitoring of the prescribing and dispensing of controlled substances in this state.

(b) The joint interim committee shall be composed of three senators appointed by the lieutenant governor and three members of the house of representatives appointed by the speaker of the house of representatives.

(c) The lieutenant governor and speaker of the house of representatives shall each designate a co-chair from among the

joint interim committee members.

(d) The joint interim committee shall convene at the joint call of the co-chairs.

(e) The joint interim committee has all other powers and duties provided to a special or select committee by the rules of the senate and house of representatives, by Subchapter B, Chapter 301, Government Code, and by policies of the senate and house committees on administration.

(f) The interim study conducted by the joint interim committee must:

(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 use and effectiveness of electronic notifications sent to prescribers and dispensers under Sections 481.0761(i) and (j), Health and Safety Code, as added by this Act;

(6) evaluate the use and effectiveness of identifying geographic anomalies in comparing delivery and dispensing data;

(7) evaluate the integration of any new data elements required to be reported under this Act, including information from veterinarians regarding controlled substances prescribed or dispensed for animals;

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

(9) 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

(10) 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.

(g) The committee shall solicit feedback from regulatory agencies, prescribers, dispensers, and patients affected by the passage of this Act.

(h) The committee shall 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.

(i) Subject to available resources, the Texas Legislative Council shall provide legal and policy research, drafts of proposed

legislation, and statistical analysis services to the joint interim committee for the purpose of the study required under this section.

(j) Notwithstanding Section 481.076, Health and Safety Code, as amended by this Act, or any other law relating to access to or disclosure of prescription drug information maintained by the Texas State Board of Pharmacy, the Texas State Board of Pharmacy shall disclose any information maintained by the board under Section 481.076, Health and Safety Code, to the Texas Legislative Council on request of the council for the purpose of assisting with the study required under this section.

(k) Not later than November 1, 2017, the lieutenant governor and speaker of the house of representatives shall appoint the members of the joint interim committee in accordance with this section.

(l) The joint interim committee created under this section is abolished and this section expires January 2, 2019.

SECTION 11. (a) Notwithstanding Section 481.0751(b), Health and Safety Code, as added by this Act:

(1) a veterinarian who dispenses a controlled substance before January 1, 2018, is not required to submit the information under that subsection to the Texas State Board of Pharmacy; and

(2) a veterinarian who dispenses a controlled substance on or after January 1, 2018, but before September 1, 2019, is required to submit the information under that subsection to the Texas State Board of Pharmacy not later than the 30th day after the date the veterinarian dispenses the controlled substance.

(b) A veterinarian who dispenses a controlled substance on or after September 1, 2019, is required to comply with Section 481.0751(b), Health and Safety Code, as added by this Act.

SECTION 12. A person is not required to comply with Section 481.0761(k), Health and Safety Code, as added by this Act, before September 1, 2019.

SECTION 13. 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 controlled substance on or after September 1, 2019; or

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

SECTION 14. This Act takes effect September 1, 2017.