By:  Sheffield, et al. (Senate Sponsor - Nelson) H.B. No. 3284

(In the Senate - Received from the House May 13, 2019; May 14, 2019, read first time and referred to Committee on Health & Human Services; May 20, 2019, reported adversely, with favorable Committee Substitute by the following vote: Yeas 9, Nays 0; May 20, 2019, sent to printer.)

COMMITTEE VOTE

                 Yea Nay Absent  PNV

Kolkhorst         X

Perry             X

Buckingham        X

Campbell          X

Flores            X

Johnson           X

Miles             X

Powell            X

Seliger           X

COMMITTEE SUBSTITUTE FOR H.B. No. 3284 By:  Perry

A BILL TO BE ENTITLED

AN ACT

relating to prescribing and dispensing controlled substances and monitoring the prescribing and dispensing of controlled substances under the Texas Controlled Substances Act; authorizing a fee; providing for administrative penalties; creating criminal offenses.

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

SECTION 1.  Subchapter C, Chapter 481, Health and Safety Code, is amended by adding Section 481.0755 to read as follows:

Sec. 481.0755.  WRITTEN, ORAL, AND TELEPHONICALLY COMMUNICATED PRESCRIPTIONS. (a) Notwithstanding Sections 481.073, 481.074, and 481.075, a person prescribing or dispensing a controlled substance must use the electronic prescription record and may not use a written, oral, or telephonically communicated prescription.

(b)  A prescriber may 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 board rule;

(3)  by a practitioner to be dispensed by a pharmacy located outside this state, as prescribed by board 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, 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)  The board shall 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. The board shall 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)  A written, oral, or telephonically communicated prescription must comply with the applicable requirements prescribed by Sections 481.074 and 481.075.

(e)  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)  The board shall enforce this section.

SECTION 2.  Section 481.076, Health and Safety Code, is amended by amending Subsections (a), (f), (g), and (h) and adding Subsection (a-6) 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 except:

(1)  the board, the Texas Medical Board, the Texas Department of Licensing and Regulation, with respect to the regulation of podiatrists [~~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 or other [~~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, if the board is provided a warrant, subpoena, or other court order compelling the disclosure;

(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;

(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);

(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), Estates Code, inquiring about the patient's prescription record, including persons who have accessed that record.

(a-6)  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, is entitled to a copy of the patient's prescription record as provided by Subsection (a)(9), including a list of persons who have accessed that record, if a completed patient data request form and any supporting documentation required by the board is submitted to the board. The board may charge a reasonable fee for providing the copy. The board shall 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)  If the board accesses [~~director permits access to~~] information under Subsection (a)(2) relating to a person licensed or regulated by an agency listed in Subsection (a)(1), the board [~~director~~] shall notify and cooperate with that agency regarding the disposition of the matter before taking action against the person, unless the board [~~director~~] determines that notification is reasonably likely to interfere with an administrative or criminal investigation or prosecution.

(g)  If the board provides [~~director permits~~] access to information under Subsection (a)(3) relating to a person licensed or regulated by an agency listed in Subsection (a)(1), the board [~~director~~] shall notify that agency of the disclosure of the information not later than the 10th working day after the date the information is disclosed.

(h)  If the board [~~director~~] withholds notification to an agency under Subsection (f), the board [~~director~~] shall notify the agency of the disclosure of the information and the reason for withholding notification when the board [~~director~~] determines that notification is no longer likely to interfere with an administrative or criminal investigation or prosecution.

SECTION 3.  Section 481.0766, Health and Safety Code, is amended by adding Subsection (c) to read as follows:

(c)  The board shall make the information reported under Subsection (a) available to the State Board of Veterinary Medical Examiners for the purpose of routine inspections and investigations.

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

Sec. 481.0767.  ADVISORY COMMITTEE. (a) The board shall establish an advisory committee to make recommendations regarding information submitted to the board and access to that information under Sections 481.074, 481.075, 481.076, and 481.0761, 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 board or the access to that information.

(b)  The board shall appoint the following members to the advisory committee:

(1)  a physician licensed in this state who practices in pain management;

(2)  a physician licensed in this state who practices in family medicine;

(3)  a physician licensed in this state who performs surgery;

(4)  a physician licensed in this state who practices in emergency medicine at a hospital;

(5)  a physician licensed in this state who practices in psychiatry;

(6)  an oral and maxillofacial surgeon;

(7)  a physician assistant or advanced practice registered nurse to whom a physician has delegated the authority to prescribe or order a drug;

(8)  a pharmacist working at a chain pharmacy;

(9)  a pharmacist working at an independent pharmacy;

(10)  an academic pharmacist; and

(11)  two representatives of the health information technology industry, at least one of whom is a representative of a company whose primary line of business is electronic medical records.

(c)  Members of the advisory committee serve three-year terms. Each member shall serve until the member's replacement has been appointed.

(d)  The advisory committee shall annually elect a presiding officer from its members.

(e)  The advisory committee shall meet at least two times a year and at the call of the presiding officer or the board.

(f)  A member of the advisory committee serves without compensation but may be reimbursed by the board for actual expenses incurred in performing the duties of the advisory committee.

Sec. 481.0768.  ADMINISTRATIVE PENALTY: DISCLOSURE OR USE OF INFORMATION. (a) A person authorized to receive information under Section 481.076(a) may not disclose or use the information in a manner not authorized by this subchapter or other law.

(b)  A regulatory agency that issues a license, certification, or registration to a prescriber or dispenser shall periodically update the administrative penalties, or any applicable disciplinary guidelines concerning the penalties, assessed by that agency for conduct that violates Subsection (a).

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

Sec. 481.0769.  CRIMINAL OFFENSES RELATED TO PRESCRIPTION INFORMATION. (a) 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)  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)  An offense under Subsection (a) is a Class A misdemeanor.

(d)  An offense under Subsection (b) is a Class C misdemeanor.

SECTION 5.  Section 801.307, Occupations Code, is amended by adding Subsection (a-1) to read as follows:

(a-1)  The board by rule shall 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.  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, 481.0755, 481.076, 481.0761, 481.0762, 481.0763, 481.0764, 481.0765, [~~and~~] 481.0766, 481.0767, 481.0768, and 481.0769. The board may adopt rules to administer Sections 481.073, 481.074, 481.075, 481.0755, 481.076, 481.0761, 481.0762, 481.0763, 481.0764, 481.0765, [~~and~~] 481.0766, 481.0767, 481.0768, and 481.0769.

SECTION 7.  Section 481.128(a), Health and Safety Code, is amended to read as follows:

(a)  A registrant or dispenser commits an offense if the registrant or dispenser knowingly:

(1)  distributes, delivers, administers, or dispenses a controlled substance in violation of Subchapter C [~~Sections 481.070-481.075~~];

(2)  manufactures a controlled substance not authorized by the person's Federal Drug Enforcement Administration registration or distributes or dispenses a controlled substance not authorized by the person's registration to another registrant or other person;

(3)  refuses or fails to make, keep, or furnish a record, report, notification, order form, statement, invoice, or information required by this chapter;

(4)  prints, manufactures, possesses, or produces an official prescription form without the approval of the board;

(5)  delivers or possesses a counterfeit official prescription form;

(6)  refuses an entry into a premise for an inspection authorized by this chapter;

(7)  refuses or fails to return an official prescription form as required by Section 481.075(k);

(8)  refuses or fails to make, keep, or furnish a record, report, notification, order form, statement, invoice, or information required by a rule adopted by the director or the board; or

(9)  refuses or fails to maintain security required by this chapter or a rule adopted under this chapter.

SECTION 8.  Section 481.129(a), Health and Safety Code, is amended to read as follows:

(a)  A person commits an offense if the person knowingly:

(1)  distributes as a registrant or dispenser a controlled substance listed in Schedule I or II, unless the person distributes the controlled substance as authorized under the federal Controlled Substances Act (21 U.S.C. Section 801 et seq.);

(2)  uses in the course of manufacturing, prescribing, or distributing a controlled substance a Federal Drug Enforcement Administration registration number that is fictitious, revoked, suspended, or issued to another person;

(3)  issues a prescription bearing a forged or fictitious signature;

(4)  uses a prescription issued to another person to prescribe a Schedule II controlled substance;

(5)  possesses, obtains, or attempts to possess or obtain a controlled substance or an increased quantity of a controlled substance:

(A)  by misrepresentation, fraud, forgery, deception, or subterfuge;

(B)  through use of a fraudulent prescription form; [~~or~~]

(C)  through use of a fraudulent oral or telephonically communicated prescription; or

(D)  through the use of a fraudulent electronic prescription; or

(6)  furnishes false or fraudulent material information in or omits material information from an application, report, record, or other document required to be kept or filed under this chapter.

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, 481.0755, 481.076, 481.0761, 481.0762, 481.0763, 481.0764, 481.0765, [~~and~~] 481.0766, 481.0767, 481.0768, and 481.0769, Health and Safety Code.

SECTION 10.  Section 565.003, Occupations Code, is amended to read as follows:

Sec. 565.003.  ADDITIONAL GROUNDS FOR DISCIPLINE REGARDING APPLICANT FOR OR HOLDER OF NONRESIDENT PHARMACY LICENSE. Unless compliance would violate the pharmacy or drug statutes or rules in the state in which the pharmacy is located, the board may discipline an applicant for or the holder of a nonresident pharmacy license if the board finds that the applicant or license holder has failed to comply with:

(1)  Subchapter C, Chapter 481 [~~Section 481.074 or 481.075~~], Health and Safety Code;

(2)  Texas substitution requirements regarding:

(A)  the practitioner's directions concerning generic substitution;

(B)  the patient's right to refuse generic substitution; or

(C)  notification to the patient of the patient's right to refuse substitution;

(3)  any board rule relating to providing drug information to the patient or the patient's agent in written form or by telephone; or

(4)  any board rule adopted under Section 554.051(a) and determined by the board to be applicable under Section 554.051(b).

SECTION 11.  Sections 481.076(a-3), (a-4), and (a-5), Health and Safety Code, are repealed.

SECTION 12.  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.  Notwithstanding Section 24, Chapter 485 (H.B. 2561), Acts of the 85th Legislature, Regular Session, 2017, Section 481.0764(a), Health and Safety Code, as added by that Act, applies only to:

(1)  a prescriber, other than a veterinarian, who issues a prescription for a controlled substance on or after March 1, 2020; or

(2)  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.  Section 481.0755, Health and Safety Code, as added by this Act, applies only to a prescription issued on or after the effective date of this Act.

SECTION 15.  Section 481.0768(a), Health and Safety Code, as added by this Act, applies only to conduct that occurs on or after the effective date of this Act.

SECTION 16.  Section 801.307(a-1), Occupations Code, as added by this Act, applies only to the renewal of a license to practice veterinary medicine on or after September 1, 2020. The renewal of a license before that date is governed by the law in effect immediately before the effective date of this Act, and the former law is continued in effect for that purpose.

SECTION 17.  This Act takes effect September 1, 2019.

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