A BILL TO BE ENTITLED 1 AN ACT 2 relating to prescribing and dispensing controlled substances and monitoring the prescribing and dispensing of controlled substances 3 under the Texas Controlled Substances Act; providing 4 for 5 administrative penalties. BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS: 6 7 SECTION 1. Subchapter C, Chapter 481, Health and Safety Code, is amended by adding Sections 481.0751 and 481.0755 to read as 8 9 follows: 10 Sec. 481.0751. DISPENSING VETERINARIANS. (a) This section applies to a veterinarian who holds a registration issued by the 11 12 Federal Drug Enforcement Administration and dispenses Schedule II, III, IV, or V controlled substances directly to the owner or handler 13 of an animal. 14 (b) Not later than the 30th day after the date the 15 16 veterinarian dispenses a controlled substance, the veterinarian shall submit to the board: 17 18 (1) the name, strength, and quantity of the substance dispensed; 19 20 (2) the date the substance was dispensed; 21 (3) the name of the animal; 22 (4) the species, gender, and actual or estimated date 23 of birth of the animal; 24 (5) the name and address of the animal's owner; and

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1 (6) the name, address, Federal Drug Enforcement 2 Administration number, and telephone number of the veterinarian at the veterinarian's usual place of business. 3 4 (c) A veterinarian shall retain a record of the information 5 submitted to the board under Subsection (b) for a period of not less than two years after the date the substance is dispensed. 6 7 (d) Failure to comply with this section is grounds for disciplinary action by the State Board of Veterinary Medical 8 Examiners. 9 10 Sec. 481.0755. WRITTEN, ORAL, AND TELEPHONICALLY COMMUNICATED PRESCRIPTIONS. (a) Notwithstanding Sections 11 12 481.073, 481.074, and 481.075, a person prescribing or dispensing a controlled substance must use the electronic prescription record 13 14 and may not use a written, oral, or telephonically communicated 15 prescription. 16 (b) A prescriber may issue a written, oral, or telephonically communicated prescription for a controlled 17 substance as authorized under this subchapter only if the 18 19 prescription is issued: 20 (1) by a veterinarian; 21 (2) in circumstances in which electronic prescribing is not available due to temporary technological or electronic 22 23 failure, as prescribed by board rule; 24 (3) by a practitioner to be dispensed by a pharmacy 25 located outside this state, as prescribed by board rule; 26 (4) when the prescriber and dispenser are the same 27 entity;

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1	(5) in circumstances in which necessary elements are
2	not supported by the most recent electronic prescription drug
3	<pre>software;</pre>
4	(6) for a drug for which the United States Food and
5	Drug Administration requires additional information in the
6	prescription that is not possible with electronic prescribing;
7	(7) for a non-patient-specific prescription pursuant
8	to a standing order, approved protocol for drug therapy,
9	collaborative drug management, or comprehensive medication
10	management, in response to a public health emergency or in other
11	circumstances in which the practitioner may issue a
12	non-patient-specific prescription;
13	(8) for a drug under a research protocol;
14	(9) by a practitioner who has received a waiver under
15	Subsection (c) from the requirement to use electronic prescribing;
16	or
17	(10) under circumstances in which the practitioner has
18	the present ability to submit an electronic prescription but
19	reasonably determines that it would be impractical for the patient
20	to obtain the drugs prescribed under the electronic prescription in
21	a timely manner and that a delay would adversely impact the
22	patient's medical condition.
23	(c) The board shall adopt rules establishing a process by
24	which a practitioner may request and receive a waiver under
25	Subsection (b)(9), not to exceed one year, from the requirement to
26	use electronic prescribing. The board shall adopt rules
27	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. Sections 481.076(a), (f), (g), and (h), 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 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

1 481.0762;

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

(3) the department <u>or other</u> [on behalf of a] 6 law 7 enforcement prosecutorial official engaged or in the administration, investigation, or enforcement of this chapter or 8 another law governing illicit drugs in this state or another state, 9 if the board is provided a warrant, subpoena, or other court order 10 compelling the disclosure; 11

12 (4) a medical examiner conducting an investigation; 13 (5) provided that accessing the information is 14 authorized under the Health Insurance Portability and 15 Accountability Act of 1996 (Pub. L. No. 104-191) and regulations adopted under that Act: 16

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

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(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

26 (ii) is inquiring about a recent Schedule27 II, III, IV, or V prescription history of a particular patient of

1 the practitioner;

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

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

7 (8) a health care facility certified by the federal
8 Centers for Medicare and Medicaid Services.

9 (f) If the board accesses [director permits access to] 10 information under Subsection (a)(2) relating to a person licensed or regulated by an agency listed in Subsection (a)(1), the board 11 [director] shall notify and cooperate with that agency regarding 12 the disposition of the matter before taking action against the 13 14 person, unless the board [director] determines that notification is 15 reasonably likely to interfere with an administrative or criminal investigation or prosecution. 16

(g) If the <u>board provides</u> [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 <u>board</u> [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.

23 (h) If the board [director] withholds notification to an 24 agency under Subsection (f), the board [director] shall notify the agency of the disclosure of the information and the reason for 25 26 withholding notification when the board [director] determines that notification is longer likely to interfere with 27 no an

1 administrative or criminal investigation or prosecution.

2 SECTION 3. Subchapter C, Chapter 481, Health and Safety 3 Code, is amended by adding Sections 481.07635, 481.07655, and 4 481.0768 to read as follows:

5 <u>Sec. 481.07635. PRESCRIPTIONS OF OPIOIDS. (a)</u> In this 6 <u>section, "acute pain" means pain with abrupt onset that is caused by</u> 7 <u>an injury or other process that is not ongoing.</u>

8 (b) For the initial treatment of acute pain, a prescriber 9 may not issue a prescription for an opioid in an amount that exceeds 10 a 14-day supply.

Sec. 481.07655. LIMITATION OF LIABILITY. (a) A prescriber 11 12 or dispenser is not liable in a civil action for damages arising from the failure to access prescription drug information as 13 required or authorized by Section 481.0764 or failure to submit the 14 information to the board as required under Section 481.074(q) or 15 481.075, unless the failure constitutes gross negligence or wilful 16 17 misconduct and the prescriber or dispenser would be liable to the claimant under other law. 18

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(b) This section does not establish a standard of care.

20 <u>Sec. 481.0768. ADMINISTRATIVE PENALTY: DISCLOSURE OR USE</u> 21 <u>OF INFORMATION. (a) A person authorized to receive information</u> 22 <u>under Section 481.076(a) may not disclose or use the information in</u> 23 <u>a manner not authorized by this subchapter or other law.</u>

(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,

1 assessed by that agency for conduct that violates Subsection (a).

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

4 SECTION 4. Section 481.003(a), Health and Safety Code, is 5 amended to read as follows:

6 (a) The director may adopt rules to administer and enforce 7 this chapter, other than Sections 481.073, 481.074, 481.075, 481.076, 481.0761, 481.0762, 481.0763, <u>481.07635</u>, 481.0764, 8 481.0765, 481.07655, [and] 481.0766, and 481.0768. The board may 9 adopt rules to administer Sections 481.073, 481.074, 481.075, 10 <u>481.0751, 481.0755,</u> 481.076, 481.0761, 481.0762, 481.0763, 11 481.07635, 481.0764, 481.0765, 481.07655, [and] 481.0766, and 12 13 481.0768.

SECTION 5. Section 481.128(a), Health and Safety Code, is amended to read as follows:

16 (a) A registrant or dispenser commits an offense if the17 registrant or dispenser knowingly:

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

(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;

26 (3) refuses or fails to make, keep, or furnish a
27 record, report, notification, order form, statement, invoice, or

1 information required by this chapter;

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

4 (5) delivers or possesses a counterfeit official5 prescription form;

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

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

10 (8) refuses or fails to make, keep, or furnish a 11 record, report, notification, order form, statement, invoice, or 12 information required by a rule adopted by the director or the board; 13 or

14 (9) refuses or fails to maintain security required by15 this chapter or a rule adopted under this chapter.

SECTION 6. Section 481.129(a), Health and Safety Code, is amended to read as follows:

18 (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;

27 (3) issues a prescription bearing a forged or

1 fictitious signature;

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

4 (5) possesses, obtains, or attempts to possess or 5 obtain a controlled substance or an increased quantity of a 6 controlled substance:

7 (A) by misrepresentation, fraud, forgery,8 deception, or subterfuge;

9 (B) through use of a fraudulent prescription 10 form; [or]

11 (C) through use of a fraudulent oral or 12 telephonically communicated prescription; or

13(D) through the use of a fraudulent electronic14prescription; 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 7. Section 554.051(a-1), Occupations Code, is amended to read as follows:

21 (a-1) The board may adopt rules to administer Sections
22 481.073, 481.074, 481.075, <u>481.0751, 481.0755</u>, 481.076, 481.0761,
23 481.0762, 481.0763, <u>481.07635</u>, 481.0764, 481.0765, <u>481.07655</u>,
24 [and] 481.0766, and 481.0768, Health and Safety Code.

25 SECTION 8. Section 565.003, Occupations Code, is amended to 26 read as follows:

27 Sec. 565.003. ADDITIONAL GROUNDS FOR DISCIPLINE REGARDING

1 APPLICANT FOR OR HOLDER OF NONRESIDENT PHARMACY LICENSE. Unless 2 compliance would violate the pharmacy or drug statutes or rules in 3 the state in which the pharmacy is located, the board may discipline 4 an applicant for or the holder of a nonresident pharmacy license if 5 the board finds that the applicant or license holder has failed to 6 comply with:

7 (1) Section <u>481.073</u>, 481.074, [or] 481.075, <u>481.0751</u>,
8 <u>481.0755</u>, <u>481.076</u>, <u>481.0761</u>, <u>481.0762</u>, <u>481.0763</u>, <u>481.07635</u>,
9 <u>481.0764</u>, <u>481.0765</u>, <u>481.07655</u>, <u>481.0766</u>, or <u>481.0768</u>, Health and
10 Safety Code;

11 (2) Texas substitution requirements regarding: 12 (A) the practitioner's directions concerning 13 generic substitution;

14 (B) the patient's right to refuse generic15 substitution; or

16 (C) notification to the patient of the patient's 17 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)
22 and determined by the board to be applicable under Section
23 554.051(b).

24 SECTION 9. Sections 481.076(a-3), (a-4), and (a-5), Health 25 and Safety Code, are repealed.

26 SECTION 10. To the extent of any conflict, this Act prevails 27 over another Act of the 86th Legislature, Regular Session, 2019,

relating to nonsubstantive additions to and corrections in enacted
 codes.

3 SECTION 11. Section 481.0751, Health and Safety Code, as 4 added by this Act, applies only to a controlled substance dispensed 5 on or after the effective date of this Act.

6 SECTION 12. Sections 481.0755, 481.07635, and 481.07655, 7 Health and Safety Code, as added by this Act, apply only to a 8 prescription issued on or after the effective date of this Act.

9 SECTION 13. Section 481.0768(a), Health and Safety Code, as 10 added by this Act, applies only to conduct that occurs on or after 11 the effective date of this Act.

12 SECTION 14. This Act takes effect September 1, 2019.