1-1 By: Sheffield, et al. (Senate Sponsor - Nelson) H.B. No. 3284 1-2 (In the Senate - Received from the House May 13, 2019; 1-3 May 14, 2019, read first time and referred to Committee on Health & 1-4 Human Services; May 20, 2019, reported adversely, with favorable 1-5 Committee Substitute by the following vote: Yeas 9, Nays 0; 1-6 May 20, 2019, sent to printer.)

1-19

1-20

COMMITTEE VOTE

1-8		Yea	Nay	Absent	PNV
1-9	Kolkhorst	Х			
1-10	Perry	Х			
1-11	Buckingham	Х			
1-12	Campbell	Х			
1-13	Flores	Х			
1-14	Johnson	Х			
1-15	Miles	Х			
1-16	Powell	Х			
1-17	Seliger	Х			
1-18	COMMITTEE SUBSTITUTE FOR	H B No	3284		Вy

By: Perry

A BILL TO BE ENTITLED AN ACT

1-21	relating to prescribing and dispensing controlled substances and
1-22	monitoring the prescribing and dispensing of controlled substances
1-23	under the Texas Controlled Substances Act; authorizing a fee;
1-24	providing for administrative penalties; creating criminal
1-25	offenses.
1-26	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
1-27	SECTION 1. Subchapter C, Chapter 481, Health and Safety
1-28	Code, is amended by adding Section 481.0755 to read as follows:
1-29	Sec. 481.0755. WRITTEN, ORAL, AND TELEPHONICALLY
1-30	COMMUNICATED PRESCRIPTIONS. (a) Notwithstanding Sections
1-31	COMMUNICATED PRESCRIPTIONS. (a) Notwithstanding Sections 481.073, 481.074, and 481.075, a person prescribing or dispensing a
1-32	controlled substance must use the electronic prescription record
1-33	and may not use a written, oral, or telephonically communicated
1-34	prescription.
1-35	(b) A prescriber may issue a written, oral, or
1-36	telephonically communicated prescription for a controlled
1-37	substance as authorized under this subchapter only if the
1-38	prescription is issued:
1-39	<pre>(1) by a veterinarian;</pre>
1-40	(2) in circumstances in which electronic prescribing
1-41	is not available due to temporary technological or electronic
1-42	failure, as prescribed by board rule;
1-43	(3) by a practitioner to be dispensed by a pharmacy
1-44	located outside this state, as prescribed by board rule;
1-45	(4) when the prescriber and dispenser are the same
1-46	entity;
1-47	(5) in circumstances in which necessary elements are
1-48	not supported by the most recent electronic prescription drug
1-49	software;
1-50	(6) for a drug for which the United States Food and
1-51	Drug Administration requires additional information in the
1-52	prescription that is not possible with electronic prescribing;
1-53	(7) for a non-patient-specific prescription pursuant
1-54	to a standing order, approved protocol for drug therapy, collaborative drug management, or comprehensive medication
1-55	collaborative drug management, or comprehensive medication
1-56	management, in response to a public health emergency or in other
1-57	circumstances in which the practitioner may issue a
1-58	non-patient-specific prescription;
1-59	(8) for a drug under a research protocol;
1-60	(9) by a prescriber who is employed by or is practicing

(9) by a prescriber who is employed by or is practicing

C.S.H.B. No. 3284 profession at a health-related institution, 2 - 1health care as defined by Section 62.161, Education Code, as added by Chapter 448 (H.B. 7), Acts of the 84th Legislature, 2015; 2-2 2-3 2-4 (10)by a practitioner who has received a waiver under Subsection (c) from the requirement to use electronic prescribing; 2-5 2-6 or 2-7 (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 2-8 2-9 to obtain the drugs prescribed under the electronic prescription in a timely manner and that a delay would adversely impact the 2-10 2-11 patient's medical condition. 2-12 2-13 The board shall adopt rules establishing a process by (c) which a practitioner may request and receive a waiver under Subsection (b)(10), not to exceed one year, from the requirement to 2-14 2**-**15 2**-**16 The board shall adopt use electronic prescribing. rules 2-17 establishing the eligibility for a waiver, including: (1) economic hardship; 2-18 technological limitations not reasonably within 2-19 (2) 2-20 2-21 the control of the practitioner; or (3) other exceptional circumstances demonstrated by 2-22 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 2-23 2-24 2-25 2-26 2-27 2-28 required to verify that the prescription is exempt from the requirement that it be submitted electronically. 2-29 (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 2-30 2-31 2-32 2-33 Subsection (a-6) to read as follows: 2-34 (a) The board may not permit any person to have access to 2-35 information submitted to the board under Section 481.074(q) or 2-36 481.075 except: 2-37 the board, the Texas Medical Board, the Texas (1)Licensing and Regulation, with respect to the 2-38 of Department podiatrists [State Board of Podiatric 2-39 regulation of Medical Examiners], 2-40 the State Board of Dental Examiners, the State Board of Veterinary Medical Examiners, the Texas Board of Nursing, or the 2-41 2-42 Texas Optometry Board for the purpose of: 2-43 (A) investigating a specific license holder; or 2-44 (B) monitoring for potentially harmful 2-45 prescribing or dispensing patterns or practices under Section 2-46 481.0762; 2-47 an [authorized officer or member of the department (2) 2-48 or] authorized employee of the board engaged in the administration, 2-49 investigation, or enforcement of this chapter or another law 2-50 governing illicit drugs in this state or another state; (3) the department <u>or other</u> [on behalf or prosecutorial official engaged 2-51 of _a] law 2-52 enforcement official engaged in the 2-53 administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state, 2-54 if the board is provided a warrant, subpoena, or other court order compelling the disclosure; 2-55 2-56 2-57 (4) a medical examiner conducting an investigation; 2-58 (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 2-59 2-60 2-61 adopted under that Act: 2-62 a pharmacist or a pharmacy technician, as (A)

defined by Section 551.003, Occupations Code, acting at the 2-63 direction of a pharmacist; or 2-64 2-65 (B)

a practitioner who:

2-66 (i) is a physician, dentist, veterinarian, 2-67 podiatrist, optometrist, or advanced practice nurse or is a physician assistant described by Section 481.002(39)(D) or an 2-68 employee or other agent of a practitioner acting at the direction of 2-69

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3-1 a practitioner; and 3-2 (ii) is inquiring about a recent Schedule 3-3 II, III, IV, or V prescription history of a particular patient of 3-4 the practitioner; 3-5 (6) a pharmacist or practitioner who is inquiring about the person's own dispensing or prescribing activity; [or] 3-6 3-7 (7) one or more states or an association of states with 3-8 which the board has an interoperability agreement, as provided by Subsection (j); 3-9 3-10 (8)a health care facility certified by the federal 3-11 Centers for Medicare and Medicaid Services; or 3-12 (9) the patient, the patient's parent legal or guar<u>dian</u>, legal 3-13 if the patient is a minor, or the patient's 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 3-14 3**-**15 3**-**16 3-17 <u>record</u>. 3-18 A patient, the patient's parent or legal guardian, (a-6) patient is a minor, or the patient's legal guardian, if the lent is an incapacitated person, as defined by Section 2.017(2), Estates Code, is entitled to a copy of the patient's 3-19 the 3-20 3-21 <u>pati</u>ent 1002.017(2), prescription record as provided by Subsection (a)(9), including a 3-22 list of persons who have accessed that record, if a completed 3-23 patient data request form and any supporting documentation required 3-24 by the board is submitted to the board. The board may charge a reasonable fee for providing the copy. The board shall adopt rules 3-25 3**-**26 to implement this subsection, including rules prescribing the 3-27 3-28 patient data request form, listing the documentation required for receiving a copy of the prescription record, and setting the fee. 3-29 (f) If the <u>board accesses</u> [$\frac{director permits access to}{director permits access to}$] information under Subsection (a)(2) relating to a person licensed 3-30 3-31 or regulated by an agency listed in Subsection $(a\bar{)}(1)$, the <u>board</u> 3-32 [director] shall notify and cooperate with that agency regarding 3-33 the disposition of the matter before taking action against the person, unless the <u>board</u> [director] determines that notification is reasonably likely to interfere with an administrative or criminal 3-34 3-35 3-36 investigation or prosecution. 3-37 3-38 (g) If the <u>board provides</u> [director permits] access to information under Subsection (a)(3) relating to a person licensed 3-39 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 3-40 3-41 3-42 3-43 information is disclosed. (h) If the <u>board</u> [director] withholds notification to an agency under Subsection (f), the <u>board</u> [director] shall notify the agency of the disclosure of the information and the reason for 3-44 3-45 3-46 withholding notification when the <u>board</u> [director] determines that 3-47 3-48 likely to interfere notification is no longer with an 3-49 administrative or criminal investigation or prosecution. SECTION 3. Section 481.0766, Health and Safety Code, 3-50 is 3-51 amended by adding Subsection (c) to read as follows: 3-52 (c) The board shall make the information reported under 3-53 Subsection (a) available to the State Board of Veterinary Medical 3-54 Examiners for the purpose of routine inspections and 3-55 investigations. 3-56 SECTION 4. Subchapter C, Chapter 481, Health and Safety 3-57 is amended by adding Sections 481.0767, 481.0768, Code, and 3-58 481.0769 to read as follows: 3-59 Sec. 481.0767. ADVISORY COMMITTEE. (a) The b<u>oard shall</u> establish an advisory committee to make recommendations regarding information submitted to the board and access to that information 3-60 3-61 under Sections 481.074, 481.075, 481.076, and 481.0761, including 3-62 3-63 recommendations for: 3-64 (1) operational improvements to the electronic system that stores the information, including implementing best practices and improvements that address system weaknesses and workflow 3-65 3-66 challenges; 3-67 (2)3-68 resolutions to identified data concerns; (3) methods to improve data accuracy, integrity, and 3-69

C.S.H.B. No. 3284 security and to reduce technical difficulties; 4-1 and (4) the addition of any new data set or service to the 4-2 submitted to the 4-3 the board or information access to that 4-4 information. The board shall appoint the following members to the 4-5 (b) 4-6 advisory committee: 4-7 (1) a physician licensed in this state who practices in pain management; 4-8 4-9 (2) a physician licensed in this state who practices 4-10 4-11 in family medicine; (3) a physician licensed in this state who performs 4-12 surgery; a physician licensed in this state who practices 4-13 (4)4-14 in emergency medicine at a hospital; 4**-**15 4**-**16 a physician licensed in this state who practices (5) in psychiatry; (6) an oral and maxillofacial surgeon; 4-17 4-18 (7)a physician assistant or advanced practice 4-19 registered nurse to whom a physician has delegated the authority to 4-20 4-21 prescribe or order a drug; (8) a pharmacist working at a chain pharmacy; 4-22 (9) a pharmacist working at an independent pharmacy; 4-23 (10)an academic pharmacist; and 4-24 (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 4-25 4**-**26 4-27 records. 4-28 (c) Members of the advisory committee serve three-year 4-29 terms. Each member shall serve until the member's replacement has been appointed. 4-30 4-31 The advisory committee shall annually elect a presiding (d) 4-32 officer from its members. 4-33 (e) The advisory committee shall meet at least two times a 4-34 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 4-35 4-36 incurred in performing the duties of the advisory committee. 4-37 4-38 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. 4-39 4-40 4-41 4-42 А regulatory that (b) agency issues license а 4-43 certification, or registration to a prescriber or dispenser shall 4-44 periodically update the administrative penalties, or any applicable disciplinary guidelines concerning the penaltie assessed by that agency for conduct that violates Subsection (a). penalties, 4-45 4-46 4-47 The agency shall set the penalties in an amount (c) sufficient to deter the conduct. 4-48 Sec. 481.0769. CRIMINAL OFFENSES RELATED TO PRESCRIPTION 4-49 INFORMATION. (a) A person authorized to receive information under Section 481.076(a) commits an offense if the person discloses or 4-50 4-51 4-52 uses the information in a manner not authorized by this subchapter 4**-**53 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 4-54 Section 4-55 4-56 4-57 request for information under that subsection. 4-58 (c) An offense under Subsection (a) is a Class А misdemeanor. 4-59 Cl<u>ass</u> 4-60 (d) An offense under Subsection (b) is а С 4-61 misdemeanor. 4-62 SECTION 5. Section 801.307, Occupations Code, is amended by 4-63 adding Subsection (a-1) to read as follows: 4-64 (a-1) The board by rule shall require a veterinarian to 4-65 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. 4-66 4-67 SECTION 6. Section 481.003(a), Health and Safety Code, is 4-68

4-69 amended to read as follows:

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(a) The director may adopt rules to administer and enforce this chapter, other than Sections 481.073, 481.074, 481.075, 5-1 5-2 481.0755, 481.076, 481.0761, 481.0762, 481.0763, 481.0764, 5-3 481.0765, [and] 481.0766, 481.0767, 481.0768, and 481.0769. board may adopt rules to administer Sections 481.073, 481. 5-4 Тhе 5-5 481.074, <u>481.0755,</u> 5-6 481.0762, 481.075, 481.076, 481.0761, 481.0763, 5-7 481.0764, 481.0765, [and] 481.0766, 481.0767, 481.0768, and 5-8 481.0769. 5-9 SECTION 7. Section 481.128(a), Health and Safety Code, is amended to read as follows: 5-10 5**-**11 (a) A registrant or dispenser commits an offense if the registrant or dispenser knowingly: 5-12 5-13 (1) distributes, delivers, administers, or dispenses 5-14 a controlled substance in violation of Subchapter C [Sections 5**-**15 5**-**16 481.070-481.075]; (2) manufactures controlled substance а not authorized by the person's Federal Drug Enforcement Administration 5-17 5-18 registration or distributes or dispenses a controlled substance not 5-19 authorized by the person's registration to another registrant or 5-20 5-21 other person; (3) refuses or fails to make, keep, or furnish a 5-22 record, report, notification, order form, statement, invoice, or 5-23 information required by this chapter; 5-24 (4) prints, manufactures, possesses, or produces an official prescription form without the approval of the board; 5-25 5-26 delivers or possesses a counterfeit official (5) 5-27 prescription form; 5-28 (6) refuses an entry into a premise for an inspection 5-29 authorized by this chapter; 5-30 (7) refuses or fails to return official an prescription form as required by Section 481.075(k); 5-31 5-32 (8) refuses or fails to make, keep, or furnish a 5-33 record, report, notification, order form, statement, invoice, or 5-34 information required by a rule adopted by the director or the board; 5-35 or 5-36 (9) refuses or fails to maintain security required by 5-37 this chapter or a rule adopted under this chapter. 5-38 SECTION 8. Section 481.129(a), Health and Safety Code, is 5-39 amended to read as follows: 5-40 A person commits an offense if the person knowingly: (a) 5-41 (1) distributes as a registrant or dispenser а 5-42 controlled substance listed in Schedule I or II, unless the person 5-43 distributes the controlled substance as authorized under the 5-44 federal Controlled Substances Act (21 U.S.C. Section 801 et seq.); 5-45 uses in the course of manufacturing, prescribing, (2)5-46 or distributing a controlled substance a Federal Drug Enforcement 5-47 Administration registration number that is fictitious, revoked, 5-48 suspended, or issued to another person; 5-49 (3) issues a prescription bearing forged а or 5-50 fictitious signature; 5-51 (4) uses a prescription issued to another person to 5-52 prescribe a Schedule II controlled substance; 5-53 (5) possesses, obtains, or attempts to possess or 5-54 obtain a controlled substance or an increased quantity of a 5-55 controlled substance: 5-56 misrepresentation, fraud, (A) by forgery, 5-57 deception, or subterfuge; 5-58 (B) through use of a fraudulent prescription 5-59 form; [or] 5-60 (C) through use of а fraudulent oral or 5-61 telephonically communicated prescription; or 5-62 (D) through the use of a fraudulent electronic prescription; or 5-63 5-64 (6) furnishes false or fraudulent material 5-65 information in or omits material information from an application, 5-66 report, record, or other document required to be kept or filed under 5-67 this chapter. SECTION 9. Section 5-68 554.051(a-1), Occupations Code, is amended to read as follows: 5-69

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(a-1) The board may adopt rules to administer Sections 481.073, 481.074, 481.075, <u>481.0755</u>, 481.076, 481.0761, 481.0762, 481.0763, 481.0764, 481.0765, [and] 481.0766, <u>481.0767</u>, 481.0768, 6-1 6-2 6-3 and 481.0769, Health and Safety Code. SECTION 10. Section 565.003, Occupations Code, is amended 6-4

6-5 6-6 to read as follows:

6-7 Sec. 565.003. ADDITIONAL GROUNDS FOR DISCIPLINE REGARDING 6-8 APPLICANT FOR OR HOLDER OF NONRESIDENT PHARMACY LICENSE. Unless compliance would violate the pharmacy or drug statutes or rules in 6-9 6**-**10 6**-**11 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 6-12 6-13 comply with:

(1) <u>Subchapter C, C</u> 481.075], Health and Safety Code; 6-14 Chapter 481 [Section 481.074 or 6**-**15 6**-**16

Texas substitution requirements regarding: (2)

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

6-19 (B) patient's refuse the right to generic 6-20 6-21 substitution; or

(C) notification to the patient of the patient's right to refuse substitution; 6-22

providing 6-23 (3) any board rule relating to druq 6-24 information to the patient or the patient's agent in written form or by telephone; or

6**-**25 6**-**26 (4) any board rule adopted under Section 554.051(a) and determined by the board to be applicable under Section 6-27 6-28 554.051(b).

Sections 481.076(a-3), (a-4), and (a-5), Health SECTION 11. 6-29 6-30 and Safety Code, are repealed.

6-31 SECTION 12. To the extent of any conflict, this Act prevails over another Act of the 86th Legislature, Regular Session, 2019, 6-32 relating to nonsubstantive additions to and corrections in enacted 6-33 6-34 codes.

SECTION 13. Notwithstanding Section 24, Chapter 485 (H.B. 2561), Acts of the 85th Legislature, Regular Session, 2017, Section 6-35 6-36 6-37 481.0764(a), Health and Safety Code, as added by that Act, applies 6-38 only to:

6-39 (1) a prescriber, other than a veterinarian, who issues a prescription for a controlled substance on or after March 6-40 6-41 1, 2020; or

6-42 a person authorized by law to dispense (2) а controlled substance, other than a veterinarian, who dispenses a 6-43 6-44 controlled substance on or after March 1, 2020.

6-45 SECTION 14. Section 481.0755, Health and Safety Code, as 6-46 added by this Act, applies only to a prescription issued on or after 6-47 the effective date of this Act.

6-48 SECTION 15. Section 481.0768(a), Health and Safety Code, as 6-49 added by this Act, applies only to conduct that occurs on or after the effective date of this Act. 6-50

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 6-51 6-52 6-53 6-54 effect immediately before the effective date of this Act, and the former law is continued in effect for that purpose. 6-55 6-56

6-57 SECTION 17. This Act takes effect September 1, 2019.

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