By: Hinojosa, et al.

S.B. No. 316

A BILL TO BE ENTITLED

AN ACT

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2 relating to powers and duties of certain prescribers and dispensers 3 of controlled substances and the regulatory agencies that issue a 4 license, certification, or registration to the prescriber or 5 dispenser; following the recommendations of the Sunset Advisory 6 Commission.

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

8 SECTION 1. Section 481.003(a), Health and Safety Code, is 9 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,
481.076, [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, 481.076, [and] 481.0761, 481.0762,
481.0763, 481.0764, and 481.0765.

SECTION 2. Section 481.074(q), Health and Safety Code, is amended to read as follows:

(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 <u>next business</u> [seventh] day after the date the prescription is completely filled.

24 SECTION 3. Section 481.075(i), Health and Safety Code, is

amended to read as follows: 1 2 (i) Each dispensing pharmacist shall: (1)fill in on the official prescription form or note 3 4 in the electronic prescription record each item of information given orally to the dispensing pharmacy under Subsection (h) and 5 the date the prescription is filled, and: 6 7 (A) for a written prescription, fill in the dispensing pharmacist's signature; or 8 9 (B) for an electronic prescription, 10 appropriately record the identity of the dispensing pharmacist in 11 the electronic prescription record; (2) retain with the records of the pharmacy for at 12 13 least two years: (A) the official prescription 14 form or the 15 electronic prescription record, as applicable; and 16 (B) the name or other patient identification 17 required by Section 481.074(m) or (n); and 18 (3) send all required information, including any information required to complete an official prescription form or 19 20 electronic prescription record, to the board by electronic transfer or another form approved by the board not later than the next 21 business [seventh] day after the date the prescription is 22 completely filled. 23 SECTION 4. Sections 481.076(a) and (d), Health and Safety 24 25 Code, are amended to read as follows: The board may not permit any person to have access to 26 (a) 27 information submitted to the board under Section 481.074(q) or

481.075 except: 1

[an investigator for] the board, the Texas Medical 2 (1)Board, the Texas State Board of Podiatric Medical Examiners, the 3 State Board of Dental Examiners, the State Board of Veterinary 4 Medical Examiners, the Texas Board of Nursing, or the Texas 5 Optometry Board for the purpose of: 6

7 (A) investigating a specific license holder; or (B) monitoring for potentially 8 harmful 9 prescribing or dispensing patterns or practices under Section 481.0762; 10

an authorized officer or member of the department 11 (2)or authorized employee of the board engaged in the administration, 12 13 investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state; 14

15 (3) the department on behalf of a law enforcement or 16 prosecutorial official engaged in the administration, investigation, or enforcement of this chapter or another law 17 governing illicit drugs in this state or another state; 18

(4) a medical examiner conducting an investigation; 19 20 (5) provided that accessing the information is authorized under the Health Insurance Portability and 21 22 Accountability Act of 1996 (Pub. L. No. 104-191) and regulations adopted under that Act: 23

24 (A) a pharmacist or a pharmacy technician, as 25 defined by Section 551.003, Occupations Code, acting at the direction of a pharmacist; or 26

(B) a practitioner who:

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1 (i) is a physician, dentist, veterinarian, 2 podiatrist, optometrist, or advanced practice nurse or is a 3 physician assistant described by Section 481.002(39)(D) or an 4 employee or other agent of a practitioner acting at the direction of 5 a practitioner; and

6 <u>(ii)</u> is inquiring about a recent Schedule 7 II, III, IV, or V prescription history of a particular patient of 8 the practitioner[, provided that the person accessing the 9 information is authorized to do so under the Health Insurance 10 Portability and Accountability Act of 1996 (Pub. L. No. 104-191) 11 and rules adopted under that Act];

12 (6) a pharmacist or practitioner who is inquiring13 about the person's own dispensing or prescribing activity; or

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

17 (d) Information submitted to the board under this section 18 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);

25 (3) the prescribing and dispensing of controlled 26 substances by a person listed in Subsection (a)(5); or

27 (4) $\left[\frac{(3)}{(3)}\right]$ dissemination by the board to the public in

1 the form of a statistical tabulation or report if all information 2 reasonably likely to reveal the identity of each patient, 3 practitioner, or other person who is a subject of the information 4 has been removed.

5 SECTION 5. Section 481.0761, Health and Safety Code, is 6 amended by adding Subsections (h), (i), (j), and (k) to read as 7 follows:

(h) The board, in consultation with the department and the 8 regulatory agencies listed in Section 481.076(a)(1), shall 9 identify potentially harmful prescribing or dispensing patterns or 10 11 practices that may suggest drug diversion or drug abuse. The board shall develop indicators for levels of prescriber or patient 12 13 activity that suggest that a potentially harmful prescribing or dispensing pattern or practice may be occurring or that drug 14 diversion or drug abuse may be occurring. 15

(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) and 481.075 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 abuse or drug diversion. 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

1 prescribers who prescribe controlled substances to the patient.
2 The board may, based on the guidelines developed under this
3 subsection, send a prescriber or dispenser an electronic
4 notification if there is reason to believe that a particular
5 patient is engaging in drug abuse or drug diversion.

6 (k) The board by rule may develop guidelines identifying 7 additional behavior that would suggest that drug diversion or drug 8 abuse is occurring. A person described by Section 481.076(a)(5)(A) 9 who observes that behavior by a person to whom a controlled 10 substance is to be dispensed shall access the information under 11 Section 481.076(a)(5) regarding the patient for whom the 12 prescription for the controlled substance was issued.

SECTION 6. 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:

16 <u>Sec. 481.0762. MONITORING BY REGULATORY AGENCY.</u> (a) Each 17 regulatory agency that issues a license, certification, or 18 registration to a prescriber shall promulgate specific guidelines 19 for prescribers regulated by that agency for the responsible 20 prescribing of opioids, benzodiazepines, barbiturates, or 21 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) and 481.075 to determine whether a prescriber is engaging in potentially harmful prescribing patterns or practices. (c) If the board sends a prescriber an electronic

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| 1 | notification authorized under Section 481.0761(i), the board shall |
| 2 | simultaneously send an electronic notification to the appropriate |
| 3 | regulatory agency. |
| 4 | (d) In determining whether a potentially harmful |
| 5 | prescribing pattern or practice is occurring, the appropriate |
| 6 | regulatory agency, at a minimum, shall consider: |
| 7 | (1) the number of times a prescriber prescribes |
| 8 | opioids, benzodiazepines, barbiturates, or carisoprodol; and |
| 9 | (2) for prescriptions described by Subdivision (1), |
| 10 | patterns of prescribing combinations of those drugs and other |
| 11 | dangerous combinations of drugs identified by the board. |
| 12 | (e) If, during a periodic check under this section, the |
| 13 | regulatory agency finds evidence that a prescriber may be engaging |
| 14 | in potentially harmful prescribing patterns or practices, the |
| 15 | regulatory agency may notify that prescriber. |
| 16 | (f) A regulatory agency may open a complaint against a |
| 17 | prescriber if the agency finds evidence during a periodic check |
| 18 | under this section that the prescriber is engaging in conduct that |
| 19 | violates this subchapter or any other statute or rule. |
| 20 | Sec. 481.0763. REGISTRATION BY REGULATORY AGENCY. A |
| 21 | regulatory agency that issues a license, certification, or |
| 22 | registration to a prescriber or dispenser shall provide the board |
| 23 | with any necessary information for each prescriber or dispenser, |
| 24 | including contact information for the notifications described by |
| 25 | Sections 481.0761(i) and (j), to register the prescriber or |
| 26 | dispenser with the system by which the prescriber or dispenser |
| 27 | receives information as authorized under Section 481.076(a)(5). |

| 1 | Sec. 481.0764. DUTIES OF PRESCRIBERS, PHARMACISTS, AND |
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| 2 | RELATED HEALTH CARE PRACTITIONERS. (a) A person authorized to |
| 3 | receive information under Section 481.076(a)(5), other than a |
| 4 | veterinarian, shall access that information with respect to the |
| 5 | patient before prescribing or dispensing opioids, benzodiazepines, |
| 6 | barbiturates, or carisoprodol. |
| 7 | (b) A person authorized to receive information under |
| 8 | Section 481.076(a)(5) may access that information with respect to |
| 9 | the patient before prescribing or dispensing any controlled |
| 10 | substance. |
| 11 | (c) A veterinarian authorized to access information under |
| 12 | Subsection (b) regarding a controlled substance may access the |
| 13 | information for prescriptions dispensed only for the animals of an |
| 14 | owner and may not consider the personal prescription history of the |
| 15 | owner. |
| 16 | (d) A violation of Subsection (a) is grounds for |
| 17 | disciplinary action by the regulatory agency that issued a license, |
| 18 | certification, or registration to the person who committed the |
| 19 | violation. |
| 20 | (e) This section does not grant a person the authority to |
| 21 | issue prescriptions for or dispense controlled substances. |
| 22 | Sec. 481.0765. EXCEPTIONS. (a) A prescriber is not |
| 23 | subject to the requirements of Section 481.0764(a) if: |
| 24 | (1) the patient has been diagnosed with cancer or the |
| 25 | patient is receiving hospice care; and |
| 26 | (2) the prescriber clearly notes in the prescription |
| 27 | record that the patient was diagnosed with cancer or is receiving |

hospice care, as applicable. 1 (b) A dispenser is not subject to the requirements of 2 Section 481.0764(a) if it is clearly noted in the prescription 3 record that the patient has been diagnosed with cancer or is 4 receiving hospice care. 5 6 (c) A prescriber or dispenser is not subject to the 7 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 8 dispenser makes a good faith attempt to comply but is unable to 9 access the information under Section 481.076(a)(5) because of 10

11 circumstances outside the control of the prescriber or dispenser.

SECTION 7. Section 554.051(a-1), Occupations Code, is amended to read as follows:

14 (a-1) The board may adopt rules to administer Sections
15 481.073, 481.074, 481.075, 481.076, [and] 481.0761, 481.0762,
16 481.0763, 481.0764, and 481.0765, Health and Safety Code.

17 SECTION 8. (a) The Senate Committee on Health and Human 18 Services shall conduct an interim study on the monitoring of the 19 prescribing and dispensing of controlled substances in this state.

20 (b) The interim study 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;

5 (4) examine controlled substance prescribing and 6 dispensing trends that may be affected by the passage and 7 implementation of this Act;

8 (5) evaluate the integration of any new data elements
9 required to be reported under this Act;

10 (6) evaluate the existence and scope of diversion of 11 controlled substances by animal owners to whom the substances are 12 dispensed by veterinarians; and

13 (7) explore the best methods for preventing the14 diversion of controlled substances by animal owners.

15 (c) The committee shall solicit feedback from regulatory 16 agencies, prescribers, dispensers, and patients affected by the 17 passage of this Act.

(d) 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.

23 SECTION 9. A person is not required to comply with Section 24 481.0761(k), Health and Safety Code, as added by this Act, before 25 September 1, 2018.

26 SECTION 10. Section 481.0764(a), Health and Safety Code, as 27 added by this Act, applies only to:

1 (1) a prescriber who issues a prescription for a 2 Schedule II controlled substance on or after September 1, 2018; (2) a prescriber who issues a prescription for a 3 controlled substance on any schedule on or after September 1, 2019; 4 5 (3) a person authorized by law to dispense a controlled substance who dispenses a Schedule II controlled 6 7 substance on or after September 1, 2018; or (4) a person authorized by law to 8 dispense а controlled substance who dispenses a controlled substance on any 9

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10 schedule on or after September 1, 2019.

11 SECTION 11. This Act takes effect September 1, 2017.