By: Zerwas H.B. No. 2766

A BILL TO BE ENTITLED

AN ACT

relating to electronically prescribing controlled substance prescriptions under the Texas Controlled Substances Act; authorizing a fee.

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

SECTION 1. Section 552.118, Government Code, is amended to read as follows:

Sec. 552.118. EXCEPTION: CONFIDENTIALITY OF OFFICIAL PRESCRIPTION PROGRAM INFORMATION. Information is excepted from the requirements of Section 552.021 if it is:

(1) information on or derived from an official prescription form filed with the Texas State Board of Pharmacy under Section 481.0755, Health and Safety Code, or an electronic prescription record filed with the Texas State Board of Pharmacy under Section 481.075, Health and Safety Code; or

(2) other information collected under Section 481.075 or 481.0755 of that code.

SECTION 2. Sections 481.002(10) and (47), Health and Safety Code, are amended to read as follows:

(10) "Designated agent" means an individual designated under Section 481.074(b-2) [~~481.073~~] to communicate a practitioner's instructions to a pharmacist in an emergency.

(47) "Official prescription form" means a prescription form that is used for a Schedule II controlled

substance under Section 481.0755 and contains the prescription information required by Section 481.0755(e) [~~481.075~~].

SECTION 3. 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, 481.0756, 481.076, 481.0761, 481.0762, 481.0763, 481.0764, 481.0765, and 481.0766. The board may adopt rules to administer Sections [~~481.073,~~] 481.074, 481.075, 481.0755, 481.0756, 481.076, 481.0761, 481.0762, 481.0763, 481.0764, 481.0765, and 481.0766.

SECTION 4. Section 481.074, Health and Safety Code, is amended by amending Subsections (b), (c), (e), (f), (g), (h), (k), and (q) and adding Subsections (b-1) and (b-2) to read as follows:

(b) Except in an emergency as defined by board rule under Subsection (b-1) [~~of the board~~] or as otherwise provided by [~~Subsection (c) or~~] Section 481.075(j) or (m) or 481.0755, a person may not dispense or administer a controlled substance [~~listed in Schedule II without a written prescription of a practitioner on an official prescription form or~~] without an electronic prescription that meets the requirements of and is completed by the practitioner in accordance with Section 481.075.

(b-1) In an emergency as defined by board rule, a person may dispense or administer a controlled substance [~~listed in Schedule II~~] on the oral or telephonically communicated prescription of a practitioner. The person who administers or dispenses the substance shall:

(1) if the person is a prescribing practitioner or a pharmacist, promptly comply with Subsection (c); or

(2) if the person is not a prescribing practitioner or a pharmacist, promptly write the oral or telephonically communicated prescription and include in the written record of the prescription the name, address, and Federal Drug Enforcement Administration number issued for prescribing a controlled substance in this state of the prescribing practitioner, all information required to be provided by a practitioner under Section 481.075(e)(1), and all information required to be provided by a dispensing pharmacist under Section 481.075(e)(2).

(b-2) In an emergency described by Subsection (b-1), an agent designated in writing by a practitioner defined by Section 481.002(39)(A) may communicate a prescription by telephone. A practitioner who designates a different agent shall designate that agent in writing and maintain the designation in the same manner in which the practitioner initially designated an agent under this subsection. On the request of a pharmacist, a practitioner shall furnish a copy of the written designation. This subsection does not relieve a practitioner or the practitioner's designated agent from the requirement of Subchapter A, Chapter 562, Occupations Code. A practitioner is personally responsible for the actions of the designated agent in communicating a prescription to a pharmacist.

(c) Not later than the seventh day after the date a prescribing practitioner authorizes an emergency oral or telephonically communicated prescription, the prescribing practitioner shall cause an [~~a written or~~] electronic prescription,

completed in the manner required by Section 481.075, to be delivered to the dispensing pharmacist at the pharmacy where the prescription was dispensed. [~~A written prescription may be delivered in person or by mail. The envelope of a prescription delivered by mail must be postmarked not later than the seventh day after the date the prescription was authorized. On receipt of a written prescription, the dispensing pharmacy shall file the transcription of the telephonically communicated prescription and the pharmacy copy and shall send information to the board as required by Section 481.075.~~] On receipt of the [~~an~~] electronic prescription, the pharmacist shall annotate the electronic prescription record with the original authorization and date of the emergency oral or telephonically communicated prescription.

(e) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible in accordance with applicable federal law[~~, if the pharmacist is unable to supply the full quantity called for in a written or electronic prescription or emergency oral prescription and the pharmacist makes a notation of the quantity supplied on the face of the written prescription, on the written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription~~].

(f) A prescription for a Schedule II controlled substance

for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question about whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner before partially filling the prescription. Both the pharmacist and the practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record the prescription [~~on an official prescription form or~~] in the electronic prescription record and must indicate [~~on the official prescription form or~~] in the electronic prescription record whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" is considered to have been filled in violation of this chapter. For each partial filling, the dispensing pharmacist shall record [~~on the back of the official prescription form or~~] in the electronic prescription record the date of the partial filling, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Before any subsequent partial filling, the pharmacist must determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed in all partial fillings may not exceed the total quantity prescribed. Schedule II prescriptions for patients in a long-term care facility or patients with a medical diagnosis documenting a terminal illness are valid for a period not to exceed 60 days following the issue

date unless sooner terminated by discontinuance of the medication.

(g) A person may not dispense a controlled substance in Schedule III or IV that is a prescription drug under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.) without a [~~written, electronic, oral, or telephonically communicated~~] prescription of a practitioner defined by Section 481.002(39)(A) or (D), except that the practitioner may dispense the substance directly to an ultimate user. A prescription for a controlled substance listed in Schedule III or IV may not be filled or refilled later than six months after the date on which the prescription is issued and may not be refilled more than five times, unless the prescription is renewed by the practitioner. A prescription under this subsection must comply with other applicable state and federal laws.

(h) A pharmacist may dispense a controlled substance listed in Schedule III, IV, or V under a [~~written, electronic, oral, or telephonically communicated~~] prescription issued by a practitioner defined by Section 481.002(39)(C) [~~and~~] only if the pharmacist determines that the prescription was issued for a valid medical purpose and in the course of professional practice. A prescription described by [~~issued under~~] this subsection may not be filled or refilled later than six months after the date the prescription is issued and may not be refilled more than five times, unless the prescription is renewed by the practitioner.

(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

(B) [~~(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, if the controlled substance is prescribed for an animal, the species of the animal and the name and address of its owner;

(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; and

(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 day after the date the prescription is completely filled.

SECTION 5. The heading to Section 481.075, Health and Safety Code, is amended to read as follows:

Sec. 481.075. SCHEDULE II PRESCRIPTIONS [~~OFFICIAL PRESCRIPTION PROGRAM~~].

SECTION 6. Sections 481.075(a), (e), (g), (h), (i), and (j), Health and Safety Code, are amended to read as follows:

(a) A practitioner who prescribes a controlled substance listed in Schedule II shall, except as provided by Section 481.074(b-1) or 481.0755 or a rule adopted under Section 481.0761, record the prescription [~~on an official prescription form or~~] in an electronic prescription that includes the information required by this section.

(e) Each [~~official prescription form or electronic~~] prescription used to prescribe a Schedule II controlled substance must contain:

(1) information provided by the prescribing practitioner, including:

(A) the date the prescription is issued;

(B) the controlled substance prescribed;

(C) the quantity of controlled substance

prescribed, shown[~~:~~

[~~(i)~~] numerically[~~, followed by the number written as a word, if the prescription is written; or~~

[~~(ii) numerically, if the prescription is electronic~~];

(D) the intended use of the controlled substance, or the diagnosis for which the controlled substance [~~it~~] is prescribed, and the instructions for use of the substance;

(E) the practitioner's name, address, and Federal Drug Enforcement Administration number issued for prescribing a controlled substance in this state;

(F) the name, address, and date of birth or age of the person for whom the controlled substance is prescribed; and

(G) if the prescription is issued to be filled at a later date under Section 481.074(d-1), the earliest date on which a pharmacy may fill the prescription;

(2) information provided by the dispensing pharmacist, including the date the prescription is filled; and

(3) [~~for a written prescription, the signatures of the prescribing practitioner and the dispensing pharmacist or for an electronic prescription,~~] the prescribing practitioner's electronic signature or other secure method of validation authorized by federal law.

(g) Except for an emergency oral or telephonically communicated prescription described by [~~prescribed under~~] Section 481.074(b-1) [~~481.074(b)~~], the prescribing practitioner shall:

(1) record [~~legibly fill in,~~] or direct a designated

agent to record [~~legibly fill in, on the official prescription form or~~] in the electronic prescription[~~,~~] each item of information required to be provided by the prescribing practitioner under Subsection (e)(1), unless the practitioner determines that:

(A) under rule adopted by the board for this purpose, it is unnecessary for the practitioner or the practitioner's agent to provide the patient identification number; or

(B) it is not in the best interest of the patient for the practitioner or practitioner's agent to provide information regarding the intended use of the controlled substance or the diagnosis for which it is prescribed; and

(2) [~~sign the official prescription form and give the form to the person authorized to receive the prescription or, in the case of an electronic prescription,~~] electronically sign or validate the electronic prescription as authorized by federal law and transmit the prescription to the dispensing pharmacy.

(h) In the case of an emergency oral or telephonically communicated prescription described by [~~prescribed under~~] Section 481.074(b-1) [~~481.074(b)~~], the prescribing practitioner shall give the dispensing pharmacy the information needed to complete the [~~official prescription form or~~] electronic prescription record.

(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 day after the date the prescription is completely filled.

(j) A medication order written for a patient who is admitted to a hospital at the time the medication order is written and filled is not required to be recorded [~~on an official prescription form or~~] in an electronic prescription record that meets the requirements of this section.

SECTION 7. Subchapter C, Chapter 481, Health and Safety Code, is amended by adding Sections 481.0755 and 481.0756 to read as follows:

Sec. 481.0755. WRITTEN, ORAL, AND TELEPHONICALLY COMMUNICATED PRESCRIPTIONS. (a) Notwithstanding Sections 481.074 and 481.075, a prescription for a controlled substance is not

required to be issued electronically and may be issued in writing 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 in the same location or under the same license;

(5) in circumstances in which necessary elements are not supported by the most recently implemented national data standard that facilitates electronic prescribing;

(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 practitioner who has received a waiver under Section 481.0756 from the requirement to use electronic prescribing;

(10) 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; or

(11) before January 1, 2021.

(b) 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. The pharmacist may dispense a controlled substance pursuant to an otherwise valid written, oral, or telephonically communicated prescription consistent with the requirements of this subchapter.

(c) Except in an emergency, a practitioner must use a written prescription to submit a prescription described by Subsection (a). In an emergency, the practitioner may submit an oral or telephonically communicated prescription as authorized under Section 481.074(b-1).

(d) A written prescription for a controlled substance other than a Schedule II controlled substance must include the information required under Section 481.074(k) and the signature of the prescribing practitioner.

(e) A written prescription for a Schedule II controlled substance must be on an official prescription form and include the information required for an electronic prescription under Section 481.075(e), the signature of the practitioner, and the signature of the dispensing pharmacist after the prescription is filled.

(f) The board by rule shall authorize a practitioner to determine whether it is necessary to obtain a particular patient identification number and to provide that number on the official prescription form.

(g) On request of a practitioner, the board shall issue official prescription forms to the practitioner for a fee covering the actual cost of printing, processing, and mailing the forms. Before mailing or otherwise delivering prescription forms to a practitioner, the board shall print on each form the number of the form and any other information the board determines is necessary.

(h) Each official prescription form must be sequentially numbered.

(i) A person may not obtain an official prescription form unless the person is a practitioner as defined by Section 481.002(39)(A) or an institutional practitioner.

(j) Not more than one Schedule II prescription may be recorded on an official prescription form.

(k) Not later than the 30th day after the date a practitioner's Federal Drug Enforcement Administration number or license to practice has been denied, suspended, canceled, surrendered, or revoked, the practitioner shall return to the board all official prescription forms in the practitioner's possession that have not been used for prescriptions.

(l) Each prescribing practitioner:

(1) may use an official prescription form only to submit a prescription described by Subsection (a);

(2) shall date or sign an official prescription form

only on the date the prescription is issued; and

(3) shall take reasonable precautionary measures to ensure that an official prescription form issued to the practitioner is not used by another person to violate this subchapter or a rule adopted under this subchapter.

(m) In the case of an emergency oral or telephonically communicated prescription described by Section 481.074(b-1), the prescribing practitioner shall give the dispensing pharmacy the information needed to complete the official prescription form if the pharmacy is not required to use the electronic prescription record.

(n) Each dispensing pharmacist receiving an oral or telephonically communicated prescription under Subsection (m) shall:

(1) fill in on the official prescription form each item of information given orally to the dispensing pharmacy under Subsection (m) and the date the prescription is filled and fill in the dispensing pharmacist's signature;

(2) retain with the records of the pharmacy for at least two years:

(A) the official prescription form; 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, to the board by electronic transfer or another form approved by the board not later than the next business day after the date the

prescription is completely filled.

Sec. 481.0756. WAIVERS FROM ELECTRONIC PRESCRIBING. (a) The appropriate regulatory agency that issued the license, certification, or registration to a prescriber is authorized to grant a prescriber a waiver from the electronic prescribing requirement under the provisions of this section.

(b) The board shall convene an interagency workgroup that includes representatives of each regulatory agency that issues a license, certification, or registration to a prescriber.

(c) The work group described by Subsection (b) shall establish recommendations and standards for circumstances in which a waiver from the electronic prescribing requirement is appropriate and a process under which a prescriber may request and receive a waiver.

(d) 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 prescriber; or

(3) other exceptional circumstances demonstrated by the prescriber.

(e) Each regulatory agency that issues a license, certification, or registration to a prescriber shall adopt rules for the granting of waivers consistent with the board rules adopted under Subsection (d).

(f) A waiver may be issued to a prescriber for a period of one year. On expiration of the waiver, the prescriber may reapply

for a waiver if the circumstances that necessitated the waiver continue.

SECTION 8. Sections 481.0761(c) and (d), Health and Safety Code, are amended to read as follows:

(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, and 481.076; and

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

(d) The board by rule shall authorize a practitioner to determine whether it is necessary to obtain a particular patient identification number and to provide that number [~~on the official~~

~~prescription form or~~] in the electronic prescription record.

SECTION 9. 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 481.0755(k) [~~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 10. 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 11. 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, 481.0756, 481.076, 481.0761, 481.0762, 481.0763, 481.0764, 481.0765, and 481.0766, Health and Safety Code.

SECTION 12. 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) Section 481.074, [~~or~~] 481.075, 481.0755, or 481.0756, 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 13. Sections 481.073, 481.074(o) and (p), and 481.075(b), (c), (d), (f), (k), and (l), Health and Safety Code, are repealed.

SECTION 14. This Act takes effect September 1, 2021.