

BILL ANALYSIS

Senate Research Center
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S.B. 1233
By: Kolkhorst
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AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

In October 2017, the President of the United States officially declared the opioid epidemic a national emergency, noting that two million Americans suffer from addiction to prescribed or illicit painkillers. In 2015 in Texas, nearly half of opioid overdose deaths involved a prescription opioid.

S.B. 1233 will help protect against prescription drug misuse and diversion by requiring e-prescribing for controlled substances, limiting opioid prescriptions to a seven-day supply for acute pain, and requiring practitioners to complete continuing education related to prescribing and dispensing opioids.

As proposed, S.B. 1233 amends current law relating to controlled substance prescriptions under the Texas Controlled Substances Act, and authorizes a fee.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to Texas State Board of Pharmacy (TSBP) in SECTION 7 (Sections 481.0755 and 481.0756, Health and Safety Code) of this bill.

Rulemaking authority previously granted to the director of the Texas Department of Public Safety is modified in SECTION 3 (Section 481.003, Health and Safety Code) of this bill.

Rulemaking authority previously granted to the director of TSBP is modified SECTION 3 (Section 481.003, Healthy and Safety Code) of this bill.

Rulemaking authority previously granted to the director of TSBP is modified SECTION 8 (Section 481.0761, Health and Safety Code) of this bill.

Rulemaking authority is expressly granted to each regulatory agency that issues a license, certification, or registration to a prescriber in SECTION 7 (Section 481.0756, Health and Safety Code) of this bill.

Rulemaking authority previously granted to TSBP is modified in SECTION 4 (Section 481.074, Health and Safety Code) of this bill.

Rulemaking authority previously granted to TSBP is modified in SECTION 13 (Section 554.051, Occupations Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 552.118, Government Code, as follows:

Sec. 552.118. EXCEPTION: CONFIDENTIALITY OF OFFICIAL PRESCRIPTION PROGRAM INFORMATION. Provides that information is excepted from the requirements of Section 552.021 (Availability of Public Information) if it is:

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

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

SECTION 2. Amends Sections 481.002(10) and (47), Health and Safety Code, as follows:

(10) Redefines "designated agent" to mean an individual designated under Section 481.074(b-2), rather than Section 481.073 (Communication of Prescriptions by Agent) to communicate a practitioner's instructions to a pharmacist in an emergency.

(47) Redefines "official prescription form" to mean 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), rather than by Section 481.075.

SECTION 3. Amends Section 481.003(a), Health and Safety Code, as follows:

(a) Deletes Section 481.073 from, and adds Sections 481.0755, 481.0756, 481.07635, and 481.0736 to, the list of sections exempted from the provision authorizing the director of the Texas Department of Public Safety (director; DPS) to adopt rules to administer and enforce Chapter 481 (Texas Controlled Substance Act). Deletes Section 481.073 from, and adds Sections 481.0755, 481.0756, 481.07635, and 481.0736 to the list of sections TSBP is authorized to adopt rules to administer.

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

(b) Prohibits a person, except in an emergency as defined by TSBP rule under Subsection (b-1) or as otherwise provided by Section 481.075(j) or (m) or 481.0755, from dispensing or administering a controlled substance without an electronic prescription that meets the requirements of and is completed by the practitioner in accordance with Section 481.075, rather than prohibiting a person except in an emergency as defined by rule of TSBP or as provided by Subsection (o) or Section 481.075(j) or (m), from dispensing or administering 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) Authorizes a person, in an emergency as defined by TSBP rule, to dispense or administer a controlled substance, rather than a controlled substance listed in Schedule II, on the oral or telephonically communicated prescription of a practitioner. Requires a person who administers or dispenses the substance to meet certain criteria.

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

(c) Requires the prescribing practitioner, not later than the seventh day after the date a prescribing practitioner authorizes an emergency oral or telephonically communicated prescription, to cause an electronic prescription, rather than 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. Deletes existing text authorizing a written prescription to be delivered in person or by mail and requiring the envelope of a prescription delivered by mail to be postmarked not later than the seventh day after the date of the prescription was authorized. Deletes existing text requiring the dispensing pharmacy, on receipt of a written prescription, to file the transcription of the telephonically communicated prescription and the pharmacy copy and to send information to the board as required by Section 481.075. Makes a nonsubstantive change.

(e) Provides that the partial filling of a prescription for a controlled substance listed in Schedule II is permissible in accordance with applicable federal law, rather than is permissible 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. Deletes existing text authorizing the remaining portion of the prescription to 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. Deletes existing text providing that no further quantity may be supplied beyond 72 hours without a prescription.

(f) Requires the pharmacist to record the prescription in the electronic prescription record, rather than on an official prescription form or in the electronic prescription record, and requires the pharmacist to indicate in the electronic prescription record, rather than on an official prescription form or in the electronic prescription record, whether the patient is "terminally ill" or an "LTCF patient." Requires the dispensing pharmacist, for each partial filling, to records in the electronic prescription record, rather on the back of the official form in 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.

(g) Prohibits a person from dispensing 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 prescription, rather than 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.

(h) Makes a conforming and a nonsubstantive change. Prohibits a prescription described by this subsection, rather than issued under this subsection, from being 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) Requires a prescription for a controlled substance to show:

(1) the quantity of the substance prescribed:

(A) deletes existing text providing that the quantity be shown numerically, followed by the number written as a word, if the prescription is written and redesignates existing paragraph (B) as paragraph (A);

(B) redesignates existing paragraph (C) as paragraph (B);

(C) deletes this paragraph;

(2)–(6) makes no changes to these subdivisions;

(7) the name, address, Federal Drug Enforcement Administration number, and telephone number of the practitioner at the practitioner's usual place of business, rather than requiring the name, address, Federal Drug Enforcement

Administration number, and telephone number of the practitioner at the practitioner's usual place of business to be legibly printed or stamped on a written prescription;

(8) deletes this subdivision that requires that if the prescription is handwritten, the signature of the prescribing practitioner be shown.

(q) Requires each dispensing pharmacist to send all required information to the TSBP by electronic transfer or another form approved by TSBP not later than the next business day after the date the prescription is completely filled, rather than requiring each dispensing pharmacist to send all required information, including any information required to complete the Schedule III through V prescription forms, to TSBP by electronic transfer or another form approved by TSBP not later than the next business day after the date the prescription is completely filled.

SECTION 5. Amends the heading to Section 481.075, Health and Safety Code, to read as follows:

Sec. 481.075. SCHEDULE II PRESCRIPTION.

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

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

(e) Requires that each prescription, rather than each official prescription form or electronic prescription, used to prescribe a Schedule II controlled substance contain:

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

(A)–(B) makes no changes to these paragraphs;

(C) the quantity of controlled substance prescribed, shown numerically and makes a nonsubstantive change;

(i)–(ii) deletes these subparagraphs;

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

(E)–(G) makes no changes to these paragraphs;

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

(3) the prescribing practitioner's electronic signature or other secure method of validation authorized by federal law, rather than 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) Requires the prescribing practitioner, except for an emergency oral or telephonically communicated prescription described by Section 481.074(b-1), rather than except for an oral prescription prescribed under Section 481.074(b), to:

(1) record or direct a designated agent to record, rather than legibly fill in, or direct a designated agent to 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 meets certain requirements; and

(2) electronically sign or validate the electronic prescription as authorized by federal law and transmit the prescription to the dispensing pharmacy. Deletes existing text requiring the prescribing practitioner to 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) Makes conforming changes.

(i) Requires each dispensing pharmacist to:

(1) 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 appropriately record the identity of the dispensing pharmacist in the electronic prescription record;

(A)-(B) deletes these existing paragraphs requiring each dispensing pharmacist to fill in on the official prescription form each item of information given orally to the dispensing pharmacy under Subsection (h) and the date the prescription is filled and for a written prescription, fill in the dispensing pharmacist's signature or 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 electronic prescription record, rather than the official prescription form or the electronic prescription record, as applicable; and

(B) makes no changes to this paragraph; and

(3) makes a conforming change.

(j) Provides that 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 in an electronic prescription record, rather than not required to be on an official prescription form or electronic prescription record, that meets the requirements of this section.

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

Sec. 481.0755. WRITTEN, ORAL, AND TELEPHONICALLY COMMUNICATED PRESCRIPTIONS. (a) Provides that, notwithstanding Sections 481.074 and 481.075, a prescription for a controlled substance is not required to be issued electronically and is authorized be issued in writing if the prescription is issued by certain enumerated persons or for certain enumerated reasons.

(b) Provides that 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. Authorizes the pharmacist to dispense a controlled substance pursuant to an otherwise valid written, oral, or telephonically communicated prescription consistent with the requirements of Subchapter C (Regulation of Manufacture,

Distribution, and Dispensation of Controlled Substances, Chemical Precursors, and Chemical Laboratory Apparatus).

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

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

(e) Requires a written prescription for a Schedule II controlled substance to 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) Requires TSBP by rule to 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) Requires TSBP, on request of a practitioner, to issue official prescription forms to the practitioner for a fee covering the actual cost of printing, processing, and mailing the forms. Requires TSBP, before mailing or otherwise delivering prescription forms to a practitioner, to print on each form the number of the form and any other information the board determines is necessary.

(h) Requires each official prescription form to be sequentially numbered.

(i) Prohibits a person from obtaining an official prescription form unless the person is a practitioner as defined by Section 481.002(39)(A) or an institutional practitioner.

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

(k) Requires the practitioner, 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, to return to the board all official prescription forms in the practitioner's possession that have not been used for prescriptions.

(l) Provides that each prescribing practitioner:

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

(2) is required to date or sign an official prescription form only on the date the prescription is issued; and

(3) is required to 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) Requires the prescribing practitioner, in the case of an emergency oral or telephonically communicated prescription described by Section 481.074(b-1), to 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) Requires each dispensing pharmacist receiving an oral or telephonically communicated prescription under Subsection (m) to:

(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 TSBP by electronic transfer or another form approved by TSBP not later than the next business day after the date the prescription is completely filled.

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

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

(c) Requires the workgroup to 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) Requires TSBP to adopt rules establishing the eligibility for a waiver, including certain criteria.

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

(f) Authorizes a waiver to be issued to a prescriber for a period of one year. Authorizes the prescriber, on expiration of the waiver, to reapply for a waiver if the circumstances that necessitated the waiver continue.

SECTION 8. Amends Sections 481.0761(c) and (d), Health and Safety Code, as follows:

(c) Redesignates existing Subsection (1-a) as Subsection (1) and deletes existing text authorizing TSBP by rule to permit more than one prescription to be administered or dispensed and recorded on one prescription form for a Schedule III through V controlled substance and makes no further changes.

(d) Makes a conforming change.

SECTION 9. Amends Subchapter C, Chapter 481, Health and Safety Code, by adding Sections 481.07635 and 481.07636, as follows:

Sec. 481.07635. CONTINUING EDUCATION. (a) Requires a person authorized to receive information under Section 481.076(a)(5) (relating to certain persons under certain conditions accessing information submitted to TSBP), not later than the first anniversary

after the person is issued a license, certification, or registration to prescribe or dispense controlled substances under this chapter, to complete two hours of professional education related to approved procedures of prescribing and monitoring controlled substances.

(b) Authorizes a person authorized to receive information to annually take the professional education course under this section to fulfil hours toward the ethics education requirement of the person's license, certification, or registration.

(c) Requires the regulatory agency that issued the license, certification, or registration to a person authorized to receive information under Section 481.076(a)(5) to approve professional education to satisfy the requirements of this section.

Sec. 481.07636. OPIOID PRESCRIPTION LIMITS. (a) Defines "acute pain."

(b) Prohibits a practitioner, for the initial treatment of acute pain, from issuing a prescription for an opioid in an amount that exceeds a seven-day supply or providing for a refill of an opioid.

(c) Provides that Subsection (b) does not apply to a prescription for an opioid approved by the United States Food and Drug Administration for the treatment of substance addiction that is issued by a practitioner for the treatment of substance addiction.

(d) Provides that a dispenser is not subject to criminal, civil, or administrative penalties for dispensing or refusing to dispense a controlled substance under a prescription that exceeds the limits provided by Subsection (b).

SECTION 10. Amends Section 481.128(a), Health and Safety Code, as follows:

(a) Provides that 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, rather than Sections 481.070–481.075;

(2)–(6) makes no changes to these subdivisions;

(7) refuses or fails to return an official prescription form as required by Section 481.0755(k), rather than Section 481.075(k);

(8)–(9) makes no changes to these subdivisions.

SECTION 11. Amends Section 481.129(a), Health and Safety Code, as follows:

(a) Provides that a person commits an offense if the person knowingly performs certain activities, including possesses, obtains, or attempts to possess or obtain a controlled substance or an increased quantity of a controlled substance through the use of a fraudulent electronic prescription. Makes nonsubstantive changes.

SECTION 12. Amends Section 32.024, Human Resources Code, by adding Subsection (z-2) to provide that the limits on prescription drugs and medications under the medical assistance program provided by Subsections (z) and (z-1) do not apply to a prescription for an opioid for the initial treatment of acute pain under Section 481.07636, Health and Safety Code.

SECTION 13. Amends Section 554.051(a-1), Occupations Code, to add Sections 481.0755, 481.0756, 481.07635, and 481.07636, Health and Safety Code, and to delete Section 481.073, Health and Safety Code, from the list of sections TSBP is required to adopt rules to administer.

SECTION 14. Amends Section 565.003, Occupations Code, as follows:

Sec. 565.003. ADDITIONAL GROUNDS FOR DISCIPLINE REGARDING APPLICANT FOR OR HOLDER OF NONRESIDENT PHARMACY LICENSE. Authorizes TSBP, unless compliance would violate the pharmacy or drug statutes or rules in the state in which the pharmacy is located, to 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, 481.075, 481.0755, 481.0756, 481.076, 481.0761, 481.0762, 481.0763, 481.07635, 481.07636, 481.0764, 481.0765, or 481.0766, Health and Safety Code, rather than Section 481.074 or Section 481.075;

(2)–(4) makes no changes to these subdivisions.

SECTION 15. Repealer: Section 481.073 (Communication of Prescriptions by Agent), Health and Safety Code.

Repealer: Section 481.074(o) (relating to authorizing a pharmacist to dispense a Schedule II controlled substance under certain conditions), Health and Safety Code.

Repealer: Section 481.074(p) (relating to requiring the dispensing pharmacy to file the facsimile copy of the prescription and send that information to TSBP), Health and Safety Code.

Repealer: Section 481.075(b) (relating to requiring each official prescription form to be sequentially filed), Health and Safety Code.

Repealer: Section 481.075(c) (relating to requiring TSBP to issue official prescription to practitioners for a fee to cover certain expenses), Health and Safety Code.

Repealer: Section 481.075(d) (relating to allowing only practitioners to obtain an official prescription form), Health and Safety Code.

Repealer: Section 481.075(f) (relating to allowing only one prescription to be recorded on each official prescription form), Health and Safety Code.

Repealer: Section 481.075(k) (relating to requiring to a practitioner to return all official prescription forms to TSBP if the practitioner's FDA number or license has been denied, suspended, cancelled, surrendered, or revoked), Health and Safety Code.

Repealer: Section 481.075(l) (relating to authorizing and requiring a prescribing practitioner to undertake certain actions), Health and Safety Code.

SECTION 16. Provides that a person who holds a license, certification, or registration to prescribe or dispense a controlled substance issued before September 1, 2020, is required to take the continuing education course provided by Section 481.07635, Health and Safety Code, as added by this Act, not later than September 1, 2021.

SECTION 17. Effective date: September 1, 2019.