BILL ANALYSIS

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S.B. 594
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AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Currently e-prescribing is a common transaction for many prescribers and pharmacists across Texas. This practice benefits patients and health care providers alike. Texas prescribers are currently limited to e-prescribing for Schedule III, IV, and V of controlled substances due to statute limitations and previous DEA rules. In the state of Texas, language in the Controlled Substances Act prohibits the dispensing of Schedule II controlled substances without a hard-copy written prescription that is issued on an official prescription form.

When the DEA rule was changed, it eliminated one of the key barriers to widespread adoption of e-prescribing. Now that DEA has adopted new rules to allow for all controlled substances, it is necessary for Texas to follow suit and amend its statutes.

S.B. 594 revises Texas statutes to accommodate the Drug Enforcement Agency (DEA)-approved process of electronic prescribing for Schedule II controlled substances prescriptions. The DEA-approved process arguably provides much more protection from diversion than the current system of paper and oral prescriptions. E-prescriptions for Schedule II controlled substances are considered one of the remaining barriers to the widespread utilization of e-prescribing. As e-prescribing technology is a critical prerequisite for adoption of electronic health records, steps need to be taken to promote e-prescribing to ensure that Texans benefit from new and improved health care practices. Resolving the remaining challenges related to e-prescribing is included as a recommendation from the Senate Committee on Health and Human Services Interim Committee Report.

As proposed, S.B. 594 amends current law relating to certain procedures applicable to electronic prescriptions for Schedule II controlled substances.

RULEMAKING AUTHORITY

Rulemaking authority previously granted to the director of the Department of Public Safety of the State of Texas is modified in SECTION 3 (Section 481.0761, Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Sections 481.074(b), (c), (d-1), (e), (f), (g), (h), and (k), Health and Safety Code, as follows:

> (b) Prohibits a person, except in an emergency as defined by rule of the director of the Department of Public Safety of the State of Texas (director) or as provided by Subsection (o) (authorizing a pharmacist to dispense a Schedule II controlled substance under certain conditions) or Section 481.075(j) (providing 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 on a form that meets the requirements of this section) or (m) (authorizing a pharmacy in the state to fill a prescription for a controlled substance listed in Schedule II issued by a practitioner in another state under certain conditions), 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. Makes a nonsubstantive change.

(c) Requires the prescribing practitioner, not later than the seventh day after the date the prescribing practitioner authorizes an emergency oral or telephonically communicated prescription, to cause 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. Authorizes a written prescription to be delivered in person or by mail. Requires that the envelope of a prescription delivered by mail be postmarked not later than seventh day after the date the prescription was authorized. Requires 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 director as required by Section 481.075. Requires the pharmacist, on receipt of an electronic prescription, to annotate the electronic prescription record with the original authorization and date of the emergency oral or telephonically communicated prescription. Makes nonsubstantive changes.

(d-1) Authorizes a prescribing practitioner, notwithstanding Subsection (d) (requiring the director by rule to establish the period after the date on which the prescription is issued that a person may fill a prescription for a controlled substance listed in Schedule II), to issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance, if certain conditions are met, including the prescribing practitioner provides instructions, rather than written instructions, on each prescription to be filled at a later date indicating the earliest date on which a pharmacy may fill each prescription.

(e) Provides that the partial filling of a prescription for a controlled substance listed in Schedule II 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.

(f) Authorizes a prescription for a Schedule II controlled substance for a patient, rather than a prescription written for a patient, in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness to be filled in partial quantities to include individual dosage units. Requires the pharmacist to record the prescription on an official prescription form or in the electronic prescription record and to indicate on the 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 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.

(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 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 change.

(k) Requires that a prescription for a controlled substance show, among other information, the quantity of the substance prescribed numerically, if the prescription is electronic; and the name, address, Federal Drug Enforcement Administration registration 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. Makes nonsubstantive changes.

SECTION 2. 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 rule adopted under Section 481.0761, to record the prescription on an official prescription form or in an electronic prescription that includes the information required by this section.

(e) Requires that 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) the date the prescription is issued, rather than written;

(B) the controlled substance prescribed;

(C) the quantity of controlled substance prescribed, shown numerically, followed by the number written as a word, if the prescription is written; or numerically, if the prescription is electronic;

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

(E) the practitioner's name, address, department registration number, and Federal Drug Enforcement Administration number;

(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) Requires the prescribing practitioner, except for an oral prescription prescribed under Section 481.074(b), to:

(1) 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:

(A) under rule adopted by the director 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) Requires the prescribing practitioner, in the case of an oral prescription prescribed under Section 481.074(b), to give the dispensing pharmacy the information needed to complete the official prescription form or electronic prescription record.

(i) Requires each dispensing pharmacy to:

(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) (authorizing a pharmacist to permit the delivery of a controlled substance by certain persons or means) or (n) (authorizing a pharmacist to permit the delivery of a controlled substance to certain persons without first requiring the identification of the person to whom the controlled substance is delivered) ; and

(3) send all information required by the director, including any information required to complete an official prescription form or electronic prescription record, to the director by electronic transfer or another form approved by the director not later than the 15th day after the last day of the month in which the prescription is completely filled.

Makes nonsubstantive changes.

(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 on an official prescription form or in an electronic prescription record that meets the requirements of this section.

SECTION 3. Amends Section 481.0761(d), Health and Safety Code, to require the director 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 or in the electronic prescription record.

SECTION 4. Amends Section 552.118, Government Code, as follows:

Sec. 552.118. New heading: EXCEPTION: OFFICIAL PRESCRIPTION PROGRAM INFORMATION. Provides that information is excepted from the requirements of Section 552.021 (Availability of Public Information) if it is information on or derived from an official prescription form or electronic prescription record filed with the director of DPS under Section 481.075, Health and Safety Code, or other information collected under Section 481.075 of that code.

SECTION 5. Amends Section 157.059(c), Occupations Code, to prohibit the physician from delegating the use of a prescription sticker or the use or issuance of an official prescription form,

or the authority to issue an electronic prescription under Section 481.075, Health and Safety Code.

SECTION 6. Makes application of the change in law made by this Act prospective.

SECTION 7. Effective date: September 1, 2011.