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| BILL ANALYSIS |

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| C.S.H.B. 2174 |
| By: Zerwas |
| Public Health |
| Committee Report (Substituted) |

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| **BACKGROUND AND PURPOSE**  There are concerns about the growing number of deaths in Texas related to the abuse of prescription drugs and opioids, particularly in light of a recent report from the Maternal Mortality and Morbidity Task Force that drug overdose is a leading cause of maternal deaths. C.S.H.B. 2174 seeks to address these concerns by making changes to the Texas Controlled Substances Act and other applicable statutes to help combat the growing rate of prescription drug abuse in Texas. |
| **CRIMINAL JUSTICE IMPACT**  It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision. |
| **RULEMAKING AUTHORITY**  It is the committee's opinion that rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTIONS 3 and 13 of this bill and to each regulatory agency that issues a license, certification, or registration to a prescriber and to the Texas State Board of Pharmacy in SECTION 7 of this bill. |
| **ANALYSIS**  C.S.H.B. 2174 amends the Health and Safety Code to revise provisions relating to controlled substance prescriptions under the Texas Controlled Substances Act. The bill establishes that a prescription for a controlled substance is not required to be issued electronically and authorizes such a prescription to be issued in writing if the prescription is issued under the following circumstances:   * by a veterinarian; * in circumstances in which electronic prescribing is not available due to temporary technological or electronic failure, as prescribed by Texas State Board of Pharmacy (TSBP) rule; * by a practitioner to be dispensed by a pharmacy located outside of Texas, as prescribed by TSBP rule; * when the prescriber and dispenser are in the same location or under the same license; * in circumstances in which necessary elements are not supported by the most recently implemented national data standard that facilitates electronic prescribing; * for a drug for which the U.S. Food and Drug Administration requires additional information in the prescription that is not possible with electronic prescribing; * 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; * for a drug under a research protocol; * by a practitioner who has received a waiver from the requirement to use electronic prescribing; * 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 * before January 1, 2021.   The bill requires a practitioner to use a written prescription to submit the prescription under those specified circumstances, except in an emergency as defined by TSBP rule, and authorizes the practitioner to submit an oral or telephonically communicated prescription in an emergency. The bill expressly does not require a dispensing pharmacist who receives a controlled substance prescription in a manner other than electronically to verify that the prescription is exempt from the requirement that it be submitted electronically and authorizes the pharmacist to dispense a controlled substance pursuant to an otherwise valid written, oral, or telephonically communicated prescription.  C.S.H.B. 2174 requires a written prescription for a controlled substance other than a Schedule II controlled substance to include certain information and the signature of the prescribing practitioner. The bill redefines "official prescription form" to limit its use to prescribing Schedule II controlled substances, requires a written prescription for a Schedule II controlled substance to be on an official prescription form and to include the information required for an electronic prescription for a Schedule II controlled substance, the signature of the practitioner, and the signature of the dispensing pharmacist after the prescription is filled.  C.S.H.B. 2174 requires the 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. The bill requires the 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 and sets out requirements for the forms. The bill prohibits a person from obtaining an official prescription form unless the person is a practitioner or an institutional practitioner and limits the number of Schedule II prescriptions that may be recorded on an official prescription form to one. The bill provides for the return of all unused official prescription forms by a practitioner who no longer has a Federal Drug Enforcement Administration number and sets out requirements for each prescribing practitioner regarding the forms.  C.S.H.B. 2174 requires a prescribing practitioner, in the case of an emergency oral or telephonically communicated prescription, 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 and sets out requirements for each dispensing pharmacist receiving such an oral or telephonically communicated prescription. The bill removes the authority of the 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. The bill repeals provisions relating to dispensing a Schedule II controlled substance by a pharmacist pursuant to a facsimile copy of an official prescription completed in the manner required by the official prescription program under the Texas Controlled Substances Act.  C.S.H.B. 2174 authorizes the appropriate regulatory agency that issued the license, certification, or registration to a prescriber to grant to a prescriber a waiver from the electronic prescribing requirement. The bill requires the TSBP to convene an interagency workgroup that includes representatives of each such appropriate regulatory agency and requires the work group 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. The bill requires the TSBP to adopt rules establishing the eligibility for a waiver. The bill requires each agency that issues a license, certification, or registration to a prescriber to adopt rules for the granting of waivers consistent with the adopted TSBP rules. The bill sets the expiration for an issued waiver at one year and authorizes a prescriber to reapply for a subsequent waiver not earlier than the 30th day before the date the waiver expires if the circumstances that necessitated the waiver continue on its expiration. The bill includes rules for administering the foregoing bill provisions regarding written, oral, and telephonically communicated prescriptions and regarding waivers from electronic prescribing among the rules the TSBP may adopt for purposes of the Texas Controlled Substances Act.  C.S.H.B. 2174 includes a violation of its provisions relating to written, oral, and telephonically communicated prescriptions among the conduct that constitutes an offense under the Texas Controlled Substances Act and expands the conduct that constitutes fraud under that act to include possessing, obtaining, or attempting to possess or obtain a controlled substance or an increased quantity of a controlled substance through the use of a fraudulent electronic prescription.  C.S.H.B. 2174 redefines "designated agent" to limit the agent's activities to activity in an emergency and repeals related provisions. The bill authorizes a duly designated agent to communicate a prescription by telephone in an emergency. The bill 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. The bill requires a practitioner, on the request of a pharmacist, to furnish a copy of the written designation. The bill expressly does not relieve a practitioner or the practitioner's designated agent from the prescription and substitution requirements and makes a practitioner personally responsible for the actions of the designated agent in communicating a prescription to a pharmacist.  C.S.H.B. 2174 removes the specified conditions under which the partial filling of a prescription for a Schedule II controlled substance is permissible and specifies that such a partial filling is permissible instead in accordance with applicable federal law. The bill specifies that a patient with a medical diagnosis documenting a terminal illness to whom a prescription for a Schedule II controlled substance may be filled in partial quantities to include individual dosage units is a hospice patient.  C.S.H.B. 2174 requires a person authorized to receive prescription history information, not later than the first anniversary after the person is issued a license, certification, or registration to prescribe or dispense controlled substances under the Texas Controlled Substances Act, to complete two hours of professional education related to approved procedures of prescribing and monitoring controlled substances. The bill authorizes such a person to annually take the professional education course to fulfil hours toward the ethics education requirement of the person's license, certification, or registration. The bill requires the regulatory agency that issued the license, certification, or registration to the person to approve professional education to satisfy the bill's continuing education requirements. The bill requires a person who holds a license, certification, or registration to prescribe or dispense a controlled substance issued before September 1, 2020, to take the continuing education course not later than September 1, 2021.  C.S.H.B. 2174 prohibits a practitioner, for the treatment of acute pain, as defined by the bill, from issuing a prescription for an opioid in an amount that exceeds a 10-day supply or providing for a refill of an opioid. The bill makes this prohibition inapplicable to a prescription for an opioid approved by the U.S. Food and Drug Administration for the treatment of substance addiction that is issued by a practitioner for such treatment. 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 the bill for treatment of acute pain. The bill includes rules for administering the foregoing bill provisions regarding continuing education and regarding opioid prescription limits among the rules the TSBP may adopt for purposes of the Texas Controlled Substances Act.  C.S.H.B. 2174 amends the Human Resources Code to make the limits on prescription drugs and medications under Medicaid inapplicable to a prescription for an opioid for the treatment of acute pain prescribed under the bill's provisions.  C.S.H.B. 2174 amends the Occupations Code to expand the grounds on which the TSBP may discipline an applicant or the holder of a nonresident pharmacy license to include the TSBP finding that the applicant or license holder has failed to comply with applicable bill provisions. The bill authorizes the TSBP to adopt rules to administer its Texas Controlled Substances Act provisions regarding written, oral, and telephonically communicated prescriptions, regarding waivers from electronic prescribing, regarding the applicable continuing education, and regarding opioid prescription limits.  C.S.H.B. 2174 amends the Government Code to make conforming changes to state public information law.  C.S.H.B. 2174 repeals the following provisions of the Health and Safety Code:   * Section 481.073 * Sections 481.074(o) and (p) * Sections 481.075(b), (c), (d), (f), (k), and (l) |
| **EFFECTIVE DATE**  September 1, 2019. |
| **COMPARISON OF ORIGINAL AND SUBSTITUTE**  While C.S.H.B. 2174 may differ from the original in minor or nonsubstantive ways, the following summarizes the substantial differences between the introduced and committee substitute versions of the bill.  The substitute includes a specification that a patient with a medical diagnosis documenting a terminal illness to whom a prescription for a Schedule II controlled substance may be filled in partial quantities to include individual dosage units is a hospice patient.  The substitute changes the date a prescriber may reapply for a subsequent waiver from electronic prescribing from the date on which the waiver expires to not earlier than the 30th day before that date.  The substitute redefines "acute pain" and specifies the types of pain not included in the definition. The substitute does not include the specification that the treatment of acute pain for which an opioid prescription is limited is the initial treatment.  The substitute increases the limit on an opioid prescription from a seven-day supply to a 10-day supply. |
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