

BILL ANALYSIS

Senate Research Center
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C.S.S.B. 1879
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Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Because of the rise of prescription drug abuse throughout the country and the law enforcement, health care, social services, and court costs to the state in fighting such abuse, many states have begun using prescription drug monitoring programs to prevent the misuse of pharmaceuticals. These programs require documentation and checks to prevent abusers from using several different methods of obtaining such drugs. Texas currently monitors only Schedule II prescription drugs and requires pharmacies to obtain controlled substance registration certificates.

C.S.S.B. 1879 extends such monitoring to Schedule III through V drugs and establishes administrative penalties for noncompliance with such monitoring. The bill also makes several changes to the current monitoring program to better ensure that all entities involved in the drug distribution process are monitored and held in compliance with the law.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the director of the Department of Public Safety in SECTION 2 (Section 481.074, Health and Safety Code) of this bill.

Rulemaking authority previously granted to the director of the Department of Public Safety is modified in SECTION 3 (Section 481.076, Health and Safety Code) and SECTION 4 (Section 481.0761, Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 481.064(a), Health and Safety Code, to authorize the director (director) of the Department of Public Safety (DPS) to charge a late fee of not more than \$50 for each renewal application received by DPS after the date the registration expires, in addition to the nonrefundable fee of not more than \$25 before processing an annual registration application. Makes conforming changes.

SECTION 2. Amends Section 481.074, Health and Safety Code, by amending Subsections (b), (d), and (k) and adding Subsection (q), as follows:

(b) Requires a person administering or dispensing a Schedule II controlled substance in an emergency situation with an orally or telephonically communicated prescription promptly to write the prescription and include in the prescription's written record the DPS registration number of the practitioner prescribing the substance, in addition to other information set forth in this subsection.

(d) Requires the director, by rule, and in consultation with the Texas Medical Board and Texas State Board of Pharmacy, to establish the period after the date on which the prescription for a Schedule II controlled substance is issued that a person is authorized to fill the prescription, except as specified by Subsection (e) and (f) (regarding the partial filling of such a prescription and the provision of a partially-filled prescription to a terminally-ill patient or patient in a long-term care facility). Deletes existing text prohibiting such a prescription from being filled after the seventh day after the date it is issued.

(k) Requires a prescription for a controlled substance to show the date of birth or age of the patient and the signatures of the prescribing practitioner and dispensing pharmacist, in addition to other information set forth in this subsection. Makes conforming changes.

(q) Requires each dispensing pharmacist to send all information required by the director, including required information to complete the Schedules III through V prescription forms, to the director by electronic transfer or other form approved by the director not later than the 15th day after the last day of the month in which a prescription is completely filled.

SECTION 3. Amends Sections 481.076(a) and (c), Health and Safety Code, as follows:

(a) Prohibits the director from permitting a person to have access to information submitted to the director under Section 481.074(q), in addition to certain other information, except for an investigator for the Texas Medical Board, rather than the Texas State Board of Medical Examiners, and other individuals set forth in this subsection.

(c) Requires the director by rule to design and implement a system for the submission of information under Section 481.074 (Prescriptions) and certain other sections to the director by electronic or other means and for the retrieval of such information. Makes a conforming change.

SECTION 4. Amends Sections 481.0761(a), (b), (c), and (e), Health and Safety Code, as follows:

(a) Requires the director to consult with the Texas State Board of Pharmacy and by rule to establish and revise as necessary a standardized database format to be used by a pharmacy to transmit the information required by Section 481.074(q), in addition to certain other information, to the director electronically or on storage media, including disks, tapes, and cassettes.

(b) Requires the director to consult with the Department of State Health Services, the Texas State Board of Pharmacy, and the Texas Medical Board and authorizes the director by rule to remove from or return to the official prescription program a controlled substance listed in Schedules II through V on the director's determination as set forth in this subsection.

(c) Authorizes the director by rule to permit multiple prescriptions to be administered or dispensed and recorded on one prescription form for a Schedule III through V controlled substance and to establish a procedure to control the release of information under Section 481.074 and certain other sections, in addition to other actions set forth in this subsection.

(e) Makes a conforming change.

SECTION 5. Amends Chapter 481, Health and Safety Code, by adding Subchapter H, as follows:

SUBCHAPTER H. ADMINISTRATIVE PENALTY

Sec. 481.301. IMPOSITION OF PENALTY. Authorizes DPS to impose an administrative penalty on a person who violates certain sections or rules or orders under those sections related to the manufacture, distribution, and dispensation of controlled substances, chemical precursors, and chemical laboratory apparatus.

Sec. 481.302. AMOUNT OF PENALTY. (a) Prohibits the penalty from exceeding \$1,000 for each violation. Provides that each day a violation continues or occurs is a separate violation for the purposes of imposing a penalty. Prohibits the total amount of penalty assessed from exceeding \$20,000 for a violation continuing or occurring on separate days under this subsection.

(b) Requires the penalty amount to be based on certain criteria set forth in this subsection.

Sec. 481.303. REPORT AND NOTICE OF VIOLATION AND PENALTY. (a) Requires DPS to give written notice of the report to the person by certified mail, registered mail, personal delivery, or another manner of delivery that records the person's receipt of the notice if DPS initially determines that a violation occurred.

(b) Requires the notice to include certain information set forth in this subsection.

Sec. 481.304. PENALTY TO BE PAID OR INFORMAL HEARING REQUESTED. (a) Authorizes a person receiving notice under Section 481.303, before the 21st day after the date the notice is received, in writing, to either accept the determination and recommended penalty or request an informal hearing held by DPS on the occurrence of the violation, the penalty amount, or both.

(b) Authorizes DPS to modify the amount of the recommended penalty at the conclusion of an informal hearing requested under Subsection (a).

(c) Requires the director by order to approve the determination and impose the recommended penalty if the person accepts the determination and recommended penalty, including any modification of the amount, or fails to timely respond to the notice.

Sec. 481.305. FORMAL HEARING. (a) Authorizes a person to request a formal hearing only after participation in an informal hearing.

(b) Requires the request to be submitted in writing and received by DPS before the 21st day after the date the person is notified of a decision from the informal hearing.

(c) Requires the director by order to approve the informal hearing's determination and impose the recommended penalty if a timely request for a formal hearing is not received.

(d) Requires the director, if a formal hearing is timely requested, to refer the matter to the State Office of Administrative Hearings (SOAH). Requires SOAH to promptly set a hearing date and give written notice of the time and place of the hearing to the director and the person requesting the hearing. Requires an administrative law judge of SOAH to conduct the hearing.

(e) Requires the judge to make findings of fact and conclusions of law and to promptly issue to the director a proposal for a decision about the occurrence of the violation and the amount of any proposed penalty.

(f) Requires the judge to include in the proposal for a decision, if a penalty is proposed under Subsection (e), a finding setting out costs, fees, expenses, and reasonable and necessary attorney's fees incurred by the state in the proceeding. Authorizes the director to adopt the finding and impose the costs, fees, and expenses on the person as part of the final order entered in the proceeding.

Sec. 481.306. DECISION. (a) Authorizes the director by order to find that a violation did or did not occur and impose a penalty, if applicable, based on the findings of fact, conclusions of law, and proposal for a decision.

(b) Requires the notice of the director's order under Subsection (a) sent to the person in the manner provided by Chapter 2001 (Administrative Procedure), Government Code, to include a statement of the person's right to judicial review of the order.

Sec. 481.307. **OPTIONS FOLLOWING DECISION: PAY OR APPEAL.** Requires the person to pay the penalty or file a petition for judicial review of the order contesting the occurrence of the violation, the amount of the penalty, or both, before the 31st day after the date a penalty order under Section 481.306 becomes final.

Sec. 481.308. **STAY OF ENFORCEMENT OF PENALTY.** (a) Authorizes a person who files a petition for judicial review within the period prescribed by Section 481.307 to stay or request the court to stay enforcement of the penalty in the manner set forth in this subsection.

(b) Authorizes the director to file with the court, before the sixth day after the date of receipt of a copy of an affidavit under Subsection (a)(2) (requesting the court to stay penalty enforcement due to financial inability to pay the penalty or provide a supersedeas bond), a contest to the affidavit. Requires the court to hold a hearing on the facts alleged in the affidavit as soon as practicable and to stay the enforcement of the penalty on finding that the alleged facts are true. Provides that the person who files such an affidavit has the burden of proving financial inability to pay the penalty or give a supersedeas bond.

Sec. 481.309. **COLLECTION OF PENALTY.** (a) Authorizes the penalty to be collected if the person does not pay the penalty and its enforcement is not stayed.

(b) Authorizes the attorney general to sue to collect the penalty.

Sec. 481.310. **DECISION BY COURT.** (a) Authorizes the court to uphold or reduce the amount of the penalty and order the person to pay the full or reduced amount if the court sustains the finding of a violation.

(b) Requires the court to order that a penalty is not owed if the court does not sustain the finding of a violation.

Sec. 481.311. **REMITTANCE OF PENALTY AND INTEREST.** (a) Requires the court, if the person paid the penalty and the penalty is reduced or not upheld by the court, to order, when the court's judgment becomes final, that the appropriate amount plus accrued interest be remitted to the person before the 31st day after the date that the judgment of the court becomes final.

(b) Provides that the interest accrues at the rate charged on loans to depository institutions by the New York Federal Reserve Bank.

(c) Requires the interest to be paid for the period beginning on the date the penalty is paid and ending on the date the penalty is remitted.

Sec. 481.312. **RELEASE OF BOND.** (a) Requires the court to order, when the court's judgment becomes final, the release of the supersedeas bond, if it was given by the person and the penalty is not upheld by the court.

(b) Requires the court, if the penalty is reduced, to order the release of a person's given supersedeas bond after the person pays the reduced penalty.

Sec. 481.313. **ADMINISTRATIVE PROCEDURE.** Provides that a proceeding to impose the penalty is considered to be a contested case under Chapter 2001, Government Code.

SECTION 6. Requires the director to adopt any rules necessary to administer and enforce Subchapter H, Chapter 481, Health and Safety Code, as added by this Act, not later than September 1, 2007. Requires the director to adopt the rules as soon as possible after that date if this section does not take effect before that date.

SECTION 7. (a) Effective date: September 1, 2007, except as provided by Subsections (b), (c), and (d) of this section.

(b) Effective date of Section 6 of this Act: upon passage or September 1, 2007.

(c) Effective date of Sections 481.074(k) and 481.076, Health and Safety Code, as amended by this Act, and Section 481.074(q), Health and Safety Code, as added by this Act: September 1, 2008, except as otherwise provided by Subsection (d) of this section. Requires the director to adopt any rules necessary to administer and enforce the changes in law made by those provisions not later than September 1, 2008.

(d) Provides that the change in law made by this Act in amending Sections 481.074(b) and (k), Health and Safety Code, requiring the use of registration numbers issued by DPS, takes effect only after DPS establishes a means by which pharmacies are able to electronically access and verify the accuracy of the numbers.