

BILL ANALYSIS

C.S.S.B. 1879
By: Williams
Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

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 of this bill.

Rulemaking authority previously granted to the director of the Department of Public Safety is modified in SECTION 3 and SECTION 4 of this bill.

Rulemaking authority is expressly granted to the public safety director of the Department of Public Safety in SECTIONS 8 and 9 of this bill.

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. The current DPS rule that requires the department to send notice to each registrant at the registrant's last known address according to the department's records at least 60 days before the expiration date of the registration is codified.

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, if the prescription is handwritten, the signature of the prescribing practitioner, in addition to other information set forth in this subsection. Makes conforming changes. Clarifies that the DPS number of the prescribing practitioner only has to be provided on the prescription if that practitioner is licensed in the state of Texas.

(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) The director may not permit any person to have access to information submitted to the director under Section 481.074(q) or 481.075 except an investigator for the Texas Medical Board, the Texas State Board of Podiatric Medical Examiners, the State Board of Dental Examiners, the State Board of Veterinary Medical Examiners, or the Texas State Board of Pharmacy; an authorized officer or member of the department engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state; or if the director finds that proper need has been shown to the director, a law enforcement or prosecutorial official engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state; a pharmacist or practitioner who is a physician, dentist, veterinarian, podiatrist, or advanced practice nurse or physician assistant described by Section 481.002(39)(D) and is inquiring about a recent Schedule II, III, IV, or V prescription history of a particular patient of the practitioner; or a pharmacist or practitioner who is inquiring about the person's own dispensing or prescribing activity.

(c) Requires the director by rule to design and implement a system for submission of information to the director by electronic or other means and for retrieval of information submitted to the director under this section and Sections 481.074 and 481.075. Requires the director to use automated information security techniques and devices to preclude improper access to the information. Requires the director to submit the system design to the Texas State Board of Pharmacy and the Texas Medical Board for review and approval or comment a reasonable time before implementation of the system and comply with the comments of those agencies unless it is unreasonable to do so.

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 Sections 481.074(q) and 481.075 (i) 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) Provides that the request must 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 administrative review 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 administrative review 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) Allows 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. (a) Creates an advisory committee to advise the Department of Public Safety on the implementation of the bill.

(b) Sets forth the membership of the advisory committee.

(c) Provides that the public safety director is the presiding officer of the advisory committee. Requires the committee to meet at the call of the presiding officer or at the request of any three members other than the director.

(d) Sets forth the duties of the advisory committee.

(e) Requires a report of the recommendations developed under subsection (d) be submitted to the governor, lieutenant governor, speaker of the house, and appropriate committees of the senate and the house not later than July 1, 2008.

(f) Provides that this section expires and the advisory committee is abolished on September 1, 2009.

SECTION 7. (a) Requires the Department of Public Safety, Texas Medical Board, Texas State Board of Pharmacy, State Board of Dental Examiners, and Board of Nurse Examiners to submit to the presiding officers of the Senate Committee on Health and Human Services and the House Committee on Public Health a report that details the number and type of actions relating to the prosecution of violations of Chapter 481, Health and Safety Code, as amended by this bill.

(b) Requires each agency to submit its initial report under Subsection (a) of this section not later than November 1, 2007. Requires each agency to submit an update of its initial report not later than May 1 and November 1 of each year.

(c) Provides that this section expires November 1, 2011.

SECTION 8. Requires the public safety director of the Department of Public Safety to adopt any rules necessary to administer and enforce Subchapter H, Chapter 481, Health and Safety Code, as added by this bill, not later than September 1, 2007, except that if this section does not take effect before that date, the public safety director is required to adopt the rules as soon as practicable after that date.

SECTION 9. (a) Provides that except as provided by Subsections (b), (c), and (d) of this section, this bill takes effect September 1, 2007.

(b) Provides that section 8 of the bill takes effect immediately if the bill receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this bill does not receive the vote necessary for immediate effect, Section 8 of this bill takes effect September 1, 2007.

(c) Provides that except as otherwise provided by Subsection (d) of this section, the changes in law made by this bill in amending Subsection (k), Section 481.074, and Section 481.076, Health and Safety Code, and in adding Subsection (q), Section 481.074 of that code, take effect

September 1, 2008. Requires the public safety director of the Department of Public Safety 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 bill in amending Subsections (b) and (k), Section 481.074, Health and Safety Code, to require the use of registration numbers issued by the Department of Public Safety takes effect only after the department establishes a means by which pharmacies are able to electronically access and verify the accuracy of the registration numbers.

EFFECTIVE DATE

SECTION 8 takes effect upon passage, or, if the Act does not receive the necessary vote, the Act takes effect September 1, 2007.

Sections 481.076, as amended, and 481.074(q), as added, Health and Safety Code, take effect September 1, 2008.

Section 481.074 (b), Health and Safety Code, as amended, becomes effective the later of September 1, 2007 or after DPS establishes a means by which pharmacies are able to electronically access and verify the accuracy of the registration numbers.

Section 481.074 (k), Health and Safety Code, as amended, becomes effective the later of September 1, 2008 or after DPS establishes a means by which pharmacies are able to electronically access and verify the accuracy of the registration numbers.

The remaining bill takes effect September 1, 2007.

COMPARISON OF ORIGINAL TO SUBSTITUTE

CSSB 1879 adds the following language to the original at the end of SECTION 1, "Not later than 60 days before the date the registration expires, the director shall send a renewal notice to the registrant at the last known address of the registrant according to department records."

CSSB 1879 removes the language "department registration number" from SECTION 2 subsection (k) (7) and adds subsection (k) (9) which states, "if the prescribing practitioner is licensed in this state, the practitioner's department registration number."

CSSB 1879 changes SECTION 3 subsection (a) (B) from "a pharmacist or practitioner who is a physician, dentist, veterinarian, or podiatrist and is inquiring about the recent Schedule II prescription history of a particular patient of the practitioner; or" to "a pharmacist or practitioner who is a physician, dentist, veterinarian, podiatrist, or advanced practice nurse or physician assistant described by Section 481.002(39)(D) and is inquiring about a recent Schedule II, III, IV, or V prescription history of a particular patient of the practitioner; or".

CSSB 1879 changes the language in SECTION 5 from "Sec. 481.301. IMPOSITION OF PENALTY. The department may impose an administrative penalty on a person who violates Section 481.061, 481.066, 481.067, 481.069-481.075, 481.077, 481.0771, 481.078, 481.080, or 481.081 or a rule or order adopted under any of those sections." to "Sec. 481.301. IMPOSITION OF PENALTY. The department may impose an administrative penalty on a person who violates Section 481.061, 481.066, 481.067, 481.069, 481.073, 481.074, 481.075, 481.077, 481.0771, 481.078, 481.080, or 481.081 or a rule or order adopted under any of those sections."

CSSB 1879 adds a new SECTION 6, creating an advisory committee to advise the Department of Public Safety on the implementation of this bill and the bill sets forth the membership and duties of the advisory committee.

CSSB 1879 adds a new SECTION 7, requiring the Department of Public Safety, Texas Medical Board, Texas State Board of Pharmacy, State Board of Dental Examiners, and Board of Nurse

C.S.S.B. 1879 80(R)

Examiners to submit to the presiding officers of the Senate Committee on Health and Human Services and the House Committee on Public Health a report that details the number and type of actions relating to the prosecution of violations of Chapter 481, Health and Safety Code, as amended by this bill

CSSB 1879 modifies the original by making conforming changes and renumbers accordingly.