

BILL ANALYSIS

Senate Research Center

C.S.S.B. 1245
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Health & Human Services
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Committee Report (Substituted)

DIGEST

Currently, the Controlled Substances Act requires that prescriptions written for Schedule II Controlled Substances be issued on special, serially numbered, triplicate prescriptions. It also closely restricts dissemination to use by specific agencies for drug-related investigations, even prohibiting release of statistical information. When a prescription is issued, one of the copies is sent to the Department of Public Safety (DPS) where the information on it is automated by data entry clerks. In 1988, 626,105 prescriptions were received, and each subsequent year, the number increased until, in 1996, 1,347,086 prescriptions were received, an increase of 115 percent. There is now technology available that will allow automated information to be collected directly from pharmacies and ultimately eliminate the need for most manual data entry.

This legislation would change the triplicate prescription to a single-copy, official prescription, and allow pharmacies to electronically transmit prescriptions to DPS rather than mail them in an effort to alleviate some of the record-keeping burden imposed under the current system. In addition, this bill would allow DPS to manage the increase in prescriptions without hiring additional employees, and would fund the program's administration and enforcement by increasing the fees collected. C.S.S.B. 1245 would also provide more recent and current information than is presently possible, and would broaden DPS' rulemaking authority regarding the official prescription program.

PURPOSE

As proposed, C.S.S.B. 1245 provides for laws regulating the distribution and dispensation of controlled substances and establishes the enforcement of those laws.

RULEMAKING AUTHORITY

Rulemaking authority is granted to the director of the Department of Public Safety or an employee of the department designated by the director in SECTIONS 2, 3, 6, and 7 (Sections 481.003, 481.064(a), 481.076(c), and 481.0761(a)-(d), Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 481.002, Health and Safety Code, by amending Subdivision (47), and by adding Subdivisions (50)-(54), to define "official prescription form," "patient identification number," "department," "driver's license," "personal identification certificate," and "prescription sticker." Deletes the definition of "triplicate prescription form."

SECTION 2. Amends Chapter 481A, Health and Safety Code, by adding Section 481.003, as follows:

Sec. 481.003. RULES. Authorizes the director of the Department of Public Safety (department), or an employee of the department designated by the director (director) to adopt rules to administer and enforce this chapter.

SECTION 3. Amends Section 481.064, Health and Safety Code, as follows:

Sec. 481.064. New heading: REGISTRATION FEES. Deletes the provision authorizing the director to adopt reasonable rules. Authorizes the director to charge an annual

registration fee of not more than \$25. Requires the director, by rule, to set the amount of the fee at the amount necessary to cover the cost of administering and enforcing this subchapter. Deletes the provision authorizing the director to charge a fee of not more than \$5 for the costs necessary to administer this chapter. Requires the director to deposit the collected fees to the credit of the operator's and chauffeur's license account in the general revenue fund, rather than in the state treasury. Makes conforming changes.

SECTION 4. Amends Section 481.074, Health and Safety Code, by amending Subsections (a)-(c) and (f), and adding Subsections (m) and (n), to prohibit a person from dispensing or administering a controlled substance listed in Schedule II without an official prescription form that meets certain requirements, with certain exceptions. Requires the person who administers or dispenses the substance, if the person is a prescribing practitioner or a pharmacist, to promptly comply with Subsection (c); or if the person is not a prescribing practitioner or a pharmacist, promptly write the prescription and include certain information in the written record of the prescription. Deletes the provision requiring the person to send a copy of the written record to the department by a certain date. Requires the pharmacist or pharmacy that employs the pharmacist to send all information required by the director to the director by specified means by a certain date, rather than sending to the department the department's copy by a certain date. Sets forth the terms by which a pharmacist is authorized to permit the delivery of a controlled substance by certain persons, and is required to retain in pharmacy records certain information regarding the delivery for a period of not less than three years. Provides an exception in the case of emergency. Makes conforming changes.

SECTION 5. Amends Section 481.075, Health and Safety Code, by amending Subsections (a)-(d), (f), (h), and (i), as follows:

Sec. 481.075. New heading: OFFICIAL PRESCRIPTION PROGRAM. Requires a practitioner who prescribes certain controlled substances to record the prescription on a prescription form that includes the information required by this section and affix to the form a prescription sticker issued by the director. Requires prescription stickers to be numbered and produced in a certain manner. Requires the director, rather than the department, to issue prescription stickers for a fee to cover certain costs. Requires each form used to prescribe a Schedule II controlled substance to contain certain information to be provided by the prescribing practitioner; information provided by the dispensing pharmacist; and the signatures of the prescribing practitioner and the dispensing pharmacist. Requires the prescribing practitioner, with certain exceptions, to fill in certain information on the form. Requires each dispensing pharmacist to fill in certain information on the form; retain the form and certain patient identification information within pharmacy records for a set period; and send certain information to the director by electronic transfer by a specified date. Requires a practitioner whose number or license has been denied, suspended, canceled, surrendered, or revoked, to return to the department all forms that have not been used for prescriptions not later than the 30th, rather than the seventh, day after the suspension, cancellation, or revocation. Authorizes each prescribing practitioner to use a prescription sticker only to prescribe a controlled substance, and sets forth other requirements of a prescribing practitioner regarding the official prescription program. Sets forth the terms by which a dispensing pharmacist is authorized to fill a prescription issued in another state. Provides that this section expires September 1, 2003. Deletes the provisions regarding the triplicate prescription program, and the provision authorizing the director to adopt rules to implement this section and Section 481.076. Makes conforming changes.

SECTION 6. Amends Section 481.076, Health and Safety Code, as follows:

Sec. 481.076. New heading: OFFICIAL PRESCRIPTION INFORMATION. Prohibits the director from permitting any person to have access to information submitted to the director under Section 481.075 except an investigator from certain boards; 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 certain law enforcement officials, prosecutorial officials, pharmacists, or practitioners, if the director finds that proper need has been shown. Provides that this section does not prohibit the director from creating, using, or disclosing statistical data about information received, provided certain

conditions are met. Requires the director, rather than the department, 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. Authorizes information submitted to the director to be used only for the administration, investigation, or enforcement of this chapter, or another law governing illicit drugs in this state or another state; investigatory purposes in connection with certain agencies; or dissemination of a statistical tabulation or report, provided certain conditions are met. Requires the director to remove certain information from the information retrieval system not later than a certain date, and authorizes the director to retain certain information necessary for an investigation until a certain date. Requires the director, if the director releases information under Subsection (a)(2), to notify and cooperate with that agency regarding the disposition of the matter before taking action against the person, unless notification is likely to interfere with an administrative or criminal investigation or prosecution; and to notify the agency of the disclosure of the information by a certain date unless certain circumstances exist. Requires the director, if he or she withholds notification, to notify the agency of the disclosure and the reason for withholding notification. Provides that information submitted to the director under Section 481.075 is confidential, and establishes that this section expires September 1, 2003. Deletes the provisions regarding triplicate prescription information. Makes conforming changes.

SECTION 7. Amends Chapter 481C, Health and Safety Code, by adding Section 481.0761, as follows:

Sec. 481.0761. RULES; AUTHORITY TO CONTRACT. Requires the director to consult with the Texas State Board of Pharmacy (board) and by rule, to establish and revise, as necessary, a standardized database format that may be used by a pharmacy to transmit the information required by Section 481.075(f) to the director. Requires the director to consult with certain entities, and to be authorized, by rule, to remove a controlled substance listed in Schedule II from the official prescription program; or return a substance previously removed from Schedule II to the official program. Authorizes the director, by rule, to permit more than one prescription to be administered or dispensed and recorded on one form; remove from or return to the program any aspect of the professional practice of practitioners or pharmacists, including administering or dispensing; waive or delay any requirement relating to the time or manner of reporting; establish compatibility protocols for electronic data transfer hardware, software, or format; permit the use of triplicate or single prescription forms; establish a procedure to control the release of information under Sections 481.075 and 481.076; and establish a minimum level of prescription activity. Requires the director, by rule, to authorize a prescribing practitioner to determine the necessity of obtaining and providing a particular patient identification number. Requires the director, in adopting a rule, to consider the economic impact of the rule on practitioners and pharmacists. Prohibits the director from adopting a rule relating to certain electronic transfers of information. Authorizes the director to authorize a contract between the department and another agency or a private vendor. Provides that this section expires September 1, 2003.

SECTION 8. Amends Section 481.127(a), Health and Safety Code, to provide that a person commits an offense if the person knowingly gives, permits, or obtains unauthorized access to information submitted to the director under Section 481.075. Makes conforming changes.

SECTION 9. Amends Section 481.128(a), Health and Safety Code, to delete the provision making it an offense if a registrant or dispenser knowingly refuses or fails to abide by a certain rule adopted before June 1, 1991. Makes conforming changes.

SECTION 10. Amends Section 481.129(a), Health and Safety Code, to make conforming changes.

SECTION 11. Amends Section 552.118, Government Code, as follows:

Sec. 552.118. New heading: EXCEPTION: OFFICIAL PRESCRIPTION FORM. Makes conforming changes.

SECTION 12. Amends Section 3.06(d)(6)(J)(i), Article 4495b, V.T.C.S., to authorize, rather than require, a physician to delegate the use of a prescription sticker or the use or issuance of an official prescription form. Makes conforming changes.

SECTION 13. Effective date: September 1, 1999, except as otherwise provided by this section.

Effective date for SECTION 7: September 1, 1997.

SECTION 14. Makes application of this Act prospective to September 1, 1999 regarding a prescription written under the triplicate prescription program.

SECTION 15. Makes application of this Act prospective to September 1, 1999 regarding an offense.

SECTION 16. Provides that the change in law made by this Act to Section 3.06(d)(6)(J)(k), Article 4495b, V.T.C.S., does not affect the dispensing of a Schedule II controlled substance by a pharmacist to certain persons.

SECTION 17. Emergency clause.

SUMMARY OF COMMITTEE CHANGES

SECTION 1.

Amends Section 481.002, Health and Safety Code, to redefine "official prescription form," and add the definition for "prescription sticker."

SECTION 4.

Amends Section 481.064, Health and Safety Code, to require a pharmacist who permits the delivery of a controlled substance by certain persons to retain certain information in the pharmacy records for not less than two, rather than three, years.

SECTION 5.

Amends Section 481.075, Health and Safety Code, to change several provisions regarding the official prescription program, particularly as it relates to the use of prescription stickers issued by the director. Replaces all references to "forms" with "prescription stickers." Changes the terms under which each prescription form used to prescribe a Schedule II controlled substance must contain certain information. Amends the responsibilities of a prescribing practitioner in filling out an official prescription form. Sets forth the terms by which a dispensing pharmacist in Texas may fill a prescription issued in another state. Provides that this section expires September 1, 2003.

SECTION 6.

Amends Section 481.076, Health and Safety Code, to replace the reference to "the recent prescription history of a particular patient" with "the recent Schedule II prescription history of a particular patient." Requires the director, if he or she permits access to information relating to a person licensed or regulated by certain agencies, to notify that agency of the disclosure by a certain date. Requires the director, if he or she withholds notification, to notify the agency of the disclosure and the reason for withholding notification. Provides that information submitted to the director is confidential, and that this section expires September 1, 2003.

SECTION 7.

Amends Section 481.0761, Health and Safety Code, to require the director, by rule, to authorize a prescribing practitioner to determine whether it is necessary to obtain a patient

identification number, rather than requiring the director, by rule, to establish a standard to be used by a prescribing practitioner in determining resolution of the same issue. Amends the terms regarding adoption of a rule by the director relating to the electronic transfer of information. Provides that this section expires September 1, 2003.

SECTION 8.

Amends Section 481.128(a), Health and Safety Code, to replace the reference to "official prescription form" with "prescription sticker or official prescription form."

SECTION 12.

Amends Section 3.06(d)(6)(J)(i), Article 4495b, V.T.C.S., to authorize, rather than require, a physician to delegate the use of a prescription sticker or the use or issuance of an official prescription form under Section 481.075, Health and Safety Code.

SECTION 14.

Changes the application of this Act regarding a prescription written under the triplicate prescription program to September 1, 1999, rather than January 1, 1999.

SECTION 16.

Provides that the change in law made by this Act to Section 3.06(d)(6)(J)(i), Article 4495b, V.T.C.S., does not affect the dispensing of a Schedule II controlled substance by a pharmacist to certain persons.