

SUBJECT: Regulation of controlled substances and those who prescribe them

COMMITTEE: Public Health — committee substitute recommended

VOTE: 6 ayes — Delisi, Jackson, Coleman, Gonzales, S. King, Olivo
0 nays
3 absent — Laubenberg, Cohen, Truitt

SENATE VOTE: On final passage, April 25 — 29-0

WITNESSES: For — Mike White, Orange County Sheriff’s Office
Against — Leland Lou, Texas Medical Association, Texas Pain Society
On — Gay Dodson, Texas State Board of Pharmacy; Johnny Hatcher, Texas Department of Public Safety; Donald Patrick, Texas Medical Board; Brad Shields, Texas Pharmacy Practice Coalition; Kristie Zamrazil, Texas Pharmacy Association)

BACKGROUND: Texas currently monitors only Schedule II prescription drugs and requires that pharmacies obtain controlled substance registration certificates.
Texas has special prescription pads for certain Schedule II drugs, including powerful painkillers.

DIGEST: CSSB 1879 would amend Health and Safety Code, ch. 481 to provide for monitoring of Schedule II through V prescription drugs, providing penalties for non-compliance with registration and control laws, and requiring studies from industry and government regulators of means for implementing monitoring and control rules and practices.
Expanded regulations. CSSB 1879 would establish a number of regulatory changes to facilitate better tracking and oversight of controlled substances and pharmaceuticals.

Sec. 481.064 would be amended to allow the director of the Department of Public Safety (DPS) to charge a late fee of not more than \$50 for each late renewal application for a Controlled Substance Registration Certificate. The director would have to send a renewal notice to registrants at least 60 days before the registration expired.

The bill would repeal the rule in sec. 481.074, Health and Safety Code, that a person could not fill a prescription for a controlled Schedule II substance after seven days from the date on which the prescription was issued. It instead would require the director, through rules and in consultation with the Texas Medical Board and the Texas State Board of Pharmacy, to establish the period after which the prescription was issued that a person could fill a prescription for a Schedule II substance.

CSSB 1879 would increase the requirements that a person had to fulfill in order to refill a prescription for a substance listed in Schedule II to include a signature of the prescribing practitioner, if the prescription were handwritten, and, if the prescribing practitioner were licensed in this state, the practitioner's department registration number.

Each dispensing pharmacist would have to send all information required by the director, including any information required to complete the Schedule III through V prescription forms, 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 was completely filled.

CSSB 1879 would empower the director, by rule, to remove a controlled substance listed in Schedules II through V from the official prescription program, if the director determined that the burden imposed by the program substantially outweighed the risk of diversion of the particular controlled substance. The director also could return a substance previously removed from Schedules II through V to the official prescription program, if the director determined that the risk of diversion substantially outweighed the burden imposed by the program on the particular controlled substance. The director by rule could permit more than one prescription to be administered or dispensed and recorded on one prescription form for Schedule III through V controlled substances.

Penalties. CSSB 1879 would impose administrative penalties on a person who violated laws requiring:

- registration of possession of a controlled substance (sec. 481.061, Health and Safety Code);
- voluntary surrender, cancellation, suspension, probation, or revocation of registry to possess a controlled substance (sec. 481.066, Health and Safety Code);
- records and inventories of controlled substances (sec. 481.067, Health and Safety Code);
- order forms for controlled substances (sec. 481.069, Health and Safety Code);
- communication of prescription by agent (sec. 481.073, Health and Safety Code);
- prescriptions for controlled substances (sec. 481.074, Health and Safety Code);
- official prescriptions program (sec. 481.075, Health and Safety Code);
- chemical precursor records and reports (sec. 481.077, Health and Safety Code);
- records and reports on pseudoephedrine (sec. 481.0771, Health and Safety Code);
- chemical precursor transfer permit (sec. 481.078, Health and Safety Code);
- chemical laboratory apparatus record keeping procedures and permit (sec. 481.080, Health and Safety Code);
- chemical laboratory apparatus transfer permit (sec. 481.081, Health and Safety Code); or
- a rule or order adopted under any of those sections.

The penalty could not exceed \$1,000 for each violation, and each day a violation continued or occurred would be a separate violation for purposes of imposing a penalty. The total amount of the penalty assessed for a violation continuing or occurring on separate days would not exceed \$20,000.

The bill would establish procedures for reporting violations and for notice and a hearing for violators before a fine could be issued.

Studies, rulemaking, and implementation. CSSB 1879 would establish an advisory committee to advise the department of Public Safety on the implementation of the bill. The committee would be chaired by the public safety director of DPS and would consist of two appointments by the

governor, two by the lieutenant governor, and two more by the governor from lists provided by speaker of the House. In addition, one member each from the Texas Medical Board, Texas State Board of Pharmacy, State Board of Dental Examiners, and the Board of Nursing Examiners would be included.

The committee would develop recommendations on:

- the improvement of the official prescription program established by sec. 481.075, Health and Safety Code;
- implementation of an electronic controlled substance monitoring system that would be used for prescriptions of controlled substances listed in Schedules II through V;
- data to be provided to DPS to support a controlled substance monitoring system, including provider identification information;
- implementation and enforcement of a controlled substance monitoring system;
- procedures necessary for real-time, point-of-service access for a practitioner authorized to prescribe or dispense controlled substances listed in Schedules II through V so that the practitioner could obtain the prescription history for a particular patient or the practitioner's own dispensing or prescribing activity; and
- procedures to be followed by DPS and the applicable licensing authority of this state, another state, or the United States when the department shared information related to diversion of controlled substances with a licensing authority for the purpose of licensing enforcement, or when a licensing authority shared information related to diversion of controlled substances with the department for the purpose of criminal enforcement.

The director would report the recommendations developed by the committee to the governor, the lieutenant governor, the speaker of the House, and appropriate committees of the Senate and House not later than July 1, 2008.

The Texas Medical Board, the Texas State Board of Pharmacy, the State Board of Dental Examiners, the Board of Nurse Examiners, and DPS would submit to the presiding officers of the Senate Committee on Health and Human Services and the House Committee on Public Health a report that detailed the number and type of actions relating to the prosecution of violations of Health and Safety Code, ch. 481, as amended by the bill.

Each agency would submit its initial report not later than November 1, 2007, and would submit an update of its initial report not later than May 1 and November 1 of each year.

CSSB 1879 would require the public safety director of DPS to adopt any rules necessary to administer and enforce subch. H, chap. 481, Health and Safety Code, not later than September 1, 2007, unless the bill did not take immediate effect in which case the public safety director would adopt the rules as soon as practicable after that date.

The bill would take immediate effect if finally passed by a two-thirds record vote of the membership of each house. Otherwise, it would take effect September 1, 2007. The changes in law made by this act in amending subsections (b) and (k), sec. 481.074, Health and Safety Code, to require the use of registration numbers issued by DPS would take effect only after the department established a means by which pharmacies were able electronically to access and verify the accuracy of registration numbers. The changes in law made by this act in amending secs. 481.074(k), 481.076, and 481.074(q) would take effect on September 1, 2008.

**SUPPORTERS
SAY:**

There has been explosive growth in the market for prescription pain killers. Texas' borders and interstate highways have witnessed a proliferation of pain clinics that frequently issue prescriptions for powerful pain killers. Many of these clinics have poor records, and state oversight boards are poorly equipped to handle the increasing number of questionable prescriptions.

CSSB 1879 would address this situation by requiring doctors and pharmacists to start recording and reporting prescriptions for and issuance of Schedule II through V controlled substances. This would facilitate appropriate government oversight. In addition, CSSB 1879 would require the implementation of a statewide records system that would allow doctors and pharmacists to track how many prescriptions an individual had. This would allow these groups to police themselves and prevent the issuance or filling of repeat prescriptions. Finally, CSSB 1879 would give government regulators the ability to issue civil fines against individuals who violated record-keeping and control legislation.

According to the Legislative Budget Board, CSSB 1879 would generate a positive impact of \$1,220,000 in general revenue through the next

biennium. These funds would be generated through late fines collected on individuals who failed to timely renew their Controlled Substance Registration Certificate. These funds will more than offset the costs of increased workload for DPS.

OPPONENTS
SAY:

This bill could interfere with patients receiving needed pain medications. While the goals of CSSB 1879 for diversion from addiction are laudable, a better solution would be to educate doctors on how to recognize symptoms of addiction and when it would be appropriate to issue certain powerful drugs. Too many patients are suffering when they do not have to. Increasing the tracking and reporting requirements for these drugs would mean fewer doctors would prescribe them because they would be viewed as too much trouble. This could mean that even fewer patients received the palliative care they needed.

CSSB 1879 would increase the amount and kinds of reporting with which pharmacists and doctors would have to comply in order to prescribe and issue controlled pharmaceuticals. Health care costs are skyrocketing in Texas, in large part due to complex payment and paperwork requirements. CSSB 1879 would contribute to the amount of time that health care workers would have to spend doing paper work, while decreasing the amount of time they could spend with patients.

NOTES:

Among the changes the House committee substitute made to the Senate-passed version was to add the advisory committee and the reports to the legislative committees on prosecutions of violators.