SUBJECT: Requiring controlled substances reports; expanding PMP access

COMMITTEE: Public Health — favorable, without amendment

VOTE: 9 ayes — S. Thompson, Wray, Allison, Frank, Guerra, Ortega, Price, Sheffield, Zedler

0 nays

2 absent — Coleman, Lucio

SENATE VOTE: On final passage, March 26 — 31-0

WITNESSES: *On House companion bill, HB 1668:*
For — (*Registered, but did not testify:* Stephanie Chiarello, Texas Pharmacy Association; Tammy Cohen, Texas Society of Health-System Pharmacists, John Heal, Texas TrueCare Pharmacies, Bradford Shields, Texas Federation of Drug Stores, Texas Society of Health-System Pharmacists)

Against — None

On — (*Registered, but did not testify:* Allison Benz, Texas State Board of Pharmacy)

BACKGROUND: The Texas Prescription Monitoring Program (PMP) is a database used to collect and monitor prescription data on all Schedule II, III, IV, and V controlled substances dispensed by a pharmacy in Texas or dispensed to a Texas resident by a pharmacy in another state.

Health and Safety Code sec. 481.0764(a) requires a person authorized under HIPAA to receive medical information submitted to the Texas State Board of Pharmacy from the PMP to access this information before prescribing or dispensing opioids and other certain Schedule II, III, and IV drugs to a patient.

Texas Attorney General Opinion No. GA-0384, issued December 21, 2005, found that provisions of SB 410 by Whitmire as enacted by the 79th Legislature relating to the licensing of Canadian pharmacies and the ability to import pharmaceutical drugs from Canada would violate the U.S. Federal Food, Drug, and Cosmetic Act of 1938.

The Texas State Board of Pharmacy does not implement the provisions of SB 410 relating to Canadian pharmacies based on the Texas Attorney General's opinion from 2005.

DIGEST:

SB 683 would require certain reports from pharmacists dispensing Schedule II controlled substances and wholesale distributors of Schedule II-V drugs, expand access to the Prescription Monitoring Program (PMP), allow Class E pharmacies licensed in other states to act as processing facilities, and repeal certain provisions of the Texas Pharmacy Act relating to Canadian pharmacies and the license renewal of pharmacies subject to disciplinary actions in other states.

Pharmacist reports. The bill would require pharmacists dispensing Schedule II controlled substances who had not dispensed any controlled substance prescriptions during a period of seven consecutive days to send a report to the Texas State Board of Pharmacy (TSBP) indicating this, unless the pharmacy had obtained a waiver or permission to delay reporting to the board.

Access to PMP. The bill would add certain individuals to the list of those who could access information submitted under the PMP, provided that access to this information also was authorized under HIPAA. These individuals would include:

- a pharmacist or pharmacist-interns, pharmacy technicians, and pharmacy technician trainees acting at the direction of a pharmacist who were inquiring about a recent Schedule II, III, IV, or V prescription history of a particular patient of the pharmacist; or
- a practitioner inquiring about the activity of an individual to whom the practitioner had delegated prescribing authority.

The bill would add pharmacists, pharmacist technicians, technician trainees, pharmacist interns, and practitioners who were authorized to electronically access the PMP to the list of people permitted to directly access prescription monitoring information available from other states pursuant to an interoperability agreement entered into by TSBP.

Wholesale distributor reports. The bill would amend reporting requirements for a wholesale distributor, requiring it to report to TSBP the distribution of all Schedules II, III, IV, and V controlled substances to a person in Texas, rather than information that the distributor was required to report to the U.S. Food and Drug Administration. The distributor would be required to report the information with the same frequency it reported to the federal Drug Enforcement Administration.

Work group meetings. The bill would require the interagency prescription monitoring work group to meet when necessary as determined by TSBP, instead of quarterly.

Out-of-state pharmacies. The bill would add to the list of out-of-state pharmacies that qualified to receive a Class E pharmacy license or nonresident pharmacy license pharmacies whose primary business was to process a prescription drug order for a patient, including a patient in Texas, or to perform another pharmaceutical service, as defined by TSBP rule.

Canadian pharmacies. The bill would repeal sections of the Occupations Code relating to the designation, inspection, on-site supervision, and practice of Canadian pharmacies.

Out-of-state pharmacy license renewal. The bill also would repeal the statute preventing a pharmacy from renewing its license in Texas if the pharmacy's license to operate in another state had been suspended, revoked, canceled, or subject to an action that prohibited the pharmacy from operating in that state.

The bill would take effect September 1, 2019.

SUPPORTERS SAY:

SB 683 would provide clarity to existing law by eliminating inconsistencies and conflicting provisions in the Texas Pharmacy Act, specifying who was authorized to access information in the Prescription Monitoring Program, and clarifying reporting requirements for pharmacies and wholesale distributors. The bill also would bring the Occupations Code in line with federal law and FDA rules by eliminating provisions requiring the Texas State Board of Pharmacy (TSBP) to designate and inspect Canadian pharmacies.

The provisions of the bill allowing pharmacists and practitioners to access the prescribing history of those to whom they have delegated prescribing authority would provide accountability in the prescribing process and ensure that physicians bear the ultimate responsibility for the actions of their delegates.

SB 683 would ensure that pharmacies were not unnecessarily penalized for actions taken against pharmacies with the same owners in other states by removing the prohibition on license renewal. This would not prevent TSBP from opening investigations, but would simply prevent pharmacies from being penalized for the actions of other pharmacies outside of Texas.

The bill also would provide for more complete drug reporting from wholesalers by requiring these distributors to provide information on all Schedule II, III, IV, and V drugs to the board.

OPPONENTS SAY:

No concerns identified.