BILL ANALYSIS

Senate Research Center

S.B. 683 By: Buckingham Health & Human Services 5/30/2019 Enrolled

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

S.B. 683 makes several recommended "clean-up" changes needed to eliminate inconsistencies and language with conflicting provisions in the Pharmacy Practice Act. The changes included in the bill are recommended by the Texas State Board of Pharmacy (TSBP). These changes are nonsubstantive and do not increase a pharmacist's scope of practice in any way.

Specifically, the proposed legislation includes the follow changes:

- requires pharmacies to submit a "zero" report if the pharmacy does not dispense any controlled substance prescriptions;
- allows pharmacist interns and pharmacist technician trainees access to the Prescription Monitoring Program (PMP) and replaces the name of the State Board of Podiatric Medical Examiners with the Texas Department of Licensing and Regulation per legislative action;
- allows physicians to view PMP prescribing history of individuals to whom they have given delegating prescribing authority;
- updates the Controlled Substances Act to require wholesale distributors to report on all controlled substances in the same format as required by the federal Food and Drug Administration;
- allows the Interagency PMP Work Group to meet "as necessary" instead of quarterly;
- allows Class E (mail order) pharmacies to be processing facilities as in other states;
- updates language that allows TSBP to regulate a pharmacist when administering an Immunization and Vaccination under certain conditions;
- repeals sections of the code requiring the licensure of Canadian pharmacies shipping prescriptions to Texas based on a Texas attorney general opinion stating this would be a violation of federal law; and
- repeals the "sister state" section that prevents a license renewal of a pharmacy in Texas if a pharmacy owned by the same company is subject to disciplinary action in another state. (Original Author's/Sponsor's Statement of Intent)

S.B. 683 amends current law relating to the licensing and regulation of pharmacists and pharmacies.

RULEMAKING AUTHORITY

Rulemaking authority previously granted to Texas State Board of Pharmacy is rescinded in SECTION 7 (Sections 554.016 and 556.0555, Occupations Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 481.075(i), Health and Safety Code, as follows:

(i) Requires each dispensing pharmacist, if the pharmacy does not dispense any controlled substance prescriptions during a period of seven consecutive days, to send a report to the Texas State Board of Pharmacy (TSBP) indicating that the pharmacy did not dispense any controlled substance prescriptions during that period, unless the pharmacy has obtained a waiver or permission to delay reporting to TSBP. Makes nonsubstantive changes.

SECTION 2. Amends Sections 481.076(a) and (k), Health and Safety Code, as follows:

(a) Prohibits TSBP from permitting any person to have access to information submitted to TSBP under Section 481.074(q) (relating to the requirement that pharmacists send certain information to TSBP) or 481.075 (Official Prescription Program) except:

(1) certain entities, including the Texas Department of Licensing and Regulation, with respect to the regulation of podiatrists, for certain purposes. Deletes from this list the Texas State Board of Podiatric Examiners;

(2)–(4) makes no changes to these subdivisions;

(5) provided that accessing the information is authorized under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and regulations adopted under that Act:

(A) a pharmacist or a pharmacist-intern, pharmacy technician, or pharmacy technician trainee, as defined by Section 551.003 (Definitions), Occupations Code, acting at the direction of a pharmacist, who is inquiring about a recent Schedule II, III, IV, or V prescription history of a particular patient of the pharmacist, rather than a pharmacist or a pharmacy technician as defined by Section 551.003, Occupations Code, acting at the direction of a pharmacist; or

(B) makes no changes to this paragraph;

(6) a pharmacist or practitioner who is inquiring about the person's own dispensing or prescribing activity or a practitioner who is inquiring about the prescribing activity of an individual to whom the practitioner has delegated prescribing authority, rather than a pharmacist or practitioner who is inquiring about the person's own dispensing or prescribing activity; or

(7) makes no changes to this subdivision.

(k) Provides that a person authorized to access information under Subsection (a)(4) or (5), rather than under (a)(4), who is registered with TSBP for electronic access to the information is entitled to directly access the information available from other states pursuant to an interoperability agreement described by Subsection (j).

SECTION 3. Amends Section 481.0766(a), Health and Safety Code, as follows:

(a) Requires a wholesale distributor to report to TSBP the distribution of all Schedules II, III, IV, and V controlled substances, rather than requiring a wholesale distributor to report to TSBP the information that the distributor is required to report to the Automation of Reports and Consolidated Orders System (ARCOS) of the Federal Drug Enforcement Administration for the distribution of a controlled substance, by the distributor to a person in this state. Require the distributor to report the information to TSBP in the same format and with the same frequency as the information is reported to the Federal Drug Enforcement Administration, rather than ARCOS.

SECTION 4. Amends Section 481.353(a), Health and Safety Code, to require the work group to meet when necessary as determined by TSBP, rather than at least quarterly.

SECTION 5. Amends Section 560.051(f), Occupations Code, as follows:

(f) Authorizes a Class E pharmacy license or nonresident pharmacy license to be issued to a pharmacy located in another state whose primary business is to:

(1) creates this subdivision from existing Paragraphs (A) and (B) and makes nonsubstantive changes;

(2) process a prescription drug order for a patient, including a patient in this state; or

(3) perform another pharmaceutical service, as defined by TSBP rule.

SECTION 6. Amends Subchapter B, Chapter 565, Occupations Code, by adding Section 565.0591, as follows:

Sec. 565.0591. REVOCATION OF PHARMACY LICENSE FOR FAILURE TO OPERATE. (a) Requires TSBP, on discovery by TSBP that a pharmacy licensed under Chapter 560 (Licensing of Pharmacies) has ceased to operate for a period of 30 days or longer, to notify the pharmacy that the license will be revoked.

(b) Requires the notice to include certain information.

(c) Authorizes the license holder, not later than the 20th day after the date the license holder receives the notice of revocation under this section, to submit a written request for a hearing to contest the revocation.

(d) Requires TSBP, if the license holder does not request a hearing within the period prescribed by Subsection (c), to:

(1) enter an order revoking the license; and

(2) notify the license holder of the order.

(e) Requires a panel of three TSBP members appointed by the president of TSBP, if the license holder requests a hearing within the period prescribed by Subsection (c), to conduct the hearing. Requires the panel, at the hearing to determine whether the license holder has violated Section 565.002(a)(7) (relating to TSBP disciplining an applicant for or the holder of a pharmacy license if the applicant failed to engage in or ceased to engage in the business described in the application for a license).

(f) Requires TSBP, if the panel determines that the license holder committed the violation, to promptly:

(1) enter an order revoking the license; and

(2) notify the license holder of the order.

(g) Provides that Chapter 2001 (Administrative Procedure), Government Code, does not apply to a determination under Subsection (e).

SECTION 7. Repealer: Section 554.016 (Canadian Pharmacy Inspection; Designation; Fees; Information), Occupations Code.

Repealer: Section 556.0555 (Inspections), Occupations Code.

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Repealer: Section 560.001(c) (relating to the prohibiting a pharmacy located in Canada from shipping, mailing, or delivering prescriptions unless certain conditions are met), Occupations Code.

Repealer: Section 560.0525 (Additional Qualification Requirements For Canadian Pharmacies), Occupations Code.

Repealer: Section 561.003(f) (relating to the prohibiting a pharmacy from renewing a license if the pharmacy's license to operate was revoked in another state), Occupations Code.

Repealer: Section 562.101 (f-1) (relating to the requirements relating to the designation of a pharmacist-in-charge for a Canadian pharmacy), Occupations Code.

Repealer: Section 562.111 (Prescription Drug Order For Consumer), Occupations Code.

Repealer Subchapter E, Chapter 562 (Practice by Canadian Pharmacy), Occupations Code.

SECTION 8. Effective date: September 1, 2019.