

BILL ANALYSIS

Senate Research Center

C.S.H.B. 2561
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Health & Human Services
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Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

H.B. 2561 is to enact the recommendations of the Sunset Advisory Commission (Sunset) regarding the Texas State Board of Pharmacy (TSBP). The legislature created TSBP in 1907 to regulate the practice of pharmacy in the State of Texas. To achieve its mission, TSBP licenses pharmacies and pharmacists, registers pharmacy technicians, trainees, and interns, sets standards for the practice of pharmacy, and investigates complaints against licensees and registrants. TSBP is subject to abolishment under the Sunset Act on September 1, 2017, unless continued by the legislature. Sunset recommended continuing TSBP for 12 years. As a result of its review of TSBP, Sunset recommended several statutory modifications that are contained in this legislation.

The legislation addresses issues differently from current law by:

- requiring pharmacists to search the Prescription Monitoring Program database before dispensing especially addictive and dangerous controlled substances;
- requiring pharmacists or their delegates to enter dispensing information in the Prescription Monitoring Program database within one business day of dispensing controlled substances, rather than the current one week, to ensure timely, complete data;
- requiring wholesale pharmaceutical distributors to report sales of controlled substances to TSBP in the same format and with the same frequency as the information is reported to the Automation of Reports and Consolidated Orders System (ARCOS) of the Federal Drug Enforcement Administration;
- authorizing TSBP to highlight potentially dangerous prescribing and dispensing patterns through proactive electronic notifications to system users;
- removing unnecessary qualifications required of applicants that could unreasonably restrict entry into practice;
- requiring TSBP to create a system of graduated penalties for late renewal of pharmacy technician registration to incentivize timely renewal while reducing overall fees;
- authorizing TSBP to delegate tasks to the executive director to increase efficiency;
- requiring TSBP to develop continuing education standards for pharmacy technicians to ensure technicians remain educated on changing developments in their field;
- authorizing TSBP to deny renewal applications from applicants noncompliant with TSBP disciplinary orders, a standard tool to better protect the public;
- updating a Sunset across-the-board recommendation to ensure TSBP members are adequately trained on their responsibilities, and requiring TSBP to publish signed receipt of training materials on TSBP's website;
- allows an applicant or licensee to use as a defense in a licensing decision or disciplinary hearing that their failure to comply with a TSBP rule, regulation, policy, or penalty was due to a sincerely held religious belief or that TSBP's rule or policy infringes upon their

free exercise of religion. Allows TSBP to defend their action against an applicant or licensee if they can demonstrate that the action was essential to enforcing a compelling governmental purpose and was narrowly tailored to accomplish that purpose; and applying a Sunset across-the-board recommendation requiring TSBP to develop a policy for negotiated rulemaking and alternative dispute resolution. (Author's / Sponsor's Original Statement of Intent)

C.S.H.B. 2561 amends current law relating to the continuation and functions of the Texas State Board of Pharmacy and authorizes a reduction in fees.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTION 3 (Section 481.0761, Health and Safety Code), SECTION 15 (Section 568.0045, Occupations Code), and SECTION 21 of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 481.074(q), Health and Safety Code, to require each dispensing pharmacist to send certain required information to the Texas State Board of Pharmacy (TSBP) by electronic transfer or another form approved by TSBP not later than the next business day after the date the prescription is completely filled, rather than not later than the seventh day after the date the prescription is completely filled.

SECTION 2. Amends Section 481.075(i), Health and Safety Code, to require each dispensing pharmacist to send certain required information to TSBP by electronic transfer or another form approved by TSBP not later than the next business day after the date the prescription is completely filled, rather than not later than the seventh day after the date the prescription is completely filled.

SECTION 3. Amends Section 481.0761, Health and Safety Code, by adding Subsections (h), (i), and (j) as follows:

(h) Requires TSBP, in consultation with the Texas Department of Public Safety (DPS) and the regulatory agencies listed in Section 481.076(a)(1) (relating to an investigator for TSBP, 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, the Texas Board of Nursing, and the Texas Optometry Board), to identify prescribing practices that may be potentially harmful and patient prescription patterns that may suggest drug diversion or drug abuse. Requires TSBP to determine the conduct that constitutes a potentially harmful prescribing pattern or practice and develop indicators for levels of prescriber or patient activity that suggest a potentially harmful prescribing pattern or practice may be occurring or drug diversion or drug abuse may be occurring.

(i) Authorizes TSBP, based on the indicators developed under Subsection (h), to send an electronic notification to a dispenser or prescriber if the information submitted under Section 481.074(q) (relating to requiring that each dispensing pharmacist send certain information to TSBP not later than a certain date) or 481.075 (Official Prescription Program) indicates potentially harmful prescribing pattern or practice may be occurring or drug diversion or drug abuse may be occurring.

(j) Authorizes TSBP, by rule, to develop guidelines identifying behavior suggesting a patient is obtaining controlled substances that indicate drug diversion or drug abuse is occurring. Requires a pharmacist who observes behavior described by this subsection by a person who is to receive a controlled substance to access the information under Section 481.076(a)(5) (relating to certain pharmacists and pharmacy technicians) regarding the patient for whom the substance is to be dispensed.

SECTION 4. Amends Subchapter C, Chapter 481, Health and Safety Code, by adding Sections 481.0763 and 481.0764, as follows:

Sec. 481.0763. DUTY OF PHARMACISTS. Requires a pharmacist to access information under Section 481.076(a)(5) with respect to a patient before dispensing opioids, benzodiazepines, barbiturates, or carisoprodol for the patient.

Sec. 481.0764. REPORTS OF WHOLESALE DISTRIBUTORS. (a) Requires 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. Requires the distributor to report the information to TSBP in the same format and with the same frequency as the information is reported to ARCOS.

(b) Provides that information reported to TSBP under Subsection (a) is confidential and not subject to disclosure under Chapter 552 (Public Information), Government Code.

SECTION 5. Amends Section 551.005, Occupations Code, to provide that, unless continued in existence as provided by Chapter 325 (Sunset Law), Government Code (Texas Sunset Act), TSBP is abolished and this subtitle (Pharmacy and Pharmacists) expires September 1, 2029, rather than September 1, 2017.

SECTION 6. Amends Chapter 551, Occupations Code, by adding Section 551.008, as follows:

Sec. 551.008. CLAIM OR DEFENSE FOR PROHIBITED RULE OR POLICY. (a) Authorizes a person to assert as an affirmative defense in an administrative hearing or as a claim or defense in a judicial proceeding under Chapter 37 (Declaratory Judgments), Civil Practice and Remedies Code, that a TSBP rule, regulation, or policy, or a penalty imposed by TSBP limits the ability of an applicant for a license or for registration under this subtitle to be licensed or registered based on a sincerely held religious belief of the applicant or burdens a license holder's or registrant's free exercise of religion, regardless of whether the burden is the result of a rule generally applicable to all license holders or registrants, as applicable, freedom of speech regarding a sincerely held religious belief, or membership in any religious organization.

(b) Provides that Subsection (a) does not apply to a rule, regulation, or policy adopted or a penalty imposed by TSBP that results in a limitation or burden described by Subsection (a) if the rule, regulation, policy, or penalty is essential to enforcing a compelling governmental purpose and narrowly tailored to accomplish that purpose.

(c) Provides that Subsection (a) does not apply to any action imposed by TSBP to enforce a minimum standard applicable to the licensing, practice, or professional conduct of a license holder or registrant, as required by a TSBP statute or rule.

(d) Authorizes a person to bring an action for injunctive relief against a violation of this section.

SECTION 7. Amends Section 552.006, Occupations Code, by amending Subsection (b) and adding Subsection (d), as follows:

(b) Requires the training program to provide the person with information regarding: the law governing TSBP's operations; the programs, functions, rules, and budget of TSBP; the scope of and limitations on the rulemaking authority of TSBP; the results of the most recent formal audit of TSBP; the requirements of certain laws, including other laws applicable to members of TSBP in performing their duties; and any applicable ethics policies adopted by TSBP or the Texas Ethics Commission (TEC), rather than with information regarding this subtitle and the programs, functions, rules, and budget of TSBP; the results of the most recent formal audit of TSBP, the requirements of certain

laws, and any applicable ethics policies adopted by TSBP or TEC. Redesignates subdivisions accordingly.

(d) Requires the executive director of TSBP (executive director) to create a training manual that includes the information required by Subsection (b). Requires the executive director to distribute a copy of the training manual annually to each TSBP member. Requires each TSBP member, on receipt of the training manual, to sign and submit to the executive director a statement acknowledging receipt of the training manual. Requires TSBP to publish a copy of each signed statement on TSBP's Internet website.

SECTION 8. Amends Section 553.003(b), Occupations Code, to include the requirement of the executive director to, under the direction of TSBP, perform the duties required by this subtitle or designated by TSBP. Makes nonsubstantive changes.

SECTION 9. Amends Subchapter A, Chapter 554, Occupations Code, by adding Section 554.0011, as follows:

Sec. 554.0011. USE OF ALTERNATIVE RULEMAKING AND DISPUTE RESOLUTION. (a) Requires TSBP to develop a policy to encourage the use of certain rulemaking and alternative dispute resolution procedures.

(b) Requires TSBP's procedures relating to alternative dispute resolution to conform, to the extent possible, to any model guidelines issued by the State Office of Administrative Hearings for the use of alternative dispute resolution by state agencies.

(c) Requires TSBP to coordinate the implementation of the policy adopted under Subsection (a), provide training as needed to implement the procedures for negotiated rulemaking or alternative dispute resolution, and collect data concerning the effectiveness of those procedures.

SECTION 10. Amends Section 558.051(a), Occupations Code, to delete the requirement that a completed application on a form prescribed by TSBP with satisfactory sworn evidence that the applicant is of good moral character be submitted to TSBP by an applicant for licensing by examination.

SECTION 11. Amends Section 558.101(a), Occupations Code, to delete the requirement of good moral character for an applicant for licensing by reciprocity.

SECTION 12. Amends Section 559.003, Occupations Code, by adding Subsection (f), to authorize TSBP to refuse to renew a license to practice pharmacy for a license holder who is in violation of a TSBP order.

SECTION 13. Amends Section 568.002(c), Occupations Code, to delete the requirement that an applicant for registration as a pharmacy technician or pharmacy technician trainee be of good moral character. Makes nonsubstantive changes.

SECTION 14. Amends Section 568.004, Occupations Code, as follows:

Sec. 568.004. RENEWAL OF REGISTRATION. (a) Creates this subsection from existing text. Makes no further changes to this subsection.

(b) Requires the registrant, to renew a pharmacy technician registration, before the expiration date of the registration, to meet certain requirements.

(c) Authorizes a person whose pharmacy technician registration has been expired for 90 days or less to renew the expired registration by paying to TSBP a renewal fee that is equal to one and one-half times the normally required renewal fee for the registration.

(d) Authorizes a person whose pharmacy technician registration has been expired for more than 90 days but less than one year to renew the expired registration by paying TSBP a renewal fee that is equal to two times the normally required renewal fee for the registration.

(e) Prohibits a person whose pharmacy technician registration has been expired for one year or more from renewing the registration. Authorizes the person to register by complying with the requirements and procedures for initially registering, including the examination requirement.

(f) Authorizes TSBP to refuse to renew a pharmacy technician registration for a registrant who is in violation of a TSBP order.

SECTION 15. Amends Chapter 568, Occupations Code, by adding Section 568.0045, as follows:

Sec. 568.0045. RULES RELATING TO CONTINUING EDUCATION. Requires TSBP to adopt rules relating to the continuing education required for pharmacy technicians. Requires that the rules include certain requirements.

SECTION 16. Provides that a pharmacist is not required to comply with a rule adopted under Section 481.0761(j), Health and Safety Code, as added by this Act, before January 1, 2018.

SECTION 17. Provides that Section 481.0763, Health and Safety Code, as added by this Act, applies only to a pharmacist who dispenses a controlled substance on or after January 1, 2018.

SECTION 18. (a) Provides that, except as provided by Subsection (b) of this section, Section 552.006, Occupations Code, as amended by this Act, applies to a member of TSBP appointed before, on, or after the effective date of this Act.

(b) Provides that a member of TSBP who, before the effective date of this Act, completed the training program required by Section 552.006, Occupations Code, as that law existed before the effective date of this Act, is required to complete additional training only on subjects added by this Act to the training program as required by Section 552.006, Occupations Code, as amended by this Act. Prohibits a TSBP member described by this subsection from voting, deliberating, or being counted as a member in attendance at a meeting of TSBP held on or after December 1, 2017, until the member completes the additional training.

SECTION 19. Makes application of Sections 558.051, 558.101, and 568.002, Occupations Code, as amended by this Act, prospective.

SECTION 20. Makes application of Section 559.003, Occupations Code, as amended by this Act, and Sections 568.004(b), (e), and (f), Occupations Code, as added by this Act, prospective.

SECTION 21. Requires TSBP to, as soon as practicable after the effective date of this Act, adopt rules to reduce the amount of the fees imposed by TSBP for the renewal of an expired pharmacy technician registration to reflect the amounts provided for by Sections 568.004(c) and (d), Occupations Code, as added by this Act. Requires a pharmacy technician who renews an expired registration certificate on or after the effective date of this Act to pay the amount provided for by Section 568.004(c) or (d), Occupations Code, as added by this Act, instead of the amount provided for under TSBP rules adopted before that date.

SECTION 22. Effective date: September 1, 2017.