

## **BILL ANALYSIS**

Senate Research Center  
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C.S.S.B. 460  
By: Schwertner  
Health & Human Services  
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Committee Report (Substituted)

### **AUTHOR'S / SPONSOR'S STATEMENT OF INTENT**

C.S.S.B. 460 updates the Pharmacy Act to close loopholes and keep pace with changing technologies. It repeals outdated and conflicting code provisions, amends portions of the statute for clarity, and makes other minor changes for the purpose of increasing efficiency at the Texas State Board of Pharmacy (TSBP) and holding bad actors accountable.

Notable changes made by C.S.S.B. 460 include allowing pharmacists to refill prescriptions of dangerous drugs during declared disasters, allowing pharmacies to use digital displays to post required notices to consumers, and clarifying that TSBP may inspect the records of pharmacists practicing in nontraditional settings.

C.S.S.B. 460:

- Removes provisions in Section 14 that would have repealed Sections 562.151(1) and (3), 562.152, and 562.153, Occupations Code, which pertain to office use compounding.
- Adds Section 11, which enables TSBP to discipline pharmacy license holders who commit insurance fraud by waiving patient copayments or deductibles for compounded drugs without a good-faith attempt to collect.
- Narrows the scope of TSBP authority to inspect financial records by tying the inspection to the investigation of a "specific complaint" and reiterates that financial records are confidential and not subject to open records requests.
- Deletes a reference to "Texas Medical Board rule" in Section 9.

C.S.S.B. 460 amends current law relating to the licensing and regulation of pharmacists and pharmacies.

### **RULEMAKING AUTHORITY**

Rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTION 2 (Section 555.002, Occupations Code) and SECTION 5 (Section 556.057, Occupations Code) of this bill.

### **SECTION BY SECTION ANALYSIS**

SECTION 1. Amends Section 483.047, Health and Safety Code, by amending Subsection (a) and adding Subsections (b-1) and (b-2), as follows:

- (a) Provides that a pharmacist commits an offense, except as authorized by Subsections (b) and (b-1), rather than Subsection (b), if the pharmacist refills a prescription unless:

(1) the prescription contains an authorization by the practitioner for the refilling of the prescription, and the pharmacist refills the prescription in the manner provided by the authorization; or

(2) at the time of refilling the prescription, the pharmacist is authorized to do so by the practitioner who issued the prescription.

(b-1) Authorizes a pharmacist, notwithstanding Subsection (b) (authorizing a pharmacist to exercise his professional judgment in refilling a prescription for a dangerous drug without the authorization of the prescribing practitioner provided certain requirements), in the event of a natural or manmade disaster, to dispense not more than a 30-day supply of a dangerous drug without the authorization of the prescribing practitioner if:

(1) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(2) the natural or manmade disaster prohibits the pharmacist from being able to contact the practitioner;

(3) the governor has declared a state of disaster under Chapter 418 (Emergency Management), Government Code; and

(4) the Texas State Board of Pharmacy (TSBP), through the executive director of TSBP, has notified pharmacies in this state that pharmacists may dispense up to a 30-day supply of a dangerous drug.

(b-2) Provides that the prescribing practitioner is not liable for an act or omission by a pharmacist in dispensing a dangerous drug under Subsection (b-1).

SECTION 2. Amends Section 555.002(a), Occupations Code, as follows:

(a) Requires TSBP by rule to establish methods by which consumers and service recipients are notified of the name, mailing address, and telephone number of TSBP for the purpose of directing complaints to TSBP. Authorizes TSBP to provide for that notice on an electronic messaging system in a font specified by TSBP rule prominently displayed in the place of business of each person regulated by TSBP. Makes nonsubstantive changes.

SECTION 3. Amends Section 556.051, Occupations Code, as follows:

Sec. 556.051. AUTHORIZATION TO ENTER AND INSPECT. (a) Creates this subsection from existing text. Authorizes TSBP or a representative of TSBP to enter and inspect a facility relative to certain contents or relative to, subject to Subsection (b), financial records relating to the operation of the facility. Makes nonsubstantive changes.

(b) Authorizes TSBP or a representative of TSBP to inspect financial records under Subsection (a) only in the course of the investigation of a specific complaint. Authorizes TSBP or representative to inspect only records related to the specific complaint. Provides that the inspection is subject to Section 565.055 (Investigation; Confidentiality of Information).

SECTION 4. Amends Section 556.054, Occupations Code, as follows:

Sec. 556.054. New heading: CONFIDENTIALITY OF CERTAIN INFORMATION. Provides that certain information obtained by TSBP during an inspection of a facility is confidential and not subject to disclosure under Chapter 552 (Public Information), Government Code. Deletes existing text providing that an inspection of the facility authorized by this chapter, unless the owner, pharmacist, or agent in charge of a facility consents in writing, may not extend to certain information.

SECTION 5. Amends Subchapter B, Chapter 556, Occupations Code, by adding Section 556.057, as follows:

Sec. 556.057. INSPECTION OF PHARMACIST RECORDS. Requires a pharmacist to provide to TSBP, on request, records of the pharmacist's practice that occurs outside of a pharmacy. Requires the pharmacist to provide the records at a time specified by TSBP rule.

SECTION 6. Amends Sections 558.055(a) and (b), Occupations Code, as follows:

(a) Authorizes an applicant who on the applicant's first attempt fails the pharmacist licensing examination (examination) to take the examination four, rather than two, additional times.

(b) Requires the applicant to provide documentation from a college of pharmacy that the applicant has successfully completed additional college course work in each examination subject area the applicant failed before an applicant who has failed the examination five, rather than three, times is allowed to retake the examination.

SECTION 7. Amends Section 560.052(b), Occupations Code, as follows:

(b) Requires an applicant, to qualify for a pharmacy license, to submit to TSBP certain documents, including a completed application that includes proof that a pharmacy license held by the applicant in this state or another state, if applicable, has not been restricted, suspended, revoked, or surrendered for any reason, and no owner of the pharmacy for which the application is made has held a pharmacist license in this state or another state, if applicable, that has been restricted, suspended, revoked, or surrendered for any reason, and includes a statement of the pharmacist license number of the pharmacist-in-charge.

SECTION 8. Amends Section 561.003(e), Occupations Code, to prohibit the pharmacy, if a pharmacy's license has been expired for 91 days or more, rather than one year or more, from renewing the license. Authorizes the pharmacy to obtain a new license by complying with the requirements and procedures for obtaining an original license.

SECTION 9. Amends Sections 562.056(a) and (a-1), Occupations Code, as follows:

(a) Prohibits a pharmacist from dispensing a prescription drug if the pharmacist knows or should know that the prescription was issued without a valid practitioner-patient relationship, rather than prohibits a pharmacist from dispensing a prescription drug if the pharmacist knows or should know that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid practitioner-patient relationship.

(a-1) Requires that a prescription, rather than a prescription for a controlled substance, to be a valid prescription, be issued for a legitimate medical purpose by a practitioner acting in the usual course of the practitioner's professional practice. Provides that the responsibility for the proper prescribing and dispensing of prescription drugs, rather than controlled substances, is on the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

SECTION 10. Amends Section 562.106, Occupations Code, by amending Subsection (a) and adding Subsection (a-1), as follows:

(a) Requires a pharmacy to report in writing to TSBP not later than the 10th day after the date of:

(1) and (2) Makes no changes to these subdivisions;

(3) Deletes existing text requiring a pharmacy to report in writing to TSBP not later than the 10th day after the date of a change of location of the pharmacy. Redesignates existing Subdivision (4) as Subdivision (3). Makes no further change to the subdivision.

(4) Redesignates existing Subdivision (5) as Subdivision (4). Makes no further change to the subdivision.

(5) Redesignates existing Subdivision (6) as Subdivision (5). Makes no further change to the subdivision.

(6) Redesignates existing Subdivision (7) as Subdivision (6). Makes no further change to the subdivision.

(7) Redesignates existing Subdivision (8) as Subdivision (7). Makes no further change to the subdivision.

(8) Redesignates existing Subdivision (9) as Subdivision (8). Makes no further change to the subdivision.

(a-1) Requires a pharmacy to report in writing to TSBP not later than the 30th day before the date of a change of location of the pharmacy.

SECTION 11. Amends Section 565.002(a), Occupations Code, to authorize TSBP to discipline an applicant for or the holder of a pharmacy license, including a Class E pharmacy license subject to Section 565.003 (Additional Grounds for Discipline Regarding Applicant for or Holder of Nonresident Pharmacy License), rather than Section 565.003(b), if TSBP finds that the applicant or license holder has waived, discounted, or reduced, or offered to waive, discount, or reduce, a patient copayment or deductible for a compounded drug in the absence of a legitimate, documented financial hardship of the patient, or evidence of a good faith effort to collect the copayment or deductible from the patient.

SECTION 12. Amends Section 565.060(d), Occupations Code, to require TSBP, if a license holder complies with and successfully completes the terms of a remedial plan, to remove all records of the remedial plan from TSBP's records at the end of the state fiscal year in which the fifth anniversary of the date TSBP issued the terms of the remedial plan occurs, rather than remove all records of the remedial plan from TSBP's records on the fifth anniversary of the date TSBP issued the terms of the remedial plan.

SECTION 13. Amends Section 565.061(a), Occupations Code, to provide that, except as provided by Chapter 564 (Program to Aid Impaired Pharmacists and Pharmacy Students; Pharmacy Peer Review), a disciplinary action taken by TSBP on the basis of a ground for discipline under Subchapter A (Grounds for Discipline of Applicant of License Holder), rather than under Section 565.060 (Remedial Plan) or on the basis of a ground for discipline under Subchapter A, is governed by Chapter 2001 (Administrative Procedure), Government Code, and the rules of practice and procedure before TSBP.

SECTION 14. Repealer: Section 561.003(d) (authorizing a pharmacy whose license has been expired for more than 90 days but less than one year to renew the expired license by paying to TSBP a renewal fee that is equal to two times the normally required renewal fee for the license), Occupations Code.

Repealer: Section 562.009(a-1) (requiring a pharmacist, in addition to the requirements of Subsection (a), to display, in a prominent place that is in clear public view where prescription drugs are dispensed, a sign, that sets forth certain language, in block letters not less than one inch in height in both English and Spanish), Occupations Code.

Repealer: Section 562.051 (Display of Pharmacist License), Occupations Code.

SECTION 15. Makes application of the change in law made by this Act to Section 483.047, Health and Safety Code, prospective.

SECTION 16. Makes application of Section 560.052(b), Occupations Code, as amended by this Act, prospective.

SECTION 17. Makes application of Section 561.003(e), Occupations Code, as amended by this Act, and the repeal of Section 561.003(d), Occupations Code, by this Act, prospective.

SECTION 18. Makes application of Section 562.106(a), Occupations Code, as amended by this Act, and Section 562.106(a-1), Occupations Code, as added by this Act, prospective to October 1, 2015.

SECTION 19. Makes application of Section 565.002(a), Occupations Code, as amended by this Act, prospective.

SECTION 20. Provides that the change in law made by this Act to Section 565.061(a), Occupations Code, is a clarification of existing law and does not imply that existing law may be construed as inconsistent with the law as amended by this Act.

SECTION 21. Effective date: September 1, 2015.