| 1-4 1-5 | By: Schwertner (In the Senate - Filed February 5, 2015; February 9, 2015, read first time and referred to Committee on Health and Human Services; March 23, 2015, reported adversely, with favorable Committee Substitute by the following vote: Yeas 9, Nays 0; March 23, 2015, sent to printer.) |
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| 1-7 | COMMITTEE VOTE |
| 1-8 1-9 1-10 1-11 1-12 1-13 1-14 1-15 1-16 1-17 | YeaNayAbsentPNVSchwertnerXKolkhorstXCampbellXEstesXPerryXRodríguezXTaylor of CollinXUrestiXZaffiriniX |
| 1-18 | COMMITTEE SUBSTITUTE FOR S.B. No. 460 By: Schwertner |
| 1-19 1-20 | A BILL TO BE ENTITLED AN ACT |
| 1-21 1-22 | relating to the licensing and regulation of pharmacists and pharmacies. |
| 1-23 1-24 1-25 1-26 1-27 1-28 1-30 1-31 1-32 1-33 1-34 1-35 1-36 1-37 1-38 1-37 1-38 1-39 1-42 1-42 1-44 1-445 1-46 1-52 1-55 1-55 1-56 | BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS: SECTION 1. Section 483.047, Health and Safety Code, is amended by amending Subsection (a) and adding Subsections (b-1) and (b-2) to read as follows: (a) Except as authorized by <u>Subsections</u> [Subsection] (b) and (b-1), a pharmacist commits an offense 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 prescription. (b-1) Notwithstanding Subsection (b), in the event of a natural or manmade disaster, a pharmacist may 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, Government Code; and (4) the board, through the executive director, has notified pharmacies in this state that pharmacists may dispense up to a 30-day supply of a dangerous drug. (b-2) 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. Section 555.002(a), Occupations Code, is amended to read as follows: (a) The board by rule shall establish methods by which |
| 1-57 1-58 1-59 1-60 | consumers and service recipients are notified of the name, mailing address, and telephone number of the board for the purpose of directing complaints to the board. The board may provide for that notice: |

C.S.S.B. No. 460 (1) on each registration form, application, or written contract for services of a person regulated by the board; 2-1 2-2 2-3 (2) on a sign prominently displayed in the place of 2-4 business of each person regulated by the board; [or] (3) on an electronic messaging system in a for specified by board rule prominently displayed in the place business of each person regulated by the board; or 2-5 in a font 2-6 of 2-7 in a 2-8 (4)bill for service provided by a person regulated by the board. 2-9 2-10 2-11 SECTION 3. Section 556.051, Occupations Code, is amended to read as follows: 2-12 Sec. 556.051. AUTHORIZATION TO ENTER AND INSPECT. (a) The 2-13 board or a representative of the board may enter and inspect a 2-14 facility relative to the following: 2**-**15 2**-**16 (1)drug storage and security; (2) equipment; 2-17 (3) components used in compounding, finished and 2-18 unfinished products, containers, and labeling of any item; 2-19 (4) sanitary conditions; [or] 2-20 2-21 (5) records, reports, or other documents required to be kept or made under this subtitle, Chapter 481 or 483, Health and 2-22 Safety Code, or the Comprehensive Drug Abuse Prevention and Control 2-23 Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws; or 2-24 2**-**25 2**-**26 (6) subject to Subsection (b), financial records relating to the operation of the facility. 2-27 The board or a representative of the board may inspect (b) 2-28 financial records under Subsection (a) only in the course of the investigation of a specific complaint. The board or representative 2-29 may inspect only records related to the specific complaint. inspection is subject to Section 565.055. 2-30 The 2-31 Section 556.054, Occupations Code, is amended to 2-32 SECTION 4. 2-33 read as follows: 2-34 Sec. 556.054. CONFIDENTIALITY INFORMATION OF CERTAIN [LIMITATION ON INSPECTION]. The following information obtained by the board during an inspection of a facility is confidential and not 2-35 2-36 subject to disclosure under Chapter 552, Government Code [Unless 2-37 2-38 the owner, pharmacist, or agent in charge of a facility consents in 2-39 writing, an inspection of the facility authorized by this chapter 2-40 may not extend to]: 2-41 (1) financial data; 2-42 sales data, other than shipment data; and [or] (2) pricing data. 2-43 (3) SECTION 5. Subchapter B, Chapter 556, Occupations Code, is amended by adding Section 556.057 to read as follows: Sec. 556.057. INSPECTION OF PHARMACIST RECORDS. A 2-44 2-45 2-46 pharmacist shall provide to the board, on request, records of the 2-47 pharmacist's practice that occurs outside of a pharmacy. 2-48 The 2-49 pharmacist shall provide the records at a time specified by board 2-50 rule. 2-51 SECTION 6. Sections 558.055(a) and (b), Occupations Code, 2-52 are amended to read as follows: 2-53 An applicant who on the applicant's first attempt fails (a) 2-54 the examination may take the examination <u>four</u> [two] additional 2-55 times. 2-56 (b) Before an applicant who has failed the examination five 2-57 [three] times is allowed to retake the examination, the applicant 2-58 must 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. SECTION 7. Section 560.052(b), Occupations Code, is amended 2-59 2-60 2-61 2-62 to read as follows: 2-63 To qualify for a pharmacy license, an applicant must (b) 2-64 submit to the board: 2-65 a license fee set by the board, except as provided (1)2-66 by Subsection (d); and 2-67 (2) a completed application that: 2-68 (A) is on a form prescribed by the board; 2-69 is given under oath; (B)

C.S.S.B. No. 460 (C) includes proof that: (i) a pharmacy license 3-1 <u>(i)</u> a <u>pharmacy</u> license held <u>by the</u> <u>applicant</u> in this state or another state, if applicable, has not 3-2 3-3 been restricted, suspended, revoked, or surrendered for any reason; 3-4 3-5 and (ii) no owner of the pharmacy for which the application is made has held a pharmacist license in this state or 3-6 3-7 3-8 another state, if applicable, that has been restricted, suspended, 3-9 revoked, or surrendered for any reason; and 3-10 3-11 (D) includes a statement of: (i) the ownership; 3-12 the location of the pharmacy; (ii)3-13 (iii) the license number of each pharmacist 3-14 who is employed by the pharmacy, if the pharmacy is located in this 3**-**15 3**-**16 state, or who is licensed to practice pharmacy in this state, if the pharmacy is located in another state; 3-17 (iv) the pharmacist license number of the 3-18 pharmacist-in-charge; and 3-19 (v)any other information the board 3-20 3-21 determines necessary. SECTION 8. Section 561.003(e), Occupations Code, is amended 3-22 to read as follows: 3-23 (e) If a pharmacy's license has been expired for 91 davs 3-24 [one year] or more, the pharmacy may not renew the license. The 3-25 pharmacy may obtain a new license by complying with the 3**-**26 requirements and procedures for obtaining an original license. 3-27 SECTION 9. Sections 562.056(a) and (a-1), Occupations Code, 3-28 are amended to read as follows: (a) Before dispensing a prescription, a pharmacist shall determine, in the exercise of sound professional judgment, that the 3-29 3-30 prescription is a valid prescription. A pharmacist may not dispense a prescription drug if the pharmacist knows or should know 3-31 3-32 3-33 that the prescription was issued [on the basis of an Internet-based 3-34 -telephonic consultation] without a valid practitioner-patient or 3-35 relationship. (a-1) To be a valid prescription, a prescription [for a controlled substance] must be issued for a legitimate medical 3-36 3-37 purpose by a practitioner acting in the usual course of the 3-38 practitioner's professional practice. The responsibility for the 3-39 proper prescribing and dispensing of <u>prescription</u> drugs [controlled substances] is on the prescribing practitioner, but a 3-40 3-41 3-42 corresponding responsibility rests with the pharmacist who fills 3-43 the prescription. 3-44 SECTION 10. Section 562.106, Occupations Code, is amended 3-45 by amending Subsection (a) and adding Subsection (a-1) to read as 3-46 follows: 3-47 (a) A pharmacy shall report in writing to the board not 3-48 later than the 10th day after the date of: 3-49 a permanent closing of the pharmacy; (1)a change of ownership of the pharmacy; [a change of location of the pharmacy; 3-50 (2) 3-51 (3) [(4)] a change of the person designated 3-52 the as pharmacist-in-charge of the pharmacy; 3-53 3-54 <u>(4)</u> [(5)] a sale or transfer of any controlled 3-55 substance or dangerous drug as a result of the permanent closing or change of ownership of the pharmacy; 3-56 3-57 (5) $[\overline{(6)}]$ any matter or occurrence that the board 3-58 requires by rule to be reported; (6) $\left[\frac{(7)}{1}\right]$ as determined by the board, an out-of-state 3-59 3-60 purchase of any controlled substance; 3-61 (7) [(8)] a final order against the pharmacy license holder by the regulatory or licensing agency of the state in which 3-62 3-63 the pharmacy is located if the pharmacy is located in another state; 3-64 or (8) [(9)] a final order against a pharmacist who is designated as the pharmacist-in-charge of the pharmacy by the 3-65 3-66 3-67 regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state. 3-68 3-69 (a-1) A pharmacy shall report in writing to the board not

C.S.S.B. No. 460 later than the 30th day before the date of a change of location of 4-1 4-2 the pharmacy. 4-3 SECTION 11. Section 565.002(a), Occupations Code, is 4 - 4amended to read as follows: 4-5 The board may discipline an applicant for or the holder (a) of a pharmacy license, including a Class E pharmacy license subject to Section <u>565.003</u> [<u>565.003(b)</u>], if the board finds that the applicant or license holder has: 4-6 4-7 4-8 4-9 of (1)been convicted placed deferred or on 4-10 4-11 adjudication community supervision or deferred disposition or the applicable federal equivalent for: 4-12 (A) a misdemeanor: 4-13 (i) involving moral turpitude; or 4-14 (ii) under Chapter 481 or 483, Health and 4**-**15 4**-**16 Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.); or 4-17 (B) a felony; 4-18 (2) advertised a prescription drug or device in a 4-19 deceitful, misleading, or fraudulent manner; 4-20 4-21 (3) violated any provision of this subtitle or any rule adopted under this subtitle or that an owner or employee of a 4-22 pharmacy has violated any provision of this subtitle or any rule 4-23 adopted under this subtitle; 4-24 (4)sold without legal authorization a prescription 4-25 drug or device to a person other than: 4-26 (A) a pharmacy licensed by the board; 4-27 (B) a practitioner; 4-28 (C) a person who procures a prescription drug or 4-29 device for lawful research, teaching, or testing, and not for 4-30 resale; 4-31 a manufacturer or wholesaler licensed by the (D) commissioner of public health as required by Chapter 431, Health 4-32 4-33 and Safety Code; or 4-34 (E) a carrier or warehouseman; 4-35 (5)allowed an employee who is not a pharmacist to 4-36 practice pharmacy; 4-37 (6) sold an adulterated or misbranded prescription or 4-38 nonprescription drug; 4-39 (7) failed to engage in or ceased to engage in the business described in the application for a license; 4-40 (8) failed to maintain records as required by this Chapter 481 or 483, Health and Safety Code, the 4-41 4-42 subtitle. 4-43 Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 4 - 44U.S.C. Section 801 et seq.), or any rule adopted under this subtitle or Chapter 483, Health and Safety Code; (9) failed to establish and maintain effective controls against diversion of prescription drugs into other than a 4-45 4-46 4 - 474-48 legitimate medical, scientific, or industrial channel as provided 4-49 by this subtitle, another state statute or rule, or a federal 4-50 statute or rule; 4-51 engaged in fraud, deceit, or misrepresentation as (10)defined by board rule in operating a pharmacy or in applying for a 4-52 4-53 license to operate a pharmacy; (11)4-54 violated a disciplinary order; 4-55 (12)been responsible for a drug audit shortage; [or] 4-56 been disciplined by the regulatory board of (13)4-57 another state for conduct substantially equivalent to conduct 4-58 described under this subsection; or (14) waived, discounted, or reduced, or offered to waive, discount, or reduce, a patient copayment or deductible for a compounded drug in the absence of: 4-59 4-60 4-61 4-62 a legitimate, documented financial hardship (A) 4-63 of the patient; or (B) 4-64 evidence of a good faith effort to collect 4-65 the copayment or deductible from the patient. SECTION 12. Section 4-66 565.060(d), Occupations Code, is 4-67 amended to read as follows:

4-68 (d) If a license holder complies with and successfully 4-69 completes the terms of a remedial plan, the board shall remove all

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records of the remedial plan from the board's records at the end of 5-1 the state fiscal year in which [on] the fifth anniversary of the 5-2 date the board issued the terms of the remedial plan occurs. 5-3

5-4 565.061(a), Occupations SECTION 13. Section Code, is 5-5 amended to read as follows:

5-6 (a) Except as provided by Chapter 564, a disciplinary action taken by the board [under Section 565.060 or] on the basis of a 5-7 ground for discipline under Subchapter A is governed by Chapter 5-8 5-9 2001, Government Code, and the rules of practice and procedure 5**-**10 5**-**11 before the board.

The following provisions of the Occupations SECTION 14. 5-12 Code are repealed:

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(1) Section 561.003(d);

(2) Section 562.009(a-1); and

Section 562.051. (3)

5**-**15 5**-**16 SECTION 15. The change in law made by this Act to Section 483.047, Health and Safety Code, applies only to an offense committed on or after the effective date of this Act. An offense 5-17 5-18 committed before the effective date of this Act is governed by the 5-19 5**-**20 5**-**21 law in effect on the date the offense was committed, and the former law is continued in effect for that purpose. For purposes of this 5-22 section, an offense was committed before the effective date of this 5-23 Act if any element of the offense occurred before that date.

SECTION 16. Section 560.052(b), Occupations Code, 5-24 as amended by this Act, applies only to an application for a pharmacy license submitted on or after the effective date of this Act. An application submitted before the effective date of this Act is 5-25 5**-**26 5-27 $\bar{gov}erned$ by the law in effect on the date the application was submitted, and the former law is continued in effect for that 5-28 5-29 5-30 purpose.

SECTION 17. Section 561.003(e), Occupations Code, as amended by this Act, and the repeal by this Act of Section 5-31 5-32 561.003(d), Occupations Code, apply only to a pharmacy license that expires on or after the effective date of this Act. A pharmacy license that expired before the effective date of this Act is governed by the law in effect on the date the license expired, and 5-33 5-34 5-35 5-36 5-37 the former law is continued in effect for that purpose.

5-38 SECTION 18. Section 562.106(a), Occupations Code, as 5-39 amended by this Act, and Section 562.106(a-1), Occupations Code, as added by this Act, apply only to a pharmacy that changes location on or after October 1, 2015. A pharmacy that changes location before 5-40 5-41 5-42 that date is governed by the law in effect immediately before the 5-43 effective date of this Act, and the former law is continued in 5-44 effect for that purpose.

5-45 SECTION 19. The change in law made by this Act to Section 565.002(a), Occupations Code, applies only to conduct that occurs on or after the effective date of this Act. Conduct that occurs 5-46 5-47 before that date is governed by the law in effect on the date the conduct occurred, and the former law is continued in effect for that 5-48 5-49 5-50 purpose.

5-51 SECTION 20. The change in law made by this Act to Section 565.061(a), Occupations Code, is a clarification of existing law 5-52 5-53 and does not imply that existing law may inconsistent with the law as amended by this Act. be construed as 5-54

5-55 SECTION 21. This Act takes effect September 1, 2015.

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