By: Schwertner

1

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## A BILL TO BE ENTITLED

## AN ACT

2 relating to the licensing and regulation of pharmacists and 3 pharmacies.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

5 SECTION 1. Section 483.047, Health and Safety Code, is 6 amended by amending Subsection (a) and adding Subsections (b-1) and 7 (b-2) to read as follows:

8 (a) Except as authorized by <u>Subsections</u> [<del>Subsection</del>] (b) 9 <u>and (b-1)</u>, a pharmacist commits an offense if the pharmacist 10 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

15 (2) at the time of refilling the prescription, the 16 pharmacist is authorized to do so by the practitioner who issued the 17 prescription.

18 (b-1) Notwithstanding Subsection (b), in the event of a 19 natural or manmade disaster, a pharmacist may dispense not more 20 than a 30-day supply of a dangerous drug without the authorization 21 of the prescribing practitioner if:

22 (1) failure to refill the prescription might result in 23 an interruption of a therapeutic regimen or create patient 24 <u>suffering;</u>

1	(2) the natural or manmade disaster prohibits the
2	pharmacist from being able to contact the practitioner;
3	(3) the governor has declared a state of disaster
4	under Chapter 418, Government Code; and
5	(4) the board, through the executive director, has
6	notified pharmacies in this state that pharmacists may dispense up
7	to a 30-day supply of a dangerous drug.
8	(b-2) The prescribing practitioner is not liable for an act
9	or omission by a pharmacist in dispensing a dangerous drug under
10	Subsection (b-1).
11	SECTION 2. Section 555.002(a), Occupations Code, is amended
12	to read as follows:
13	(a) The board by rule shall establish methods by which
14	consumers and service recipients are notified of the name, mailing
15	address, and telephone number of the board for the purpose of
16	directing complaints to the board. The board may provide for that
17	notice:
18	(1) on each registration form, application, or written
19	contract for services of a person regulated by the board;
20	(2) on a sign prominently displayed in the place of
21	business of each person regulated by the board; [ <del>or</del> ]
22	(3) <u>on an electronic messaging system in a font</u>
23	specified by board rule prominently displayed in the place of
24	business of each person regulated by the board; or
25	(4) in a bill for service provided by a person
26	regulated by the board.
27	SECTION 3. Section 556.051, Occupations Code, is amended to

S.B. No. 460 read as follows: 1 2 Sec. 556.051. AUTHORIZATION TO ENTER AND INSPECT. (a) The board or a representative of the board may enter and inspect a 3 4 facility relative to the following: 5 (1)drug storage and security; (2) 6 equipment; 7 (3) components used in compounding, finished and unfinished products, containers, and labeling of any item; 8 9 (4) sanitary conditions; [or] 10 (5) records, reports, or other documents required to 11 be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control 12 Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under 13 one of those laws; or 14 15 (6) subject to Subsection (b), financial records 16 relating to the operation of the facility. 17 (b) The board or a representative of the board may inspect financial records under Subsection (a) only in the course of the 18 investigation of a specific complaint. The board or representative 19 20 may inspect only records related to the specific complaint. The inspection is subject to Section 565.055. 21 22 SECTION 4. Section 556.054, Occupations Code, is amended to read as follows: 23 24 Sec. 556.054. CONFIDENTIALITY OF CERTAIN INFORMATION [LIMITATION ON INSPECTION]. The following information obtained by 25 the board during an inspection of a facility is confidential and not 26 27 subject to disclosure under Chapter 552, Government Code [Unless

the owner, pharmacist, or agent in charge of a facility consents in 1 2 writing, an inspection of the facility authorized by this chapter may not extend to]: 3 4 (1)financial data; sales data, other than shipment data; and [or] 5 (2) (3) pricing data. 6 7 SECTION 5. Subchapter B, Chapter 556, Occupations Code, is amended by adding Section 556.057 to read as follows: 8 Sec. 556.057. INSPECTION OF PHARMACIST RECORDS. 9 А pharmacist shall provide to the board, on request, records of the 10 pharmacist's practice that occurs outside of a pharmacy. 11 The pharmacist shall provide the records at a time specified by board 12 13 rule. SECTION 6. Sections 558.055(a) and (b), Occupations Code, 14 15 are amended to read as follows: An applicant who on the applicant's first attempt fails 16 (a) the examination may take the examination four [two] additional 17 18 times. (b) Before an applicant who has failed the examination five 19 [three] times is allowed to retake the examination, the applicant 20 must provide documentation from a college of pharmacy that the 21 applicant has successfully completed additional college course 22 work in each examination subject area the applicant failed. 23 SECTION 7. Section 560.052(b), Occupations Code, is amended 24 25 to read as follows: To qualify for a pharmacy license, an applicant must 26 (b) 27 submit to the board:

S.B. No. 460 1 a license fee set by the board, except as provided (1)2 by Subsection (d); and (2) a completed application that: 3 4 (A) is on a form prescribed by the board; is given under oath; 5 (B) includes proof that: 6 (C) 7 pharmacy license (i) а held by the applicant in this state or another state, if applicable, has not 8 9 been restricted, suspended, revoked, or surrendered for any reason; 10 and 11 (ii) no owner of the pharmacy for which the application is made has held a pharmacist license in this state or 12 13 another state, if applicable, that has been restricted, suspended, revoked, or surrendered for any reason; and 14 15 (D) includes a statement of: 16 (i) the ownership; 17 (ii) the location of the pharmacy; 18 (iii) the license number of each pharmacist who is employed by the pharmacy, if the pharmacy is located in this 19 20 state, or who is licensed to practice pharmacy in this state, if the pharmacy is located in another state; 21 22 (iv) the pharmacist license number of the pharmacist-in-charge; and 23 24 information (v) any other the board 25 determines necessary. SECTION 8. Section 561.003(e), Occupations Code, is amended 26 27 to read as follows:

(e) If a pharmacy's license has been expired for <u>91 days</u>
 [<del>one year</del>] or more, the pharmacy may not renew the license. The
 pharmacy may obtain a new license by complying with the
 requirements and procedures for obtaining an original license.

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5 SECTION 9. Sections 562.056(a) and (a-1), Occupations Code, 6 are amended to read as follows:

7 (a) Before dispensing a prescription, a pharmacist shall 8 determine, in the exercise of sound professional judgment, that the 9 prescription is a valid prescription. A pharmacist may not 10 dispense a prescription drug if the pharmacist knows or should know 11 that the prescription was issued [on the basis of an Internet-based 12 or telephonic consultation] without a valid practitioner-patient 13 relationship.

(a-1) To be a valid prescription, a prescription [for a 14 15 controlled substance] must be issued for a legitimate medical purpose by a practitioner acting in the usual course of the 16 practitioner's professional practice. The responsibility for the 17 prescribing and dispensing of prescription drugs 18 proper [controlled substances] is on the prescribing practitioner, but a 19 20 corresponding responsibility rests with the pharmacist who fills 21 the prescription.

22 SECTION 10. Section 562.106, Occupations Code, is amended 23 by amending Subsection (a) and adding Subsection (a-1) to read as 24 follows:

(a) A pharmacy shall report in writing to the board notlater than the 10th day after the date of:

27 (1) a permanent closing of the pharmacy;

a change of ownership of the pharmacy; 1 (2) [a change of location of the pharmacy; 2 (3) [(4)] a change of the person designated 3 as the 4 pharmacist-in-charge of the pharmacy; 5 (4)  $\left[\frac{(5)}{(5)}\right]$  a sale or transfer of any controlled substance or dangerous drug as a result of the permanent closing or 6 7 change of ownership of the pharmacy; (5) [(6)] any matter or occurrence that the board 8 9 requires by rule to be reported; 10 (6)  $\left[\frac{(7)}{1}\right]$  as determined by the board, an out-of-state 11 purchase of any controlled substance; (7) [(8)] a final order against the pharmacy license 12 13 holder by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state; 14 15 or 16 (8) [(9)] a final order against a pharmacist who is designated as the pharmacist-in-charge of the pharmacy by the 17 regulatory or licensing agency of the state in which the pharmacy is 18 located if the pharmacy is located in another state. 19 20 (a-1) A pharmacy shall report in writing to the board not later than the 30th day before the date of a change of location of 21 22 the pharmacy. SECTION 11. Section 565.002(a), Occupations 23 Code, is 24 amended to read as follows: 25 (a) The board may discipline an applicant for or the holder of a pharmacy license, including a Class E pharmacy license subject 26 to Section 565.003 [565.003(b)], if the board finds that the 27

applicant or license holder has: 1 2 (1)been convicted of or placed on deferred adjudication community supervision or deferred disposition or the 3 4 applicable federal equivalent for: 5 (A) a misdemeanor: (i) involving moral turpitude; or 6 7 (ii) under Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control 8 9 Act of 1970 (21 U.S.C. Section 801 et seq.); or 10 (B) a felony; 11 (2) advertised a prescription drug or device in a 12 deceitful, misleading, or fraudulent manner; 13 (3) violated any provision of this subtitle or any rule adopted under this subtitle or that an owner or employee of a 14 pharmacy has violated any provision of this subtitle or any rule 15 16 adopted under this subtitle; 17 (4) sold without legal authorization a prescription 18 drug or device to a person other than: a pharmacy licensed by the board; 19 (A) 20 (B) a practitioner; a person who procures a prescription drug or 21 (C) 22 device for lawful research, teaching, or testing, and not for 23 resale; 24 (D) a manufacturer or wholesaler licensed by the 25 commissioner of public health as required by Chapter 431, Health and Safety Code; or 26 27 (E) a carrier or warehouseman;

1 (5) allowed an employee who is not a pharmacist to
2 practice pharmacy;

3 (6) sold an adulterated or misbranded prescription or 4 nonprescription drug;

5 (7) failed to engage in or ceased to engage in the 6 business described in the application for a license;

7 (8) failed to maintain records as required by this
8 subtitle, Chapter 481 or 483, Health and Safety Code, the
9 Comprehensive Drug Abuse Prevention and Control Act of 1970 (21
10 U.S.C. Section 801 et seq.), or any rule adopted under this subtitle
11 or Chapter 483, Health and Safety Code;

(9) failed to establish and maintain effective controls against diversion of prescription drugs into other than a legitimate medical, scientific, or industrial channel as provided by this subtitle, another state statute or rule, or a federal statute or rule;

(10) engaged in fraud, deceit, or misrepresentation as defined by board rule in operating a pharmacy or in applying for a license to operate a pharmacy;

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(11) violated a disciplinary order;

21 (12) been responsible for a drug audit shortage; [<del>or</del>]

(13) been disciplined by the regulatory board of another state for conduct substantially equivalent to conduct described under this subsection; or

25 <u>(14) waived, discounted, or reduced, or offered to</u>
26 waive, discount, or reduce, a patient copayment or deductible for a
27 compounded drug in the absence of:

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1	(A) a legitimate, documented financial hardship
2	of the patient; or
3	(B) evidence of a good faith effort to collect
4	the copayment or deductible from the patient.
5	SECTION 12. Section 565.060(d), Occupations Code, is
6	amended to read as follows:
7	(d) If a license holder complies with and successfully
8	completes the terms of a remedial plan, the board shall remove all
9	records of the remedial plan from the board's records <u>at the end of</u>
10	the state fiscal year in which [ <del>on</del> ] the fifth anniversary of the
11	date the board issued the terms of the remedial plan $\underline{\operatorname{occurs}}$ .
12	SECTION 13. Section 565.061(a), Occupations Code, is
13	amended to read as follows:
14	(a) Except as provided by Chapter 564, a disciplinary action
15	taken by the board [ <del>under Section 565.060 or</del> ] on the basis of a
16	ground for discipline under Subchapter A is governed by Chapter
17	2001, Government Code, and the rules of practice and procedure
18	before the board.
19	SECTION 14. The following provisions of the Occupations
20	Code are repealed:
21	(1) Section 561.003(d);
22	(2) Section 562.009(a-1); and
23	(3) Section 562.051.
24	SECTION 15. The change in law made by this Act to Section
25	483.047, Health and Safety Code, applies only to an offense
26	committed on or after the effective date of this Act. An offense
27	committed before the effective date of this Act is governed by the

1 law in effect on the date the offense was committed, and the former 2 law is continued in effect for that purpose. For purposes of this 3 section, an offense was committed before the effective date of this 4 Act if any element of the offense occurred before that date.

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5 SECTION 16. Section 560.052(b), Occupations Code, as amended by this Act, applies only to an application for a pharmacy 6 7 license submitted on or after the effective date of this Act. An application submitted before the effective date of this Act is 8 9 governed by the law in effect on the date the application was submitted, and the former law is continued in effect for that 10 11 purpose.

SECTION 17. Section 561.003(e), Occupations Code, 12 as 13 amended by this Act, and the repeal by this Act of Section 561.003(d), Occupations Code, apply only to a pharmacy license that 14 15 expires on or after the effective date of this Act. A pharmacy 16 license that expired before the effective date of this Act is governed by the law in effect on the date the license expired, and 17 the former law is continued in effect for that purpose. 18

SECTION 18. Section 562.106(a), Occupations 19 Code, as 20 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 21 22 or after October 1, 2015. A pharmacy that changes location before that date is governed by the law in effect immediately before the 23 effective date of this Act, and the former law is continued in 24 25 effect for that purpose.

26 SECTION 19. The change in law made by this Act to Section 27 565.002(a), Occupations Code, applies only to conduct that occurs

1 on or after the effective date of this Act. Conduct that occurs 2 before that date is governed by the law in effect on the date the 3 conduct occurred, and the former law is continued in effect for that 4 purpose.

5 SECTION 20. The change in law made by this Act to Section 6 565.061(a), Occupations Code, is a clarification of existing law 7 and does not imply that existing law may be construed as 8 inconsistent with the law as amended by this Act.

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SECTION 21. This Act takes effect September 1, 2015.