

By: Van de Putte

S.B. No. 1100

A BILL TO BE ENTITLED

AN ACT

relating to the licensing and inspection of certain out-of-state pharmacies by the Texas State Board of Pharmacy; authorizing fees.

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

SECTION 1. Subchapter B, Chapter 556, Occupations Code, is amended by adding Section 556.0551 to read as follows:

Sec. 556.0551. INSPECTION OF LICENSED NONRESIDENT PHARMACY. (a) The board may inspect a nonresident pharmacy licensed by the board that compounds sterile preparations as necessary to ensure compliance with the safety standards and other requirements of this subtitle and board rules.

(b) A nonresident pharmacy shall reimburse the board for all expenses, including travel, incurred by the board in inspecting the pharmacy as provided by Subsection (a).

SECTION 2. Subsection (b), Section 560.001, Occupations Code, is amended to read as follows:

(b) A pharmacy located in another state may not ship, mail, or deliver to this state a prescription drug or device dispensed under a prescription drug order, or dispensed or delivered as authorized by Subchapter D, Chapter 562, ~~[to a resident of this state]~~ unless the pharmacy is licensed by the board or is exempt under Section 560.004.

SECTION 3. Section 560.052, Occupations Code, is amended by amending Subsections (b) and (c) and adding Subsections (g) and (h)

1 to read as follows:

2 (b) To qualify for a pharmacy license, an applicant must  
3 submit to the board:

4 (1) a license fee set by the board, except as provided  
5 by Subsection (d); and

6 (2) a completed application that:

7 (A) is on a form prescribed by the board;

8 (B) is given under oath; and

9 (C) includes a statement of:

10 (i) the ownership;

11 (ii) the location of the pharmacy;

12 (iii) the license number of each pharmacist  
13 who is employed by the pharmacy, if the pharmacy is located in this  
14 state, or who is licensed to practice pharmacy in this state, if the  
15 pharmacy is located in another state [~~a Class E pharmacy~~];

16 (iv) the license number of the  
17 pharmacist-in-charge; and

18 (v) any other information the board  
19 determines necessary.

20 (c) A pharmacy located in another state that applies for a  
21 license [~~To qualify for a Class E pharmacy license, an applicant~~],  
22 in addition to satisfying the other requirements of this chapter,  
23 must provide to the board:

24 (1) evidence that the applicant holds a pharmacy  
25 license, registration, or permit in good standing issued by the  
26 state in which the pharmacy is located;

27 (2) the name of the owner and pharmacist-in-charge of

1 the pharmacy for service of process;

2 (3) evidence of the applicant's ability to provide to  
3 the board a record of a prescription drug order dispensed or  
4 delivered as authorized by Subchapter D, Chapter 562, by the  
5 applicant to a resident of or practitioner in this state not later  
6 than 72 hours after the time the board requests the record;

7 (4) an affidavit by the pharmacist-in-charge that  
8 states that the pharmacist has read and understands the laws and  
9 rules relating to the applicable license [~~a Class E pharmacy~~];

10 (5) proof of creditworthiness; [~~and~~]

11 (6) an inspection report issued:

12 (A) not more than two years before the date the  
13 license application is received; and

14 (B) by the pharmacy licensing board in the state  
15 of the pharmacy's physical location, except as provided by  
16 Subsection (f); and

17 (7) any other information the board determines  
18 necessary.

19 (g) A license may not be issued to a pharmacy that compounds  
20 sterile preparations unless the pharmacy has been inspected by the  
21 board to ensure the pharmacy meets the safety standards and other  
22 requirements of this subtitle and board rules.

23 (h) The board may accept, as satisfying the inspection  
24 requirement in Subsection (g) for a pharmacy located in another  
25 state, an inspection report issued by the pharmacy licensing board  
26 in the state in which the pharmacy is located if:

27 (1) the board determines that the other state has

1 comparable standards and regulations applicable to pharmacies,  
2 including standards and regulations related to health and safety;  
3 and

4 (2) the pharmacy provides to the board any requested  
5 documentation related to the inspection.

6 SECTION 4. Chapter 561, Occupations Code, is amended by  
7 adding Section 561.0032 to read as follows:

8 Sec. 561.0032. ADDITIONAL RENEWAL REQUIREMENT FOR  
9 COMPOUNDING PHARMACY. (a) In addition to the renewal requirements  
10 under Section 561.003, a pharmacy that compounds sterile  
11 preparations may not renew a pharmacy license unless the pharmacy:

12 (1) has been inspected as provided by board rule; and

13 (2) if the pharmacy is located in another state, has  
14 reimbursed the board for all expenses, including travel, incurred  
15 by the board in inspecting the pharmacy during the term of the  
16 expiring license.

17 (b) The board may accept, as satisfying the inspection  
18 requirement in Subsection (a) for a pharmacy located in another  
19 state, an inspection report issued by the pharmacy licensing board  
20 in the state in which the pharmacy is located if:

21 (1) the board determines that the other state has  
22 comparable standards and regulations applicable to pharmacies,  
23 including standards and regulations related to health and safety;  
24 and

25 (2) the pharmacy provides to the board any requested  
26 documentation related to the inspection.

27 SECTION 5. Subsection (a), Section 562.106, Occupations

1 Code, is amended to read as follows:

2 (a) A pharmacy shall report in writing to the board not  
3 later than the 10th day after the date of:

4 (1) a permanent closing of the pharmacy;

5 (2) a change of ownership of the pharmacy;

6 (3) a change of location of the pharmacy;

7 (4) a change of the person designated as the  
8 pharmacist-in-charge of the pharmacy;

9 (5) a sale or transfer of any controlled substance or  
10 dangerous drug as a result of the permanent closing or change of  
11 ownership of the pharmacy;

12 (6) any matter or occurrence that the board requires  
13 by rule to be reported;

14 (7) as determined by the board, an out-of-state  
15 purchase of any controlled substance;

16 (8) a final order against the pharmacy license holder  
17 by the regulatory or licensing agency of the state in which the  
18 pharmacy is located if the pharmacy is located in another state [~~a~~  
19 ~~Class E pharmacy~~]; or

20 (9) a final order against a pharmacist who is  
21 designated as the pharmacist-in-charge of the pharmacy by the  
22 regulatory or licensing agency of the state in which the pharmacy is  
23 located if the pharmacy is located in another state [~~a Class E~~  
24 ~~pharmacy~~].

25 SECTION 6. Subchapter D, Chapter 562, Occupations Code, is  
26 amended by adding Section 562.156 to read as follows:

27 Sec. 562.156. COMPOUNDED STERILE PREPARATION; NOTICE TO

1 BOARD. (a) A pharmacy may not compound and dispense a sterile  
2 preparation unless the pharmacy holds a license as required by  
3 board rule.

4 (b) A pharmacy that compounds a sterile preparation shall  
5 notify the board:

6 (1) immediately of any adverse effects reported to the  
7 pharmacy or that are known by the pharmacy to be potentially  
8 attributable to a sterile preparation compounded by the pharmacy;  
9 and

10 (2) not later than 24 hours after the pharmacy issues a  
11 recall for a sterile preparation compounded by the pharmacy.

12 SECTION 7. Section 565.003, Occupations Code, is amended to  
13 read as follows:

14 Sec. 565.003. ADDITIONAL GROUNDS FOR DISCIPLINE REGARDING  
15 APPLICANT FOR OR HOLDER OF NONRESIDENT [~~CLASS E~~] PHARMACY LICENSE.

16 [~~(b)~~] Unless compliance would violate the pharmacy or drug  
17 statutes or rules in the state in which the pharmacy is located the  
18 board may discipline an applicant for or the holder of a nonresident  
19 [~~Class E~~] pharmacy license if the board finds that the applicant or  
20 license holder has failed to comply with:

21 (1) Section 481.074 or 481.075, Health and Safety  
22 Code;

23 (2) Texas substitution requirements regarding:

24 (A) the practitioner's directions concerning  
25 generic substitution;

26 (B) the patient's right to refuse generic  
27 substitution; or

1 (C) notification to the patient of the patient's  
2 right to refuse substitution;

3 (3) any board rule relating to providing drug  
4 information to the patient or the patient's agent in written form or  
5 by telephone; or

6 (4) any board rule adopted under Section 554.051(a)  
7 and determined by the board to be applicable under Section  
8 554.051(b).

9 SECTION 8. Section 565.053, Occupations Code, is amended to  
10 read as follows:

11 Sec. 565.053. DISCIPLINE OF NONRESIDENT [~~CLASS E~~] PHARMACY;  
12 NOTICE TO RESIDENT STATE. The board shall give notice of a  
13 disciplinary action by the board against a license [~~the~~] holder  
14 located in another state [~~of a Class E pharmacy license~~] to the  
15 regulatory or licensing agency of the state in which the pharmacy is  
16 located.

17 SECTION 9. The heading to Section 565.054, Occupations  
18 Code, is amended to read as follows:

19 Sec. 565.054. SERVICE OF PROCESS ON NONRESIDENT [~~CLASS E~~]  
20 PHARMACY.

21 SECTION 10. Subsection (a), Section 565.054, Occupations  
22 Code, is amended to read as follows:

23 (a) Service of process on a nonresident [~~Class E~~] pharmacy  
24 under Section 565.058 or 566.051 or for disciplinary action taken  
25 by the board under Section 565.061 shall be on the owner and  
26 pharmacist-in-charge of the pharmacy, as designated on the  
27 pharmacy's license application.

1           SECTION 11. Not later than March 1, 2014, the Texas State  
2 Board of Pharmacy shall adopt rules necessary to implement the  
3 changes in law made by this Act.

4           SECTION 12. Section 560.052, Occupations Code, as amended  
5 by this Act, applies only to an application for a pharmacy license  
6 submitted to the Texas State Board of Pharmacy on or after the  
7 effective date of this Act. An application for a license submitted  
8 before the effective date of this Act is governed by the law in  
9 effect on the date the application was submitted, and the former law  
10 is continued in effect for that purpose.

11          SECTION 13. Section 561.0032, Occupations Code, as added by  
12 this Act, applies only to the renewal of a pharmacy license that  
13 expires on or after the effective date of this Act. A license that  
14 expires before the effective date of this Act is governed by the law  
15 in effect on the date the license expired, and the former law is  
16 continued in effect for that purpose.

17          SECTION 14. This Act takes effect September 1, 2013.