

1-1 By: Van de Putte S.B. No. 1100
 1-2 (In the Senate - Filed March 5, 2013; March 12, 2013, read
 1-3 first time and referred to Committee on Health and Human Services;
 1-4 April 25, 2013, reported adversely, with favorable Committee
 1-5 Substitute by the following vote: Yeas 7, Nays 0; April 25, 2013,
 1-6 sent to printer.)

1-7 COMMITTEE VOTE

	Yea	Nay	Absent	PNV
1-8 Nelson	X			
1-9 Deuell	X			
1-10 Huffman	X			
1-11 Nichols			X	
1-12 Schwertner	X			
1-13 Taylor	X			
1-14 Uresti			X	
1-15 West	X			
1-16 Zaffirini	X			

1-18 COMMITTEE SUBSTITUTE FOR S.B. No. 1100 By: Deuell

1-19 A BILL TO BE ENTITLED
 1-20 AN ACT

1-21 relating to the licensing and inspection of certain out-of-state
 1-22 pharmacies by the Texas State Board of Pharmacy; authorizing fees.

1-23 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

1-24 SECTION 1. Subchapter B, Chapter 556, Occupations Code, is
 1-25 amended by adding Section 556.0551 to read as follows:

1-26 Sec. 556.0551. INSPECTION OF LICENSED NONRESIDENT
 1-27 PHARMACY. (a) The board may inspect a nonresident pharmacy
 1-28 licensed by the board that compounds sterile preparations as
 1-29 necessary to ensure compliance with the safety standards and other
 1-30 requirements of this subtitle and board rules.

1-31 (b) A nonresident pharmacy shall reimburse the board for all
 1-32 expenses, including travel, incurred by the board in inspecting the
 1-33 pharmacy as provided by Subsection (a).

1-34 SECTION 2. Subsection (b), Section 560.001, Occupations
 1-35 Code, is amended to read as follows:

1-36 (b) A pharmacy located in another state may not ship, mail,
 1-37 or deliver to this state a prescription drug or device dispensed
 1-38 under a prescription drug order, or dispensed or delivered as
 1-39 authorized by Subchapter D, Chapter 562, [to a resident of this
 1-40 state] unless the pharmacy is licensed by the board or is exempt
 1-41 under Section 560.004.

1-42 SECTION 3. Section 560.052, Occupations Code, is amended by
 1-43 amending Subsections (b) and (c) and adding Subsections (g) and (h)
 1-44 to read as follows:

1-45 (b) To qualify for a pharmacy license, an applicant must
 1-46 submit to the board:

1-47 (1) a license fee set by the board, except as provided
 1-48 by Subsection (d); and

1-49 (2) a completed application that:

1-50 (A) is on a form prescribed by the board;

1-51 (B) is given under oath; and

1-52 (C) includes a statement of:

1-53 (i) the ownership;

1-54 (ii) the location of the pharmacy;

1-55 (iii) the license number of each pharmacist

1-56 who is employed by the pharmacy, if the pharmacy is located in this

1-57 state, or who is licensed to practice pharmacy in this state, if the

1-58 pharmacy is located in another state [a Class E pharmacy];

1-59 (iv) the license number of the

1-60 pharmacist-in-charge; and

2-1 (v) any other information the board
2-2 determines necessary.

2-3 (c) A pharmacy located in another state that applies for a
2-4 license [~~To qualify for a Class E pharmacy license, an applicant~~],
2-5 in addition to satisfying the other requirements of this chapter,
2-6 must provide to the board:

2-7 (1) evidence that the applicant holds a pharmacy
2-8 license, registration, or permit in good standing issued by the
2-9 state in which the pharmacy is located;

2-10 (2) the name of the owner and pharmacist-in-charge of
2-11 the pharmacy for service of process;

2-12 (3) evidence of the applicant's ability to provide to
2-13 the board a record of a prescription drug order dispensed or
2-14 delivered as authorized by Subchapter D, Chapter 562, by the
2-15 applicant to a resident of or practitioner in this state not later
2-16 than 72 hours after the time the board requests the record;

2-17 (4) an affidavit by the pharmacist-in-charge that
2-18 states that the pharmacist has read and understands the laws and
2-19 rules relating to the applicable license [~~a Class E pharmacy~~];

2-20 (5) proof of creditworthiness; and

2-21 (6) an inspection report issued:

2-22 (A) not more than two years before the date the
2-23 license application is received; [~~and~~]

2-24 (B) by the pharmacy licensing board in the state
2-25 of the pharmacy's physical location, except as provided by
2-26 Subsection (f); and

2-27 (7) any other information the board determines
2-28 necessary.

2-29 (g) A license may not be issued to a pharmacy that compounds
2-30 sterile preparations unless the pharmacy has been inspected by the
2-31 board to ensure the pharmacy meets the safety standards and other
2-32 requirements of this subtitle and board rules.

2-33 (h) The board may accept, as satisfying the inspection
2-34 requirement in Subsection (g) for a pharmacy located in another
2-35 state, an inspection report issued by the pharmacy licensing board
2-36 in the state in which the pharmacy is located if:

2-37 (1) the board determines that the other state has
2-38 comparable standards and regulations applicable to pharmacies,
2-39 including standards and regulations related to health and safety;
2-40 and

2-41 (2) the pharmacy provides to the board any requested
2-42 documentation related to the inspection.

2-43 SECTION 4. Chapter 561, Occupations Code, is amended by
2-44 adding Section 561.0032 to read as follows:

2-45 Sec. 561.0032. ADDITIONAL RENEWAL REQUIREMENT FOR
2-46 COMPOUNDING PHARMACY. (a) In addition to the renewal requirements
2-47 under Section 561.003, a pharmacy that compounds sterile
2-48 preparations may not renew a pharmacy license unless the pharmacy:

2-49 (1) has been inspected as provided by board rule; and

2-50 (2) if the pharmacy is located in another state, has
2-51 reimbursed the board for all expenses, including travel, incurred
2-52 by the board in inspecting the pharmacy during the term of the
2-53 expiring license.

2-54 (b) The board may accept, as satisfying the inspection
2-55 requirement in Subsection (a) for a pharmacy located in another
2-56 state, an inspection report issued by the pharmacy licensing board
2-57 in the state in which the pharmacy is located if:

2-58 (1) the board determines that the other state has
2-59 comparable standards and regulations applicable to pharmacies,
2-60 including standards and regulations related to health and safety;
2-61 and

2-62 (2) the pharmacy provides to the board any requested
2-63 documentation related to the inspection.

2-64 SECTION 5. Subsection (a), Section 562.106, Occupations
2-65 Code, is amended to read as follows:

2-66 (a) A pharmacy shall report in writing to the board not
2-67 later than the 10th day after the date of:

2-68 (1) a permanent closing of the pharmacy;

2-69 (2) a change of ownership of the pharmacy;

- 3-1 (3) a change of location of the pharmacy;
- 3-2 (4) a change of the person designated as the
- 3-3 pharmacist-in-charge of the pharmacy;
- 3-4 (5) a sale or transfer of any controlled substance or
- 3-5 dangerous drug as a result of the permanent closing or change of
- 3-6 ownership of the pharmacy;
- 3-7 (6) any matter or occurrence that the board requires
- 3-8 by rule to be reported;
- 3-9 (7) as determined by the board, an out-of-state
- 3-10 purchase of any controlled substance;
- 3-11 (8) a final order against the pharmacy license holder
- 3-12 by the regulatory or licensing agency of the state in which the
- 3-13 pharmacy is located if the pharmacy is located in another state [~~a~~
- 3-14 ~~Class E pharmacy~~]; or

- 3-15 (9) a final order against a pharmacist who is
- 3-16 designated as the pharmacist-in-charge of the pharmacy by the
- 3-17 regulatory or licensing agency of the state in which the pharmacy is
- 3-18 located if the pharmacy is located in another state [~~a Class E~~
- 3-19 ~~pharmacy~~].

3-20 SECTION 6. Subchapter D, Chapter 562, Occupations Code, is

3-21 amended by adding Section 562.156 to read as follows:

3-22 Sec. 562.156. COMPOUNDED STERILE PREPARATION; NOTICE TO

3-23 BOARD. (a) A pharmacy may not compound and dispense a sterile

3-24 preparation unless the pharmacy holds a license as required by

3-25 board rule.

3-26 (b) A pharmacy that compounds a sterile preparation shall

3-27 notify the board:

3-28 (1) immediately of any adverse effects reported to the

3-29 pharmacy or that are known by the pharmacy to be potentially

3-30 attributable to a sterile preparation compounded by the pharmacy;

3-31 and

3-32 (2) not later than 24 hours after the pharmacy issues a

3-33 recall for a sterile preparation compounded by the pharmacy.

3-34 SECTION 7. Section 565.003, Occupations Code, is amended to

3-35 read as follows:

3-36 Sec. 565.003. ADDITIONAL GROUNDS FOR DISCIPLINE REGARDING

3-37 APPLICANT FOR OR HOLDER OF NONRESIDENT [~~CLASS E~~] PHARMACY LICENSE.

3-38 [~~(b)~~] Unless compliance would violate the pharmacy or drug

3-39 statutes or rules in the state in which the pharmacy is located the

3-40 board may discipline an applicant for or the holder of a nonresident

3-41 [~~Class E~~] pharmacy license if the board finds that the applicant or

3-42 license holder has failed to comply with:

3-43 (1) Section 481.074 or 481.075, Health and Safety

3-44 Code;

3-45 (2) Texas substitution requirements regarding:

3-46 (A) the practitioner's directions concerning

3-47 generic substitution;

3-48 (B) the patient's right to refuse generic

3-49 substitution; or

3-50 (C) notification to the patient of the patient's

3-51 right to refuse substitution;

3-52 (3) any board rule relating to providing drug

3-53 information to the patient or the patient's agent in written form or

3-54 by telephone; or

3-55 (4) any board rule adopted under Section 554.051(a)

3-56 and determined by the board to be applicable under Section

3-57 554.051(b).

3-58 SECTION 8. Section 565.053, Occupations Code, is amended to

3-59 read as follows:

3-60 Sec. 565.053. DISCIPLINE OF NONRESIDENT [~~CLASS E~~] PHARMACY;

3-61 NOTICE TO RESIDENT STATE. The board shall give notice of a

3-62 disciplinary action by the board against a license [~~the~~] holder

3-63 located in another state [~~of a Class E pharmacy license~~] to the

3-64 regulatory or licensing agency of the state in which the pharmacy is

3-65 located.

3-66 SECTION 9. The heading to Section 565.054, Occupations

3-67 Code, is amended to read as follows:

3-68 Sec. 565.054. SERVICE OF PROCESS ON NONRESIDENT [~~CLASS E~~]

3-69 PHARMACY.

4-1 SECTION 10. Subsection (a), Section 565.054, Occupations
4-2 Code, is amended to read as follows:

4-3 (a) Service of process on a nonresident [~~Class E~~] pharmacy
4-4 under Section 565.058 or 566.051 or for disciplinary action taken
4-5 by the board under Section 565.061 shall be on the owner and
4-6 pharmacist-in-charge of the pharmacy, as designated on the
4-7 pharmacy's license application.

4-8 SECTION 11. Not later than March 1, 2014, the Texas State
4-9 Board of Pharmacy shall adopt rules necessary to implement the
4-10 changes in law made by this Act.

4-11 SECTION 12. Section 560.052, Occupations Code, as amended
4-12 by this Act, applies only to an application for a pharmacy license
4-13 submitted to the Texas State Board of Pharmacy on or after the
4-14 effective date of this Act. An application for a license submitted
4-15 before the effective date of this Act is governed by the law in
4-16 effect on the date the application was submitted, and the former law
4-17 is continued in effect for that purpose.

4-18 SECTION 13. Section 561.0032, Occupations Code, as added by
4-19 this Act, applies only to the renewal of a pharmacy license that
4-20 expires on or after the effective date of this Act. A license that
4-21 expires before the effective date of this Act is governed by the law
4-22 in effect on the date the license expired, and the former law is
4-23 continued in effect for that purpose.

4-24 SECTION 14. This Act takes effect September 1, 2013.

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