CH. 608 83rd LEGISLATURE-REGULAR SESSION

CHAPTER 608

S.B. No. 1100

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) to read as follows:

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

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

(2) a completed application that:

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

(B) is given under oath; and

(C) includes a statement of:

(i) the ownership;

(ii) the location of the pharmacy;

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

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

(v) any other information the board determines necessary.

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

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

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

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

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

(5) proof of creditworthiness; [and]
an inspection report issued:

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

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

(7) any other information the board determines necessary.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 562.156. COMPOUNDED STERILE PREPARATION; NOTICE TO BOARD. (a) A pharmacy may not compound and dispense a sterile preparation unless the pharmacy holds a license as required by board rule.

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

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

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

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

Sec. 565.003. ADDITIONAL GROUNDS FOR DISCIPLINE REGARDING APPLICANT FOR OR HOLDER OF NONRESIDENT [CLASS E] PHARMACY LICENSE. (b) Unless compliance would violate the pharmacy or drug statutes or rules in the state in which the pharmacy is located the board may discipline an applicant for or the holder of a nonresident [Class E] pharmacy license if the board finds that the applicant or license holder has failed to comply with:

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

(2) Texas substitution requirements regarding:

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

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

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

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

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

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

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

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

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

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

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

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

SECTION 12. Section 560.052, Occupations Code, as amended by this Act, applies only to an application for a pharmacy license submitted to the Texas State Board of Pharmacy on or after the effective date of this Act. An application for a license submitted before the effective date of this Act is governed by the law in effect on the date the application was submitted, and the former law is continued in effect for that purpose.
SECTION 13. Section 561.0032, Occupations Code, as added by this Act, applies only to the renewal of a pharmacy license that expires on or after the effective date of this Act. A license that expires before the effective date of this Act is governed by the law in effect on the date the license expired, and the former law is continued in effect for that purpose.

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

Passed the Senate on May 1, 2013: Yeas 31, Nays 0; passed the House on May 22, 2013: Yeas 143, Nays 5, two present not voting.

Approved June 14, 2013.

Effective September 1, 2013.

CHAPTER 609

S.B. No. 1175

AN ACT
relating to the establishment of a reuse program for durable medical equipment provided to recipients under the Medicaid program.

Be it enacted by the Legislature of the State of Texas:

SECTION 1. Subchapter B, Chapter 531, Government Code, is amended by adding Section 531.0843 to read as follows:

Sec. 531.0843. DURABLE MEDICAL EQUIPMENT REUSE PROGRAM. (a) In this section:

(1) “Complex rehabilitation technology equipment” means equipment that is classified as durable medical equipment under the Medicare program on January 1, 2013, configured specifically for an individual to meet the individual's unique medical, physical, and functional needs and capabilities for basic and instrumental daily living activities, and medically necessary to prevent the individual's hospitalization or institutionalization. The term includes a complex rehabilitation power wheelchair, highly configurable manual wheelchair, adaptive seating and positioning system, standing frame, and gait trainer.

(2) “Durable medical equipment” means equipment, including repair and replacement parts for the equipment, but excluding complex rehabilitation technology equipment, that:

(A) can withstand repeated use;

(B) is primarily and customarily used to serve a medical purpose;

(C) generally is not useful to a person in the absence of illness or injury; and

(D) is appropriate and safe for use in the home.

(b) If the commission determines that it is cost-effective, the executive commissioner by rule shall establish a program to facilitate the reuse of durable medical equipment provided to recipients under the Medicaid program.

(c) The program must include provisions for ensuring that:

(1) reused equipment meets applicable standards of functionality and sanitation; and

(2) a Medicaid recipient's participation in the reuse program is voluntary.

(d) The program does not:

(1) waive any immunity from liability of the commission or an employee of the commission; or

(2) create a cause of action against the commission or an employee of the commission arising from the provision of reused durable medical equipment under the program.

(e) In accordance with Chapter 551 or 2001, as applicable, the executive commissioner shall provide notice of each proposed rule, adopted rule, and hearing that relates to establishing the program under this section.

1631