

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED RULE

Short Title: Inspections of Non-resident Pharmacies

Rule Numbers: §291.104

Statutory Authority: Texas Pharmacy Act, Chapter 551-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The amendments, if adopted, update the rules to require non-resident (Class E) pharmacies to submit an inspection conducted within the last 2 years as part of the pharmacy application. The proposed change makes the requirement consistent with other sections of the rules.

The Board reviewed and voted to propose the amendments during the November 3, 2015, meeting. The proposed amendments were published in the December 18, 2015, issue of the *Texas Register* at 40 TexReg 9066.

1 **CHAPTER 291. PHARMACIES**

2 **SUBCHAPTER F. NON-RESIDENT PHARMACY (CLASS E)**

3 **22 TAC §291.104**

4 The Texas State Board of Pharmacy proposes amendments to §291.104 concerning Operational
5 Standards. The amendments, if adopted, clarify the inspection requirements for Class E (Non-
6 resident) pharmacies.

7 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
8 period the rule is in effect, there will be no fiscal implications for state or local government as a
9 result of enforcing or administering the rule.

10 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
11 effect, the public benefit anticipated as a result of enforcing the amendments will ensure the non-
12 resident pharmacies are appropriately licensed and have been inspected within the previous two
13 years. There is no fiscal impact for individuals, small or large businesses, or to other entities
14 which are required to comply with this section.

15 Written comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director
16 of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,
17 Austin, Texas 78701, FAX (512) 305-6778. Comments must be received by 5:00 p.m., January
18 22, 2016.

19 The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act
20 (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as
21 authorizing the agency to protect the public through the effective control and regulation of the
22 practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules
23 for the proper administration and enforcement of the Act.

24 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 -
25 569, Texas Occupations Code.

26 ***§291.104.Operational Standards.***

27 (a) Licensing requirements.

28 (1) A Class E pharmacy shall register with the board on a pharmacy license application provided
29 by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy
30 License Application).

31 (2) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this
32 title (relating to Pharmacy License Application) and then provide the following additional
33 information specified in §560.052(c) and (f) of the Act (relating to Qualifications):

34 (A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the
35 state in which the pharmacy is located;

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

37 (C) evidence of the applicant's ability to provide to the board a record of a prescription drug
38 order dispensed by the applicant to a resident of this state not later than 72 hours after the time
39 the board requests the record;

40 (D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read and
41 understands the laws and rules relating to a Class E pharmacy;

42 (E) proof of creditworthiness; and

43 (F) an inspection report issued not more than two years before the date the license application is
44 received and conducted by the pharmacy licensing board in the state of the pharmacy's physical
45 location.

46 ~~[(i)] A Class E pharmacy may submit an inspection report issued by the board or its designee [an
47 entity other than the pharmacy licensing board of the state in which the pharmacy is physically
48 located] if the state's licensing board does not conduct inspections. [as follows:]~~

49 ~~[(I) an individual approved by the board who is not employed by the pharmacy but acting as a
50 consultant to inspect the pharmacy;]~~

51 ~~[(II) an agent of the National Association of Boards of Pharmacy;]~~

52 ~~[(III) an agent of another State Board of Pharmacy; or]~~

53 ~~[(IV) an agent of an accrediting body, such as the Joint Commission on Accreditation of
54 Healthcare Organizations.]~~

55 ~~[(i) The inspection must be substantively equivalent to an inspection conducted by the board.]~~

56 (3) On renewal of a license prior to September 1, 2016, the pharmacy shall complete the renewal
57 application provided by the board and, as specified in §561.0031 of the Act, provide an
58 inspection report issued not more than three years before the date the renewal application is
59 received and conducted by the pharmacy licensing board in the state of the pharmacy's physical
60 location.

61 (A) A Class E pharmacy may submit an inspection report issued by an entity other than the
62 pharmacy licensing board of the state in which the pharmacy is physically located if the state's
63 licensing board does not conduct inspections as follows:

64 (i) an individual approved by the board who is not employed by the pharmacy but acting as a
65 consultant to inspect the pharmacy;

- 66 (ii) an agent of the National Association of Boards of Pharmacy;
- 67 (iii) an agent of another State Board of Pharmacy; or
- 68 (iv) an agent of an accrediting body, such as the Joint Commission on Accreditation of
69 Healthcare Organizations.
- 70 (B) The inspection must be substantively equivalent to an inspection conducted by the board.
- 71 (4) On renewal of a license on or after September 1, 2016, the pharmacy shall complete the
72 renewal application provided by the board and, as specified in §561.031 of the Act, provide an
73 inspection report issued not more than three years before the date the renewal application is
74 received and conducted by the pharmacy licensing board in the state of the pharmacy's physical
75 location. A Class E pharmacy may submit an inspection report issued by the board or its
76 designee if the state's licensing board does not conduct inspections.
- 77 (5) [(4)] A Class E pharmacy which changes ownership shall notify the board within ten days of
78 the change of ownership and apply for a new and separate license as specified in §291.3 of this
79 title (relating to Required Notifications).
- 80 (6) [(5)] A Class E pharmacy which changes location [~~and/or name~~] shall notify the board not
81 later than thirty days before the date [~~within ten days~~] of the change and file for an amended
82 license as specified in §291.3 of this title.
- 83 (7) [(6)] A Class E pharmacy owned by a partnership or corporation which changes managing
84 officers shall notify the board in writing of the names of the new managing officers within ten
85 days of the change, following the procedures in §291.3 of this title.
- 86 (8) [(7)] A Class E pharmacy shall notify the board in writing within ten days of closing.
- 87 (9) [(8)] A separate license is required for each principal place of business and only one
88 pharmacy license may be issued to a specific location.
- 89 (10) [(9)] A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
90 charged for the issuance and renewal of a license and the issuance of an amended license.
- 91 (11) [(10)] The board may grant an exemption from the licensing requirements of this Act on the
92 application of a pharmacy located in a state of the United States other than this state that restricts
93 its dispensing of prescription drugs or devices to residents of this state to isolated transactions.
- 94 (12) [(11)] A Class E pharmacy engaged in the centralized dispensing of prescription drug or
95 medication orders shall comply with the provisions of §291.125 of this title (relating to
96 Centralized Prescription Dispensing).

97 (13) [~~(12)~~] A Class E pharmacy engaged in central processing of prescription drug or medication
98 orders shall comply with the provisions of §291.123 of this title (relating to Central Prescription
99 or Medication Order Processing).

100 (14) [~~(13)~~] A Class E pharmacy engaged in the compounding of non-sterile preparations shall
101 comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-
102 Sterile Preparations).

103 (15) [~~(14)~~] Effective August 31, 2014, a [~~A~~] Class E pharmacy shall not compound sterile
104 preparations unless the pharmacy has applied for and obtained a Class E-S pharmacy.

105 Class E pharmacy personnel shall not compound sterile preparations unless the pharmacy has
106 applied for and obtained a Class E-S pharmacy.

107 (16) [~~(15)~~] A Class E pharmacy, which operates as a community type of pharmacy which would
108 otherwise be required to be licensed under the Act §560.051(a)(1) (Community Pharmacy (Class
109 A)), shall comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of
110 this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34
111 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription
112 Records), contained in Community Pharmacy (Class A); or which operates as a nuclear type of
113 pharmacy which would otherwise be required to be licensed under the Act §560.051(a)(2)
114 (Nuclear Pharmacy (Class B)), shall comply with the provisions of §291.51 of this title (relating
115 to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to
116 Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title
117 (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are
118 applicable to the operation of the pharmacy.

119 (b) - (f) (No change.)