

RULE ANALYSIS

Introduction: THE NEW RULE IS SUBMITTED TO THE BOARD FOR CONSIDERATION AS A ADOPTED RULE

Short Title: Concerning the Pharmacist-in-Charge of Class E Pharmacies

Rule Numbers: §291.103

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 amendment, if adopted, requires the pharmacist-in-charge of non-resident pharmacy (Class E) to be licensed in Texas.

The Board reviewed and voted to propose the amendments during the August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register* at 40 TexReg 6530.

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

2 **22 TAC §291.103, §291.104**

3 The Texas State Board of Pharmacy proposes amendments to §291.103 concerning Personnel
4 and §291.104 concerning Operational Standards. The amendments, if adopted, implement
5 provisions of S.B. 460 and HB 751 passed by the 84th Texas Legislature. The amendment to
6 §291.103, if adopted, require the pharmacist-in-charge of a non-resident pharmacy (Class E) to
7 be licensed in Texas. The amendments to §291.104, if adopted, update the requirements with
8 regard to interchangeable biological products and correct grammar.

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

12 Ms. Dodson has determined that, for each year of the first five-year period the rules will be in
13 effect, the public benefit anticipated as a result of enforcing the amendments will ensure the non-
14 resident pharmacies are supervised by appropriately licensed pharmacists; and pharmacies
15 appropriately dispense interchangeable biological products. There is no fiscal impact for
16 individuals, small or large businesses, or to other entities which are required to comply with
17 these sections.

18 Comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of
19 Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,
20 Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., October
21 30, 2015.

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

27 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 -
28 569, Texas Occupations Code.

29 **§291.103. Personnel.**

30 As specified in §562.101(f) of the Act (relating to Supervision of Pharmacy), a Class E
31 pharmacy shall be under the continuous on-site supervision of a pharmacist and shall designate
32 one pharmacist licensed to practice pharmacy by the regulatory or licensing agency of the state
33 in which the Class E pharmacy is located and effective September 1, 2016, is licensed as a
34 pharmacist in Texas to serve as the pharmacist-in-charge of the Class E pharmacy license.

35 §291.104. Operational Standards.

- 36 (a) Licensing requirements.
- 37 (1) - (2) (No change.)
- 38 (3) On renewal of a license, the pharmacy shall complete the renewal application provided by the
39 board and, as specified in §561.0031 [~~§561.031~~] of the Act, provide an inspection report issued
40 not more than three years before the date the renewal application is received and conducted by
41 the pharmacy licensing board in the state of the pharmacy's physical location.
- 42 (A) A Class E pharmacy may submit an inspection report issued by an entity other than the
43 pharmacy licensing board of the state in which the pharmacy is physically located if the state's
44 licensing board does not conduct inspections as follows:
- 45 (i) an individual approved by the board who is not employed by the pharmacy but acting as a
46 consultant to inspect the pharmacy;
- 47 (ii) an agent of the National Association of Boards of Pharmacy;
- 48 (iii) an agent of another State Board of Pharmacy; or
- 49 (iv) an agent of an accrediting body, such as the Joint Commission on Accreditation of
50 Healthcare Organizations.
- 51 (B) The inspection must be substantively equivalent to an inspection conducted by the board.
- 52 (4) A Class E pharmacy which changes ownership shall notify the board within ten days of the
53 change of ownership and apply for a new and separate license as specified in §291.3 of this title
54 (relating to Required Notifications).
- 55 (5) A Class E pharmacy which changes location and/or name shall notify the board within ten
56 days of the change and file for an amended license as specified in §291.3 of this title.
- 57 (6) A Class E pharmacy owned by a partnership or corporation which changes managing officers
58 shall notify the board in writing of the names of the new managing officers within ten days of the
59 change, following the procedures in §291.3 of this title.
- 60 (7) A Class E pharmacy shall notify the board in writing within ten days of closing.
- 61 (8) A separate license is required for each principal place of business and only one pharmacy
62 license may be issued to a specific location.
- 63 (9) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged
64 for the issuance and renewal of a license and the issuance of an amended license.

65 (10) The board may grant an exemption from the licensing requirements of this Act on the
66 application of a pharmacy located in a state of the United States other than this state that restricts
67 its dispensing of prescription drugs or devices to residents of this state to isolated transactions.

68 (11) A Class E pharmacy engaged in the centralized dispensing of prescription drug or
69 medication orders shall comply with the provisions of §291.125 of this title (relating to
70 Centralized Prescription Dispensing).

71 (12) A Class E pharmacy engaged in central processing of prescription drug or medication orders
72 shall comply with the provisions of §291.123 of this title (relating to Central Prescription or
73 Medication Order Processing).

74 (13) A Class E pharmacy engaged in the compounding of non-sterile preparations shall comply
75 with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile
76 Preparations).

77 ~~[(14) Prior to August 31, 2014, a Class E pharmacy engaged in the compounding of sterile
78 preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies
79 Compounding Sterile Preparations).]~~

80 (14) ~~[(15)]~~ ~~[Effective August 31, 2014, a]~~ Class E pharmacy personnel shall not compound
81 sterile preparations unless the pharmacy has applied for and obtained a Class E-S pharmacy.

82 (15) ~~[(16)]~~ A Class E pharmacy, which operates as a community type of pharmacy which would
83 otherwise be required to be licensed under the Act §560.051(a)(1) (Community Pharmacy (Class
84 A)), shall comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of
85 this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34
86 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription
87 Records), contained in Community Pharmacy (Class A); or which operates as a nuclear type of
88 pharmacy which would otherwise be required to be licensed under the Act §560.051(a)(2)
89 (Nuclear Pharmacy (Class B)), shall comply with the provisions of §291.51 of this title (relating
90 to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to
91 Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title
92 (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are
93 applicable to the operation of the pharmacy.

94 (b) (No change.)

95 (c) ~~[Generic]~~ Substitution requirements.

96 (1) Unless compliance would violate the pharmacy or drug laws or rules in the state in which the
97 pharmacy is located a pharmacist in a Class E pharmacy may dispense a generically equivalent
98 drug or interchangeable biological product and shall comply with the provisions of §309.3 of this
99 title (relating to ~~[Generic-]~~ Substitution Requirements) and §309.7 of this title (relating to
100 Dispensing Responsibilities).

101 (2) The pharmacy must include on the prescription order form completed by the patient or the
102 patient's agent information that clearly and conspicuously:

103 (A) states that if a less expensive generically equivalent drug or interchangeable biological
104 product is available for the brand prescribed, the patient or the patient's agent may choose
105 between the generically equivalent drug or interchangeable biological product and the brand
106 prescribed; and

107 (B) allows the patient or the patient's agent to indicate the choice of the generically equivalent
108 drug or interchangeable biological product or the brand prescribed.

109 (d) (No change.)

110 (e) Transfer of Prescription Drug Order Information. Unless compliance would violate the
111 pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a
112 Class E pharmacy may not refuse to transfer prescriptions to another pharmacy that is making
113 the transfer request on behalf of the patient. The transfer of original prescription information
114 must be done within four business hours of the request [~~in a timely manner~~].

115 (f) (No change.)

116 The agency certifies that legal counsel has reviewed the proposal and found it to be within the
117 state agency's legal authority to adopt.

118 Filed with the Office of the Secretary of State on September 14, 2015.

119 TRD-201503753

120 Gay Dodson, R.Ph.

121 Executive Director

122 Texas State Board of Pharmacy

123 Earliest possible date of adoption: October 25, 2015

124 For further information, please call: (512) 305-8028

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From: Mcallister, Dennis (WDC]
Sent: Wednesday, September 30, 2015 1:29 PM
To: Allison Benz
Subject: RE: Proposed rules

Allison,

Thanks for the quick reply. I would suggest additional language that would allow for turnover of the Texas licensed PIC. Oregon adopted a good compromise that allows for notification, interim responsible person and a 90 allowance for a new person to obtain an Texas license. Here is the adopted language from Oregon:

(5) Every non-resident pharmacy will have a pharmacist-in-charge (PIC) who is licensed in Oregon within four months of initial licensure of the pharmacy, or within 90 days of a change in PIC.

(6) When a change of PIC occurs, the non-resident pharmacy will notify the Board within five business days and identify a contact person. The pharmacy will have an Oregon licensed PIC employed within 90 days. The contact person must be a licensed pharmacist in the pharmacy's state of residence and is responsible for the following:

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