

RULE ANALYSIS

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

Short Title: Pharmacy License

Rule Numbers: §§291.5, 291.14

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 to §291.5, if adopted, clarify the requirements for closing a pharmacy and eliminate the requirements for a pharmacy to transfer records to a pharmacy within a reasonable distance. The amendments to §291.14, if adopted, implement provisions of S.B. 460 passed during the 84th Texas Legislative session which change the expiration date for a pharmacy license that has expired from one year to 91 days and allows the board to not renew the license of a pharmacy if the board determines that the pharmacy is not located or no longer exists at the pharmacy's address of record.

The Board reviewed and voted to propose the amendments during the February 2, 2016, meeting. The proposed amendments were published in the March 11, 2016, issue of the *Texas Register* at 41 TexReg 1795.

1 **CHAPTER 291. PHARMACIES**

2 **SUBCHAPTER A. ALL CLASSES OF PHARMACIES**

3 **22 TAC §291.5, §291.14**

4 The Texas State Board of Pharmacy proposes amendments to §291.5, concerning Closing a
5 Pharmacy, and §291.14, concerning Pharmacy License Renewal. The amendments to §291.5 if
6 adopted, clarify the requirements for closing a pharmacy and eliminate the requirements for a
7 pharmacy to transfer records to a pharmacy within a reasonable distance. The amendments to
8 §291.14, if adopted, implement provisions of S.B. 460 passed during the 84th Texas Legislative
9 session which change the expiration date for a pharmacy license that has expired from one year
10 to 91 days and allows the board to not renew the license of a pharmacy if the board determines
11 that the pharmacy is not located or no longer exists at the pharmacy's address of record.

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

15 Ms. Dodson has determined that, for each year of the first five-year period the rules will be in
16 effect, the public benefit anticipated as a result of enforcing the amendments to §291.5 will
17 ensure that pharmacies that close provide adequate notice and the public benefit anticipated as a
18 result of enforcing the amendments to §291.14 will ensure that pharmacies no longer operating
19 are not renewed and are closed in a reasonable time. There is no fiscal impact for individuals,
20 small or large businesses, or to other entities which are required to comply with these sections.

21 Written comments on the amendments may be submitted to Allison Vordenbaumen Benz, R.Ph.,
22 M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street,
23 Suite 3-600, Austin, Texas 78701, FAX (512) 305-6778. Comments must be received by 5 p.m.,
24 April 25, 2016.

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

30 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas
31 Occupations Code.

32 **§291.5. Closing a Pharmacy.**

33 (a) Prior to closing. At least 14 days prior to the closing of a pharmacy that dispenses
34 prescription drug orders, the pharmacist-in-charge shall post a closing notice sign in a
35 conspicuous place in the front of the prescription department and at all public entrance doors to

36 the pharmacy. Such closing notice sign shall contain the following information: [comply with the
37 following.]

38 (1) the date of closing; and [if the pharmacy is registered to possess controlled substances, send a
39 written notification to the appropriate divisional office of the Drug Enforcement Administration
40 (DEA) containing the following information:]

41 ~~[(A) the name, address, and DEA registration number of the pharmacy;]~~

42 ~~[(B) the anticipated date of closing;]~~

43 ~~[(C) the name, address, and DEA registration number of the pharmacy acquiring the controlled~~
44 ~~substances; and]~~

45 ~~[(D) the date on which the transfer of controlled substances will occur.]~~

46 (2) ~~[If the pharmacy dispenses prescription drug orders, post a closing notice sign in a~~
47 ~~conspicuous place in the front of the prescription department and at all public entrance doors to~~
48 ~~the pharmacy. Such closing notice sign shall contain the following information:]~~

49 ~~[(A) the date of closing; and]~~

50 ~~[(B)]~~ the name, address, and telephone number of the pharmacy acquiring the prescription drug
51 orders, including refill information and patient medication records of the pharmacy.

52 (b) Closing day. On the date of closing, the pharmacist-in-charge shall comply with the
53 following:

54 (1) take an inventory as specified in §291.17 of this title (relating to Inventory Requirements);

55 (2) remove all prescription drugs from the pharmacy by one or a combination of the following
56 methods:

57 (A) return prescription drugs to manufacturer or supplier (for credit/disposal);

58 (B) transfer (sell or give away) prescription drugs to a person who is legally entitled to possess
59 drugs, such as a hospital, or another pharmacy; and

60 (C) destroy the prescription drugs following procedures specified in §303.2 of this title (relating
61 to Disposal of Stock Prescription Drugs);

62 (3) if the pharmacy dispenses prescription drug orders:

63 (A) transfer the prescription drug order files, including refill information, and patient medication
64 records to a licensed pharmacy ~~[within a reasonable distance of the closing pharmacy];~~ and

65 (B) ~~remove~~ [~~move~~] all signs or notify the landlord or owner of the property that it is unlawful to
66 use the word "pharmacy" either in English or any other language, or any other word or
67 combination of words of the same or similar meaning, or any graphic representation that would
68 mislead or tend to mislead the public that a pharmacy is located at the address.

69 (c) After closing.

70 (1) Within ten days after the closing of the pharmacy, the pharmacist-in-charge shall forward to
71 the board a written notice of the closing which includes the following information:

72 (A) the actual date of closing;

73 (B) the license issued to the pharmacy;

74 (C) a statement attesting:

75 (i) that an inventory as specified in §291.17 of this title (relating to Inventory Requirements) has
76 been conducted; and

77 (ii) the manner by which the dangerous drugs and controlled substances possessed by the
78 pharmacy were transferred or disposed; and

79 (D) if the pharmacy dispenses prescription drug orders, the name and address of the pharmacy to
80 which the prescription drug orders, including refill information, and patient medication records
81 were transferred.

82 (2) If the pharmacy is registered to possess controlled substances, send notification [~~a letter~~] to
83 the[;]

84 [~~(A)~~] appropriate DEA divisional office explaining that the pharmacy has closed and include[-
85 ~~include~~] the following items [~~with the letter~~]:

86 (A) [~~(i)~~] DEA registration certificate; and

87 (B) [~~(ii)~~] all unused DEA order forms (222) with the word VOID written on the face of each
88 order form[; ~~and~~]

89 [~~(iii)~~] copy 2 of any DEA order forms (222) used to transfer Schedule II controlled from the
90 closed pharmacy[-.

91 [~~(B)~~] the Texas Department of Public Safety (DPS) explaining that the pharmacy has closed and
92 include the DPS registration certificate.[-

93 (3) Once the pharmacy has notified the board that the pharmacy is closed, the license may not be
94 renewed. The pharmacy may apply for a new license as specified in §291.1 of this title (relating
95 to Pharmacy License Application).

96 (d) Emergency closing. If pharmacy is closed suddenly due to fire, destruction, natural disaster,
97 death, property seizure, eviction, bankruptcy, or other emergency circumstances and the
98 pharmacist-in-charge cannot provide notification 14 days prior to the closing, the pharmacist-in-
99 charge shall comply with the provisions of subsection (a) of this section as far in advance of the
100 closing as allowed by the circumstances.

101 (e) Joint responsibility. If the pharmacist-in-charge is not available to comply with the
102 requirements of this section, the owner shall be responsible for compliance with the provisions of
103 this section.

104 **§291.14. Pharmacy License Renewal.**

105 (a) Renewal requirements.

106 (1) A license to operate a pharmacy expires on the last day of the assigned expiration month.

107 ~~[(2) Timely receipt of the completed application and renewal fee means the receipt in the board's~~
108 ~~office of such application and renewal fee.]~~

109 (2) ~~[(3)]~~ The provision of the Act, §561.005, shall apply if the completed application and a
110 renewal fee is not received in the board's office on or before the last day of the assigned
111 expiration month.

112 (3) ~~[(4)]~~ An expired license may be renewed according to the following schedule:

113 (A) If the license has been expired for 90 days or less, the license may be renewed by paying to
114 the board a renewal fee that is equal to one and one-half times the required renewal fee as
115 specified in §291.6 of this title (relating to Pharmacy License Fees).

116 ~~[(B) If the license has been expired for more than 90 days but less than one year, the license may~~
117 ~~be renewed by paying to the board a renewal fee that is equal to two times the required renewal~~
118 ~~fee as specified in §291.6 of this title.]~~

119 (B) ~~[(C)]~~ If the license has been expired for 91 days ~~[one year]~~ or more, the license may not be
120 renewed. The pharmacy may apply for a new license as specified in §291.1 of this title (relating
121 to Pharmacy License Application).

122 (b) If the board determines on inspection at the pharmacy's address on or after the expiration date
123 of the license that no pharmacy is located or exists at the pharmacy's address (e.g., the building is
124 vacated or for sale or lease, or another business is operating at the location), the board shall not
125 renew the license.

126 (c) ~~[(b)]~~ Additional renewal requirements for Class E pharmacies. In addition to the renewal
127 requirements in subsection (a) of this section, a Class E pharmacy shall have on file with the
128 Board an inspection report issued:

- 129 (1) not more than three years before the date the renewal application is received; and
- 130 (2) by the pharmacy licensing board in the state of the pharmacy's physical location except as
- 131 provided in §291.104 of this title (relating to Operational Standards).