

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED 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.

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER A ALL CLASSES OF PHARMACIES

5
6 **§291.5 Closing a Pharmacy**
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9 (a) Prior to closing. At least 14 days prior to the closing of a pharmacy **that dispenses**
10 **prescription drug orders**, the pharmacist-in-charge shall **post a closing notice sign in a**
11 **conspicuous place in the front of the prescription department and at all public entrance**
12 **doors to the pharmacy. Such closing notice sign shall contain the following information:**
13 [comply with the following].

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

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19 —(A) the name, address, and DEA registration number of the pharmacy;

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21 —(B) the anticipated date of closing;

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23 —(C) the name, address, and DEA registration number of the pharmacy acquiring the
24 controlled substances; and

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26 —(D) the date on which the transfer of controlled substances will occur.]

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

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32 [(A) the date of closing; and]

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

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

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

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

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

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

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

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(3) if the pharmacy dispenses prescription drug orders:

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

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

(c) After closing.

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

(A) the actual date of closing;

(B) the license issued to the pharmacy;

(C) a statement attesting:

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

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

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

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

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

(A) [(i)] DEA registration certificate; **and**

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

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

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

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

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

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

115 116 117 118 **§291.14 Pharmacy License Renewal**

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120 (a) Renewal requirements.

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

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

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

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131 **(3)** ~~[(4)]~~ An expired license may be renewed according to the following schedule:

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

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

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

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

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150 **(c)** Additional renewal requirements for Class E pharmacies. In addition to the renewal
151 requirements in subsection (a) of this section, a Class E pharmacy shall have on file with the
152 Board an inspection report issued:

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154 (1) not more than three years before the date the renewal application is received; and

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156 (2) by the pharmacy licensing board in the state of the pharmacy's physical location except as
157 provided in §291.104 of this title (relating to Operational Standards).

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