

## RULE ANALYSIS

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

**Short Title:** Licensing Requirements

**Rule Numbers:** §291.106

**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, specify that a Class E-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board or its designee within the last two year renewal cycle to be consistent with other sections.

1 TITLE 22 EXAMINING BOARDS  
2 PART 15 TEXAS STATE BOARD OF PHARMACY  
3 CHAPTER 291 PHARMACIES  
4 SUBCHAPTER F NON-RESIDENT PHARMACY (CLASS E)

5  
6 **§291.106 Pharmacies Compounding Sterile Preparations (Class E-S)**  
7

8 Licensing requirements. A non-resident pharmacy engaged in the compounding of sterile  
9 preparations shall be licensed as a Class E-S pharmacy.

10  
11 (1) A Class E-S pharmacy shall register with the board on a pharmacy license application  
12 provided by the board, following the procedures specified in §291.1 of this title (relating to  
13 Pharmacy License Application).

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15 (2) A Class E-S license may not be issued unless the pharmacy has been inspected by the  
16 board or its designee to ensure the pharmacy meets the requirements as specified in §291.133  
17 of this title (relating to Pharmacies Compounding Sterile Preparations). A Class E-S pharmacy  
18 shall reimburse the board for all expenses, including travel, related to the inspection of the Class  
19 E-S pharmacy.

20  
21 (3) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this  
22 title and then provide the following additional information specified in §560.052(c) and (f) of the  
23 Act (relating to Qualifications):

24  
25 (A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the  
26 state in which the pharmacy is located;

27  
28 (B) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;

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

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

36  
37 (E) proof of creditworthiness.

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39 (4) A Class E-S pharmacy may not renew a pharmacy license unless the pharmacy has been  
40 inspected by the board or its designee within the last **renewal period** [~~two years~~].

41  
42 (5) A Class E-S pharmacy which changes ownership shall notify the board within ten days of  
43 the change of ownership and apply for a new and separate license as specified in §291.3 of this  
44 title (relating to Required Notifications).

45  
46 (6) A Class E-S pharmacy which changes location and/or name shall notify the board [~~within~~  
47 ~~ten days of the change and file for an amended license~~] as specified in §291.3 of this title.  
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49 (7) A Class E-S pharmacy owned by a partnership or corporation which changes managing  
50 officers shall notify the board in writing of the names of the new managing officers within ten  
51 days of the change, **as specified** [~~following the procedures~~] in §291.3 of this title.

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53 (8) A Class E-S pharmacy shall notify the board in writing within ten days of closing.

54  
55 (9) A separate license is required for each principal place of business and only one pharmacy  
56 license may be issued to a specific location.

57  
58 (10) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be  
59 charged for the issuance and renewal of a license and the issuance of an amended license.

60  
61 (11) The board may grant an exemption from the licensing requirements of this Act on the  
62 application of a pharmacy located in a state of the United States other than this state that  
63 restricts its dispensing of prescription drugs or devices to residents of this state to isolated  
64 transactions.

65  
66 (12) A Class E-S pharmacy engaged in the centralized dispensing of prescription drug or  
67 medication orders shall comply with the provisions of §291.125 of this title (relating to  
68 Centralized Prescription Dispensing).

69  
70 (13) A Class E-S pharmacy engaged in central processing of prescription drug or medication  
71 orders shall comply with the provisions of §291.123 of this title (relating to Central Prescription  
72 or Medication Order Processing).

73  
74 (14) A Class E-S pharmacy engaged in the compounding of non-sterile preparations shall  
75 comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-  
76 Sterile Preparations).

77  
78 (15) A Class E-S pharmacy engaged in the compounding of sterile preparations shall comply  
79 with the provisions of §291.133 of this title.

80  
81 (16) A Class E-S pharmacy which would otherwise be required to be licensed under the Act,  
82 §560.051(a)(5) concerning Non-Resident Pharmacy (Class E) is required to comply with the  
83 provisions of §291.101 of this title (relating to Purpose), §291.102 of this title (relating to  
84 Definitions), §291.103 of this title (relating to Personnel), §291.104 of this title (relating to  
85 Operational Standards) and §291.105 of this title (relating to Records).