

## RULE ANALYSIS

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

**Short Title:** Operational Standards

**Rule Numbers:** §§291.104, 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, clarify the requirements for Class E pharmacies; and update the patient counseling and prescription transfer requirements to be consistent with other sections.

**The Board reviewed and voted to propose the amendments during the February 3, 2015, meeting. The proposed amendments were published in the March 27, 2015, issue of the Texas Register at 40 TexReg 1786.**

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 **22 TAC §291.104, §291.106**

6 The Texas State Board of Pharmacy proposes amendments to §291.104 concerning Operational  
7 Standards and §291.106 concerning Pharmacies Compounding Sterile Preparations (Class E-S).  
8 The amendments, if adopted, clarify the requirements for Class E pharmacies; and update the  
9 patient counseling and prescription transfer requirements to be consistent with other sections.

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

13 Ms. Dodson has determined that, for each year of the first five-year period the rules will be in  
14 effect, the public benefit anticipated as a result of enforcing the amendments will be to ensure the  
15 requirements for Class E pharmacies; and to update the patient counseling and prescription  
16 transfer requirements to be consistent with other sections. There is no fiscal impact for  
17 individuals, small or large businesses, or to other entities which are required to comply with  
18 these sections.

19 Comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of  
20 Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,  
21 Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., April 30,  
22 2015.

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

28 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 -  
29 569, Texas Occupations Code.

30 **§291.104. Operational Standards.**

31 (a) Licensing requirements.

32 (1) - (15) (No change.)

33 (16) A Class E pharmacy, which operates as a community type of pharmacy which would  
34 otherwise be required to be licensed under the Act §560.051(a)(1) (Community Pharmacy (Class  
35 A)), shall comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of  
36 this title (relating to Personnel), §291.33 of this title (relating to Operational

37 Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to  
38 Official Prescription Records), contained in Community Pharmacy (Class A); or which operates  
39 as a nuclear type of pharmacy which would otherwise be required to be licensed under the Act  
40 §560.051(a)(2) (Nuclear Pharmacy (Class B)), shall comply with the provisions of §291.51 of  
41 this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title  
42 (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of  
43 this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such  
44 sections are applicable to the operation of the pharmacy.

45 (b) Prescription dispensing and delivery.

46 (1) - (2) (No change.)

47 (3) Patient counseling and provision of drug information.

48 (A) (No change.)

49 (B) Such communication shall be:

50 (i) ~~[shall be]~~ provided to new and existing patients of a pharmacy with each new prescription  
51 drug order. A new prescription drug order is one that has not been dispensed by the pharmacy to  
52 the patient in the same dosage and strength within the last year; ~~[with each new prescription drug~~  
53 order;]

54 (ii) ~~[shall be]~~ provided for any prescription drug order dispensed by the pharmacy on the request  
55 of the patient or patient's agent;

56 (iii) ~~[shall be]~~ communicated orally in person unless the patient or patient's agent is not at the  
57 pharmacy or a specific communication barrier prohibits such oral communication; and

58 (iv) ~~[shall be]~~ reinforced with written information. The following is applicable concerning this  
59 written information:

60 (I) Written information must be in plain language designed for the patient and printed in an  
61 easily readable font comparable to but no smaller than ten-point Times Roman. This information  
62 may be provided to the patient in an electronic format, such as by e-mail, if the patient or  
63 patient's agent requests the information in an electronic format and the pharmacy documents the  
64 request. ~~[designed for the consumer, such as the USP-DI patient information leaflets, shall be~~  
65 provided.]

66 (II) - (III) (No change.)

67 (IV) ~~The [Effective January 1, 2011, the]~~ written information accompanying the prescription or  
68 the prescription label shall contain the statement "Do not flush unused medications or pour down  
69 a sink or drain." A drug product on a list developed by the Federal Food and Drug  
70 Administration of medicines recommended for disposal by flushing is not required to bear this  
71 statement.

72 (C) - (H) (No change.)

73 (4) Labeling. At the time of delivery, the dispensing container shall bear a label that contains the  
74 following information:

75 (A) the name, physical address, and phone number of the pharmacy;

76 (B) ~~[effective June 1, 2010,]~~ if the drug is dispensed in a container other than the manufacturer's  
77 original container, the date after which the prescription should not be used or beyond-use-date.  
78 Unless otherwise specified by the manufacturer ~~[manufacture]~~, the beyond-use-date shall be one  
79 year from the date the drug is dispensed or the manufacturer's expiration date, whichever is  
80 earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached  
81 to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a  
82 person at the time of release from prison or jail if the prescription is for not more than a 10-day  
83 supply of medication;

84 (C) ~~[effective January 1, 2011,]~~ either on the prescription label or the written information  
85 accompanying the prescription, the statement, "Do not flush unused medications or pour down a  
86 sink or drain." A drug product on a list developed by the Federal Food and Drug Administration  
87 of medicines recommended for disposal by flushing is not required to bear this statement; and

88 (D) any other information that is required by the pharmacy or drug laws or rules in the state in  
89 which the pharmacy is located.

90 (c) - (d) (No change.)

91 (e) Transfer of Prescription Drug Order Information. Unless compliance would violate the  
92 pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a  
93 Class E pharmacy may not refuse to transfer prescriptions to another pharmacy that is making  
94 the transfer request on behalf of the patient. The transfer of original prescription information  
95 must be done in a timely manner.

96 (f) (No change.)

97 **§291.106.Pharmacies Compounding Sterile Preparations (Class E-S).**

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

100 (1) - (15) (No change.)

101 (16) A Class E-S pharmacy which would otherwise be required to be licensed under the Act,  
102 §560.051(a)(5) concerning Non-Resident Pharmacy (Class E) is required to comply with the  
103 provisions of §291.101 of this title (relating to Purpose), §291.102 of this title (relating to  
104 Definitions), §291.103 of this title (relating to Personnel), §291.104 of this title (relating to  
105 Operational Standards) and §291.105 of this title (relating to Records).

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