

RULE ANALYSIS

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

Short Title: Records

Rule Numbers: §291.105

Statutory Authority: Texas Pharmacy Act, Chapter 551-566 and 568-569, 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, add requirements for Class E pharmacies using auto-refill programs.

Background: Board staff presents these amendments to clarify the requirements for Class E pharmacies using auto-refill programs.

The Board reviewed and voted to propose the amendments during the August 6, 2013, meeting. The proposed amendments were published in the September 27, 2013, issue of the *Texas Register* at 38 TexReg 6512.

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

2 **§ 291.105**

3 The Texas State Board of Pharmacy (TSBP) proposes amendments to §291.104, concerning
4 Operational Standards, and §291.105, concerning Records, and new §291.106, concerning
5 Pharmacies Compounding Sterile Preparations (Class E-S).

6 The proposed amendments to §291.104, if adopted, clarify that Class E pharmacies will no
7 longer be able to compound sterile preparations after June 1, 2014, unless the pharmacy obtains a
8 Class E-S pharmacy license. The proposed amendments to §291.105, if adopted, add
9 requirements for auto-refill programs. The proposed new rule §291.106, if adopted, outlines the
10 requirements for a new class of pharmacy regarding pharmacies compounding sterile
11 preparations, implement recommendations of the TSBP appointment Task Force on
12 Compounding Sterile Preparations (Task Force) and implements Senate Bill 1100 passed during
13 the 83rd Regular Session of the Texas Legislature regarding compounding pharmacies.

14 The TSBP established the Task Force in December 2012 to review the current standards of
15 practice for pharmacy compounding and was charged with: (1) reviewing current federal and
16 state requirements for sterile compounding; and (2) making recommendations to the Board of
17 Pharmacy regarding standards for pharmacy compounding in Texas that provide necessary
18 compounded medications while protecting the health, safety, and welfare of the public. The Task
19 Force met three times and presented its recommendations to the Board at the August 6, 2013,
20 meeting. The Task Force was composed of representatives from the pharmacy community
21 appointed by the three major pharmacy associations in Texas and pharmacists primarily involved
22 in compounding.

23 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
24 period the proposed amendments and new rule are in effect, there will be no fiscal implications
25 for state or local government as a result of enforcing or administering the rules.

26 Ms. Dodson has determined that, for each year of the first five-year period the proposed
27 amendments and new rule will be in effect, the public benefit anticipated as a result of enforcing
28 the amendments and new rule will be to ensure safe compounding of sterile preparations and that
29 pharmacies engaged in sterile compounding are appropriately licensed.

30 There may be an adverse economic effect on micro, small, and large businesses or to other
31 entities/persons who are required to comply with the proposed amendments and new rule for
32 pharmacies compounding sterile preparations. Based on the significant variances in pharmacies'
33 physical structure and layout, it is difficult for TSBP to determine the actual cost to businesses
34 required to comply with the rules. These costs would involve bringing the sterile compounding
35 area of pharmacies into compliance with the new provisions and in establishing media fill test
36 procedures. TSBP cannot precisely determine the number of pharmacies affected because TSBP
37 records do not provide complete information about the details of the pharmacies' compounding
38 operations. In addition, TSBP is unable to reduce these costs because to do so would

39 compromise the purposes of these rules which are intended to protect the health and safety of the
40 public.

41 A public hearing to receive comments on proposed §§291.104 - 291.106 will be held at 1:00 p.m.
42 on Monday, November 4, 2013, at the Health Professions Council Board Room, 333 Guadalupe
43 Street, Tower II, Room 225, Austin, Texas 78701. Persons planning to present comments to the
44 Board are asked to provide a written copy of their comments prior to the hearing or to bring 20
45 copies to the hearing. Written comments on the amendments and new rule may be submitted to
46 Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy,
47 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-8008. Comments must
48 be received by 5:00 p.m., October 31, 2013.

49 The amendments and new rule are proposed under §§551.002, 551.003, 554.001, 554.051, and
50 560.053 of the Texas Pharmacy Act (Chapters 551 - 566, 568 and 569, Texas Occupations
51 Code). The Board interprets §551.002 as authorizing the agency to protect the public through the
52 effective control and regulation of the practice of pharmacy. The Board interprets §551.003(9) as
53 authorizing the agency to adopt rules concerning the compounding of prescriptions. The Board
54 interprets §551.003(33) as authorizing the agency to adopt rules concerning the practice of
55 pharmacy. The Board interprets §554.001(a) as authorizing the agency to adopt rules to
56 administer and enforce the Act and rules adopted under the Act as well as enforce other laws
57 relating to the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency
58 to adopt rules for the proper administration and enforcement of the Act. The Board interprets
59 §560.053 as authorizing the agency to adopt rules establishing additional pharmacy
60 classifications.

61 The statutes affected by the amendments and new rule: Texas Pharmacy Act, Chapters 551 - 566,
62 568 and 569, Texas Occupations Code.

63 **§291.105.Records.**

64 (a) (No change.)

65 (b) Auto-Refill Programs. A pharmacy may use a program that automatically refills prescriptions
66 that have existing refills available in order to improve patient compliance with and adherence to
67 prescribed medication therapy. The following is applicable in order to enroll patients into an
68 auto-refill program.

69 (1) Notice of the availability of an auto-refill program shall be given to the patient or patient's
70 agent, and the patient or patient's agent must affirmatively indicate that they wish to enroll in
71 such a program and the pharmacy shall document such indication.

72 (2) The patients or patient's agent shall have the option to withdraw from such a program at any
73 time.

74 (3) Auto-refill programs may be used for refills of dangerous drugs, and schedule IV and V
75 controlled substances. Schedule II and III controlled substances may not be dispensed by an
76 auto-refill program.

77 (4) As is required for all prescriptions, a drug regimen review shall be completed on all
78 prescriptions filled as a result of the auto-refill program. Special attention shall be noted for drug
79 regimen review warnings of duplication of therapy and all such conflicts shall be resolved with
80 the prescribing practitioner prior to refilling the prescription.

81 (c) [(b)] Civil litigation and complaint records. A Class E pharmacy shall keep a permanent
82 record of:

83 (1) any civil litigation commenced against the pharmacy by a Texas resident; and

84 (2) complaints that arise out of a prescription for a Texas resident lost during delivery.