

RULE ANALYSIS

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

Short Title: Sterile Compounding

Rule Numbers: §291.133

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, clarify that this section applies to Class B pharmacies preparing non-radioactive sterile preparations.

1 **PART 15. TEXAS STATE BOARD OF PHARMACY**

2 **CHAPTER 291. PHARMACIES**

3 **SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES**

4
5 **22 TAC §291.133**

6 The Texas State Board of Pharmacy proposes amendments to §291.133, concerning Pharmacies
7 Compounding Sterile Preparations. The amendments, if adopted, clarify that the section applies
8 to Class B pharmacies preparing non-radioactive sterile preparations and not radioactive
9 pharmaceuticals.

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

13 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
14 effect, the public benefit anticipated as a result of enforcing the amendments will be to ensure
15 nuclear pharmacies are preparing non-radioactive preparations in compliance with the section.
16 There is no fiscal impact for individuals, small or large businesses, or to other entities which are
17 required to comply with this section.

18 Comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of
19 Professional Services, Texas State Board of Pharmacy, by mail at 333 Guadalupe Street, Suite 3-
20 600, Austin, Texas 78701 or by fax at (512) 305-8008. Comments must be received by 5:00
21 p.m., October 31, 2014.

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

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

29 ***§291.133. Pharmacies Compounding Sterile Preparations.***

30 (a) Purpose. Pharmacies compounding sterile preparations, prepackaging pharmaceutical
31 products, and distributing those products shall comply with all requirements for their specific
32 license classification and this section. The purpose of this section is to provide standards for the:

33 (1) compounding of sterile preparations pursuant to a prescription or medication order for a
34 patient from a practitioner in Class A-S, [~~Class B-~~] Class C-S, and Class E-S pharmacies; and

35 compounding of sterile non-radioactive preparations pursuant to a prescription or medication
36 order for a patient from a practitioner in a Class B pharmacy;

37 (2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile
38 preparation in Class A-S, [~~Class B,~~] Class C-S, and Class E-S pharmacies to a practitioner's
39 office for office use by the practitioner; and compounding, dispensing, and delivery of a
40 reasonable quantity of a compounded sterile non-radioactive preparation in a Class B pharmacy
41 to a practitioner's office for office use by the practitioner;

42 (3) compounding and distribution of compounded sterile preparations by a Class A-S pharmacy
43 for a Class C-S pharmacy; and

44 (4) compounding of sterile preparations by a Class C-S pharmacy and the distribution of the
45 compounded preparations to other Class C or Class C-S pharmacies under common ownership.

46 (b) - (g) (No change.)

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

49 Filed with the Office of the Secretary of State on September 15, 2014.

50 TRD-201404388

51 Gay Dodson, R.Ph.

52 Executive Director

53 Texas State Board of Pharmacy

54 Earliest possible date of adoption: October 26, 2014

55 For further information, please call: (512) 305-8028

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