

RULE ANALYSIS

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

Short Title: Pharmacies Compounding Sterile Preparations

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 the training requirements for pharmacy technicians in ASHP accredited programs.

The Board reviewed and voted to propose the amendments during the May 6, 2014, meeting. The proposed amendments were published in the June 13, 2014, issue of the *Texas Register* at 39 TexReg 4604.

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

2 **22 TAC §291.133**

3 The Texas State Board of Pharmacy proposes amendments to §291.133, concerning Pharmacies
4 Compounding Sterile Preparations. The proposed amendments, if adopted, clarify the training
5 requirements for pharmacy technicians in American Society of Health-System Pharmacists
6 accredited programs.

7 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
8 period the rule is in effect, there will be no fiscal implications for state or local government as a
9 result of enforcing or administering the rule. There is no anticipated cost to individuals.

10 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
11 effect, the public benefit anticipated as a result of enforcing the amendments will ensure
12 adequate training for individuals involved in compounding of sterile preparations.

13 Written comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director
14 of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,
15 Austin, Texas 78701, fax (512) 305-8008. Comments must be received by 5:00 p.m., July 31,
16 2014.

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

22 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566, 568 and
23 569, Texas Occupations Code.

24 ***§291.133. Pharmacies Compounding Sterile Preparations.***

25 (a) - (b) (No change.)

26 (c) Personnel.

27 (1) - (2) (No change.)

28 (3) Pharmacy technicians and pharmacy technician trainees.

29 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training
30 requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy
31 Technician Trainee Training).

32 (B) Prior to September 1, 2015 - initial training and continuing education. In addition to specific
33 qualifications for registration, all pharmacy technicians and pharmacy technician trainees who
34 compound sterile preparations for administration to patients shall:

35 (i) have initial training obtained either through completion of:

36 (I) a single course, a minimum of 40 hours of instruction and experience in the areas listed in
37 paragraph (4)(D) of this subsection. Such training may be obtained through:

38 (-a-) completion of a structured on-the-job didactic and experiential training program at this
39 pharmacy which provides 40 hours of instruction and experience. Such training may not be
40 transferred to another pharmacy unless the pharmacies are under common ownership and control
41 and use a common training program; or

42 (-b-) completion of a course sponsored by an ACPE accredited provider which provides 40 hours
43 of instruction and experience; or

44 (II) a training program which is accredited by the American Society of Health-System
45 Pharmacists. Individuals enrolled in training programs accredited by the American Society of
46 Health-System Pharmacists may compound sterile preparations in a licensed pharmacy provided:

47 (-a-) the compounding occurs only during times the individual is assigned to a pharmacy as a
48 part of the experiential component of the American Society of Health-System Pharmacists
49 training program;

50 (-b-) the individual is under the direct supervision of and responsible to a pharmacist who has
51 completed training as specified in paragraph (2) of this subsection; and

52 (-c-) the supervising pharmacist conducts in-process and final checks.

53 (ii) acquire the required experiential portion of the training programs specified in this
54 subparagraph under the supervision of an individual who has already completed training as
55 specified in paragraph (2) of this subsection or this paragraph.

56 (C) Effective September 1, 2015 - initial training and continuing education.

57 (i) Pharmacy technicians and pharmacy technician trainees may compound sterile preparations
58 provided the pharmacy technicians and/or pharmacy technician trainees are supervised by a
59 pharmacist who has completed the training specified in paragraph (2) of this subsection,
60 conducts in-process and final checks, and affixes his or her initials to the appropriate quality
61 control records.

62 (ii) All pharmacy technicians and pharmacy technician trainees who compound sterile
63 preparations for administration to patients shall [~~comply with the following~~]:

64 (I) have initial training obtained either through completion of:

65 ~~(-a-) [(I)] [complete through completion of]~~ a single course, a minimum of 40 hours of
66 instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training
67 shall be obtained through completion of a course sponsored by an ACPE accredited provider
68 which provides 40 hours of instruction and experience; or

69 (-b-) a training program which is accredited by the American Society of Health-System
70 Pharmacists.

71 (II) and

72 ~~(-a-) [(II)]~~ complete a structured on-the-job didactic and experiential training program at this
73 pharmacy which provides sufficient hours of instruction and experience in the facility's sterile
74 compounding processes and procedures ~~[the areas]~~. Such training may not be transferred to
75 another pharmacy unless the pharmacies are under common ownership and control and use a
76 common training program; and

77 ~~(-b-) [(III)]~~ possess knowledge about:

78 ~~(-1-) [(a)]~~ aseptic processing;

79 ~~(-2-) [(b)]~~ quality control and quality assurance as related to environmental, component, and
80 finished preparation release checks and tests;

81 ~~(-3-) [(c)]~~ chemical, pharmaceutical, and clinical properties of drugs;

82 ~~(-4-) [(d)]~~ container, equipment, and closure system selection; and

83 ~~(-5-) [(e)]~~ sterilization techniques.

84 (iii) Individuals enrolled in training programs accredited by the American Society of Health-
85 System Pharmacists may compound sterile preparations in a licensed pharmacy provided:

86 (I) the compounding occurs only during times the individual is assigned to a pharmacy as a part
87 of the experiential component of the American Society of Health-System Pharmacists training
88 program;

89 (II) the individual is under the direct supervision of and responsible to a pharmacist who has
90 completed training as specified in paragraph (2) of this subsection; and

91 (III) the supervising pharmacist conducts in-process and final checks.

92 (iv) The required experiential portion of the training programs specified in this subparagraph
93 must be supervised by an individual who is actively engaged in performing sterile compounding,
94 is qualified and has completed training as specified in paragraph (2) of this subsection or this
95 paragraph.

96 (v) In order to renew a registration as a pharmacy technician, during the previous registration
97 period, a pharmacy technician engaged in sterile compounding shall complete a minimum of:

98 (I) two hours of ACPE accredited continuing education relating to one or more of the areas listed
99 in paragraph (4)(D) of this subsection if the pharmacy technician is engaged in compounding low
100 and medium risk sterile preparations; or

101 (II) four hours of ACPE accredited continuing education relating to one or more of the areas
102 listed in paragraph (4)(D) of this subsection if pharmacy technician is engaged in compounding
103 high risk sterile preparations.

104 (4) - (5) (No change.)

105 (d) - (g) (No change.)

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.

108 Filed with the Office of the Secretary of State on May 30, 2014.

109 TRD-201402548

110 Gay Dodson, R.Ph.

111 Executive Director

112 Texas State Board of Pharmacy

113 Earliest possible date of adoption: July 13, 2014

114 For further information, please call: (512) 305-8073

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