

## RULE ANALYSIS

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

1 **TITLE 22 EXAMINING BOARDS**  
2 **PART 15 TEXAS STATE BOARD OF PHARMACY**  
3 **CHAPTER 291 PHARMACIES**  
4 **SUBCHAPTER G SERVICES PROVIDED BY PHARMACIES**

5  
6 **§291.133 Pharmacies Compounding Sterile Preparations**  
7

8 (a) - (b) (No change.)  
9

10 (c) Personnel.

11  
12 (1) – (2) (No change.)  
13

14 (3) Pharmacy technicians and pharmacy technician trainees.  
15

16 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the  
17 training requirements specified in §297.6 of this title (relating to Pharmacy Technician and  
18 Pharmacy Technician Trainee Training).  
19

20 (B) Prior to September 1, 2015 - initial training and continuing education. In addition to  
21 specific qualifications for registration, all pharmacy technicians and pharmacy technician  
22 trainees who compound sterile preparations for administration to patients shall:  
23

24 (i) have initial training obtained either through completion of:  
25

26 (I) a single course, a minimum of 40 hours of instruction and experience in the areas listed  
27 in paragraph (4)(D) of this subsection. Such training may be obtained through:  
28

29 (-a-) completion of a structured on-the-job didactic and experiential training program at  
30 this pharmacy which provides 40 hours of instruction and experience. Such training may not be  
31 transferred to another pharmacy unless the pharmacies are under common ownership and  
32 control and use a common training program; or  
33

34 (-b-) completion of a course sponsored by an ACPE accredited provider which provides  
35 40 hours of instruction and experience; or  
36

37 (II) a training program which is accredited by the American Society of Health-System  
38 Pharmacists. Individuals enrolled in training programs accredited by the American Society of  
39 Health-System Pharmacists may compound sterile preparations in a licensed pharmacy  
40 provided:  
41

42 (-a-) the compounding occurs only during times the individual is assigned to a pharmacy  
43 as a part of the experiential component of the American Society of Health-System Pharmacists  
44 training program;  
45

46 (-b-) the individual is under the direct supervision of and responsible to a pharmacist who  
47 has completed training as specified in paragraph (2) of this subsection; and  
48

49 (-c-) the supervising pharmacist conducts in-process and final checks.  
50

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

54  
55 (C) Effective September 1, 2015 - initial training and continuing education.

56  
57 (i) Pharmacy technicians and pharmacy technician trainees may compound sterile  
58 preparations provided the pharmacy technicians and/or pharmacy technician trainees are  
59 supervised by a pharmacist who has completed the training specified in paragraph (2) of this  
60 subsection, conducts in-process and final checks, and affixes his or her initials to the  
61 appropriate quality control records.

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

65  
66 **(I) have initial training obtained either through completion of:**

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

72  
73 **(-b-) a training program which is accredited by the American Society of Health-System**  
74 **Pharmacists.**

75  
76 **(II) and**

77  
78 ~~(-a-)~~ [(II)] complete a structured on-the-job didactic and experiential training program at  
79 this pharmacy which provides sufficient hours of instruction and experience in the facility's  
80 sterile compounding processes and procedures the areas. Such training may not be transferred  
81 to another pharmacy unless the pharmacies are under common ownership and control and use  
82 a common training program; and

83  
84 ~~(-b-)~~ [(III)] possess knowledge about:

85  
86 ~~(-1-)~~ [(a)] aseptic processing;

87  
88 ~~(-2-)~~ [(b)] quality control and quality assurance as related to environmental, component,  
89 and finished preparation release checks and tests;

90  
91 ~~(-3-)~~ [(c)] chemical, pharmaceutical, and clinical properties of drugs;

92  
93 ~~(-4-)~~ [(d)] container, equipment, and closure system selection; and

94  
95 ~~(-5-)~~ [(e)] sterilization techniques.

96  
97 (iii) Individuals enrolled in training programs accredited by the American Society of Health-  
98 System Pharmacists may compound sterile preparations in a licensed pharmacy provided:

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

103  
104 (II) the individual is under the direct supervision of and responsible to a pharmacist who  
105 has completed training as specified in paragraph (2) of this subsection; and

106  
107 (III) the supervising pharmacist conducts in-process and final checks.

108  
109 (iv) The required experiential portion of the training programs specified in this subparagraph  
110 must be supervised by an individual who is actively engaged in performing sterile compounding,  
111 is qualified and has completed training as specified in paragraph (2) of this subsection or this  
112 paragraph.

113  
114 (v) In order to renew a registration as a pharmacy technician, during the previous  
115 registration period, a pharmacy technician engaged in sterile compounding shall complete a  
116 minimum of:

117  
118 (I) two hours of ACPE accredited continuing education relating to one or more of the areas  
119 listed in paragraph (4)(D) of this subsection if the pharmacy technician is engaged in  
120 compounding low and medium risk sterile preparations; or

121  
122 (II) four hours of ACPE accredited continuing education relating to one or more of the  
123 areas listed in paragraph (4)(D) of this subsection if pharmacy technician is engaged in  
124 compounding high risk sterile preparations.

125  
126 (4) – (5) (No change.)

127  
128 (d) – (g) (No change.)