

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

7 **§291.133 Pharmacies Compounding Sterile Preparations**
8

9 (a) – (b) (No change.)
10

11 (c) Personnel.
12

13 (1) (No change.)
14

15 (2) Pharmacists.
16

16 (A) General.

17 (i) A pharmacist is responsible for ensuring that compounded sterile preparations are
18 accurately identified, measured, diluted, and mixed and are correctly purified, sterilized,
19 packaged, sealed, labeled, stored, dispensed, and distributed.

20 (ii) A pharmacist shall inspect and approve all components, drug preparation containers,
21 closures, labeling, and any other materials involved in the compounding process.

22 (iii) A pharmacist shall review all compounding records for accuracy and conduct periodic in-
23 process checks as defined in the pharmacy's policy and procedures.

24 (iv) A pharmacist shall review all compounding records for accuracy and conduct a final
25 check.

26 (v) A pharmacist is responsible for ensuring the proper maintenance, cleanliness, and use of
27 all equipment used in the compounding process.

28 (vi) A pharmacist shall be accessible at all times, 24 hours a day, to respond to patients' and
29 other health professionals' questions and needs.

30 (B) Initial training and continuing education.

31 (i) All pharmacists who compound sterile preparations or supervise pharmacy technicians
32 and pharmacy technician trainees compounding sterile preparations shall comply with the
33 following:

34 (I) complete through a single course, a minimum of 20 hours of instruction and experience
35 in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through
36 completion of a recognized course in an accredited college of pharmacy or a course sponsored
37 by an ACPE accredited provider;

38 (II) complete a structured on-the-job didactic and experiential training program at this
39 pharmacy which provides sufficient hours of instruction and experience in the facility's sterile
40 compounding processes and procedures. Such training may not be transferred to another
41 pharmacy unless the pharmacies are under common ownership and control and use a common
42 training program; and

43 (III) possess knowledge about:

44 (-a-) aseptic processing;

45 (-b-) quality control and quality assurance as related to environmental, component, and
46 finished preparation release checks and tests;

47 (-c-) chemical, pharmaceutical, and clinical properties of drugs;

48 (-d-) container, equipment, and closure system selection; and

49 (-e-) sterilization techniques.

50 (ii) The required experiential portion of the training programs specified in this subparagraph
51 must be supervised by an individual who is actively engaged in performing sterile compounding

52 and is qualified and has completed training as specified in this paragraph or paragraph (3) of
53 this subsection.

54 (iii) In order to renew a license to practice pharmacy, during the previous licensure period, a
55 pharmacist engaged in sterile compounding shall complete a minimum of:

56 (I) two hours of ACPE-accredited continuing education relating to one or more of the areas
57 listed in paragraph (4)(D) of this subsection if the pharmacist is engaged in compounding low
58 and medium risk sterile preparations; or

59 (II) four hours of ACPE-accredited continuing education relating to one or more of the
60 areas listed in paragraph (4)(D) of this subsection if the pharmacist is engaged in compounding
61 high risk sterile preparations.

62

63 (3) Pharmacy technicians and pharmacy technician trainees.

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

67 (B) Initial training and continuing education.

68 (i) Pharmacy technicians and pharmacy technician trainees may compound sterile
69 preparations provided the pharmacy technicians and/or pharmacy technician trainees are
70 supervised by a pharmacist as specified in paragraph (2) of this subsection.

71 (ii) All pharmacy technicians and pharmacy technician trainees who compound sterile
72 preparations for administration to patients shall:

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

74 (-a-) a single course, a minimum of 40 hours of instruction and experience in the areas
75 listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion
76 of a course sponsored by an ACPE accredited provider which provides 40 hours of instruction
77 and experience; or

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

80 (II) and

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

86 (-b-) possess knowledge about:

87 (-1-) aseptic processing;

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

90 (-3-) chemical, pharmaceutical, and clinical properties of drugs;

91 (-4-) container, equipment, and closure system selection; and

92 (-5-) sterilization techniques.

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

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

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

100 (III) supervising pharmacist conducts periodic in-process checks as defined in the
101 pharmacy's policy and procedures; and

102 (IV) supervising pharmacist conducts a final check.

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

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

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

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

116

117 (4) – (5) (No change.)

118

119 (d) – (g) (No change.)