

## RULE ANALYSIS

**Introduction:** THE AMENDMENTS AND NEW RULE ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS ADOPTED RULES

**Short Title:** Compounding of Sterile Preparations Concerning Class A Pharmacies

**Rule Numbers:** §§291.33 and 291.36

**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 and new rule, if adopted, outline the requirements for pharmacies that compound sterile preparations, implement recommendations of the TSBP appointment Task Force on Compounding Sterile Preparations (Task Force), and implement S.B. 1100 passed by the 83<sup>rd</sup> Regular Session of the Texas Legislature regarding compounding pharmacies.

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

**The Board reviewed and voted to propose the amendments and new rule during the August 6, 2013, meeting. The proposed amendments and new rule were published in the September 27, 2013, issue of the *Texas Register* at 38 TexReg 6504.**

1 **SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)**  
2 **§§ 291.33, 291.36**

3 The Texas State Board of Pharmacy (TSBP) proposes amendments to §291.32, concerning  
4 Personnel, and §291.33, concerning Operational Standards, and new §291.36, concerning  
5 Pharmacies Compounding Sterile Preparations (Class A-S).

6 The proposed amendments to §291.32, if adopted, eliminate the pharmacist to technician ratio  
7 for Class A pharmacies. The proposed amendments to §291.33, if adopted, clarify that Class A  
8 pharmacies will no longer be able to compound sterile preparations after June 1, 2013, unless the  
9 pharmacy obtains a Class A-S pharmacy license. Proposed new §291.36, if adopted, outlines the  
10 requirements for pharmacies that compound sterile preparations, implements recommendations  
11 of the TSBP appointment Task Force on Compounding Sterile Preparations (Task Force), and  
12 implements Senate Bill 1100 passed by the 83rd Regular Session of the Texas Legislature  
13 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 to §291.32 will be allowing a pharmacist in a Class A pharmacy to determine  
29 the appropriate number of pharmacy technicians to safely operate the pharmacy as well as  
30 allowing the pharmacist to be more directly involved with the patient. The amendments to  
31 §291.33 and new §291.36 will ensure pharmacies engaged in sterile compounding are  
32 appropriately licensed and establish standards for the safe compounding of sterile preparations.

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

41 reduce these costs because to do so would compromise the purposes of these rules which is  
42 intended to protect the health and safety of the public.

43 A public hearing to receive comments on the proposed §§291.32, 291.33, and 291.36 will be  
44 held at 1:00 p.m. on Monday, November 4, 2013, at the Health Professions Council Board  
45 Room, 333 Guadalupe Street, Tower II, Room 225, Austin, Texas 78701. Persons planning to  
46 present comments to the Board are asked to provide a written copy of their comments prior to the  
47 hearing or to bring 20 copies to the hearing. Written comments on the amendments and new rule  
48 may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State  
49 Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-  
50 8008. Comments must be received by 5:00 p.m., October 31, 2013.

51 The amendments and new rule are proposed under §§551.002, 551.003, 554.001, 554.051,  
52 554.053, and 560.053 of the Texas Pharmacy Act (Chapters 551 - 566, 568 and 569, Texas  
53 Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the  
54 public through the effective control and regulation of the practice of pharmacy. The Board  
55 interprets §551.003(9) as authorizing the agency to adopt rules concerning the compounding of  
56 prescriptions. The Board interprets §551.003(33) as authorizing the agency to adopt rules  
57 concerning the practice of pharmacy. The Board interprets §554.001(a) as authorizing the agency  
58 to adopt rules to administer and enforce the Act and rules adopted under the Act as well as  
59 enforce other laws relating to the practice of pharmacy. The Board interprets §554.051(a) as  
60 authorizing the agency to adopt rules for the proper administration and enforcement of the Act.  
61 The Board interprets §554.053 as authorizing the agency to determine the ratio of pharmacists to  
62 pharmacy technicians in a pharmacy. The Board interprets §560.053 as authorizing the agency to  
63 adopt rules establishing additional pharmacy classifications.

64 The statutes affected by the amendments and new rule: Texas Pharmacy Act, Chapters 551 - 566,  
65 568 and 569, Texas Occupations Code.

66 **§291.33. Operational Standards.**

67 (a) Licensing requirements.

68 (1) - (8) (No change.)

69 (9) A Class A pharmacy engaged in the compounding of non-sterile preparations shall comply  
70 with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile  
71 Preparations).

72 (10) Prior to June 1, 2014, a [A] Class A pharmacy engaged in the compounding of sterile  
73 preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies  
74 Compounding Sterile Preparations).

75 (11) Effective June 1, 2014, a Class A pharmacy shall not compound sterile preparations unless  
76 the pharmacy has applied for and obtained a Class A-S pharmacy license.

77 ~~(12)~~ [(41)] A Class A pharmacy engaged in the provision of remote pharmacy services, including  
78 storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of  
79 this title (relating to Remote Pharmacy Services).

80 (13) [(42)] Class A pharmacy engaged in centralized prescription dispensing and/or prescription  
81 drug or medication order processing shall comply with the provisions of §291.123 of this title  
82 (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of  
83 this title (relating to Centralized Prescription Dispensing).

84 (b) - (i) (No change.)

85 §291.36. Pharmacies Compounding Sterile Preparations (Class A-S).

86 Licensing Requirements. A community pharmacy engaged in the compounding of sterile  
87 preparations shall be designated as a Class A-S pharmacy.

88 (1) A Class A-S pharmacy shall register annually or biennially with the board on a pharmacy  
89 license application provided by the board, following the procedures as specified in §291.1 of this  
90 title (relating to Pharmacy License Application). A Class A-S license may not be issued unless  
91 the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as  
92 specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

93 (2) A Class A-S pharmacy may not renew a pharmacy license unless the pharmacy has been  
94 inspected by the board within the last renewal period.

95 (3) A Class A-S pharmacy which changes ownership shall notify the board within ten days of the  
96 change of ownership and apply for a new and separate license as specified in §291.3 of this title  
97 (relating to Required Notifications).

98 (4) A Class A-S pharmacy which changes location and/or name shall notify the board within ten  
99 days of the change and file for an amended license as specified in §291.3 of this title.

100 (5) A Class A-S pharmacy owned by a partnership or corporation which changes managing  
101 officers shall notify the board in writing of the names of the new managing officers within ten  
102 days of the change, following the procedures as specified in §291.3 of this title.

103 (6) A Class A-S pharmacy shall notify the board in writing within ten days of closing, following  
104 the procedures as specified in §291.5 of this title (relating to Closing a Pharmacy).

105 (7) A separate license is required for each principal place of business and only one pharmacy  
106 license may be issued to a specific location.

107 (8) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged  
108 for the issuance and renewal of a license and the issuance of an amended license.

109 (9) A Class A-S pharmacy which would otherwise be required to be licensed under the Act,  
110 §560.051(a)(1) concerning Community Pharmacy (Class A) is required to comply with the  
111 provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to  
112 Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating  
113 to Records), §291.35 of this title (relating to Official Prescription Requirements), and §291.133  
114 of this title.

115 (10) A Class A-S pharmacy engaged in the compounding of non-sterile preparations shall  
116 comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-  
117 Sterile Preparations).

118 (11) A Class A-S pharmacy engaged in the provision of remote pharmacy services, including  
119 storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of  
120 this title (relating to Remote Pharmacy Services).

121 (12) A Class A-S pharmacy engaged in centralized prescription dispensing and/or prescription  
122 drug or medication order processing shall comply with the provisions of §291.123 of this title  
123 (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of  
124 this title (relating to Centralized Prescription Dispensing).

125

## RULE ANALYSIS

**Introduction:** THE AMENDMENTS AND NEW RULE ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS ADOPTED RULES

**Short Title:** Compounding of Sterile Preparations Concerning Class B Pharmacies

**Rule Numbers:** §§291.54 and 291.56

**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 and new rule, if adopted, outline the requirements for pharmacies that compound sterile preparations, implement recommendations of the TSBP appointment Task Force on Compounding Sterile Preparations (Task Force), and implement S.B. 1100 passed by the 83<sup>rd</sup> Regular Session of the Texas Legislature regarding compounding pharmacies.

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

**The Board reviewed and voted to propose the amendments and new rule during the August 6, 2013, meeting. The proposed amendments and new rule were published in the September 27, 2013, issue of the *Texas Register* at 38 TexReg 6506.**

1 **SUBCHAPTER C. NUCLEAR PHARMACY (CLASS B)**  
2 **§§291.54, 291.56**

3 The Texas State Board of Pharmacy (TSBP) proposes amendments to §291.53, concerning  
4 Personnel, and §291.54, concerning Operational Standards, and new §291.56, concerning  
5 Pharmacies Compounding Sterile Preparations (Class B-S).

6 The proposed amendments to §291.53, if adopted, eliminate the pharmacist to technician ratio  
7 for Class B pharmacies. The proposed amendments to §291.54, if adopted, clarify that Class B  
8 pharmacies will no longer be able to compound sterile preparations after June 1, 2014, unless the  
9 pharmacy obtains a Class B-S pharmacy license. Proposed new §291.56, if adopted, outlines the  
10 requirements for pharmacies that compound sterile preparations, implements recommendations  
11 of the TSBP appointment Task Force on Compounding Sterile Preparations (Task Force), and  
12 implements Senate Bill 1100 passed by the 83rd Regular Session of the Texas Legislature  
13 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 to §291.53 is allowing a pharmacist in a Class B pharmacy to determine the  
29 appropriate number of pharmacy technicians needed to safely operate the pharmacy as well as  
30 allowing the pharmacist to be more directly involved with the patient. The amendments to  
31 §291.54 and new §291.56 will ensure pharmacies engaged in sterile compounding are  
32 appropriately licensed and establish standards for the compounding of sterile preparations.

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

41 reduce these costs because to do so would compromise the purposes of these rules which is  
42 intended to protect the health and safety of the public.

43 A public hearing to receive comments on proposed §§291.53, 291.54, and 291.56 will be held at  
44 1:00 p.m. on Monday, November 4, 2013, at the Health Professions Council Board Room, 333  
45 Guadalupe Street, Tower II, Room 225, Austin, Texas 78701. Persons planning to present  
46 comments to the Board are asked to provide a written copy of their comments prior to the  
47 hearing or to bring 20 copies to the hearing. Written comments on the amendments and new rule  
48 may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State  
49 Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-  
50 8008. Comments must be received by 5:00 p.m., October 31, 2013.

51 The amendments and new rule are proposed under §§551.002, 551.003, 554.001, 554.051,  
52 554.053, and 560.053 of the Texas Pharmacy Act (Chapters 551 - 566, 568 and 569, Texas  
53 Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the  
54 public through the effective control and regulation of the practice of pharmacy. The Board  
55 interprets §551.003(9) as authorizing the agency to adopt rules concerning the compounding of  
56 prescriptions. The Board interprets §551.003(33) as authorizing the agency to adopt rules  
57 concerning the practice of pharmacy. The Board interprets §554.001(a) as authorizing the agency  
58 to adopt rules to administer and enforce the Act and rules adopted under the Act as well as  
59 enforce other laws relating to the practice of pharmacy. The Board interprets §554.051(a) as  
60 authorizing the agency to adopt rules for the proper administration and enforcement of the Act.  
61 The Board interprets §554.053 as authorizing the agency to determine the ratio of pharmacists to  
62 pharmacy technicians in a pharmacy. The Board interprets §560.053 as authorizing the agency to  
63 adopt rules establishing additional pharmacy classifications.

64 The statutes affected by the amendments and new rule: Texas Pharmacy Act, Chapters 551 - 566,  
65 568 and 569, Texas Occupations Code.

66 **§291.54. Operational Standards.**

67 (a) Licensing requirements.

68 (1) - (10) (No change.)

69 (11) A Class B [~~nuclear~~] pharmacy engaged in the compounding of non-sterile non-radioactive  
70 preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies  
71 Compounding Non-Sterile Preparations).

72 (12) Prior to June 1, 2014, a [A] Class B [~~nuclear~~] pharmacy engaged in the compounding of  
73 sterile non-radioactive preparations shall comply with the provisions of §291.133 of this title  
74 (relating to Pharmacies Compounding Sterile Preparations).

75 (13) Effective June 1, 2014, a Class B pharmacy shall not compound sterile preparations unless  
76 the pharmacy has applied for and obtained a Class B-S pharmacy license.

77 (b) - (i) (No change.)

78 §291.56. Pharmacies Compounding Sterile Preparations (Class B-S).

79 Licensing requirements. A nuclear pharmacy engaged in the compounding of sterile preparations  
80 shall be designated as a Class B-S pharmacy.

81 (1) It is unlawful for a person to provide radioactive drug services unless such provision is  
82 performed by a person licensed to act as an authorized nuclear pharmacist, as defined by the  
83 board, or is a person acting under the direct supervision of an authorized nuclear pharmacist  
84 acting in accordance with the Act and its rules, and the regulations of the Texas Department of  
85 State Health Services, Radiation Control Program. This paragraph does not apply to:

86 (A) a licensed practitioner or his or her designated agent for administration to his or her patient,  
87 provided no person may receive, possess, use, transfer, own, acquire, or dispose of  
88 radiopharmaceuticals except as authorized in a specific or a general license as provided in  
89 accordance with the requirements of the Texas Department of State Health Services, Radiation  
90 Control Program, Texas Administrative Code, Title 25, Chapter 289, Subchapter F, §289.252,  
91 relating to Licensing of Radioactive Material, or the Act;

92 (B) institutions and/or facilities with nuclear medicine services operated by practitioners and who  
93 are licensed by the Texas Department of State Health Services, Radiation Control Program, to  
94 prescribe, administer, and dispense radioactive materials (drugs and/or devices).

95 (2) An applicant for a Class B-S pharmacy shall provide evidence to the board of the possession  
96 of a Texas Department of State Health Services radioactive material license or proof of  
97 application for a radioactive material license.

98 (3) A Class B-S pharmacy shall register annually or biennially with the board on a pharmacy  
99 license application provided by the board, following the procedures as specified in §291.1 of this  
100 title (relating to Pharmacy License Application). A Class B-S license may not be issued unless  
101 the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as  
102 specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

103 (4) A Class B-S pharmacy may not renew a pharmacy license unless the pharmacy has been  
104 inspected by the board within the last renewal period.

105 (5) A Class B-S pharmacy which changes ownership shall notify the board within ten days of the  
106 change of ownership and apply for a new and separate license as specified in §291.3 of this title  
107 (relating to Required Notifications).

108 (6) A Class B-S pharmacy which changes location and/or name shall notify the board within ten  
109 days of the change and file for an amended license as specified in §291.3 of this title.

- 110 (7) A Class B-S pharmacy owned by a partnership or corporation which changes managing  
111 officers shall notify the board in writing of the names of the new managing officers within ten  
112 days of the change, following the procedures as specified in §291.3 of this title.
- 113 (8) A Class B-S pharmacy shall notify the board in writing within ten days of closing, following  
114 the procedures as specified in §291.5 of this title (relating to Closing a Pharmacy).
- 115 (9) A separate license is required for each principal place of business and only one pharmacy  
116 license may be issued to a specific location.
- 117 (10) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged  
118 for the issuance and renewal of a license and the issuance of an amended license.
- 119 (11) A Class B-S pharmacy which would otherwise be required to be licensed under the Act,  
120 §560.051(a)(1) concerning Community Pharmacy (Class A) is required to comply with the  
121 provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to  
122 Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating  
123 to Records), and §291.35 of this title (relating to Official Prescription Requirements) and  
124 §291.133 of this title.
- 125 (12) A Class B-S pharmacy engaged in the compounding of non-sterile preparations shall  
126 comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-  
127 Sterile Preparations).
- 128 (13) A Class B-S pharmacy engaged in the provision of remote pharmacy services, including  
129 storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of  
130 this title (relating to Remote Pharmacy Services).
- 131 (14) A Class B-S pharmacy engaged in centralized prescription dispensing and/or prescription  
132 drug or medication order processing shall comply with the provisions of §291.123 of this title  
133 (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of  
134 this title (relating to Centralized Prescription Dispensing).

135

## RULE ANALYSIS

**Introduction:** THE AMENDMENTS AND NEW RULE ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS ADOPTED RULES

**Short Title:** Compounding of Sterile Preparations Concerning Class C Pharmacies

**Rule Numbers:** §§291.74, 291.76, and 291.77

**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 and new rule, if adopted, outline the requirements for a new class of pharmacy regarding pharmacies compounding sterile preparations, implement recommendations of the TSBP appointment Task Force on Compounding Sterile Preparations (Task Force), and implement S.B. 1100 passed by the 83<sup>rd</sup> Regular Session of the Texas Legislature regarding compounding pharmacies.

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

**The Board reviewed and voted to propose the amendments and new rule during the August 6, 2013, meeting. The proposed amendments and new rule were published in the September 27, 2013, issue of the *Texas Register* at 38 TexReg 6509.**

1 **SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)**  
2 **§§291.74, 291.76, 291.77**

3 The Texas State Board of Pharmacy (TSBP) proposes amendments to §291.74, concerning  
4 Operational Standards, and §291.76, concerning Class C Pharmacies Located in a Freestanding  
5 Ambulatory Surgical Center, and new §291.77, concerning Pharmacies Compounding Sterile  
6 Preparations (Class C-S).

7 The proposed amendments to §291.74 and §291.76, if adopted, clarify that Class C pharmacies  
8 will no longer be able to compound sterile preparations after June 1, 2014, unless the pharmacy  
9 obtains a Class C-S pharmacy license. Proposed new §291.77, if adopted, outlines the  
10 requirements for a new class of pharmacy regarding pharmacies compounding sterile  
11 preparations, implements recommendations of the TSBP appointment Task Force on  
12 Compounding Sterile Preparations (Task Force), and implements Senate Bill 1100 passed by the  
13 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 rules, will be to ensure pharmacies engaged in sterile compounding are  
29 appropriately licensed and establish standards for the safe compounding of sterile preparations.

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 rules for pharmacies  
32 compounding sterile preparations. Based on the significant variances in pharmacies' physical  
33 structure and layout, it is difficult for TSBP to determine the actual cost to businesses required to  
34 comply with these rules. These costs would involve bringing the sterile compounding area of  
35 pharmacies into compliance with the new provisions. TSBP cannot precisely determine the  
36 number of pharmacies affected because TSBP records do not provide complete information  
37 about the details of the pharmacies' compounding operations. In addition, TSBP is unable to  
38 reduce these costs because to do so would compromise the purposes of these rules which is  
39 intended to protect the health and safety of the public.

40 A public hearing to receive comments on the proposed §§291.74, 291.76, and 291.77 will be  
41 held at 1:00 p.m. on Monday, November 4, 2013, at the Health Professions Council Board  
42 Room, 333 Guadalupe Street, Tower II, Room 225, Austin, Texas 78701. Persons planning to  
43 present comments to the Board are asked to provide a written copy of their comments prior to the  
44 hearing or to bring 20 copies to the hearing. Written comments on the amendments and new rule  
45 may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State  
46 Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-  
47 8008. Comments must be received by 5:00 p.m., October 31, 2013.

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

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

62 **§291.74.Operational Standards.**

63 (a) Licensing requirements.

64 (1) - (9) (No change.)

65 (10) A Class C [~~Institutional~~] pharmacy engaged in the compounding of non-sterile  
66 preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies  
67 Compounding Non-sterile Preparations).

68 (11) Prior to June 1, 2014, a [A] Class C [~~Institutional~~] pharmacy engaged in the compounding  
69 of sterile preparations shall comply with the provisions of §291.133 of this title (relating to  
70 Pharmacies Compounding Sterile Preparations).

71 (12) Effective June 1, 2014, a Class C pharmacy shall not compound sterile preparations unless  
72 the pharmacy has applied for and obtained a Class C-S pharmacy.

73 (13) [(12)] A Class C [~~Institutional~~] pharmacy engaged in the provision of remote pharmacy  
74 services, including storage and dispensing of prescription drugs, shall comply with the provisions  
75 of §291.121 of this title (relating to Remote Pharmacy Services).

76 ~~(14)~~ [(13)] A Class C [~~Institutional~~] pharmacy engaged in centralized prescription dispensing  
77 and/or prescription drug or medication order processing shall comply with the provisions of  
78 §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing)  
79 and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

80 ~~(15)~~ [(14)] A Class C [~~Institutional~~] pharmacy with an ongoing clinical pharmacy program that  
81 proposes to allow a pharmacy technician to verify the accuracy of work performed by another  
82 pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a  
83 patient admitted to the hospital if the patient's orders have previously been reviewed and  
84 approved by a pharmacist shall make application to the board as follows.

85 (A) The pharmacist-in-charge must submit an application on a form provided by the board,  
86 containing the following information:

87 (i) name, address, and pharmacy license number;

88 (ii) name and license number of the pharmacist-in-charge;

89 (iii) name and registration numbers of the pharmacy technicians;

90 (iv) anticipated date the pharmacy plans to begin allowing a pharmacy technician to verify the  
91 accuracy of work performed by another pharmacy technician;

92 (v) documentation that the pharmacy has an ongoing clinical pharmacy program; and

93 (vi) any other information specified on the application.

94 (B) The pharmacy may not allow a pharmacy technician to check the work of another pharmacy  
95 technician until the board has reviewed and approved the application and issued an amended  
96 license to the pharmacy.

97 (C) Every two years, in connection with the application for renewal of the pharmacy license, the  
98 pharmacy shall provide updated documentation that the pharmacy continues to have an ongoing  
99 clinical pharmacy program as specified in subparagraph (A)(v) of this paragraph.

100 ~~(16)~~ [(15)] A rural hospital that wishes to allow a pharmacy technician to perform the duties  
101 specified in §291.73(e)(2)(D) of this title (relating to Personnel), shall make application to the  
102 board as follows.

103 ~~{(A) For an initial applications prior to September 1, 2010, the pharmacist in charge must submit  
104 a letter to the board containing the following information:}~~

105 ~~{(i) name, address, and pharmacy license number;}~~

106 ~~{(ii) name and license number of the pharmacist in charge;}~~

107 ~~{(iii) name and registration number of the pharmacy technicians;}~~

108 ~~{(iv) a statement indicating that pharmacy technicians will be performing the duties specified in~~  
109 ~~§291.73(e)(2)(D) of this title; and}~~

110 ~~{(v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural~~  
111 ~~hospital is either:}~~

112 ~~{(I) located in a county with a population of 50,000 or less as defined by the United States~~  
113 ~~Census Bureau in the most recent U.S. census; or}~~

114 ~~{(II) designated by the Centers for Medicare and Medicaid Services as a critical access hospital,~~  
115 ~~rural referral center, or sole community hospital.}~~

116 (A) ~~[(B)]~~ Prior ~~[After September 1, 2010 and prior]~~ to allowing a pharmacy technician to  
117 perform the duties specified in §291.73(e)(2)(D) of this title, the pharmacist-in-charge must  
118 submit an application on a form provided by the board, containing the following information:

119 (i) name, address, and pharmacy license number;

120 (ii) name and license number of the pharmacist-in-charge;

121 (iii) name and registration number of the pharmacy technicians;

122 (iv) proposed date the pharmacy wishes to start allowing pharmacy technicians to perform the  
123 duties specified in §291.73(e)(2)(D) of this title;

124 (v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural  
125 hospital is either:

126 (I) located in a county with a population of 50,000 or less as defined by the United States Census  
127 Bureau in the most recent U.S. census; or

128 (II) designated by the Centers for Medicare and Medicaid Services as a critical access hospital,  
129 rural referral center, or sole community hospital; and

130 (vi) any other information specified on the application.

131 (B) ~~[(C)]~~ A rural hospital ~~[that makes application after September 1, 2010]~~ may not allow a  
132 pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title until the  
133 board has reviewed and approved the application and issued an amended license to the  
134 pharmacy.

135 (C) ~~[(D)]~~ Every two years in conjunction with the application for renewal of the pharmacy  
136 license, the pharmacist-in-charge shall update the application for pharmacy technicians to  
137 perform the duties specified in §291.73(e)(2)(D) of this title.

138 (b) - (j) (No change.)

139 *§291.76. Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center.*

140 (a) - (c) (No change.)

141 (d) Operational standards.

142 (1) Licensing requirements.

143 (A) - (I) (No change.)

144 (J) An ASC pharmacy engaged in the compounding of non-sterile preparations shall comply with  
145 the provisions of §291.131 of this title.

146 (K) Prior to June 1, 2014, an [A#] ASC pharmacy engaged in the compounding of sterile  
147 preparations shall comply with the provisions of §291.133 of this title.

148 (L) Effective June 1, 2014, an ASC pharmacy shall not compound sterile preparations unless the  
149 pharmacy has applied for and obtained a Class C-S pharmacy.

150 (M) [(L)] An ASC pharmacy engaged in the provision of remote pharmacy services, including  
151 storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of  
152 this title (relating to Remote Pharmacy Services).

153 (N) [(M)] An ASC pharmacy engaged in centralized prescription dispensing and/or prescription  
154 drug or medication order processing shall comply with the provisions of §291.123 of this title  
155 (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of  
156 this title (relating to Centralized Prescription Dispensing).

157 (2) - (9) (No change.)

158 (e) (No change.)

159 *§291.77. Pharmacies Compounding Sterile Preparations (Class C-S).*

160 Licensing requirements. A institutional or ASC pharmacy engaged in the compounding of sterile  
161 preparations shall be designated as a Class C-S pharmacy.

162 (1) A Class C-S pharmacy shall register annually or biennially with the board on a pharmacy  
163 license application provided by the board, following the procedures specified in §291.1 of this  
164 title (relating to Pharmacy License Application). A Class C-S license may not be issued unless  
165 the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as  
166 specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

167 (2) A Class C-S pharmacy may not renew a pharmacy license unless the pharmacy has been  
168 inspected by the board within the last renewal period.

169 (3) If the Class C-S pharmacy is owned or operated by a hospital management or consulting  
170 firm, the following conditions apply.

171 (A) The pharmacy license application shall list the hospital management or consulting firm as the  
172 owner or operator.

173 (B) The hospital management or consulting firm shall obtain DEA and DPS controlled substance  
174 registrations that are issued in their name, unless the following occurs:

175 (i) the hospital management or consulting firm and the facility cosign a contractual pharmacy  
176 service agreement which assigns overall responsibility for controlled substances to the facility;  
177 and

178 (ii) such hospital pharmacy management or consulting firm maintains dual responsibility for the  
179 controlled substances.

180 (4) A Class C-S pharmacy which changes ownership shall notify the board within 10 days of the  
181 change of ownership and apply for a new and separate license as specified in §291.3 of this title  
182 (relating to Required Notifications).

183 (5) A Class C-S pharmacy which changes location and/or name shall notify the board within 10  
184 days of the change and file for an amended license as specified in §291.3 of this title.

185 (6) A Class C-S pharmacy owned by a partnership or corporation which changes managing  
186 officers shall notify the board in writing of the names of the new managing officers within 10  
187 days of the change following the procedures in §291.3 of this title.

188 (7) A Class C-S pharmacy shall notify the board in writing within 10 days of closing, following  
189 the procedures in §291.5 of this title (relating to Closing a Pharmacy).

190 (8) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged  
191 for the issuance and renewal of a license and the issuance of an amended license.

192 (9) A separate license is required for each principal place of business and only one pharmacy  
193 license may be issued to a specific location.

194 (10) A Class C-S pharmacy, licensed under the Act, §560.051(a)(3), which also operates another  
195 type of pharmacy which would otherwise be required to be licensed under the Act,  
196 §560.051(a)(1) (Community Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear Pharmacy  
197 (Class B)), is not required to secure a license for the such other type of pharmacy; provided,  
198 however, such licensee is required to comply with the provisions of §291.31 of this title (relating  
199 to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to  
200 Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title

201 (relating to Official Prescription Requirements), contained in Community Pharmacy (Class A),  
202 or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions),  
203 §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational  
204 Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class  
205 B), to the extent such sections are applicable to the operation of the pharmacy.

206 (11) A Class C-S pharmacy engaged in the compounding of non-sterile preparations shall  
207 comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-  
208 Sterile Preparations).

209 (12) A Class C-S pharmacy engaged in the provision of remote pharmacy services, including  
210 storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of  
211 this title (relating to Remote Pharmacy Services).

212 (13) A Class C-S pharmacy engaged in centralized prescription dispensing and/or prescription  
213 drug or medication order processing shall comply with the provisions of §291.123 of this title  
214 (relating to Central Prescription Drug or Medication Order Processing) and/or §291.125 of this  
215 title (relating to Centralized Prescription Dispensing).

216 (14) A Class C-S pharmacy with an ongoing clinical pharmacy program that proposes to allow a  
217 pharmacy technician to verify the accuracy of work performed by another pharmacy technician  
218 relating to the filling of floor stock and unit dose distribution systems for a patient admitted to  
219 the hospital if the patient's orders have previously been reviewed and approved by a pharmacist  
220 shall make application to the board as follows.

221 (A) The pharmacist-in-charge must submit an application on a form provided by the board,  
222 containing the following information:

223 (i) name, address, and pharmacy license number;

224 (ii) name and license number of the pharmacist-in-charge;

225 (iii) name and registration numbers of the pharmacy technicians;

226 (iv) anticipated date the pharmacy plans to begin allowing a pharmacy technician to verify the  
227 accuracy of work performed by another pharmacy technician;

228 (v) documentation that the pharmacy has an ongoing clinical pharmacy program; and

229 (vi) any other information specified on the application.

230 (B) The pharmacy may not allow a pharmacy technician to check the work of another pharmacy  
231 technician until the board has reviewed and approved the application and issued an amended  
232 license to the pharmacy.

233 (C) Every two years, in connection with the application for renewal of the pharmacy license, the  
234 pharmacy shall provide updated documentation that the pharmacy continues to have an ongoing  
235 clinical pharmacy program as specified in subparagraph (A)(v) of this paragraph.

236 (15) A rural hospital that wishes to allow a pharmacy technician to perform the duties specified  
237 in §291.73(e)(2)(D) of this title (relating to Personnel) shall make application to the board as  
238 follows.

239 (A) Prior to allowing a pharmacy technician to perform the duties specified in §291.73(e)(2)(D)  
240 of this title, the pharmacist-in-charge must submit an application on a form provided by the  
241 board, containing the following information:

242 (i) name, address, and pharmacy license number;

243 (ii) name and license number of the pharmacist-in-charge;

244 (iii) name and registration number of the pharmacy technicians;

245 (iv) proposed date the pharmacy wishes to start allowing pharmacy technicians to perform the  
246 duties specified in §291.73(e)(2)(D) of this title;

247 (v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural  
248 hospital is either:

249 (I) located in a county with a population of 50,000 or less as defined by the United States Census  
250 Bureau in the most recent U.S. census; or

251 (II) designated by the Centers for Medicare and Medicaid Services as a critical access hospital,  
252 rural referral center, or sole community hospital; and

253 (vi) any other information specified on the application.

254 (B) A rural hospital may not allow a pharmacy technician to perform the duties specified in  
255 §291.73(e)(2)(D) of this title until the board has reviewed and approved the application and  
256 issued an amended license to the pharmacy.

257 (C) Every two years in conjunction with the application for renewal of the pharmacy license, the  
258 pharmacist-in-charge shall update the application for pharmacy technicians to perform the duties  
259 specified in §291.73(e)(2)(D) of this title.

260

## RULE ANALYSIS

**Introduction:** THE AMENDMENTS AND NEW RULE ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS ADOPTED RULES

**Short Title:** Compounding of Sterile Preparations Concerning Class E Pharmacies

**Rule Numbers:** §§291.104 and 291.106

**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 and new rule, if adopted, outline the requirements for a new class of pharmacy regarding pharmacies compounding sterile preparations, implement recommendations of the TSBP appointment Task Force on Compounding Sterile Preparations (Task Force), and implement S.B. 1100 passed by the 83<sup>rd</sup> Regular Session of the Texas Legislature regarding compounding pharmacies.

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

**The Board reviewed and voted to propose the amendments and new rule during the August 6, 2013, meeting. The proposed amendments and new rule 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 **§§291.104, 291.106**

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 **§291.104.Operational Standards.**

64 (a) Licensing requirements.

65 (1) - (12) (No change.)

66 (13) A Class E [~~(Non-Resident)~~] pharmacy engaged in the compounding of non-sterile  
67 preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies  
68 Compounding Non-Sterile Preparations).

69 (14) Prior to June 1, 2014, a [A] Class E [~~(Non-Resident)~~] pharmacy engaged in the  
70 compounding of sterile preparations shall comply with the provisions of §291.133 of this title  
71 (relating to Pharmacies Compounding Sterile Preparations).

72 (15) Effective June 1, 2014, a Class E pharmacy shall not compound sterile preparations unless  
73 the pharmacy has applied for and obtained a Class E-S pharmacy.

74 (b) - (f) (No change.)

75 **§291.106.Pharmacies Compounding Sterile Preparations (Class E-S).**

76 Licensing requirements. A non-resident pharmacy engaged in the compounding of sterile  
77 preparations shall be licensed as a Class E-S pharmacy.

78 (1) A Class E-S pharmacy shall register with the board on a pharmacy license application  
79 provided by the board, following the procedures specified in §291.1 of this title (relating to  
80 Pharmacy License Application).

81 (2) A Class E-S license may not be issued unless the pharmacy has been inspected by the board  
82 or its designee to ensure the pharmacy meets the requirements as specified in §291.133 of this  
83 title (relating to Pharmacies Compounding Sterile Preparations). A Class E-S pharmacy shall  
84 reimburse the board for all expenses, including travel, related to the inspection of the Class E-S  
85 pharmacy.

86 (3) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this  
87 title and then provide the following additional information specified in §560.052(c) and (f) of the  
88 Act (relating to Qualifications):

89 (A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the  
90 state in which the pharmacy is located;

91 (B) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;

92 (C) evidence of the applicant's ability to provide to the board a record of a prescription drug  
93 order dispensed by the applicant to a resident of this state not later than 72 hours after the time  
94 the board requests the record;

95 (D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read and  
96 understands the laws and rules relating to a Class E pharmacy; and

97 (E) proof of creditworthiness.

98 (4) A Class E-S pharmacy may not renew a pharmacy license unless the pharmacy has been  
99 inspected by the board or its designee within the last two years.

100 (5) A Class E-S pharmacy which changes ownership shall notify the board within ten days of the  
101 change of ownership and apply for a new and separate license as specified in §291.3 of this title  
102 (relating to Required Notifications).

103 (6) A Class E-S pharmacy which changes location and/or name shall notify the board within ten  
104 days of the change and file for an amended license as specified in §291.3 of this title.

105 (7) A Class E-S pharmacy owned by a partnership or corporation which changes managing  
106 officers shall notify the board in writing of the names of the new managing officers within ten  
107 days of the change, following the procedures in §291.3 of this title.

108 (8) A Class E-S pharmacy shall notify the board in writing within ten days of closing.

109 (9) A separate license is required for each principal place of business and only one pharmacy  
110 license may be issued to a specific location.

111 (10) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged  
112 for the issuance and renewal of a license and the issuance of an amended license.

113 (11) The board may grant an exemption from the licensing requirements of this Act on the  
114 application of a pharmacy located in a state of the United States other than this state that restricts  
115 its dispensing of prescription drugs or devices to residents of this state to isolated transactions.

116 (12) A Class E-S pharmacy engaged in the centralized dispensing of prescription drug or  
117 medication orders shall comply with the provisions of §291.125 of this title (relating to  
118 Centralized Prescription Dispensing).

119 (13) A Class E-S pharmacy engaged in central processing of prescription drug or medication  
120 orders shall comply with the provisions of §291.123 of this title (relating to Central Prescription  
121 or Medication Order Processing).

122 (14) A Class E-S pharmacy engaged in the compounding of non-sterile preparations shall  
123 comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-  
124 Sterile Preparations).

125 (15) A Class E-S pharmacy engaged in the compounding of sterile preparations shall comply  
126 with the provisions of §291.133 of this title.

127

## RULE ANALYSIS

**Introduction:** THE REPEAL AND NEW RULE ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS ADOPTED RULES

**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 repeal and new rule, if adopted, will outline operating standards for pharmacies that compound sterile preparations, implement the recommendations of the TSBP appointed Task Force on Compounding (Task Force), incorporate provisions included in the United States Pharmacopeia (USP) General Chapter 797 and implement SB 1100 passed during the 83rd Regular Session of the Texas Legislature regarding pharmacies compounding sterile preparations.

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

**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 6515.**

1 **SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES**  
2 **§291.133**

3 The Texas State Board of Pharmacy (TSBP) proposes the repeal of §291.133, concerning  
4 Pharmacies Compounding Sterile Preparations, and simultaneously proposes new §291.133,  
5 concerning Pharmacies Compounding Sterile Preparations. The proposed new §291.133, if  
6 adopted, will outline operating standards for pharmacies that compound sterile preparations,  
7 implement the recommendations of the TSBP appointed Task Force on Compounding (Task  
8 Force), incorporate provisions included in the United States Pharmacopeia (USP) General  
9 Chapter 797 and implement Senate Bill 1100 passed during the 83rd Regular Session of the  
10 Texas Legislature regarding pharmacies compounding sterile preparations.

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

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

23 Ms. Dodson has determined that, for each year of the first five-year period the new rule will be in  
24 effect, the public benefit anticipated as a result of enforcing new §291.133 will be the safe  
25 compounding of sterile preparations and the assurance that pharmacies engaged in sterile  
26 compounding are appropriately licensed.

27 There may be an adverse economic effect on micro, small, and large businesses or to other  
28 entities/persons who are required to comply with the new section concerning pharmacies  
29 compounding sterile preparations. Based on the significant variances in pharmacies' physical  
30 structure and layout, it is difficult for TSBP to determine the actual cost to businesses required to  
31 comply with this rule. These costs would involve bringing the sterile compounding area of  
32 pharmacies into compliance with the new provisions. TSBP cannot precisely determine the  
33 number of pharmacies affected because TSBP records do not provide complete information  
34 about the details of the pharmacies' compounding operations. In addition, TSBP is unable to  
35 reduce these costs because to do so would compromise the purposes of this rule which is  
36 intended to protect the health and safety of the public.

37 A public hearing to receive comments on the proposed repeal and new §291.133 will be held at  
38 1:00 p.m. on Monday, November 4, 2013, at the Health Professions Council Board Room, 333  
39 Guadalupe Street, Tower II, Room 225, Austin, Texas 78701. Persons planning to present  
40 comments to the Board are asked to provide a written copy of their comments prior to the

41 hearing or to bring 20 copies to the hearing. Written comments on the proposed repeal and new  
42 rule may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas  
43 State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512)  
44 305-8008. Comments must be received by 5:00 p.m., October 31, 2013.

45 The repeal is proposed under §§551.002, 551.003, 554.001, 554.051, and 560.053 of the Texas  
46 Pharmacy Act (Chapters 551 - 566, 568 and 569, Texas Occupations Code). The Board interprets  
47 §551.002 as authorizing the agency to protect the public through the effective control and  
48 regulation of the practice of pharmacy. The Board interprets §551.003(9) as authorizing the  
49 agency to adopt rules concerning the compounding of prescriptions. The Board interprets  
50 §551.003(33) as authorizing the agency to adopt rules concerning the practice of pharmacy. The  
51 Board interprets §554.001(a) as authorizing the agency to adopt rules to administer and enforce  
52 the Act and rules adopted under the Act as well as enforce other laws relating to the practice of  
53 pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the  
54 proper administration and enforcement of the Act. The Board interprets §560.053 as authorizing  
55 the agency to adopt rules establishing additional pharmacy classifications.

56 The new rule is proposed under §§551.002, 551.003, 554.001, 554.051, and 560.053 of the  
57 Texas Pharmacy Act (Chapters 551 - 566, 568 and 569, Texas Occupations Code). The Board  
58 interprets §551.002 as authorizing the agency to protect the public through the effective control  
59 and regulation of the practice of pharmacy. The Board interprets §551.003(9) as authorizing the  
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65 proper administration and enforcement of the Act. The Board interprets §560.053 as authorizing  
66 the agency to adopt rules establishing additional pharmacy classifications.

67 The statutes affected by the repeal: Texas Pharmacy Act, Chapters 551 - 566, 568 and 569,  
68 Texas Occupations Code.

69 §291.133. Pharmacies Compounding Sterile Preparations.

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

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

75 (2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile  
76 preparation in Class A-S, Class B-S, Class C-S, and Class E-S pharmacies to a practitioner's  
77 office for office use by the practitioner;

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

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

82 (b) Definitions. In addition to the definitions for specific license classifications, the following  
83 words and terms, when used in this section, shall have the following meanings, unless the  
84 context clearly indicates otherwise.

85 (1) ACPE--Accreditation Council for Pharmacy Education.

86 (2) Airborne particulate cleanliness class--The level of cleanliness specified by the maximum  
87 allowable number of particles per cubic meter of air as specified in the International  
88 Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For  
89 example:

90 (A) ISO Class 5 (formerly Class 100) is an atmospheric environment that contains less than  
91 3,520 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100 particles  
92 0.5 microns in diameter per cubic foot of air);

93 (B) ISO Class 7 (formerly Class 10,000) is an atmospheric environment that contains less than  
94 352,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 10,000  
95 particles 0.5 microns in diameter per cubic foot of air); and

96 (C) ISO Class 8 (formerly Class 100,000) is an atmospheric environment that contains less than  
97 3,520,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100,000  
98 particles 0.5 microns in diameter per cubic foot of air).

99 (3) Ancillary supplies--Supplies necessary for the preparation and administration of compounded  
100 sterile preparations.

101 (4) Ante-area--An ISO Class 8 or better area where personnel may perform hand hygiene and  
102 garbing procedures, staging of components, order entry, labeling, and other high-particulate  
103 generating activities. It is also a transition area that:

104 (A) provides assurance that pressure relationships are constantly maintained so that air flows  
105 from clean to dirty areas; and

106 (B) reduces the need for the heating, ventilating and air conditioning (HVAC) control system to  
107 respond to large disturbances.

108 (5) Aseptic Processing--A mode of processing pharmaceutical and medical preparations that  
109 involves the separate sterilization of the preparation and of the package (containers-closures or  
110 packaging material for medical devices) and the transfer of the preparation into the container and  
111 its closure under at least ISO Class 5 conditions.

- 112 (6) Automated compounding device--An automated device that compounds, measures, and/or  
113 packages a specified quantity of individual components in a predetermined sequence for a  
114 designated sterile preparation.
- 115 (7) Batch--A specific quantity of a drug or other material that is intended to have uniform  
116 character and quality, within specified limits, and is produced during a single preparation cycle.
- 117 (8) Batch preparation compounding--Compounding of multiple sterile preparation units, in a  
118 single discrete process, by the same individual(s), carried out during one limited time period.  
119 Batch preparation/compounding does not include the preparation of multiple sterile preparation  
120 units pursuant to patient specific medication orders.
- 121 (9) Beyond-use date--The date or time after which the compounded sterile preparation shall not  
122 be stored or transported or begin to be administered to a patient. The beyond-use date is  
123 determined from the date or time the preparation is compounded.
- 124 (10) Biological Safety Cabinet, Class II--A ventilated cabinet for personnel, product or  
125 preparation, and environmental protection having an open front with inward airflow for  
126 personnel protection, downward HEPA filtered laminar airflow for product protection, and  
127 HEPA filtered exhausted air for environmental protection.
- 128 (11) Buffer Area--An ISO Class 7 area where the primary engineering control area is physically  
129 located. Activities that occur in this area include the preparation and staging of components and  
130 supplies used when compounding sterile preparations.
- 131 (12) Clean room--A room in which the concentration of airborne particles is controlled to meet a  
132 specified airborne particulate cleanliness class. Microorganisms in the environment are  
133 monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a  
134 specified cleanliness class.
- 135 (13) Component--Any ingredient intended for use in the compounding of a drug preparation,  
136 including those that may not appear in such preparation.
- 137 (14) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or  
138 device:
- 139 (A) as the result of a practitioner's prescription drug or medication order based on the  
140 practitioner-patient-pharmacist relationship in the course of professional practice;
- 141 (B) for administration to a patient by a practitioner as the result of a practitioner's initiative based  
142 on the practitioner-patient-pharmacist relationship in the course of professional practice;
- 143 (C) in anticipation of prescription drug or medication orders based on routine, regularly observed  
144 prescribing patterns; or

145 (D) for or as an incident to research, teaching, or chemical analysis and not for sale or  
146 dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.

147 (15) Compounding Aseptic Isolator--A form of barrier isolator specifically designed for  
148 compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic  
149 compounding environment within the isolator throughout the compounding and material transfer  
150 processes. Air exchange into the isolator from the surrounding environment shall not occur  
151 unless it has first passed through a microbial retentive filter (HEPA minimum).

152 (16) Compounding Aseptic Containment Isolator--A compounding aseptic isolator designed to  
153 provide worker protection from exposure to undesirable levels of airborne drug throughout the  
154 compounding and material transfer processes and to provide an aseptic environment for  
155 compounding sterile preparations. Air exchange with the surrounding environment should not  
156 occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system  
157 capable of containing airborne concentrations of the physical size and state of the drug being  
158 compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator  
159 should be appropriately removed by properly designed building ventilation.

160 (17) Critical Area--An ISO Class 5 environment.

161 (18) Critical Sites--A location that includes any component or fluid pathway surfaces (e.g., vial  
162 septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at  
163 risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and  
164 mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the  
165 critical site increases with the size of the openings and exposure time.

166 (19) Device--An instrument, apparatus, implement, machine, contrivance, implant, in-vitro  
167 reagent, or other similar or related article, including any component part or accessory, that is  
168 required under federal or state law to be ordered or prescribed by a practitioner.

169 (20) Direct Compounding Area--A critical area within the ISO Class 5 primary engineering  
170 control where critical sites are exposed to unidirectional HEPA-filtered air, also known as first  
171 air.

172 (21) Disinfectant--An agent that frees from infection, usually a chemical agent but sometimes a  
173 physical one, and that destroys disease-causing pathogens or other harmful microorganisms but  
174 may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.

175 (22) First Air--The air exiting the HEPA filter in a unidirectional air stream that is essentially  
176 particle free.

177 (23) Hazardous Drugs--Drugs that, studies in animals or humans indicate exposure to the drugs,  
178 have a potential for causing cancer, development or reproductive toxicity, or harm to organs.

179 (24) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of  
180 105 degrees F (41 degrees C).

- 181 (25) HVAC--Heating, ventilation, and air conditioning.
- 182 (26) Immediate use--A sterile preparation that is not prepared according to USP 797 standards  
183 (i.e., outside the pharmacy and most likely not by pharmacy personnel) which shall be stored for  
184 no longer than one hour after completion of the preparation.
- 185 (27) IPA--Isopropyl alcohol (2-propanol).
- 186 (28) Labeling--All labels and other written, printed, or graphic matter on an immediate container  
187 of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except  
188 any outer shipping container. The term "label" designates that part of the labeling on the  
189 immediate container.
- 190 (29) Media-Fill Test--A test used to qualify aseptic technique of compounding personnel or  
191 processes and to ensure that the processes used are able to produce sterile preparation without  
192 microbial contamination. During this test, a microbiological growth medium such as Soybean-  
193 Casein Digest Medium is substituted for the actual drug preparation to simulate admixture  
194 compounding. The issues to consider in the development of a media-fill test are the following:  
195 media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection  
196 of filled units, documentation, interpretation of results, and possible corrective actions required.
- 197 (30) Multiple-Dose Container--A multiple-unit container for articles or preparations intended for  
198 potential administration only and usually contains antimicrobial preservatives. The beyond-use  
199 date for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial  
200 preservatives is 28 days, unless otherwise specified by the manufacturer.
- 201 (31) Negative Pressure Room--A room that is at a lower pressure compared to adjacent spaces  
202 and, therefore, the net flow of air is into the room.
- 203 (32) Office use--The administration of a compounded drug to a patient by a practitioner in the  
204 practitioner's office or by the practitioner in a health care facility or treatment setting, including a  
205 hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 562 of the Act, or  
206 for administration or provision by a veterinarian in accordance with §563.054 of the Act.
- 207 (33) Pharmacy Bulk Package--A container of a sterile preparation for potential use that contains  
208 many single doses. The contents are intended for use in a pharmacy admixture program and are  
209 restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for  
210 the filling of empty sterile syringes. The closure shall be penetrated only one time after  
211 constitution with a suitable sterile transfer device or dispensing set, which allows measured  
212 dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area  
213 such as a laminar flow hood (or an equivalent clean air compounding area).
- 214 (34) Prepackaging--The act of repackaging and relabeling quantities of drug products from a  
215 manufacturer's original container into unit dose packaging or a multiple dose container for  
216 distribution within a facility licensed as a Class C pharmacy or to other pharmacies under

217 common ownership for distribution within those facilities. The term as defined does not prohibit  
218 the prepackaging of drug products for use within other pharmacy classes.

219 (35) Preparation or Compounded Sterile Preparation--A sterile admixture compounded in a  
220 licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed  
221 prescriber. The components of the preparation may or may not be sterile products.

222 (36) Primary Engineering Control--A device or room that provides an ISO Class 5 environment  
223 for the exposure of critical sites when compounding sterile preparations. Such devices include,  
224 but may not be limited to, laminar airflow workbenches, biological safety cabinets, compounding  
225 aseptic isolators, and compounding aseptic containment isolators.

226 (37) Product--A commercially manufactured sterile drug or nutrient that has been evaluated for  
227 safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are accompanied  
228 by full prescribing information, which is commonly known as the FDA-approved manufacturer's  
229 labeling or product package insert.

230 (38) Positive Control--A quality assurance sample prepared to test positive for microbial growth.

231 (39) Positive Pressure Room--A room that is at a higher pressure compared to adjacent spaces  
232 and, therefore, the net airflow is out of the room.

233 (40) Quality assurance--The set of activities used to ensure that the process used in the  
234 preparation of sterile drug preparations lead to preparations that meet predetermined standards of  
235 quality.

236 (41) Quality control--The set of testing activities used to determine that the ingredients,  
237 components (e.g., containers), and final compounded sterile preparations prepared meet  
238 predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.

239 (42) Reasonable quantity--An amount of a compounded drug that:

240 (A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office  
241 or facility before the beyond use date of the drug;

242 (B) is reasonable considering the intended use of the compounded drug and the nature of the  
243 practitioner's practice; and

244 (C) for any practitioner and all practitioners as a whole, is not greater than an amount the  
245 pharmacy is capable of compounding in compliance with pharmaceutical standards for identity,  
246 strength, quality, and purity of the compounded drug that are consistent with United States  
247 Pharmacopoeia guidelines and accreditation practices.

248 (43) Segregated Compounding Area--A designated space, either a demarcated area or room, that  
249 is restricted to preparing low-risk level compounded sterile preparations with 12-hour or less  
250 beyond-use date. Such area shall contain a device that provides unidirectional airflow of ISO

251 Class 5 air quality for preparation of compounded sterile preparations and shall be void of  
252 activities and materials that are extraneous to sterile compounding.

253 (44) Single-dose container--A single-unit container for articles or preparations intended for  
254 parenteral administration only. It is intended for a single use. A single-dose container is labeled  
255 as such. Examples of single-dose containers include pre-filled syringes, cartridges, fusion-sealed  
256 containers, and closure-sealed containers when so labeled.

257 (45) SOPs--Standard operating procedures.

258 (46) Sterilizing Grade Membranes--Membranes that are documented to retain 100% of a culture  
259 of 10<sup>7</sup> microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta per square  
260 centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter  
261 membranes are nominally at 0.22- $\mu$ m or 0.2- $\mu$ m nominal pore size, depending on the  
262 manufacturer's practice.

263 (47) Sterilization by Filtration--Passage of a fluid or solution through a sterilizing grade  
264 membrane to produce a sterile effluent.

265 (48) Terminal Sterilization--The application of a lethal process, e.g., steam under pressure or  
266 autoclaving, to sealed final preparation containers for the purpose of achieving a predetermined  
267 sterility assurance level of usually less than 10<sup>-6</sup> or a probability of less than one in one million  
268 of a non-sterile unit.

269 (49) Unidirectional Flow--An airflow moving in a single direction in a robust and uniform  
270 manner and at sufficient speed to reproducibly sweep particles away from the critical processing  
271 or testing area.

272 (50) USP/NF--The current edition of the United States Pharmacopeia/National Formulary.

273 (c) Personnel.

274 (1) Pharmacist-in-charge.

275 (A) General. The pharmacy shall have a pharmacist-in-charge in compliance with the specific  
276 license classification of the pharmacy.

277 (B) Responsibilities. In addition to the responsibilities for the specific class of pharmacy, the  
278 pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning  
279 the compounding of sterile preparations:

280 (i) developing a system to ensure that all pharmacy personnel responsible for compounding  
281 and/or supervising the compounding of sterile preparations within the pharmacy receive  
282 appropriate education and training and competency evaluation;

- 283 (ii) determining that all personnel involved in compounding sterile preparations obtain  
284 continuing education appropriate for the type of compounding done by the personnel;
- 285 (iii) supervising a system to ensure appropriate procurement of drugs and devices and storage of  
286 all pharmaceutical materials including pharmaceuticals, components used in the compounding of  
287 sterile preparations, and drug delivery devices;
- 288 (iv) ensuring that the equipment used in compounding is properly maintained;
- 289 (v) developing a system for the disposal and distribution of drugs from the pharmacy;
- 290 (vi) developing a system for bulk compounding or batch preparation of drugs;
- 291 (vii) developing a system for the compounding, sterility assurance, quality assurance, and quality  
292 control of sterile preparations; and
- 293 (viii) if applicable, ensuring that the pharmacy has a system to dispose of hazardous waste in a  
294 manner so as not to endanger the public health.

295 (2) Pharmacists.

296 (A) General.

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

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

302 (iii) A pharmacist shall review all compounding records for accuracy and conduct in-process and  
303 final checks and verification of calculations to ensure that errors have not occurred in the  
304 compounding process.

305 (iv) A pharmacist is responsible for ensuring the proper maintenance, cleanliness, and use of all  
306 equipment used in the compounding process.

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

309 (B) Initial training and continuing education.

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

312 (I) complete through a single course, a minimum of 20 hours of instruction and experience in the  
313 areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through  
314 completion of a recognized course in an accredited college of pharmacy or a course sponsored by  
315 an ACPE accredited provider which provides 20 hours of instruction and experience in the areas  
316 listed in paragraph (4)(D) of this subsection;

317 (II) complete a structured on-the-job didactic and experiential training program at this pharmacy  
318 which provides 20 hours of instruction and experience in the areas listed in paragraph (4)(D) of  
319 this subsection. Such training may not be transferred to another pharmacy unless the pharmacies  
320 are under common ownership and control and use a common training program; and

321 (III) possess knowledge about:

322 (-a-) aseptic processing;

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

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

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

327 (-e-) sterilization techniques.

328 (ii) The required experiential portion of the training programs specified in this subparagraph  
329 must be supervised by an individual who is actively engaged in performing sterile compounding  
330 and is qualified and has completed training as specified in paragraph (2) or (3) of this subsection.

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

333 (I) two hours of ACPE-accredited continuing education relating to the areas listed in clause  
334 (i)(II) of this subparagraph if the pharmacist is engaged in compounding low and medium risk  
335 sterile preparations; or

336 (II) four hours of ACPE-accredited continuing education relating to the areas listed in clause  
337 (i)(II) of this subparagraph if the pharmacist is engaged in compounding high risk sterile  
338 preparations.

339 (3) Pharmacy technicians and pharmacy technician trainees.

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

343 (B) Initial training and continuing education.

344 (i) Pharmacy technicians and pharmacy technician trainees may compound sterile preparations  
345 provided the pharmacy technicians and/or pharmacy technician trainees are supervised by a  
346 pharmacist who has completed the training specified in paragraph (4)(D) of this subsection,  
347 conducts in-process and final checks, and affixes his or her initials to the appropriate quality  
348 control records.

349 (ii) All pharmacy technicians and pharmacy technician trainees who compound sterile  
350 preparations for administration to patients shall comply with the following:

351 (I) complete through completion of a single course, a minimum of 40 hours of instruction and  
352 experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be  
353 obtained through completion of a course sponsored by an ACPE accredited provider which  
354 provides 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this  
355 subsection;

356 (II) complete a structured on-the-job didactic and experiential training program at this pharmacy  
357 which provides 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of  
358 this subsection. Such training may not be transferred to another pharmacy unless the pharmacies  
359 are under common ownership and control and use a common training program; and

360 (III) possess knowledge about:

361 (-a-) aseptic processing;

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

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

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

366 (-e-) sterilization techniques.

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

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

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

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

375 (iv) The required experiential portion of the training programs specified in this subparagraph  
376 must be supervised by an individual who is actively engaged in performing sterile compounding,  
377 is qualified and has completed training as specified in paragraph (2) or (3) of this subsection.

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

380 (I) two hours of ACPE accredited continuing education relating to the areas listed in clause  
381 (ii)(III) of this subparagraph if the pharmacy technician is engaged in compounding low and  
382 medium risk sterile preparations; or

383 (II) four hours of ACPE accredited continuing education relating to the areas listed in clause  
384 (ii)(III) of this subparagraph if pharmacy technician is engaged in compounding high risk sterile  
385 preparations.

386 (4) Evaluation and testing requirements.

387 (A) All pharmacy personnel preparing sterile preparations shall be trained conscientiously and  
388 skillfully by expert personnel through multimedia instructional sources and professional  
389 publications in the theoretical principles and practical skills of aseptic manipulations, garbing  
390 procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental  
391 conditions, and cleaning and disinfection procedures before beginning to prepare compounded  
392 sterile preparations.

393 (B) All pharmacy personnel shall perform didactic review and pass written and media-fill testing  
394 of aseptic manipulative skills initially followed by:

395 (i) every 12 months for low- and medium-risk level compounding; and

396 (ii) every six months for high-risk level compounding.

397 (C) Pharmacy personnel who fail written tests or whose media-fill test vials result in gross  
398 microbial colonization shall:

399 (i) be immediately re-instructed and re-evaluated by expert compounding personnel to ensure  
400 correction of all aseptic practice deficiencies; and

401 (ii) not be allowed to compound sterile preparations for patient use until passing results are  
402 achieved.

403 (D) The didactic and experiential training shall include instruction, experience, and demonstrated  
404 proficiency in the following areas:

405 (i) aseptic technique;

406 (ii) critical area contamination factors;

- 407 (iii) environmental monitoring;
- 408 (iv) structure and engineering controls related to facilities;
- 409 (v) equipment and supplies;
- 410 (vi) sterile preparation calculations and terminology;
- 411 (vii) sterile preparation compounding documentation;
- 412 (viii) quality assurance procedures;
- 413 (ix) aseptic preparation procedures including proper gowning and gloving technique;
- 414 (x) handling of hazardous drugs, if applicable;
- 415 (xi) cleaning procedures; and
- 416 (xii) general conduct in the clean room.
- 417 (E) The aseptic technique of each person compounding or responsible for the direct supervision  
418 of personnel compounding sterile preparations shall be observed and evaluated by expert  
419 personnel as satisfactory through written and practical tests, and media-fill challenge testing, and  
420 such evaluation documented.
- 421 (F) Media-fill tests must be conducted at each pharmacy where an individual compounds sterile  
422 preparations. No preparation intended for patient use shall be compounded by an individual until  
423 the on-site media-fill tests test indicates that the individual can competently perform aseptic  
424 procedures, except that a pharmacist may temporarily compound sterile preparations and  
425 supervise pharmacy technicians compounding sterile preparations without media-fill tests  
426 provided the pharmacist completes the on-site media-fill tests within seven days of commencing  
427 work at the pharmacy.
- 428 (G) Media-fill tests procedures for assessing the preparation of specific types of sterile  
429 preparations shall be representative of the most challenging or stressful conditions encountered  
430 by the pharmacy personnel being evaluated for each risk level and for sterilizing high-risk level  
431 compounded sterile preparations.
- 432 (H) Media-fill challenge tests simulating high-risk level compounding shall be used to verify the  
433 capability of the compounding environment and process to produce a sterile preparation.
- 434 (I) Commercially available sterile fluid culture media, such as Soybean-Casein Digest Medium  
435 shall be able to promote exponential colonization of bacteria that are most likely to be  
436 transmitted to compounding sterile preparations from the compounding personnel and  
437 environment. Media-filled vials are generally incubated at 20 to 25 or at 30 to 35 for a minimum  
438 of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled

439 containers should be incubated for at least 7 days at each temperature. Failure is indicated by  
440 visible turbidity in the medium on or before 14 days.

441 (J) The pharmacist-in-charge shall ensure continuing competency of pharmacy personnel through  
442 in-service education, training, and media-fill tests to supplement initial training. Personnel  
443 competency shall be evaluated:

444 (i) during orientation and training prior to the regular performance of those tasks;

445 (ii) whenever the quality assurance program yields an unacceptable result;

446 (iii) whenever unacceptable techniques are observed;and

447 (iv) at least on an annual basis for low- and medium-risk level compounding, and every six  
448 months for high-risk level compounding.

449 (K) The pharmacist-in-charge shall ensure that proper hand hygiene and garbing practices of  
450 compounding personnel are evaluated prior to compounding sterile preparations intended for  
451 patient use and whenever an aseptic media fill is performed.

452 (i) Sampling of compounding personnel glove fingertips shall be performed for all risk level  
453 compounding.

454 (ii) All compounding personnel shall demonstrate competency in proper hand hygiene and  
455 garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces,  
456 routine disinfection of gloved hands).

457 (iii) Sterile contact agar plates shall be used to sample the gloved fingertips of compounding  
458 personnel after garbing in order to assess garbing competency and after completing the media-fill  
459 preparation (without applying sterile 70% IPA).

460 (iv) The visual observation shall be documented and maintained to provide a permanent record  
461 and long-term assessment of personnel competency.

462 (v) All compounding personnel shall successfully complete an initial competency evaluation and  
463 gloved fingertip/thumb sampling procedure no less than three times before initially being  
464 allowed to compound sterile preparations for patient use. Immediately after the compounding  
465 personnel completes the hand hygiene and garbing procedure (e.g., donning of sterile gloves  
466 prior to any disinfection with sterile 70% IPA), the evaluator will collect a gloved fingertip and  
467 thumb sample from both hands from the compounding personnel onto agar plates by lightly  
468 pressing each fingertip into the agar. The plates will be incubated for the appropriate incubation  
469 period and at the appropriate temperature. Re-evaluation of all compounding personnel shall  
470 occur at least annually for compounding personnel who compound low and medium risk level  
471 preparations and every six months for compounding personnel who compound high risk level  
472 preparations.

473 (L) The pharmacist-in-charge shall ensure surface sampling shall be conducted in all ISO  
474 classified areas on a periodic basis. Sampling shall be accomplished using contact plates at the  
475 conclusion of compounding. The sample area shall be gently touched with the agar surface by  
476 rolling the plate across the surface to be sampled.

477 (5) Documentation of Training. The pharmacy shall maintain a record of the training and  
478 continuing education on each person who compounds sterile preparations. The record shall  
479 contain, at a minimum, a written record of initial and in-service training, education, and the  
480 results of written and practical testing and media-fill testing of pharmacy personnel. The record  
481 shall be maintained and available for inspection by the board and contain the following  
482 information:

483 (A) name of the person receiving the training or completing the testing or media-fill tests;

484 (B) date(s) of the training, testing, or media-fill challenge testing;

485 (C) general description of the topics covered in the training or testing or of the process validated;

486 (D) name of the person supervising the training, testing, or media-fill challenge testing; and

487 (E) signature or initials of the person receiving the training or completing the testing or media-  
488 fill challenge testing and the pharmacist-in-charge or other pharmacist employed by the  
489 pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or  
490 media-fill challenge testing of personnel.

491 (d) Operational Standards.

492 (1) General Requirements.

493 (A) Sterile preparations may be compounded:

494 (i) upon presentation of a practitioner's prescription drug or medication order based on a valid  
495 pharmacist/patient/prescriber relationship;

496 (ii) in anticipation of future prescription drug or medication orders based on routine, regularly  
497 observed prescribing patterns; or

498 (iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.

499 (B) Sterile compounding in anticipation of future prescription drug or medication orders must be  
500 based upon a history of receiving valid prescriptions issued within an established  
501 pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional  
502 judgment the quantity prepared is stable for the anticipated shelf time.

503 (i) The pharmacist's professional judgment shall be based on the criteria used to determine a  
504 beyond-use date outlined in paragraph (6)(G) of this subsection.

505 (ii) Documentation of the criteria used to determine the stability for the anticipated shelf time  
506 must be maintained and be available for inspection.

507 (iii) Any preparation compounded in anticipation of future prescription drug or medication  
508 orders shall be labeled. Such label shall contain:

509 (I) name and strength of the compounded preparation or list of the active ingredients and  
510 strengths;

511 (II) facility's lot number;

512 (III) beyond-use date as determined by the pharmacist using appropriate documented criteria as  
513 outlined in paragraph (6)(G) of this subsection;

514 (IV) quantity or amount in the container;

515 (V) appropriate ancillary instructions, such as storage instructions or cautionary statements,  
516 including hazardous drug warning labels where appropriate; and

517 (VI) device-specific instructions, where appropriate.

518 (C) Commercially available products may be compounded for dispensing to individual patients  
519 or for office use provided the following conditions are met:

520 (i) the commercial product is not reasonably available from normal distribution channels in a  
521 timely manner to meet patient's needs;

522 (ii) the pharmacy maintains documentation that the product is not reasonably available due to a  
523 drug shortage or unavailability from the manufacturer; and

524 (iii) the prescribing practitioner has requested that the drug be compounded as described in  
525 subparagraph (D) of this paragraph.

526 (D) A pharmacy may not compound preparations that are essentially copies of commercially  
527 available products (e.g., the preparation is dispensed in a strength that is only slightly different  
528 from a commercially available product) unless the prescribing practitioner specifically orders the  
529 strength or dosage form and specifies why the patient needs the particular strength or dosage  
530 form of the preparation or why the preparation for office use is needed in the particular strength  
531 or dosage form of the preparation. The prescribing practitioner shall provide documentation of a  
532 patient specific medical need and the preparation produces a clinically significant therapeutic  
533 response (e.g., the physician requests an alternate preparation due to hypersensitivity to  
534 excipients or preservative in the FDA-approved product, or the physician requests an effective  
535 alternate dosage form) or if the drug product is not commercially available. The unavailability of  
536 such drug product must be documented prior to compounding. The methodology for  
537 documenting unavailability includes maintaining a copy of the wholesaler's notification showing

538 back-ordered, discontinued, or out-of-stock items. This documentation must be available in hard-  
539 copy or electronic format for inspection by the board.

540 (E) A pharmacy may enter into an agreement to compound and dispense prescription/medication  
541 orders for another pharmacy provided the pharmacy complies with the provisions of §291.125 of  
542 this title (relating to Centralized Prescription Dispensing).

543 (F) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide  
544 sterile prescription compounding services, which may include specific drug preparations and  
545 classes of drugs.

546 (G) A pharmacy may not compound veterinary preparations for use in food producing animals  
547 except in accordance with federal guidelines.

548 (2) Microbial Contamination Risk Levels. Risk Levels for sterile compounded preparations shall  
549 be as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF and  
550 as listed in this paragraph.

551 (A) Low-risk level compounded sterile preparations.

552 (i) Low-Risk conditions. Low-risk level compounded sterile preparations are those compounded  
553 under all of the following conditions.

554 (I) The compounded sterile preparations are compounded with aseptic manipulations entirely  
555 within ISO Class 5 or better air quality using only sterile ingredients, products, components, and  
556 devices.

557 (II) The compounding involves only transfer, measuring, and mixing manipulations using not  
558 more than three commercially manufactured packages of sterile products and not more than two  
559 entries into any one sterile container or package (e.g., bag, vial) of sterile product or  
560 administration container/device to prepare the compounded sterile preparation.

561 (III) Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on  
562 vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile  
563 administration devices, package containers of other sterile products, and containers for storage  
564 and dispensing.

565 (IV) For a low-risk preparation, in the absence of direct sterility testing results or appropriate  
566 information sources that justify different limits, the storage periods may not exceed the following  
567 periods: before administration the compounded sterile preparation is stored properly and are  
568 exposed for not more than 48 hours at controlled room temperature, for not more than 14 days if  
569 stored at a cold temperature, and for 45 days if stored in a frozen state between minus 25 degrees  
570 Celsius and minus 10 degrees Celsius. For delayed activation device systems, the storage period  
571 begins when the device is activated.

572 (ii) Examples of Low-Risk Compounding. Examples of low-risk compounding include the  
573 following.

574 (I) Single volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using  
575 sterile syringes with sterile needles, other administration devices, and other sterile containers.  
576 The solution content of ampules shall be passed through a sterile filter to remove any particles.

577 (II) Simple aseptic measuring and transferring with not more than three packages of  
578 manufactured sterile products, including an infusion or diluent solution to compound drug  
579 admixtures and nutritional solutions.

580 (B) Low-Risk Level compounded sterile preparations with 12-hour or less beyond-use date.  
581 Low-risk level compounded sterile preparations are those compounded pursuant to a physician's  
582 order for a specific patient under all of the following conditions.

583 (i) The compounded sterile preparations are compounded in compounding aseptic isolator or  
584 compounding aseptic containment isolator that does not meet the requirements described in  
585 paragraph (6)(A)(ii)(II) of this subsection relating to Low and Medium Risk Preparations or the  
586 compounded sterile preparations are compounded in laminar airflow workbench or a biological  
587 safety cabinet that cannot be located within an ISO Class 7 buffer area.

588 (ii) The primary engineering control device shall be certified and maintain ISO Class 5 for  
589 exposure of critical sites and shall be located in a segregated compounding area restricted to  
590 sterile compounding activities that minimizes the risk of contamination of the compounded  
591 sterile preparation.

592 (iii) The segregated compounding area shall not be in a location that has unsealed windows or  
593 doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites,  
594 warehouses, or food preparation.

595 (iv) For a low-risk preparation compounded as described in clauses (i) - (iii) of this  
596 subparagraph, administration of such compounded sterile preparations must commence within 12  
597 hours of preparation or as recommended in the manufacturers' package insert, whichever is less.

598 (C) Medium-risk level compounded sterile preparations.

599 (i) Medium-Risk Conditions. Medium-risk level compounded sterile preparations, are those  
600 compounded aseptically under low-risk conditions and one or more of the following conditions  
601 exists.

602 (I) Multiple individual or small doses of sterile products are combined or pooled to prepare a  
603 compounded sterile preparation that will be administered either to multiple patients or to one  
604 patient on multiple occasions.

605 (II) The compounding process includes complex aseptic manipulations other than the single-  
606 volume transfer.

607 (III) The compounding process requires unusually long duration, such as that required to  
608 complete the dissolution or homogenous mixing (e.g., reconstitution of intravenous  
609 immunoglobulin or other intravenous protein products).

610 (IV) The compounded sterile preparations do not contain broad spectrum bacteriostatic  
611 substances and they are administered over several days (e.g., an externally worn infusion  
612 device).

613 (V) For a medium-risk preparation, in the absence of direct sterility testing results the beyond use  
614 dates may not exceed the following time periods: before administration, the compounded sterile  
615 preparations are properly stored and are exposed for not more than 30 hours at controlled room  
616 temperature, for not more than 9 days at a cold temperature, and for 45 days in solid frozen state  
617 between minus 25 degrees Celsius and minus 10 degrees Celsius.

618 (ii) Examples of medium-risk compounding. Examples of medium-risk compounding include the  
619 following.

620 (I) Compounding of total parenteral nutrition fluids using a manual or automated device during  
621 which there are multiple injections, detachments, and attachments of nutrient source products to  
622 the device or machine to deliver all nutritional components to a final sterile container.

623 (II) Filling of reservoirs of injection and infusion devices with more than three sterile drug  
624 products and evacuations of air from those reservoirs before the filled device is dispensed.

625 (III) Filling of reservoirs of injection and infusion devices with volumes of sterile drug solutions  
626 that will be administered over several days at ambient temperatures between 25 and 40 degrees  
627 Celsius (77 and 104 degrees Fahrenheit).

628 (IV) Transfer of volumes from multiple ampuls or vials into a single, final sterile container or  
629 product.

630 (D) High-risk level compounded sterile preparations.

631 (i) High-risk Conditions. High-risk level compounded sterile preparations are those compounded  
632 under any of the following conditions.

633 (I) Non-sterile ingredients, including manufactured products not intended for sterile routes of  
634 administration (e.g., oral) are incorporated or a non-sterile device is employed before terminal  
635 sterilization.

636 (II) Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour:

637 (-a-) sterile contents of commercially manufactured products;

638 (-b-) CSPs that lack effective antimicrobial preservatives; and

639 (-c-) sterile surfaces of devices and containers for the preparation, transfer, sterilization, and  
640 packaging of CSPs.

641 (III) Compounding personnel are improperly garbed and gloved.

642 (IV) Non-sterile water-containing preparations are exposed no more than 6 hours before being  
643 sterilized.

644 (V) It is assumed, and not verified by examination of labeling and documentation from suppliers  
645 or by direct determination, that the chemical purity and content strength of ingredients meet their  
646 original or compendial specifications in unopened or in opened packages of bulk ingredients.

647 (VI) For a sterilized high-risk level preparation, in the absence of passing a sterility test, the  
648 storage periods cannot exceed the following time periods: before administration, the  
649 compounded sterile preparations are properly stored and are exposed for not more than 24 hours  
650 at controlled room temperature, for not more than 3 days at a cold temperature, and for 45 days  
651 in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius.

652 (VII) All non-sterile measuring, mixing, and purifying devices are rinsed thoroughly with sterile,  
653 pyrogen-free water, and then thoroughly drained or dried immediately before use for high-risk  
654 compounding. All high-risk compounded sterile solutions subjected to terminal sterilization are  
655 prefiltered by passing through a filter with a nominal pore size not larger than 1.2 micron  
656 preceding or during filling into their final containers to remove particulate matter. Sterilization of  
657 high-risk level compounded sterile preparations by filtration shall be performed with a sterile 0.2  
658 micrometer or 0.22 micrometer nominal pore size filter entirely within an ISO Class 5 or  
659 superior air quality environment.

660 (ii) Examples of high-risk compounding. Examples of high-risk compounding include the  
661 following.

662 (I) Dissolving non-sterile bulk drug powders to make solutions, which will be terminally  
663 sterilized.

664 (II) Exposing the sterile ingredients and components used to prepare and package compounded  
665 sterile preparations to room air quality worse than ISO Class 5 for more than one hour.

666 (III) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is  
667 performed.

668 (IV) Assuming, without appropriate evidence or direct determination, that packages of bulk  
669 ingredients contain at least 95% by weight of their active chemical moiety and have not been  
670 contaminated or adulterated between uses.

671 (3) Immediate Use Compounded Sterile Preparations. For the purpose of emergency or  
672 immediate patient care, such situations may include cardiopulmonary resuscitation, emergency  
673 room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the

674 compounded sterile preparation under low-risk level conditions would subject the patient to  
675 additional risk due to delays in therapy. Compounded sterile preparations are exempted from the  
676 requirements described in this paragraph for low-risk level compounded sterile preparations  
677 when all of the following criteria are met.

678 (A) Only simple aseptic measuring and transfer manipulations are performed with not more than  
679 three sterile non-hazardous commercial drug and diagnostic radiopharmaceutical drug products,  
680 including an infusion or diluent solution, from the manufacturers' original containers and not  
681 more than two entries into any one container or package of sterile infusion solution or  
682 administration container/device.

683 (B) Unless required for the preparation, the compounding procedure occurs continuously without  
684 delays or interruptions and does not exceed 1 hour.

685 (C) During preparation, aseptic technique is followed and, if not immediately administered, the  
686 finished compounded sterile preparation is under continuous supervision to minimize the  
687 potential for contact with nonsterile surfaces, introduction of particulate matter of biological  
688 fluids, mix-ups with other compounded sterile preparations, and direct contact of outside  
689 surfaces.

690 (D) Administration begins not later than one hour following the completion of preparing the  
691 compounded sterile preparation.

692 (E) When the compounded sterile preparations is not administered by the person who prepared it,  
693 or its administration is not witnessed by the person who prepared it, the compounded sterile  
694 preparation shall bear a label listing patient identification information such as name and  
695 identification number(s), the names and amounts of all ingredients, the name or initials of the  
696 person who prepared the compounded sterile preparation, and the exact 1-hour beyond-use time  
697 and date.

698 (F) If administration has not begun within one hour following the completion of preparing the  
699 compounded sterile preparation, the compounded sterile preparation is promptly and safely  
700 discarded. Immediate use compounded sterile preparations shall not be stored for later use.

701 (G) Hazardous drugs shall not be prepared as immediate use compounded sterile preparations.

702 (4) Single-dose and multiple dose containers.

703 (A) Opened or needle punctured single-dose containers, such as bags bottles, syringes, and vials  
704 of sterile products shall be used within one hour if opened in worse than ISO Class 5 air quality.  
705 Any remaining contents must be discarded.

706 (B) Single-dose containers, including single-dose large volume parenteral solutions and single-  
707 dose vials, exposed to ISO Class 5 or cleaner air may be used up to six hours after initial needle  
708 puncture.

709 (C) Opened single-dose fusion sealed containers shall not be stored for any time period.

710 (D) Multiple-dose containers may be used up to 28 days after initial needle puncture unless  
711 otherwise specified by the manufacturer.

712 (5) Library. In addition to the library requirements of the pharmacy's specific license  
713 classification, a pharmacy shall maintain current or updated copies in hard-copy or electronic  
714 format of each of the following:

715 (A) a reference text on injectable drug preparations, such as Handbook on Injectable Drug  
716 Products;

717 (B) a specialty reference text appropriate for the scope of pharmacy services provided by the  
718 pharmacy, e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of  
719 hazardous drugs; and

720 (C) the United States Pharmacopeia/National Formulary containing USP Chapter 71, Sterility  
721 Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding--Nonsterile  
722 Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile  
723 Preparations, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.

724 (6) Environment. Compounding facilities shall be physically designed and environmentally  
725 controlled to minimize airborne contamination from contacting critical sites.

726 (A) Low and Medium Risk Preparations.

727 (i) A pharmacy that prepares low- and medium-risk preparations shall have a clean room for the  
728 compounding of sterile preparations that is constructed to minimize the opportunities for  
729 particulate and microbial contamination. The clean room shall:

730 (I) be clean, well lit, and of sufficient size to support sterile compounding activities;

731 (II) be maintained at a comfortable temperature (e.g., 20 degrees Celsius or cooler) allowing  
732 compounding personnel to perform flawlessly when attired in the required aseptic compounding  
733 garb;

734 (III) be used only for the compounding of sterile preparations;

735 (IV) be designed such that hand sanitizing and gowning occurs outside the buffer area but allows  
736 hands-free access by compounding personnel to the buffer area;

737 (V) have non-porous and washable floors or floor covering to enable regular disinfection;

738 (VI) be ventilated in a manner to avoid disruption from the HVAC system and room cross-drafts;

739 (VII) have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth,  
740 impervious, free from cracks and crevices (e.g., coved), non-shedding and resistant to damage by  
741 disinfectant agents;

742 (VIII) have junctures of ceilings to walls coved or caulked to avoid cracks and crevices;

743 (IX) have drugs and supplies stored on shelving areas above the floor to permit adequate floor  
744 cleaning;

745 (X) contain only the appropriate compounding supplies and not be used for bulk storage for  
746 supplies and materials. Objects that shed particles shall not be brought into the clean room;

747 (XI) contain an ante-area that provides at least an ISO class 8 air quality and contains a sink with  
748 hot and cold running water that enables hands-free use with a closed system of soap dispensing  
749 to minimize the risk of extrinsic contamination; and

750 (XII) contain a buffer area designed to maintain at least ISO Class 7 conditions for 0.5- $\mu$ m and  
751 larger particles under dynamic working conditions. The following is applicable for the buffer  
752 area.

753 (-a-) There shall be some demarcation designation that delineates the ante-area from the buffer  
754 area. The demarcation shall be such that it does not create conditions that could adversely affect  
755 the cleanliness of the area.

756 (-b-) The buffer area shall be segregated from surrounding, unclassified spaces to reduce the risk  
757 of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional  
758 airflow environment, and this segregation should be continuously monitored.

759 (-c-) A buffer area that is not physically separated from the ante-area shall employ the principle  
760 of displacement airflow as defined in Chapter 797, Pharmaceutical Compounding--Sterile  
761 Preparations, of the USP/NF, with limited access to personnel.

762 (-d-) The buffer area shall not contain sources of water (i.e., sinks) or floor drains.

763 (ii) The pharmacy shall prepare sterile preparations in a primary engineering control device, such  
764 as a laminar air flow hood, biological safety cabinet, compounding aseptic isolator,  
765 compounding aseptic containment isolator which is capable of maintaining at least ISO Class 5  
766 conditions for 0.5- $\mu$ m particles while compounding sterile preparations.

767 (I) The primary engineering control shall:

768 (-a-) be located in the buffer area and placed in the buffer area in a manner as to avoid conditions  
769 that could adversely affect its operation such as strong air currents from opened doors, personnel  
770 traffic, or air streams from the heating, ventilating and air condition system.

771 (-b-) be certified by a qualified independent contractor according to the International  
772 Organization of Standardization (ISO) Classification of Particulate Matter in Room Air (ISO  
773 14644-1) for operational efficiency at least every six months and whenever the device or room is  
774 relocated or altered or major service to the facility is performed, in accordance with the  
775 manufacturer's specifications;

776 (-c-) have pre-filters inspected periodically and replaced as needed, in accordance with written  
777 policies and procedures and the manufacturer's specification, and the inspection and/or  
778 replacement date documented; and

779 (-d-) be located in a buffer area that has a minimum differential positive pressure of 0.02 to 0.05  
780 inches water column.

781 (II) The compounding aseptic isolator or compounding aseptic containment isolator must be  
782 placed in an ISO Class 7 buffer area unless the isolator meets all of the following conditions.

783 (-a-) The isolator must provide isolation from the room and maintain ISO Class 5 during  
784 dynamic operating conditions including transferring ingredients, components, and devices into  
785 and out of the isolator and during preparation of compounded sterile preparations.

786 (-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site  
787 must maintain ISO Class 5 levels during compounding operations.

788 (-c-) The pharmacy shall maintain documentation from the manufacturer that the isolator meets  
789 this standard when located in worse than ISO Class 7 environments.

790 (B) High-risk Preparations.

791 (i) In addition to the requirements in subparagraph (A) of this paragraph, when high-risk  
792 preparations are compounded, the primary engineering control shall be located in a buffer area  
793 that provides a physical separation, through the use of walls, doors and pass-throughs and has a  
794 minimum differential positive pressure of 0.02 to 0.05 inches water column.

795 (ii) Presterilization procedures for high-risk level compounded sterile preparations, such as  
796 weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.

797 (C) Automated compounding device. If automated compounding devices are used, the pharmacy  
798 shall have a method to calibrate and verify the accuracy of automated compounding devices used  
799 in aseptic processing and document the calibration and verification on a daily basis, based on the  
800 manufacturer's recommendations, and review the results at least weekly.

801 (D) Hazardous drugs. If the preparation is hazardous, the following is also applicable.

802 (i) General.

803 (I) Hazardous drugs shall be prepared only under conditions that protect personnel during  
804 preparation and storage.

805 (II) Hazardous drugs shall be stored separately from other inventory in a manner to prevent  
806 contamination and personnel exposure.

807 (III) All personnel involved in the compounding of hazardous drugs shall wear appropriate  
808 protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or  
809 dedicated shoes, and appropriate gloving at all times when handling hazardous drugs, including  
810 receiving, distribution, stocking, inventorying, preparation, for administration and disposal.

811 (IV) Appropriate safety and containment techniques for compounding hazardous drugs shall be  
812 used in conjunction with aseptic techniques required for preparing sterile preparations.

813 (V) Disposal of hazardous waste shall comply with all applicable local, state, and federal  
814 requirements.

815 (VI) Prepared doses of hazardous drugs must be dispensed, labeled with proper precautions  
816 inside and outside, and distributed in a manner to minimize patient contact with hazardous  
817 agents.

818 (ii) Primary engineering control device. Hazardous drugs shall be prepared in a Class II or III  
819 vertical flow biological safety cabinet or compounding aseptic containment isolator located in an  
820 ISO Class 7 area that is physically separated from other preparation areas. The area for  
821 preparation of sterile chemotherapeutic preparations shall:

822 (I) have not less than 0.01 inches water column negative pressure to the adjacent positive  
823 pressure ISO Class 7 or better ante-area; and

824 (II) have a pressure indicator that can be readily monitored for correct room pressurization.

825 (iii) Facilities that prepare a low volume of hazardous drugs. Pharmacies that prepare a low  
826 volume of hazardous drugs, are not required to comply with the provisions of clause (ii) of this  
827 subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., closed-  
828 system vial transfer device within a BSC or CACI that is located in a non-negative pressure  
829 room).

830 (E) Cleaning and disinfecting the sterile compounding areas. The following cleaning and  
831 disinfecting practices and frequencies apply to direct and contiguous compounding areas, which  
832 include ISO Class 5 compounding areas for exposure of critical sites as well as buffer areas,  
833 ante-areas, and segregated compounding areas.

834 (i) The pharmacist-in-charge is responsible for developing written procedures for cleaning and  
835 disinfecting the direct and contiguous compounding areas and assuring the procedures are  
836 followed.

837 (ii) These procedures shall be conducted at the beginning of each work shift, before each batch  
838 preparation is started, every 30 minutes during continuous compounding of individual  
839 compounded sterile preparations, when there are spills, and when surface contamination is  
840 known or suspected from procedural breaches.

841 (iii) Before compounding is performed, all items shall be removed from the direct and  
842 contiguous compounding areas and all surfaces are cleaned by removing loose material and  
843 residue from spills, followed by an application of a residue-free disinfecting agent (e.g., IPA),  
844 which is allowed to dry before compounding begins.

845 (iv) Work surfaces in the ISO Class 7 buffer areas and ISO Class 8 ante-areas, as well as  
846 segregated compounding areas, shall be cleaned and disinfected at least daily. Dust and debris  
847 shall be removed when necessary from storage sites for compounding ingredients and supplies  
848 using a method that does not degrade the ISO Class 7 or 8 air quality.

849 (v) Floors in the buffer area, ante-area, and segregated compounding area are cleaned by  
850 mopping with a cleaning and disinfecting agent at least once daily when no aseptic operations  
851 are in progress. Mopping shall be performed by trained personnel using approved agents and  
852 procedures described in the written SOPs. It is incumbent on compounding personnel to ensure  
853 that such cleaning is performed properly.

854 (vi) In the buffer area, ante-area, and segregated compounding area, walls, ceilings, and shelving  
855 shall be cleaned and disinfected monthly. Cleaning and disinfecting agents shall be used with  
856 careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues.

857 (vii) All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, and  
858 dedicated to use in the buffer area, ante-area, and segregated compounding areas and shall not be  
859 removed from these areas except for disposal. Floor mops may be used in both the buffer area  
860 and ante-area, but only in that order. If cleaning materials are reused, procedures shall be  
861 developed that ensure that the effectiveness of the cleaning device is maintained and that  
862 repeated use does not add to the bio-burden of the area being cleaned.

863 (viii) Supplies and equipment removed from shipping cartons must be wiped with a disinfecting  
864 agent, such as sterile IPA. After the disinfectant is sprayed or wiped on a surface to be  
865 disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used  
866 for compounding purposes. However, if sterile supplies are received in sealed pouches, the  
867 pouches may be removed as the supplies are introduced into the ISO Class 5 area without the  
868 need to disinfect the individual sterile supply items. No shipping or other external cartons may be  
869 taken into the buffer area or segregated compounding area.

870 (ix) Storage shelving emptied of all supplies, walls, and ceilings are cleaned and disinfected at  
871 planned intervals, monthly, if not more frequently.

872 (x) Cleaning must be done by personnel trained in appropriate cleaning techniques.

873 (xi) Proper documentation and frequency of cleaning must be maintained and shall contain the  
874 following:

875 (I) date and time of cleaning;

876 (II) type of cleaning performed; and

877 (III) name of individual who performed the cleaning.

878 (F) Security requirements. The pharmacist-in-charge may authorize personnel to gain access to  
879 that area of the pharmacy containing dispensed sterile preparations, in the absence of the  
880 pharmacist, for the purpose of retrieving dispensed prescriptions to deliver to patients. If the  
881 pharmacy allows such after-hours access, the area containing the dispensed sterile preparations  
882 shall be an enclosed and lockable area separate from the area containing undispensed  
883 prescription drugs. A list of the authorized personnel having such access shall be in the  
884 pharmacy's policy and procedure manual.

885 (G) Storage requirements and beyond-use dating.

886 (i) Storage requirements. All drugs shall be stored at the proper temperature and conditions, as  
887 defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).

888 (ii) Beyond-use dating.

889 (I) Beyond-use dates for compounded sterile preparations shall be assigned based on professional  
890 experience, which shall include careful interpretation of appropriate information sources for the  
891 same or similar formulations.

892 (II) Beyond-use dates for compounded sterile preparations that are prepared strictly in  
893 accordance with manufacturers' product labeling must be those specified in that labeling, or from  
894 appropriate literature sources or direct testing.

895 (III) Beyond-use dates for compounded sterile preparations that lack justification from either  
896 appropriate literature sources or by direct testing evidence shall be assigned as described in  
897 Chapter 795, in Stability Criteria and Beyond-Use Dating under Pharmaceutical Compounding-  
898 Nonsterile Preparations of the USP/NF.

899 (IV) When assigning a beyond-use date, compounding personnel shall consult and apply drug-  
900 specific and general stability documentation and literature where available, and they should  
901 consider the nature of the drug and its degradation mechanism, the container in which it is  
902 packaged, the expected storage conditions, and the intended duration of therapy.

903 (V) The sterility and storage and stability beyond-use date for attached and activated container  
904 pairs of drug products for intravascular administration shall be applied as indicated by the  
905 manufacturer.

906 (7) Equipment and supplies. Pharmacies compounding sterile preparations shall have the  
907 following equipment and supplies:

908 (A) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure that  
909 proper storage requirements are met, if sterile preparations are stored in the refrigerator;

910 (B) a calibrated system or device to monitor the temperature where bulk chemicals are stored;

911 (C) a temperature-sensing mechanism suitably placed in the controlled temperature storage space  
912 to reflect accurately the true temperature;

913 (D) if applicable, a Class A prescription balance, or analytical balance and weights. Such balance  
914 shall be properly maintained and subject to periodic inspection by the Texas State Board of  
915 Pharmacy;

916 (E) equipment and utensils necessary for the proper compounding of sterile preparations. Such  
917 equipment and utensils used in the compounding process shall be:

918 (i) of appropriate design, appropriate capacity, and be operated within designed operational  
919 limits;

920 (ii) of suitable composition so that surfaces that contact components, in-process material, or drug  
921 products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength,  
922 quality, or purity of the drug preparation beyond the desired result;

923 (iii) cleaned and sanitized immediately prior to and after each use; and

924 (iv) routinely inspected, calibrated(if necessary), or checked to ensure proper performance;

925 (F) appropriate disposal containers for used needles, syringes, etc., and if applicable, hazardous  
926 waste from the preparation of hazardous drugs and/or biohazardous waste;

927 (G) appropriate packaging or delivery containers to maintain proper storage conditions for sterile  
928 preparations;

929 (H) infusion devices, if applicable; and

930 (I) all necessary supplies, including:

931 (i) disposable needles, syringes, and other supplies for aseptic mixing;

932 (ii) disinfectant cleaning solutions;

933 (iii) hand washing agents with bactericidal action;

934 (iv) disposable, lint free towels or wipes;

935 (v) appropriate filters and filtration equipment;

936 (vi) hazardous spill kits, if applicable; and

937 (vii) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.

938 (8) Labeling.

939 (A) Prescription drug or medication orders. In addition to the labeling requirements for the  
940 pharmacy's specific license classification, the label dispensed or distributed pursuant to a  
941 prescription drug or medication order shall contain the following:

942 (i) the generic name(s) or the official name(s) of the principal active ingredient(s) of the  
943 compounded sterile preparation;

944 (ii) for outpatient prescription orders only, a statement that the compounded sterile preparation  
945 has been compounded by the pharmacy. (An auxiliary label may be used on the container to  
946 meet this requirement);

947 (iii) a beyond-use date. The beyond-use date shall be determined as outlined in Chapter 797,  
948 Pharmacy Compounding--Sterile Preparations of the USP/NF, and paragraph (7)(G) of this  
949 subsection;

950 (B) Batch. If the sterile preparation is compounded in a batch, the following shall also be  
951 included on the batch label:

952 (i) unique lot number assigned to the batch;

953 (ii) quantity;

954 (iii) appropriate ancillary instructions, such as storage instructions or cautionary statements,  
955 including hazardous drug warning labels where appropriate; and

956 (iv) device-specific instructions, where appropriate.

957 (C) Pharmacy bulk package. The label of a pharmacy bulk package shall:

958 (i) state prominently "Pharmacy Bulk Package--Not for Direct Infusion;"

959 (ii) contain or refer to information on proper techniques to help ensure safe use of the  
960 preparation; and

961 (iii) bear a statement limiting the time frame in which the container may be used once it has been  
962 entered, provided it is held under the labeled storage conditions.

963 (9) Written drug information for prescription drug orders only. Written information about the  
964 compounded preparation or its major active ingredient(s) shall be given to the patient at the time  
965 of dispensing a prescription drug order. A statement which indicates that the preparation was  
966 compounded by the pharmacy must be included in this written information. If there is no written  
967 information available, the patient shall be advised that the drug has been compounded and how  
968 to contact a pharmacist, and if appropriate, the prescriber, concerning the drug.

969 (10) Pharmaceutical Care Services. In addition to the pharmaceutical care requirements for the  
970 pharmacy's specific license classification, the following requirements for sterile preparations  
971 compounded pursuant to prescription drug orders must be met.

972 (A) Primary provider. There shall be a designated physician primarily responsible for the  
973 patient's medical care. There shall be a clear understanding between the physician, the patient,  
974 and the pharmacy of the responsibilities of each in the areas of the delivery of care, and the  
975 monitoring of the patient. This shall be documented in the patient medication record (PMR).

976 (B) Patient training. The pharmacist-in-charge shall develop policies to ensure that the patient  
977 and/or patient's caregiver receives information regarding drugs and their safe and appropriate  
978 use, including instruction when applicable, regarding:

979 (i) appropriate disposition of hazardous solutions and ancillary supplies;

980 (ii) proper disposition of controlled substances in the home;

981 (iii) self-administration of drugs, where appropriate;

982 (iv) emergency procedures, including how to contact an appropriate individual in the event of  
983 problems or emergencies related to drug therapy; and

984 (v) if the patient or patient's caregiver prepares sterile preparations in the home, the following  
985 additional information shall be provided:

986 (I) safeguards against microbial contamination, including aseptic techniques for compounding  
987 intravenous admixtures and aseptic techniques for injecting additives to premixed intravenous  
988 solutions;

989 (II) appropriate storage methods, including storage durations for sterile pharmaceuticals and  
990 expirations of self-mixed solutions;

991 (III) handling and disposition of premixed and self-mixed intravenous admixtures; and

992 (IV) proper disposition of intravenous admixture compounding supplies such as syringes, vials,  
993 ampules, and intravenous solution containers.

994 (C) Pharmacist-patient relationship. It is imperative that a pharmacist-patient relationship be  
995 established and maintained throughout the patient's course of therapy. This shall be documented  
996 in the patient's medication record (PMR).

997 (D) Patient monitoring. The pharmacist-in-charge shall develop policies to ensure that:

998 (i) the patient's response to drug therapy is monitored and conveyed to the appropriate health  
999 care provider;

1000 (ii) the first dose of any new drug therapy is administered in the presence of an individual  
1001 qualified to monitor for and respond to adverse drug reactions; and

1002 (iii) reports of adverse events with a compounded sterile preparation are reviewed promptly and  
1003 thoroughly to correct and prevent future occurrences.

1004 (11) Drugs, components, and materials used in sterile compounding.

1005 (A) Drugs used in sterile compounding shall be a USP/NF grade substances manufactured in an  
1006 FDA-registered facility.

1007 (B) If USP/NF grade substances are not available shall be of a chemical grade in one of the  
1008 following categories:

1009 (i) Chemically Pure (CP);

1010 (ii) Analytical Reagent (AR);

1011 (iii) American Chemical Society (ACS); or

1012 (iv) Food Chemical Codex.

1013 (C) If a drug, component or material is not purchased from a FDA-registered facility, the  
1014 pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the  
1015 supplier and the pharmacist shall compare the monograph of drugs in a similar class to the  
1016 Certificate of Analysis.

1017 (D) All components shall:

1018 (i) be manufactured in an FDA-registered facility;or

1019 (ii) in the professional judgment of the pharmacist, be of high quality and obtained from  
1020 acceptable and reliable alternative sources; and

1021 (iii) stored in properly labeled containers in a clean, dry area, under proper temperatures.

1022 (E) Drug preparation containers and closures shall not be reactive, additive, or absorptive so as to  
1023 alter the safety, identity, strength, quality, or purity of the compounded drug preparation beyond  
1024 the desired result.

1025 (F) Components, drug preparation containers, and closures shall be rotated so that the oldest  
1026 stock is used first.

1027 (G) Container closure systems shall provide adequate protection against foreseeable external  
1028 factors in storage and use that can cause deterioration or contamination of the compounded drug  
1029 preparation.

1030 (H) A pharmacy may not compound a preparation that contains ingredients appearing on a  
1031 federal Food and Drug Administration list of drug products withdrawn or removed from the  
1032 market for safety reasons.

1033 (12) Compounding process.

1034 (A) Standard operating procedures (SOPs). All significant procedures performed in the  
1035 compounding area shall be covered by written SOPs designed to ensure accountability, accuracy,  
1036 quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be  
1037 developed and implemented for:

1038 (i) the facility;

1039 (ii) equipment;

1040 (iii) personnel;

1041 (iv) preparation evaluation;

1042 (v) quality assurance;

1043 (vi) preparation recall;

1044 (vii) packaging; and

1045 (viii) storage of compounded sterile preparations.

1046 (B) USP/NF. Any compounded formulation with an official monograph in the USP/NF shall be  
1047 compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

1048 (C) Personnel Cleansing and Garbing.

1049 (i) Any person with an apparent illness or open lesion, including rashes, sunburn, weeping sores,  
1050 conjunctivitis, and active respiratory infection, that may adversely affect the safety or quality of a

1051 drug preparation being compounded shall be excluded from working in ISO Class 5 and ISO  
1052 Class 7 compounding areas until the condition is remedied.

1053 (ii) Before entering the buffer area, compounding personnel must remove the following:

1054 (I) personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests);

1055 (II) all cosmetics, because they shed flakes and particles;and

1056 (III) all hand, wrist, and other body jewelry or piercings (e.g., earrings, lip or eyebrow piercings)  
1057 that can interfere with the effectiveness of personal protective equipment (e.g., fit of gloves and  
1058 cuffs of sleeves).

1059 (iii) The wearing of artificial nails or extenders is prohibited while working in the sterile  
1060 compounding environment. Natural nails shall be kept neat and trimmed.

1061 (iv) Personnel shall don personal protective equipment and perform hand hygiene in an order that  
1062 proceeds from the dirtiest to the cleanest activities as follows:

1063 (I) Activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and  
1064 facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye shield. Eye  
1065 shields are optional unless working with irritants like germicidal disinfecting agents or when  
1066 preparing hazardous drugs.

1067 (II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks,  
1068 personnel shall perform a hand hygiene procedure by removing debris from underneath  
1069 finger nails using a nail cleaner under running warm water followed by vigorous hand washing.  
1070 Personnel shall begin washing arms at the hands and continue washing to elbows for at least 30  
1071 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in  
1072 the ante-area. Hands and forearms to the elbows shall be completely dried using lint-free  
1073 disposable towels, an electronic hands-free hand dryer, or a HEPA filtered hands dryer.

1074 (III) After completion of hand washing, personnel shall don clean non-shedding gowns with  
1075 sleeves that fit snugly around the wrists and enclosed at the neck.

1076 (IV) Once inside the buffer area or segregated compounding area, and prior to donning sterile  
1077 powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based  
1078 surgical hand scrub with persistent activity following manufacturers' recommendations. Hands  
1079 shall be allowed to dry thoroughly before donning sterile gloves.

1080 (V) Sterile gloves that form a continuous barrier with the gown shall be the last item donned  
1081 before compounding begins. Routine application of sterile 70% IPA shall occur throughout the  
1082 compounding day and whenever nonsterile surfaces are touched.

1083 (v) When compounding personnel shall temporarily exit the ISO Class 7 environment during a  
1084 work shift, the exterior gown, if not visibly soiled, may be removed and retained in the ISO Class

1085 8 ante-area, to be re-donned during that same work shift only. However, shoe covers, hair and  
1086 facial hair covers, face mask/eye shield, and gloves shall be replaced with new ones before re-  
1087 entering the ISO Class 7 clean environment along with performing proper hand hygiene.

1088 (vi) During high-risk compounding activities that precede terminal sterilization, such as  
1089 weighing and mixing of nonsterile ingredients, compounding personnel shall be garbed and  
1090 gloved the same as when performing compounding in an ISO Class 5 environment. Properly  
1091 garbed and gloved compounding personnel who are exposed to air quality that is either known or  
1092 suspected to be worse than ISO Class 7 shall re-garb personal protective equipment along with  
1093 washing their hands properly, performing antiseptic hand cleansing with a waterless alcohol-  
1094 based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7 buffer  
1095 area.

1096 (vii) When compounding aseptic isolators or compounding aseptic containment isolators are the  
1097 source of the ISO Class 5 environment, the compounding personnel should follow the  
1098 requirements as specified in this subparagraph, unless the isolator manufacturer can provide  
1099 written documentation based on validated environmental testing that any components of personal  
1100 protective equipment or cleansing are not required.

1101 (13) Quality Assurance.

1102 (A) Initial Formula Validation. Prior to routine compounding of a sterile preparation, a pharmacy  
1103 shall conduct an evaluation that shows that the pharmacy is capable of compounding a  
1104 preparation that is sterile and that contains the stated amount of active ingredient(s).

1105 (i) Low risk preparations.

1106 (I) Quality assurance practices include, but are not limited to the following:

1107 (-a-) Routine disinfection and air quality testing of the direct compounding environment to  
1108 minimize microbial surface contamination and maintain ISO Class 5 air quality.

1109 (-b-) Visual confirmation that compounding personnel are properly donning and wearing  
1110 appropriate items and types of protective garments and goggles.

1111 (-c-) Review of all orders and packages of ingredients to ensure that the correct identity and  
1112 amounts of ingredients were compounded.

1113 (-d-) Visual inspection of compounded sterile preparations to ensure the absence of particulate  
1114 matter in solutions, the absence of leakage from vials and bags, and the accuracy and  
1115 thoroughness of labeling.

1116 (II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least  
1117 annually by each person authorized to compound in a low-risk level under conditions that closely  
1118 simulate the most challenging or stressful conditions encountered during compounding of low-  
1119 risk level sterile preparations. Once begun, this test is completed without interruption within an

1120 ISO Class 5 air quality environment. Three sets of four 5-milliliter aliquots of sterile Soybean-  
1121 Casein Digest Medium are transferred with the same sterile 10-milliliter syringe and vented  
1122 needle combination into separate sealed, empty, sterile 30-milliliter clear vials (i.e., four 5-  
1123 milliliter aliquots into each of three 30-milliliter vials). Sterile adhesive seals are aseptically  
1124 affixed to the rubber closures on the three filled vials. The vials are incubated within a range of  
1125 20 - 35 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the  
1126 medium on or before 14 days. The media-fill test must include a positive-control sample.

1127 (ii) Medium risk preparations.

1128 (I) Quality assurance procedures for medium-risk level compounded sterile preparations include  
1129 all those for low-risk level compounded sterile preparations, as well as a more challenging  
1130 media-fill test passed annually, or more frequently.

1131 (II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least  
1132 annually under conditions that closely simulate the most challenging or stressful conditions  
1133 encountered during compounding. This test is completed without interruption within an ISO  
1134 Class 5 air quality environment. Six 100-milliliter aliquots of sterile Soybean-Casein Digest  
1135 Medium are aseptically transferred by gravity through separate tubing sets into separate  
1136 evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-  
1137 milliliter syringe and 18-gauge needle combination is used to exchange two 5-milliliter aliquots  
1138 of medium from one container to the other container in the pair. For example, after a 5-milliliter  
1139 aliquot from the first container is added to the second container in the pair, the second container  
1140 is agitated for 10 seconds, then a 5-milliliter aliquot is removed and returned to the first container  
1141 in the pair. The first container is then agitated for 10 seconds, and the next 5-milliliter aliquot is  
1142 transferred from it back to the second container in the pair. Following the two 5-milliliter aliquot  
1143 exchanges in each pair of containers, a 5-milliliter aliquot of medium from each container is  
1144 aseptically injected into a sealed, empty, sterile 10-milliliter clear vial, using a sterile 10-  
1145 milliliter syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber  
1146 closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees  
1147 Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the medium on or  
1148 before 14 days. The media-fill test must include a positive-control sample.

1149 (iii) High risk preparations.

1150 (I) Procedures for high-risk level compounded sterile preparations include all those for low-risk  
1151 level compounded sterile preparations. In addition, a media-fill test that represents high-risk level  
1152 compounding is performed twice a year by each person authorized to compound high-risk level  
1153 compounded sterile preparations.

1154 (II) Example of a Media-Fill Test Procedure Compounded Sterile Preparations Sterilized by  
1155 Filtration. This test, or an equivalent test, is performed under conditions that closely simulate the  
1156 most challenging or stressful conditions encountered when compounding high-risk level  
1157 compounded sterile preparations. Note: Sterility tests for autoclaved compounded sterile  
1158 preparations are not required unless they are prepared in batches of more than 25 units. This test  
1159 is completed without interruption in the following sequence:

- 1160 (-a-) Dissolve 3 grams of nonsterile commercially available Soybean-Casein Digest Medium in  
1161 100 milliliters of non-bacteriostatic water to make a 3% nonsterile solution.
- 1162 (-b-) Draw 25 milliliters of the medium into each of three 30-milliliter sterile syringes. Transfer 5  
1163 milliliters from each syringe into separate sterile 10-milliliter vials. These vials are the positive  
1164 controls to generate exponential microbial growth, which is indicated by visible turbidity upon  
1165 incubation.
- 1166 (-c-) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron porosity  
1167 filter unit and a 20-gauge needle to each syringe. Inject the next 10 milliliters from each syringe  
1168 into three separate 10-milliliter sterile vials. Repeat the process for three more vials. Label all  
1169 vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20 to 35  
1170 degrees Celsius for a minimum of 14 days. Inspect for microbial growth over 14 days as  
1171 described in Chapter 797 Pharmaceutical Compounding--Sterile Preparations, of the USP/NF.
- 1172 (B) Finished preparation release checks and tests.
- 1173 (i) All high-risk level compounded sterile preparations that are prepared in groups of more than  
1174 25 identical individual single-dose packages (such as ampuls, bags, syringes, and vials), or in  
1175 multiple dose vials for administration to multiple patients, or are exposed longer than 12 hours at  
1176 2 - 8 degrees Celsius and longer than six hours at warmer than 8 degrees Celsius before they are  
1177 sterilized shall be tested to ensure they are sterile and do not contain excessive bacterial  
1178 endotoxins as specified in Chapter 71, Sterility Tests of the USP/NF before being dispensed or  
1179 administered.
- 1180 (ii) All compounded sterile preparations that are intended to be solutions must be visually  
1181 examined for the presence of particulate matter and not administered or dispensed when such  
1182 matter is observed.
- 1183 (iii) The prescription drug and medication orders, written compounding procedure, preparation  
1184 records, and expended materials used to make compounded sterile preparations at all  
1185 contamination risk levels shall be inspected for accuracy of correct identities and amounts of  
1186 ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical  
1187 appearance before they are dispensed or administered.
- 1188 (C) Viable and nonviable environmental sampling testing. Environmental sampling shall occur,  
1189 at a minimum, every six months as part of a comprehensive quality management program and  
1190 under any of the following conditions:
- 1191 (i) as part of the commissioning and certification of new facilities and equipment;
- 1192 (ii) following any servicing of facilities and equipment;
- 1193 (iii) as part of the re-certification of facilities and equipment;
- 1194 (iv) in response to identified problems with end products or staff technique; or

1195 (v) in response to issues with compounded sterile preparations, observed compounding personnel  
1196 work practices, or patient-related infections (where the compounded sterile preparation is being  
1197 considered as a potential source of the infection).

1198 (D) Total particle counts. Certification that each ISO classified area (e.g., ISO Class 5, 7, and 8),  
1199 is within established guidelines shall be performed no less than every six months and whenever  
1200 the equipment is relocated or the physical structure of the buffer area or ante-area has been  
1201 altered. All certification records shall be maintained and reviewed to ensure that the controlled  
1202 environments comply with the proper air cleanliness, room pressures, and air changes per hour.  
1203 Testing shall be performed by qualified operators using current, state-of-the-art equipment, with  
1204 results of the following:

1205 (i) ISO Class 5 - not more than 3520 particles 0.5 µm and larger size per cubic meter of air;

1206 (ii) ISO Class 7 - not more than 352,000 particles of 0.5 µm and larger size per cubic meter of air  
1207 for any buffer area; and

1208 (iii) ISO Class 8 - not more than 3,520,000 particles of 0.5 µm and larger size per cubic meter of  
1209 air for any ante-area.

1210 (E) Pressure differential monitoring. A pressure gauge or velocity meter shall be installed to  
1211 monitor the pressure differential or airflow between the buffer area and the ante-area and  
1212 between the ante-area and the general environment outside the compounding area. The results  
1213 shall be reviewed and documented on a log at least every work shift (minimum frequency shall  
1214 be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 and  
1215 the general pharmacy area shall not be less than 0.02 inch water column.

1216 (F) Sampling plan. An appropriate environmental sampling plan shall be developed for airborne  
1217 viable particles based on a risk assessment of compounding activities performed. Selected  
1218 sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class  
1219 7 and 8 areas and in the segregated compounding areas at greatest risk of contamination. The  
1220 plan shall include sample location, method of collection, frequency of sampling, volume of air  
1221 sampled, and time of day as related to activity in the compounding area and action levels.

1222 (G) Viable air sampling. Evaluation of airborne microorganisms using volumetric collection  
1223 methods in the controlled air environments shall be performed by properly trained individuals for  
1224 all compounding risk levels. For low-, medium-, and high-risk level compounding, air sampling  
1225 shall be performed at locations that are prone to contamination during compounding activities  
1226 and during other activities such as staging, labeling, gowning, and cleaning. Locations shall  
1227 include zones of air backwash turbulence within the laminar airflow workbench and other areas  
1228 where air backwash turbulence may enter the compounding area. For low-risk level compounded  
1229 sterile preparations within 12-hour or less beyond-use-date prepared in a primary engineering  
1230 control that maintains an ISO Class 5, air sampling shall be performed at locations inside the ISO  
1231 Class 5 environment and other areas that are in close proximity to the ISO Class 5 environment  
1232 during the certification of the primary engineering control.

1233 (H) Air sampling frequency and process. Air sampling shall be performed at least every 6  
1234 months as a part of the re-certification of facilities and equipment. A sufficient volume of air  
1235 shall be sampled and the manufacturer's guidelines for use of the electronic air sampling  
1236 equipment followed. At the end of the designated sampling or exposure period for air sampling  
1237 activities, the microbial growth media plates are recovered and their covers secured and they are  
1238 inverted and incubated at a temperature and for a time period conducive to multiplication of  
1239 microorganisms. Sampling data shall be collected and reviewed on a periodic basis as a means of  
1240 evaluating the overall control of the compounding environment. If an activity consistently shows  
1241 elevated levels of microbial growth, competent microbiology personnel shall be consulted.

1242 (I) Compounding accuracy checks. Written procedures for double-checking compounding  
1243 accuracy shall be followed for every compounded sterile preparation during preparation and  
1244 immediately prior to release, including label accuracy and the accuracy of the addition of all drug  
1245 products or ingredients used to prepare the finished preparation and their volumes or quantities.  
1246 At each step of the compounding process, the pharmacist shall ensure that components used in  
1247 compounding are accurately weighed, measured, or subdivided as appropriate to conform to the  
1248 formula being prepared.

1249 (14) Quality control.

1250 (A) Quality control procedures. The pharmacy shall follow established quality control  
1251 procedures to monitor the compounding environment and quality of compounded drug  
1252 preparations for conformity with the quality indicators established for the preparation. When  
1253 developing these procedures, pharmacy personnel shall consider the provisions of USP Chapter  
1254 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding--  
1255 Nonsterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--  
1256 Sterile Preparations, Chapter 1075, Good Compounding Practices, and Chapter 1160,  
1257 Pharmaceutical Calculations in Prescription Compounding, and USP Chapter 1163, Quality  
1258 Assurance in Pharmaceutical Compounding of the current USP/NF. Such procedures shall be  
1259 documented and be available for inspection.

1260 (B) Verification of compounding accuracy and sterility.

1261 (i) The accuracy of identities, concentrations, amounts, and purities of ingredients in  
1262 compounded sterile preparations shall be confirmed by reviewing labels on packages, observing  
1263 and documenting correct measurements with approved and correctly standardized devices, and  
1264 reviewing information in labeling and certificates of analysis provided by suppliers.

1265 (ii) If the correct identity, purity, strength, and sterility of ingredients and components of  
1266 compounded sterile preparations cannot be confirmed such ingredients and components shall be  
1267 discarded immediately.

1268 (iii) If individual ingredients, such as bulk drug substances, are not labeled with expiration dates,  
1269 when the drug substances are stable indefinitely in their commercial packages under labeled  
1270 storage conditions, such ingredients may gain or lose moisture during storage and use and shall

1271 require testing to determine the correct amount to weigh for accurate content of active chemical  
1272 moieties in compounded sterile preparations.

1273 (e) Records. Any testing, cleaning, procedures, or other activities required in this subsection shall  
1274 be documented and such documentation shall be maintained by the pharmacy.

1275 (1) Maintenance of records. Every record required under this section must be:

1276 (A) kept by the pharmacy and be available, for at least two years for inspecting and copying by  
1277 the board or its representative and to other authorized local, state, or federal law enforcement  
1278 agencies; and

1279 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas  
1280 State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the  
1281 requested records must be provided in an electronic format. Failure to provide the records set out  
1282 in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to  
1283 keep and maintain records in violation of the Act.

1284 (2) Compounding records.

1285 (A) Compounding pursuant to patient specific prescription drug orders. Compounding records  
1286 for all compounded preparations shall be maintained by the pharmacy electronically or manually  
1287 as part of the prescription drug or medication order, formula record, formula book, or  
1288 compounding log and shall include:

1289 (i) the date of preparation;

1290 (ii) a complete formula, including methodology and necessary equipment which includes the  
1291 brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name  
1292 and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of each;

1293 (iii) signature or initials of the pharmacist or pharmacy technician or pharmacy technician trainee  
1294 performing the compounding;

1295 (iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians or  
1296 pharmacy technician trainees and conducting in-process and finals checks of compounded  
1297 pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the  
1298 compounding function;

1299 (v) the quantity in units of finished preparation or amount of raw materials;

1300 (vi) the container used and the number of units prepared; and

1301 (vii) a reference to the location of the following documentation which may be maintained with  
1302 other records, such as quality control records:

- 1303 (I) the criteria used to determine the beyond-use date; and
- 1304 (II) documentation of performance of quality control procedures.
- 1305 (B) Compounding records when batch compounding or compounding in anticipation of future  
1306 prescription drug or medication orders.
- 1307 (i) Master work sheet. A master work sheet shall be developed and approved by a pharmacist for  
1308 preparations prepared in batch. Once approved, a duplicate of the master work sheet shall be  
1309 used as the preparation work sheet from which each batch is prepared and on which all  
1310 documentation for that batch occurs. The master work sheet shall contain at a minimum:
- 1311 (I) the formula;
- 1312 (II) the components;
- 1313 (III) the compounding directions;
- 1314 (IV) a sample label;
- 1315 (V) evaluation and testing requirements;
- 1316 (VI) specific equipment used during preparation; and
- 1317 (VII) storage requirements.
- 1318 (ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall  
1319 document the following:
- 1320 (I) identity of all solutions and ingredients and their corresponding amounts, concentrations, or  
1321 volumes;
- 1322 (II) lot number for each component;
- 1323 (III) component manufacturer/distributor or suitable identifying number;
- 1324 (IV) container specifications (e.g., syringe, pump cassette);
- 1325 (V) unique lot or control number assigned to batch;
- 1326 (VI) expiration date of batch-prepared preparations;
- 1327 (VII) date of preparation;
- 1328 (VIII) name, initials, or electronic signature of the person(s) involved in the preparation;

- 1329 (IX) name, initials, or electronic signature of the responsible pharmacist;
- 1330 (X) finished preparation evaluation and testing specifications, if applicable; and
- 1331 (XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.
- 1332 (f) Office Use Compounding and Distribution of Sterile Compounded Preparations
- 1333 (1) General.
- 1334 (A) A pharmacy may compound, dispense, deliver, and distribute a compounded sterile  
1335 preparation as specified in Subchapter D, Texas Pharmacy Act Chapter 562.
- 1336 (B) A Class A-S pharmacy is not required to register or be licensed under Chapter 431, Health  
1337 and Safety Code, to distribute sterile compounded preparations to a Class C or Class C-S  
1338 pharmacy.
- 1339 (C) A Class C-S pharmacy is not required to register or be licensed under Chapter 431, Health  
1340 and Safety Code, to distribute sterile compounded preparations that the Class C-S pharmacy has  
1341 compounded for other Class C or Class C-S pharmacies under common ownership.
- 1342 (D) To compound and deliver a compounded preparation under this subsection, a pharmacy  
1343 must:
- 1344 (i) verify the source of the raw materials to be used in a compounded drug;
- 1345 (ii) comply with applicable United States Pharmacopoeia guidelines, including the testing  
1346 requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No.  
1347 104-191);
- 1348 (iii) enter into a written agreement with a practitioner for the practitioner's office use of a  
1349 compounded preparation;
- 1350 (iv) comply with all applicable competency and accrediting standards as determined by the  
1351 board; and
- 1352 (v) comply with the provisions of this subsection.
- 1353 (2) Written Agreement. A pharmacy that provides sterile compounded preparations to  
1354 practitioners for office use or to another pharmacy shall enter into a written agreement with the  
1355 practitioner or pharmacy. The written agreement shall:
- 1356 (A) address acceptable standards of practice for a compounding pharmacy and a practitioner and  
1357 receiving pharmacy that enter into the agreement including a statement that the compounded  
1358 drugs may only be administered to the patient and may not be dispensed to the patient or sold to  
1359 any other person or entity except to a veterinarian as authorized by §563.054 of the Act;

1360 (B) require the practitioner or receiving pharmacy to include on a patient's chart, medication  
1361 order or medication administration record the lot number and beyond-use date of a compounded  
1362 preparation administered to a patient;

1363 (C) describe the scope of services to be performed by the pharmacy and practitioner or receiving  
1364 pharmacy, including a statement of the process for:

1365 (i) a patient to report an adverse reaction or submit a complaint; and

1366 (ii) the pharmacy to recall batches of compounded preparations.

1367 (3) Recordkeeping.

1368 (A) Maintenance of Records.

1369 (i) Records of orders and distribution of sterile compounded preparations to a practitioner for  
1370 office use or to an institutional pharmacy for administration to a patient shall:

1371 (I) be kept by the pharmacy and be available, for at least two years from the date of the record,  
1372 for inspecting and copying by the board or its representative and to other authorized local, state,  
1373 or federal law enforcement agencies;

1374 (II) maintained separately from the records of preparations dispensed pursuant to a prescription  
1375 or medication order; and

1376 (III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas  
1377 State Board of Pharmacy or its representative. If the pharmacy maintains the records in an  
1378 electronic format, the requested records must be provided in an electronic format. Failure to  
1379 provide the records set out in this subsection, either on site or within 72 hours for whatever  
1380 reason, constitutes prima facie evidence of failure to keep and maintain records.

1381 (ii) Records may be maintained in an alternative data retention system, such as a data processing  
1382 system or direct imaging system provided the data processing system is capable of producing a  
1383 hard copy of the record upon the request of the board, its representative, or other authorized  
1384 local, state, or federal law enforcement or regulatory agencies.

1385 (B) Orders. The pharmacy shall maintain a record of all sterile compounded preparations ordered  
1386 by a practitioner for office use or by an institutional pharmacy for administration to a patient.  
1387 The record shall include the following information:

1388 (i) date of the order;

1389 (ii) name, address, and phone number of the practitioner who ordered the preparation and if  
1390 applicable, the name, address and phone number of the institutional pharmacy ordering the  
1391 preparation; and

- 1392 (iii) name, strength, and quantity of the preparation ordered.
- 1393 (C) Distributions. The pharmacy shall maintain a record of all sterile compounded preparations  
1394 distributed pursuant to an order to a practitioner for office use or by an institutional pharmacy for  
1395 administration to a patient. The record shall include the following information:
- 1396 (i) date the preparation was compounded;
- 1397 (ii) date the preparation was distributed;
- 1398 (iii) name, strength and quantity in each container of the preparation;
- 1399 (iv) pharmacy's lot number;
- 1400 (v) quantity of containers shipped; and
- 1401 (vi) name, address, and phone number of the practitioner or institutional pharmacy to whom the  
1402 preparation is distributed.
- 1403 (D) Audit Trail.
- 1404 (i) The pharmacy shall store the order and distribution records of preparations for all sterile  
1405 compounded preparations ordered by and or distributed to a practitioner for office use or by a  
1406 Class S pharmacy for administration to a patient in such a manner as to be able to provide an  
1407 audit trail for all orders and distributions of any of the following during a specified time period:
- 1408 (I) any strength and dosage form of a preparation (by either brand or generic name or both);
- 1409 (II) any ingredient;
- 1410 (III) any lot number;
- 1411 (IV) any practitioner;
- 1412 (V) any facility; and
- 1413 (VI) any pharmacy, if applicable.
- 1414 (ii) The audit trail shall contain the following information:
- 1415 (I) date of order and date of the distribution;
- 1416 (II) practitioner's name, address, and name of the institutional pharmacy, if applicable;
- 1417 (III) name, strength and quantity of the preparation in each container of the preparation;

- 1418 (IV) name and quantity of each active ingredient;
- 1419 (V) quantity of containers distributed; and
- 1420 (VI) pharmacy's lot number.
- 1421 (4) Labeling. The pharmacy shall affix a label to the preparation containing the following  
1422 information:
- 1423 (A) name, address, and phone number of the compounding pharmacy;
- 1424 (B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is  
1425 distributed to a veterinarian the statement: "Compounded Preparation";
- 1426 (C) name and strength of the preparation or list of the active ingredients and strengths;
- 1427 (D) pharmacy's lot number;
- 1428 (E) beyond-use date as determined by the pharmacist using appropriate documented criteria;
- 1429 (F) quantity or amount in the container;
- 1430 (G) appropriate ancillary instructions, such as storage instructions or cautionary statements,  
1431 including hazardous drug warning labels where appropriate; and
- 1432 (H) device-specific instructions, where appropriate.
- 1433 (g) Recall Procedures.
- 1434 (1) The pharmacy shall have written procedures for the recall of any compounded sterile  
1435 preparation provided to a patient, to a practitioner for office use, or a pharmacy for  
1436 administration. Written procedures shall include, but not be limited to the requirements as  
1437 specified in paragraph (3) of this subsection.
- 1438 (2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by  
1439 the pharmacy upon identification of a potential or confirmed harm to a patient.
- 1440 (3) In the event of a recall, the pharmacist-in-charge shall ensure that:
- 1441 (A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is  
1442 notified, in writing, of the recall;
- 1443 (B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;
- 1444 (C) the board is notified of the recall, in writing, not later than 24 hours after the recall is issued;

- 1445 (D) if the preparation is distributed for office use, the Texas Department of State Health  
1446 Services, Drugs and Medical Devices Group, is notified of the recall, in writing;
- 1447 (E) the preparation is quarantined; and
- 1448 (F) the pharmacy keeps a written record of the recall including all actions taken to notify all  
1449 parties and steps taken to ensure corrective measures.
- 1450 (4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if  
1451 there is potential for or confirmed harm to a patient.
- 1452 (5) A pharmacy that compounds sterile preparations shall notify the board immediately of any  
1453 adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially  
1454 attributable to a sterile preparation compounded by the pharmacy.

-----Original Message-----

From: Jeff Carson

Sent: Monday, August 19, 2013 2:08 PM

To: Becky Damon

Subject: Technician ratios in the state of Texas

To whom it may concern,

My family has owned and operated pharmacies in the San Antonio area for over forty years. We have seen a lot of changes in that time, some good and some bad. This is a potential change that could be both. I certainly agree that in today's practice of pharmacy technicians can do a lot of great things and decrease the overall burden to pharmacists. However, there needs to be a limit or that decrease in burden could become an increase in liability. Our pharmacies are what you would call hybrids. We do both conventional pharmacy as well as prescription compounding both sterile and non-sterile. In the regular dispensing pharmacy, there are only so many prescriptions a pharmacist can SAFELY check. At some point, you can have too many technicians producing too many prescriptions for one pharmacist to check. So in this instance, my experience tells me that having more than 4 techs per one pharmacist is about maxed out. I don't see where it is either efficient or safe for technicians to produce more completed, ready to check prescriptions than the pharmacist can check in a reasonable amount of time. This does NOT free up the pharmacist to provide more cognitive services like counseling. It simply pushes more and more prescriptions thru the workflow faster than the pharmacist can do final verifications. Having huge piles of prescriptions waiting final verification sitting around in piles creates a cluttered environment that is more likely to result in a dispensing error than a clean and organized environment.

However, there are other pharmacy environments that could see significant benefit from increased ratios beyond 3 or 4 per pharmacist. For example, long term care specialty pharmacies are quite different from traditional dispensing pharmacies. Since there is very little contact (if any) with the patient, and therefore very little interruptions in the process of final verification being completed by the pharmacist on duty, there would be an appropriate need for say up to 6 technicians per pharmacist. You may even be able to argue for 7. Also, in the pharmacy engaged in compounding both sterile and non-sterile, there could also be some significant advantages. In order to stay compliant with USP guidelines, as well as state and federal guidelines, there are a significant and growing number of continuous quality improvement and control issues that require an ever increasing amount of time to complete and stay up to date with. It would be of significant benefit to have say up to 6 technicians per pharmacist to help with this. But here again, at some point there are just too many technicians producing too much finished product for one pharmacist to keep track of.

At some point more is not better. At some point more is actually dangerous. I just cannot support going from a restricted 3 all the way to unlimited! That just isn't a rational change. I am always for change that improves outcomes. But have we not learned our lessons from the past that too much change too fast leads to human failures?

I am very excited about adding the new class of pharmacy A-S. Let's go one step further and add Class A-NS (non-sterile compounder) and Class A-SNS (sterile and non-sterile compounder) as well as Class-ALTC (long term care specialty). Then we can assign appropriate technician ratios to each category as well as start training our compliance officers in the specific areas of expertise.

In addition, I would also be in support of increased fees with each of these new categories in order to provide more resources to the TSBP in hopes of improving it's ability to regulate in these areas of expertise.

Sincerely,

Jeff Carson, R.Ph.

Chief-of-Staff

Oakdell Pharmacy, Inc.

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[Richie@richiespharmacy.com](mailto:Richie@richiespharmacy.com)

October 22, 2013

Allison Benz, R.Ph., M.S.  
Director of Professional Services  
Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-600  
Austin, Texas 78701

*Via Facsimile (512) 305-8008, Email, and Federal Express*

Re: Proposed amendments to 22 TAC 291.32, 291.33, 291.36, and 291.133

Dear Director Benz:

Richie's Specialty Pharmacy is a specialty compounding pharmacy located in Conroe, Texas. I am writing to submit comments on the Texas State Board of Pharmacy's proposed regulations and amendments cited above, which address Class A pharmacy operations and pharmacy compounding.

I support the designation of a separate class of sterile compounding pharmacy for each existing class of pharmacies.

I support the amendments proposed to 22 TAC 291.32.

My only concern about the proposed amendments to 22 TAC 291.33 is whether the Texas State Board of Pharmacy will actually be able to inspect and issue Class A-S pharmacy licenses to all applicant pharmacies prior to June 1, 2014. If there is a reasonable doubt as to whether the TSBOP can timely inspect and process all such applications by June 1, 2014, I suggest that an applicant pharmacy currently compounding sterile preparations be allowed to continue to do so until such inspection occurs and the pharmacy passes inspection and receives its Class A-S license. If the inspection reveals deficiencies and the pharmacy applicant fails to pass the inspection, then the pharmacy can be ordered to cease compounding sterile products until it receives a Class A-S license. Further, if the pharmacy has never provided compounded sterile medications within the state of Texas, I support the prohibition of such provision until such time as the inspection and issuance of a Class A-S pharmacy license occurs.

Regarding the proposed 22 TAC 291.36, and based on the proposed language in 22 TAC 291.33, it is not clear when there is a change in ownership whether the new owner of a Class A-S pharmacy can continue to operate and compound sterile preparations prior to a new Class A-S license is issued, or whether the new owner must obtain such a license before being able to compound sterile preparations. This should be addressed and resolved in a manner that protects patients but does not result in an arbitrary break in pharmacy services.

I suggest the following revisions to the proposed 22 TAC 291.133:

1. In the definition of Terminal Sterilization, the reference to "10-6" should be 10<sup>n</sup> where "n" is -6.

2. In subsections (c)(2)(B)(iii) (I) and (II), the reference to “clause (i)(II) of this subparagraph” should be changed to “paragraph 4(D) of this subsection”.
3. In subsection (c)(3)(B)(ii) the phrase “for administration to patients” should be stricken.
4. In subsection (c)(3)(B)(iii)(II), the reference to “paragraph (2)(C)” should instead reference “paragraph (2)(B).
5. In subsections (c)(3)(B)(v) (I) and (II), the reference to “clause (ii)(III) of this subparagraph” should be changed to “paragraph 4(D) of this subsection”.
6. In subsection (c)(4)(B), the phrase “preparing sterile preparations” should be added after the phrase “All pharmacy personnel”.
7. In subsection (c)(4)(F), the phrase “media fill tests test indicates” should be changed to “media fill tests indicate”.
8. In subsection (d)(6)(E)(vii), the phrase “ant-area” should be changed to “ante-area”.
9. In subsection (f)(3)(D)(i), the phrase “Class S pharmacy” should be changed to “institutional pharmacy”.

I appreciate both the opportunity to submit comments on these proposed rules and your consideration of our suggested revisions. Please feel free to contact me at 936-588-5601 or by email at [richie@richiespharmacy.com](mailto:richie@richiespharmacy.com) if you have any questions.

Sincerely,



Richie Ray, Registered Pharmacist  
Pharmacist-In-Charge  
President / CEO