

TASK FORCE ON COMPOUNDING OF STERILE PREPARATIONS

FINAL REPORT

**Presented to the Texas State Board of Pharmacy
August 6, 2013**

INTRODUCTION

The Task Force was established by the Texas State Board of Pharmacy to review the current regulations for sterile compounding pharmacies.

The Task Force met three times on January 15, February 20, and April 9, 2013. The Task Force respectfully submits the following recommendations to the Texas State Board of Pharmacy.

RECOMMENDATIONS

- (1) Update definitions to be consistent with USP 797
- (2) Training requirements:
 - (A) Require pharmacists to obtain twenty (20) hours of training from an ACPE accredited provider and twenty (20) hours of on-the-job training in sterile compounding.
 - (B) Require pharmacy technicians to obtain forty (40) hours of training from an ACPE accredited provider and forty (40) hours of on-the-job training in sterile compounding.
 - (C) Pharmacists and pharmacy technicians engaged in low and medium risk sterile compounding must obtain two hours of continuing education credit related to specific areas each renewal period. Pharmacists and pharmacy technicians engaged in high risk compounding must obtain four hours of continuing education credit related to specific areas each renewal period.
- (3) Implement additional USP 797 requirements including testing, sampling, and cleaning procedures.

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1
2 **TITLE 22 EXAMINING BOARDS**
3 **PART 15 TEXAS STATE BOARD OF PHARMACY**
4 **CHAPTER 291 PHARMACIES**
5 **SUBCHAPTER B COMMUNITY PHARMACY (CLASS A)**

6
7 **§291.33 Operational Standards**

8
9 (a) Licensing requirements.

10
11 (1) – (8) (No change.)

12
13 (9) A Class A pharmacy engaged in the compounding of non-sterile preparations shall comply
14 with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile
15 Preparations).

16
17 (10) **A Class A pharmacy shall not begin compounding sterile preparations unless the**
18 **pharmacy is licensed as a Class A-S pharmacy.** [~~A Class A pharmacy engaged in the~~
19 ~~compounding of sterile preparations shall comply with the provisions of §291.133 of this title~~
20 ~~(relating to Pharmacies Compounding Sterile Preparations).]~~

21
22 **(11) Effective September 1, 2014, a Class A pharmacy must discontinue compounding**
23 **sterile preparations and shall be licensed as a Class A-S pharmacy.**

24
25 **(12)** [~~(14)~~] A Class A pharmacy engaged in the provision of remote pharmacy services,
26 including storage and dispensing of prescription drugs, shall comply with the provisions of
27 §291.121 of this title (relating to Remote Pharmacy Services).

28
29 **(13)** [~~(12)~~] Class A pharmacy engaged in centralized prescription dispensing and/or prescription
30 drug or medication order processing shall comply with the provisions of §291.123 of this title
31 (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of
32 this title (relating to Centralized Prescription Dispensing).

33
34 (c) – (i) (No change.)

35
36
37 **§291.36 Pharmacies Compounding Sterile Preparations (Class A-S)**

38
39 **Licensing requirements. A pharmacy engaged in the compounding of sterile**
40 **preparations shall be designated as a Class A-S pharmacy.**

41
42 **(1) A Class A-S pharmacy shall register annually or biennially with the board on a**
43 **pharmacy license application provided by the board, following the procedures as**
44 **specified in §291.1 of this title (relating to Pharmacy License Application). A Class A-S**
45 **license may not be issued unless the pharmacy has been inspected by the board to**
46 **ensure the pharmacy meets the requirements as specified in §291.133 of this chapter**
47 **(relating to Pharmacies Compounding Sterile Preparations).**

48
49 **(2) A Class A-S pharmacy may not renew a pharmacy license unless the pharmacy has**
50 **been inspected by the board.**

52 (3) A Class A-S pharmacy which changes ownership shall notify the board within ten
53 days of the change of ownership and apply for a new and separate license as specified in
54 §291.3 of this title (relating to Required Notifications).

55
56 (4) A Class A-S pharmacy which changes location and/or name shall notify the board
57 within ten days of the change and file for an amended license as specified in §291.3 of
58 this title.

59
60 (5) A Class A-S pharmacy owned by a partnership or corporation which changes
61 managing officers shall notify the board in writing of the names of the new managing
62 officers within ten days of the change, following the procedures as specified in §291.3 of
63 this title.

64
65 (6) A Class A-S pharmacy shall notify the board in writing within ten days of closing,
66 following the procedures as specified in §291.5 of this title (relating to Closing a
67 Pharmacy).

68
69 (7) A separate license is required for each principal place of business and only one
70 pharmacy license may be issued to a specific location.

71
72 (8) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
73 charged for the issuance and renewal of a license and the issuance of an amended
74 license.

75
76 (9) A Class A-S pharmacy which would otherwise be required to be licensed under the
77 Act, §560.051(a)(1) concerning Community Pharmacy (Class A) is required to comply
78 with the provisions of §291.31 of this subchapter (relating to Definitions), §291.32 of this
79 subchapter (relating to Personnel), §291.33 of this subchapter (relating to Operational
80 Standards), §291.34 of this subchapter (relating to Records), §291.35 of this subchapter
81 (relating to Official Prescription Records), and §291.133 of this title (relating to
82 Pharmacies Compounding Sterile Preparations).

83
84 (10) A Class A-S pharmacy engaged in the compounding of non-sterile preparations
85 shall comply with the provisions of §291.131 of this title (relating to Pharmacies
86 Compounding Non-Sterile Preparations).

87
88 (11) A Class A-S pharmacy engaged in the provision of remote pharmacy services,
89 including storage and dispensing of prescription drugs, shall comply with the provisions
90 of §291.121 of this title (relating to Remote Pharmacy Services).

91
92 (12) A Class A-S pharmacy engaged in centralized prescription dispensing and/or
93 prescription drug or medication order processing shall comply with the provisions of
94 §291.123 of this title (relating to Centralized Prescription Drug or Medication Order
95 Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).
96

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER C NUCLEAR PHARMACY (CLASS B)

5
6 **§291.54 Operational Standards**
7

8 (a) Licensing requirements.

9
10 (1) – (10) (No change.)

11
12 (11) A Class B (nuclear) pharmacy engaged in the compounding of non-sterile non-radioactive
13 preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies
14 Compounding Non-Sterile Preparations).

15
16 (12) **A Class B pharmacy shall not begin compounding sterile preparations unless the**
17 **pharmacy is licensed as a Class B-S pharmacy.** [~~A Class B (nuclear) pharmacy engaged in~~
18 ~~the compounding of sterile non-radioactive preparations shall comply with the provisions of~~
19 ~~§291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).]~~

20
21 (b) – (i) (No change.)
22
23

24 **§291.56 Pharmacies Compounding Sterile Preparations (Class B-S)**
25

26 **Licensing requirements. A pharmacy engaged in the compounding of sterile**
27 **preparations shall be designated as a Class B-S pharmacy.**

28
29 **(1) It is unlawful for a person to provide radioactive drug services unless such provision**
30 **is performed by a person licensed to act as an authorized nuclear pharmacist, as defined**
31 **by the board, or is a person acting under the direct supervision of an authorized nuclear**
32 **pharmacist acting in accordance with the Act and its rules, and the regulations of the**
33 **Texas Department of State Health Services, Radiation Control Program. Subsection (a) of**
34 **this section does not apply to:**

35 **(A) a licensed practitioner or his or her designated agent for administration to his or**
36 **her patient, provided no person may receive, possess, use, transfer, own, acquire, or**
37 **dispose of radiopharmaceuticals except as authorized in a specific or a general license**
38 **as provided in accordance with the requirements of the Texas Department of State Health**
39 **Services, Radiation Control Program, Texas Administrative Code, Title 25, Part 1,**
40 **Subchapter F, §289.252 relating to Licensing of Radioactive Material, or the Act;**

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

45
46 **(2) An applicant for a Class B-S pharmacy shall provide evidence to the board of the**
47 **possession of a Texas Department of State Health Services radioactive material license**
48 **or proof of application for a radioactive material license.**

49
50 **(3) A Class B-S pharmacy shall register annually or biennially with the board on a**
51 **pharmacy license application provided by the board, following the procedures as**

52 specified in §291.1 of this title (relating to Pharmacy License Application). A Class B-S
53 license may not be issued unless the pharmacy has been inspected by the board to
54 ensure the pharmacy meets the requirements as specified in §291.133 of this chapter
55 (relating to Pharmacies Compounding Sterile Preparations).

56
57 (4) A Class B-S pharmacy may not renew a pharmacy license unless the pharmacy has
58 been inspected by the board.

59
60 (5) A Class B-S pharmacy which changes ownership shall notify the board within ten
61 days of the change of ownership and apply for a new and separate license as specified in
62 §291.3 of this title (relating to Required Notifications).

63
64 (6) A Class B-S pharmacy which changes location and/or name shall notify the board
65 within ten days of the change and file for an amended license as specified in §291.3 of
66 this title.

67
68 (7) A Class B-S pharmacy owned by a partnership or corporation which changes
69 managing officers shall notify the board in writing of the names of the new managing
70 officers within ten days of the change, following the procedures as specified in §291.3 of
71 this title.

72
73 (8) A Class B-S pharmacy shall notify the board in writing within ten days of closing,
74 following the procedures as specified in §291.5 of this title (relating to Closing a
75 Pharmacy).

76
77 (9) A separate license is required for each principal place of business and only one
78 pharmacy license may be issued to a specific location.

79
80 (10) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
81 charged for the issuance and renewal of a license and the issuance of an amended
82 license.

83
84 (11) A Class B-S pharmacy which would otherwise be required to be licensed under the
85 Act, §560.051(a)(1) concerning Community Pharmacy (Class A) is required to comply
86 with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title
87 (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of
88 this title (relating to Records), and §291.35 of this title (relating to Official Prescription
89 Records), and §291.133 of this title (relating to Pharmacies Compounding Sterile
90 Preparations).

91
92 (12) A Class B-S pharmacy engaged in the compounding of non-sterile preparations
93 shall comply with the provisions of §291.131 of this title (relating to Pharmacies
94 Compounding Non-Sterile Preparations).

95
96 (13) A Class B-S pharmacy engaged in the provision of remote pharmacy services,
97 including storage and dispensing of prescription drugs, shall comply with the provisions
98 of §291.121 of this title (relating to Remote Pharmacy Services).

99
100 (14) A Class B-S pharmacy engaged in centralized prescription dispensing and/or
101 prescription drug or medication order processing shall comply with the provisions of

102 **§291.123 of this title (relating to Centralized Prescription Drug or Medication Order**
103 **Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).**
104

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER D INSTITUTIONAL PHARMACY (CLASS C)

5
6 **§291.74 Operational Standards**
7

8 (a) Licensing requirements.
9

10 (1) – (9) (No change.)
11

12 (10) A Class C ~~[(Institutional)]~~ pharmacy engaged in the compounding of non-sterile
13 preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies
14 Compounding Non-sterile Preparations).
15

16 (11) **A Class C pharmacy shall not begin compounding sterile preparations unless the**
17 **pharmacy is licensed as a Class C-S pharmacy.** ~~[A Class C (Institutional) pharmacy~~
18 ~~engaged in the compounding of sterile preparations shall comply with the provisions of~~
19 ~~§291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).]~~
20

21 **(12) Effective September 1, 2014, a Class C pharmacy must discontinue compounding**
22 **sterile preparations and shall be licensed as a Class C-S pharmacy.**
23

24 **(13)** ~~[(12)]~~ A Class C ~~[(Institutional)]~~ pharmacy engaged in the provision of remote pharmacy
25 services, including storage and dispensing of prescription drugs, shall comply with the
26 provisions of §291.121 of this title (relating to Remote Pharmacy Services).
27

28 **(14)** ~~[(13)]~~ A Class C ~~[(Institutional)]~~ pharmacy engaged in centralized prescription dispensing
29 and/or prescription drug or medication order processing shall comply with the provisions of
30 §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing)
31 and/or §291.125 of this title (relating to Centralized Prescription Dispensing).
32

33 **(15)** ~~[(14)]~~ A Class C ~~[(Institutional)]~~ pharmacy with an ongoing clinical pharmacy program that
34 proposes to allow a pharmacy technician to verify the accuracy of work performed by another
35 pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a
36 patient admitted to the hospital if the patient's orders have previously been reviewed and
37 approved by a pharmacist shall make application to the board as follows.
38

39 (A) The pharmacist-in-charge must submit an application on a form provided by the board,
40 containing the following information:
41

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

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

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

45 (iv) anticipated date the pharmacy plans to begin allowing a pharmacy technician to verify
46 the accuracy of work performed by another pharmacy technician;
47

48 (v) documentation that the pharmacy has an ongoing clinical pharmacy program; and
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52
53 (vi) any other information specified on the application.
54

55 (B) The pharmacy may not allow a pharmacy technician to check the work of another
56 pharmacy technician until the board has reviewed and approved the application and issued an
57 amended license to the pharmacy.
58

59 (C) Every two years, in connection with the application for renewal of the pharmacy license,
60 the pharmacy shall provide updated documentation that the pharmacy continues to have an
61 ongoing clinical pharmacy program as specified in subparagraph (A)(v) of this paragraph.
62

63 **(16)** ~~[(15)]~~ A rural hospital that wishes to allow a pharmacy technician to perform the duties
64 specified in §291.73(e)(2)(D) of this title (relating to Personnel), shall make application to the
65 board as follows.
66

67 ~~[(A) For an initial applications prior to September 1, 2010, the pharmacist-in-charge must~~
68 ~~submit a letter to the board containing the following information:~~
69

70 ~~—(i) name, address, and pharmacy license number;~~
71

72 ~~—(ii) name and license number of the pharmacist-in-charge;~~
73

74 ~~—(iii) name and registration number of the pharmacy technicians;~~
75

76 ~~—(iv) a statement indicating that pharmacy technicians will be performing the duties specified~~
77 ~~in §291.73(e)(2)(D) of this title; and~~
78

79 ~~—(v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural~~
80 ~~hospital is either:~~
81

82 ~~—(I) located in a county with a population of 50,000 or less as defined by the United States~~
83 ~~Census Bureau in the most recent U.S. census; or~~
84

85 ~~—(II) designated by the Centers for Medicare and Medicaid Services as a critical access~~
86 ~~hospital, rural-referral center, or sole community hospital.]~~
87

88 **(A)** ~~[(B) After September 1, 2010 and prior]~~ **Prior** to allowing a pharmacy technician to perform
89 the duties specified in §291.73(e)(2)(D) of this title, the pharmacist-in-charge must submit an
90 application on a form provided by the board, containing the following information:
91

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

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

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

95
96 (iv) proposed date the pharmacy wishes to start allowing pharmacy technicians to perform
97 the duties specified in §291.73(e)(2)(D) of this title;
98

99 (v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural
100 hospital is either:
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(I) located in a county with a population of 50,000 or less as defined by the United States Census Bureau in the most recent U.S. census; or

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

(vi) any other information specified on the application.

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

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

(b) – (j) (No change.)

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

(a) – (c) (No change.)

(d) Operational standards.

(1) Licensing requirements.

(A) – (I) (No change.)

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

(K) An ASC pharmacy shall not begin compounding sterile preparations unless the pharmacy is licensed as a Class C-S pharmacy. ~~[An ASC pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133 of this title.]~~

(L) Effective September 1, 2014, an ASC pharmacy must discontinue compounding sterile preparations and shall be licensed as a Class C-S pharmacy.

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

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

(2) – (9) (No change.)

154 (e) (No change.)

155
156 **§291.77 Pharmacies Compounding Sterile Preparations (Class C-S)**

157
158 Licensing requirements. A pharmacy engaged in the compounding of sterile
159 preparations shall be designated as a Class C-S pharmacy.

160
161 (1) A Class C-S pharmacy shall register annually or biennially with the board on a
162 pharmacy license application provided by the board, following the procedures specified
163 in §291.1 of this title (relating to Pharmacy License Application). A Class C-S license
164 may not be issued unless the pharmacy has been inspected by the board to ensure the
165 pharmacy meets the requirements as specified in §291.133 of this chapter (relating to
166 Pharmacies Compounding Sterile Preparations).

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

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

173
174 (A) The pharmacy license application shall list the hospital management or consulting
175 firm as the owner or operator.

176
177 (B) The hospital management or consulting firm shall obtain DEA and DPS controlled
178 substance registrations that are issued in their name, unless the following occurs:

179
180 (i) the hospital management or consulting firm and the facility cosign a contractual
181 pharmacy service agreement which assigns overall responsibility for controlled
182 substances to the facility; and

183
184 (ii) such hospital pharmacy management or consulting firm maintains dual
185 responsibility for the controlled substances.

186
187 (4) A Class C-S pharmacy which changes ownership shall notify the board within 10
188 days of the change of ownership and apply for a new and separate license as specified in
189 §291.3 of this title (relating to Required Notifications).

190
191 (5) A Class C-S pharmacy which changes location and/or name shall notify the board
192 within 10 days of the change and file for an amended license as specified in §291.3 of
193 this title.

194
195 (6) A Class C-S pharmacy owned by a partnership or corporation which changes
196 managing officers shall notify the board in writing of the names of the new managing
197 officers within 10 days of the change following the procedures in §291.3 of this title.

198
199 (7) A Class C-S pharmacy shall notify the board in writing within 10 days of closing,
200 following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

201
202 (8) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
203 charged for the issuance and renewal of a license and the issuance of an amended
204 license.

205
206 (9) A separate license is required for each principal place of business and only one
207 pharmacy license may be issued to a specific location.
208

209 (10) A Class C-S pharmacy, licensed under the Act, §560.051(a)(3), which also operates
210 another type of pharmacy which would otherwise be required to be licensed under the
211 Act, §560.051(a)(1) (Community Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear
212 Pharmacy (Class B)), is not required to secure a license for the such other type of
213 pharmacy; provided, however, such licensee is required to comply with the provisions of
214 §291.31 of this subchapter (relating to Definitions), §291.32 of this subchapter (relating to
215 Personnel), §291.33 of this subchapter (relating to Operational Standards), §291.34 of this
216 subchapter (relating to Records), and §291.35 of this subchapter (relating to Official
217 Prescription Records), contained in Community Pharmacy (Class A), or §291.51 of this
218 title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title
219 (relating to Personnel), §291.54 of this title (relating to Operational Standards), and
220 §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the
221 extent such sections are applicable to the operation of the pharmacy.
222

223 (11) A Class C-S pharmacy engaged in the compounding of non-sterile preparations
224 shall comply with the provisions of §291.131 of this title (relating to Pharmacies
225 Compounding Non-sterile Preparations).
226

227 (12) A Class C-S pharmacy engaged in the provision of remote pharmacy services,
228 including storage and dispensing of prescription drugs, shall comply with the provisions
229 of §291.121 of this title (relating to Remote Pharmacy Services).
230

231 (13) A Class C-S pharmacy engaged in centralized prescription dispensing and/or
232 prescription drug or medication order processing shall comply with the provisions of
233 §291.123 of this title (relating to Central Prescription Drug or Medication Order
234 Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).
235

236 (14) A Class C-S pharmacy with an ongoing clinical pharmacy program that proposes to
237 allow a pharmacy technician to verify the accuracy of work performed by another
238 pharmacy technician relating to the filling of floor stock and unit dose distribution
239 systems for a patient admitted to the hospital if the patient's orders have previously been
240 reviewed and approved by a pharmacist shall make application to the board as follows.
241

242 (A) The pharmacist-in-charge must submit an application on a form provided by the
243 board, containing the following information:
244

245 (i) name, address, and pharmacy license number;
246

247 (ii) name and license number of the pharmacist-in-charge;
248

249 (iii) name and registration numbers of the pharmacy technicians;
250

251 (iv) anticipated date the pharmacy plans to begin allowing a pharmacy technician to
252 verify the accuracy of work performed by another pharmacy technician;
253

254 (v) documentation that the pharmacy has an ongoing clinical pharmacy program; and
255

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

257

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

261

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

266

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

270

271 (A) Prior to allowing a pharmacy technician to perform the duties specified in
272 §291.73(e)(2)(D) of this title, the pharmacist-in-charge must submit an application on a
273 form provided by the board, containing the following information:

274

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

276

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

278

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

280

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

283

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

286

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

289

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

292

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

294

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

298

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

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER F NON-RESIDENT PHARMACY (CLASS E)

5
6 **§291.104 Operational Standards**

7
8 (a) Licensing requirements.

9
10 (1) – (12) (No change.)

11
12 (13) A Class E (Non-Resident) pharmacy engaged in the compounding of non-sterile
13 preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies
14 Compounding Non-Sterile Preparations).

15
16 (14) **A Class E pharmacy shall not begin compounding sterile preparations unless the**
17 **pharmacy is licensed as a Class E-S pharmacy.** [~~A Class E (Non-Resident) pharmacy~~
18 ~~engaged in the compounding of sterile preparations shall comply with the provisions of~~
19 ~~§291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).]~~

20
21 **(15) Effective September 1, 2014, a Class E pharmacy must discontinue compounding**
22 **sterile preparations and shall be licensed as a Class E-S pharmacy.**

23
24 (b) – (f) (No change.)

25
26
27 **§291.106 Pharmacies Compounding Sterile Preparations (Class E-S)**

28
29 **Licensing requirements. A pharmacy engaged in the compounding of sterile**
30 **preparations shall be designated as a Class E-S pharmacy.**

31
32 **(1) A Class E-S pharmacy shall register with the board on a pharmacy license application**
33 **provided by the board, following the procedures specified in §291.1 of this title (relating**
34 **to Pharmacy License Application).**

35
36 **(2) A Class E-S license may not be issued unless the pharmacy has been inspected by**
37 **the board or its designee to ensure the pharmacy meets the requirements as specified in**
38 **§291.133 of this chapter (relating to Pharmacies Compounding Sterile Preparations). A**
39 **Class E-S pharmacy shall reimburse the board for all expenses, including travel, related**
40 **to the inspection of the Class E-S pharmacy.**

41
42 **(3) On initial application, the pharmacy shall follow the procedures specified in §291.1 of**
43 **this title (relating to Pharmacy License Application) and then provide the following**
44 **additional information specified in §560.052(c) and (f) of the Act (relating to**
45 **Qualifications):**

46
47 **(A) evidence that the applicant holds a pharmacy license, registration, or permit issued**
48 **by the state in which the pharmacy is located;**

49
50 **(B) the name of the owner and pharmacist-in-charge of the pharmacy for service of**
51 **process;**

52
53 (C) evidence of the applicant's ability to provide to the board a record of a prescription
54 drug order dispensed by the applicant to a resident of this state not later than 72 hours
55 after the time the board requests the record;

56
57 (D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read
58 and understands the laws and rules relating to a Class E pharmacy; and

59
60 (E) proof of creditworthiness.

61
62 (4) A Class E-S pharmacy may not renew a pharmacy license unless the pharmacy
63 has been inspected by the board or its designee within the last 2 years.

64
65 (5) A Class E-S pharmacy which changes ownership shall notify the board within ten
66 days of the change of ownership and apply for a new and separate license as specified in
67 §291.3 of this title (relating to Required Notifications).

68
69 (6) A Class E-S pharmacy which changes location and/or name shall notify the board
70 within ten days of the change and file for an amended license as specified in §291.3 of
71 this title.

72
73 (7) A Class E-S pharmacy owned by a partnership or corporation which changes
74 managing officers shall notify the board in writing of the names of the new managing
75 officers within ten days of the change, following the procedures in §291.3 of this title.

76
77 (8) A Class E-S pharmacy shall notify the board in writing within ten days of closing.

78
79 (9) A separate license is required for each principal place of business and only one
80 pharmacy license may be issued to a specific location.

81
82 (10) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
83 charged for the issuance and renewal of a license and the issuance of an amended
84 license.

85
86 (11) The board may grant an exemption from the licensing requirements of this Act on
87 the application of a pharmacy located in a state of the United States other than this state
88 that restricts its dispensing of prescription drugs or devices to residents of this state to
89 isolated transactions.

90
91 (12) A Class E-S pharmacy engaged in the centralized dispensing of prescription drug
92 or medication orders shall comply with the provisions of §291.125 of this title (relating to
93 Centralized Prescription Dispensing).

94
95 (13) A Class E-S pharmacy engaged in central processing of prescription drug or
96 medication orders shall comply with the provisions of §291.123 of this title (relating to
97 Central Prescription or Medication Order Processing).

98
99 (14) A Class E (Non-Resident) pharmacy engaged in the compounding of non-sterile
100 preparations shall comply with the provisions of §291.131 of this title (relating to
101 Pharmacies Compounding Non-Sterile Preparations).

§291.133 Pharmacies Compounding Sterile Preparations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 52
- 53 (5) Aseptic Processing-- A mode of processing pharmaceutical and medical preparations that
54 involves the separate sterilization of the preparation and of the package (containers--closures or
55 packaging material for medical devices) and the transfer of the preparation into the container
56 and its closure under at least ISO Class 5 conditions.
- 57
- 58 (6) Automated compounding device--An automated device that compounds, measures, and/or
59 packages a specified quantity of individual components in a predetermined sequence for a
60 designated sterile preparation.
- 61
- 62 (7) Batch--A specific quantity of a drug or other material that is intended to have uniform
63 character and quality, within specified limits, and is produced during a single preparation cycle.
- 64
- 65 (8) Batch preparation compounding--Compounding of multiple sterile preparation units, in a
66 single discrete process, by the same individual(s), carried out during one limited time period.
67 Batch preparation/compounding does not include the preparation of multiple sterile preparation
68 units pursuant to patient specific medication orders.
- 69
- 70 (9) Beyond-use date--The date or time after which the compounded sterile preparation shall
71 not be stored or transported or begin to be administered to a patient. The beyond-use date is
72 determined from the date or time the preparation is compounded.
- 73
- 74 (10) Biological Safety Cabinet, Class II--A ventilated cabinet for personnel, product or
75 preparation, and environmental protection having an open front with inward airflow for personnel
76 protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered
77 exhausted air for environmental protection.
- 78
- 79 (11) Buffer Area--An ISO Class 7 area where the primary engineering control area is physically
80 located. Activities that occur in this area include the preparation and staging of components and
81 supplies used when compounding sterile preparations.
- 82
- 83 (12) Clean room--A room in which the concentration of airborne particles is controlled to meet
84 a specified airborne particulate cleanliness class. Microorganisms in the environment are
85 monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a
86 specified cleanliness class.
- 87
- 88 (13) Component--Any ingredient intended for use in the compounding of a drug preparation,
89 including those that may not appear in such preparation.
- 90
- 91 (14) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or
92 device:
- 93
- 94 (A) as the result of a practitioner's prescription drug or medication order based on the
95 practitioner-patient-pharmacist relationship in the course of professional practice;
- 96
- 97 (B) for administration to a patient by a practitioner as the result of a practitioner's initiative
98 based on the practitioner-patient-pharmacist relationship in the course of professional practice;
- 99
- 100 (C) in anticipation of prescription drug or medication orders based on routine, regularly
101 observed prescribing patterns; or
102

103 (D) for or as an incident to research, teaching, or chemical analysis and not for sale or
104 dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.
105

106 (15) Compounding Aseptic Isolator--A form of barrier isolator specifically designed for
107 compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic
108 compounding environment within the isolator throughout the compounding and material transfer
109 processes. Air exchange into the isolator from the surrounding environment shall not occur
110 unless it has first passed through a microbial retentive filter (HEPA minimum).
111

112 (16) Compounding Aseptic Containment Isolator--A compounding aseptic isolator designed to
113 provide worker protection from exposure to undesirable levels of airborne drug throughout the
114 compounding and material transfer processes and to provide an aseptic environment for
115 compounding sterile preparations. Air exchange with the surrounding environment should not
116 occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system
117 capable of containing airborne concentrations of the physical size and state of the drug being
118 compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator
119 should be appropriately removed by properly designed building ventilation.
120

121 (17) Critical Area—An ISO Class 5 environment.
122

123 (18) Critical Sites-- A location that includes any component or fluid pathway surfaces (e.g., vial
124 septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at
125 risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and
126 mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the
127 critical site increases with the size of the openings and exposure time.
128

129 (19) Device--An instrument, apparatus, implement, machine, contrivance, implant, in-vitro
130 reagent, or other similar or related article, including any component part or accessory, that is
131 required under federal or state law to be ordered or prescribed by a practitioner.
132

133 (20) Direct Compounding Area--A critical area within the ISO Class 5 primary engineering
134 control where critical sites are exposed to unidirectional HEPA-filtered air, also known as first
135 air.
136

137 (21) Disinfectant—An agent that frees from infection, usually a chemical agent but sometimes
138 a physical one, and that destroys disease-causing pathogens or other harmful microorganisms
139 but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.
140

141 (22) First Air--The air exiting the HEPA filter in a unidirectional air stream that is essentially
142 particle free.
143

144 (23) Hazardous Drugs—Drugs that, studies in animals or humans indicate exposure to the
145 drugs, have a potential for causing cancer, development or reproductive toxicity, or harm to
146 organs.
147

148 (24) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum
149 of 105 degrees F (41 degrees C).
150

151 (25) HVAC--Heating, ventilation, and air conditioning.
152

153 (26) Immediate use--A sterile preparation that is not prepared according to USP 797 standards
154 (i.e. outside the pharmacy and most likely not by pharmacy personnel) which shall be stored for
155 no longer than one hour after completion of the preparation.

156
157 (27) IPA--Isopropyl alcohol (2-propanol).

158
159 (28) Labeling—All labels and other written, printed, or graphic matter on an immediate
160 container of an article or preparation or on, or in, any package or wrapper in which it is
161 enclosed, except any outer shipping container. The term “label” designates that part of the
162 labeling on the immediate container.

163
164 (29) Media-Fill Test--A test used to qualify aseptic technique of compounding personnel or
165 processes and to ensure that the processes used are able to produce sterile preparation without
166 microbial contamination. During this test, a microbiological growth medium such as Soybean--
167 Casein Digest Medium is substituted for the actual drug preparation to simulate admixture
168 compounding. The issues to consider in the development of a media-fill test are the following:
169 media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection
170 of filled units, documentation, interpretation of results, and possible corrective actions required.

171
172 (30) Multiple-Dose Container--A multiple-unit container for articles or preparations intended for
173 potential administration only and usually contains antimicrobial preservatives. The beyond-use
174 date for an opened or entered (e.g., needle-punctured) multiple-dose container with
175 antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.

176
177 (31) Negative Pressure Room--A room that is at a lower pressure compared to adjacent
178 spaces and, therefore, the net flow of air is into the room.

179
180 (32) Office use--The administration of a compounded drug to a patient by a practitioner in the
181 practitioner's office or by the practitioner in a health care facility or treatment setting, including a
182 hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 562 of the Act, or
183 for administration or provision by a veterinarian in accordance with §563.054 of the Act.

184
185 (33) Pharmacy Bulk Package--A container of a sterile preparation for potential use that
186 contains many single doses. The contents are intended for use in a pharmacy admixture
187 program and are restricted to the preparation of admixtures for infusion or, through a sterile
188 transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one
189 time after constitution with a suitable sterile transfer device or dispensing set, which allows
190 measured dispensing of the contents. The pharmacy bulk package is to be used only in a
191 suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).

192
193 (34) Prepackaging--The act of repackaging and relabeling quantities of drug products from a
194 manufacturer's original container into unit dose packaging or a multiple dose container for
195 distribution within a facility licensed as a Class C pharmacy or to other pharmacies under
196 common ownership for distribution within those facilities. The term as defined does not prohibit
197 the prepackaging of drug products for use within other pharmacy classes.

198
199 (35) Preparation or Compounded Sterile Preparation--A sterile admixture compounded in a
200 licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed
201 prescriber. The components of the preparation may or may not be sterile products.

202

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

207
208 (37) Product--A commercially manufactured sterile drug or nutrient that has been evaluated for
209 safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are accompanied
210 by full prescribing information, which is commonly known as the FDA-approved manufacturer's
211 labeling or product package insert.

212
213 (38) Positive Control--A quality assurance sample prepared to test positive for microbial
214 growth.

215
216 (39) Positive Pressure Room--A room that is at a higher pressure compared to adjacent
217 spaces and, therefore, the net airflow is out of the room.

218
219 (40) Quality assurance--The set of activities used to ensure that the process used in the
220 preparation of sterile drug preparations lead to preparations that meet predetermined standards
221 of quality.

222
223 (41) Quality control--The set of testing activities used to determine that the ingredients,
224 components (e.g., containers), and final compounded sterile preparations prepared meet
225 predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.

226
227 (42) Reasonable quantity--An amount of a compounded drug that:

228
229 (A) does not exceed the amount a practitioner anticipates may be used in the practitioner's
230 office or facility before the beyond use date of the drug;

231
232 (B) is reasonable considering the intended use of the compounded drug and the nature of the
233 practitioner's practice; and

234
235 (C) for any practitioner and all practitioners as a whole, is not greater than an amount the
236 pharmacy is capable of compounding in compliance with pharmaceutical standards for identity,
237 strength, quality, and purity of the compounded drug that are consistent with United States
238 Pharmacopoeia guidelines and accreditation practices.

239
240 (43) Segregated Compounding Area--A designated space, either a demarcated area or room,
241 that is restricted to preparing low-risk level compounded sterile preparations with 12-hour or less
242 beyond-use date. Such area shall contain a device that provides unidirectional airflow of ISO
243 Class 5 air quality for preparation of compounded sterile preparations and shall be void of
244 activities and materials that are extraneous to sterile compounding.

245
246 (44) Single-dose container—A single-unit container for articles or preparations intended for
247 parenteral administration only. It is intended for a single use. A single-dose container is labeled
248 as such. Examples of single-dose containers include pre-filled syringes, cartridges, fusion-
249 sealed containers, and closure-sealed containers when so labeled.

250
251 (45) SOPs--Standard operating procedures.

252

253 (46) Sterilizing Grade Membranes— Membranes that are documented to retain 100% of a
254 culture of 107 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta per
255 square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such
256 filter membranes are nominally at 0.22-µm or 0.2-µm nominal pore size, depending on the
257 manufacturer's practice.

258
259 (47) Sterilization by Filtration— Passage of a fluid or solution through a sterilizing grade
260 membrane to produce a sterile effluent.

261
262 (48) Terminal Sterilization--The application of a lethal process, e.g., steam under pressure or
263 autoclaving, to sealed final preparation containers for the purpose of achieving a predetermined
264 sterility assurance level of usually less than 10⁻⁶ or a probability of less than one in one million of
265 a non-sterile unit.

266
267 (49) Unidirectional Flow--An airflow moving in a single direction in a robust and uniform
268 manner and at sufficient speed to reproducibly sweep particles away from the critical processing
269 or testing area.

270
271 (50) USP/NF--The current edition of the United States Pharmacopeia/National Formulary.

272
273 (c) Personnel.

274
275 (1) Pharmacist-in-charge.

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

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

283
284 (i) developing a system to ensure that all pharmacy personnel responsible for compounding
285 and/or supervising the compounding of sterile preparations within the pharmacy receive
286 appropriate education and training and competency evaluation;

287
288 (ii) determining that all personnel involved in compounding sterile preparations obtain
289 continuing education appropriate for the type of compounding done by the personnel;

290
291 (iii) supervising a system to ensure appropriate procurement of drugs and devices and
292 storage of all pharmaceutical materials including pharmaceuticals, components used in the
293 compounding of sterile preparations, and drug delivery devices;

294
295 (iv) ensuring that the equipment used in compounding is properly maintained;

296
297 (v) developing a system for the disposal and distribution of drugs from the pharmacy;

298
299 (vi) developing a system for bulk compounding or batch preparation of drugs;

300
301 (vii) developing a system for the compounding, sterility assurance, quality assurance, and
302 quality control of sterile preparations; and

303 (viii) if applicable, ensuring that the pharmacy has a system to dispose of hazardous waste
304 in a manner so as not to endanger the public health.

305
306 (2) Pharmacists.

307
308 (A) General.

309
310 (i) A pharmacist is responsible for ensuring that compounded sterile preparations are
311 accurately identified, measured, diluted, and mixed and are correctly purified, sterilized,
312 packaged, sealed, labeled, stored, dispensed, and distributed.

313
314 (ii) A pharmacist shall inspect and approve all components, drug preparation containers,
315 closures, labeling, and any other materials involved in the compounding process.

316
317 (iii) A pharmacist shall review all compounding records for accuracy and conduct in-process
318 and final checks and verification of calculations to ensure that errors have not occurred in the
319 compounding process.

320
321 (iv) A pharmacist is responsible for ensuring the proper maintenance, cleanliness, and use
322 of all equipment used in the compounding process.

323
324 (v) A pharmacist shall be accessible at all times, 24 hours a day, to respond to patients' and
325 other health professionals' questions and needs.

326
327 (B) Initial training and continuing education.

328
329 (i) All pharmacists who compound sterile preparations or supervise pharmacy technicians
330 and pharmacy technician trainees compounding sterile preparations shall comply with the
331 following:

332
333 (I) complete through a single course, a minimum of 20 hours of instruction and experience
334 in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through
335 completion of a recognized course in an accredited college of pharmacy or a course sponsored
336 by an ACPE accredited provider which provides 20 hours of instruction and experience in the
337 areas listed in paragraph (4)(D);

338
339 (II) complete a structured on-the-job didactic and experiential training program at this
340 pharmacy which provides 20 hours of instruction and experience in the areas listed in paragraph
341 (4)(D) of this subsection. Such training may not be transferred to another pharmacy unless the
342 pharmacies are under common ownership and control and use a common training program; and

343
344 (III) possess knowledge about:

345
346 (-a-) aseptic processing;

347
348 (-b-) quality control and quality assurance as related to environmental, component, and
349 finished preparation release checks and tests;

350
351 (-c-) chemical, pharmaceutical, and clinical properties of drugs;

352
353 (-d-) container, equipment, and closure system selection; and

354
355 (-e-) sterilization techniques.

356
357 (ii) The required experiential portion of the training programs specified in this subparagraph
358 must be supervised by an individual who is actively engaged in performing sterile compounding
359 and is qualified and has completed training as specified in paragraph (2) or (3) of this
360 subsection.

361
362 (iii) In order to renew a license to practice pharmacy, during the previous licensure period, a
363 pharmacist engaged in sterile compounding shall complete a minimum of:

364
365 (I) two hours of ACPE-accredited continuing education relating to the areas listed in clause
366 (i)(II) of this subparagraph if the pharmacist is engaged in compounding low and medium risk
367 sterile preparations; or

368
369 (II) four hours of ACPE-accredited continuing education relating to the areas listed in clause
370 (i)(II) of this subparagraph if the pharmacist is engaged in compounding high risk sterile
371 preparations.

372
373 (3) Pharmacy technicians and pharmacy technician trainees.

374
375 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the
376 training requirements specified in §297.6 of this title (relating to Pharmacy Technician and
377 Pharmacy Technician Trainee Training).

378
379 (B) Initial training and continuing education.

380
381 (i) Pharmacy technicians and pharmacy technician trainees may compound sterile
382 preparations provided the pharmacy technicians and/or pharmacy technician trainees are
383 supervised by a pharmacist who has completed the training specified in paragraph (4)(D) of this
384 subsection, conducts in-process and final checks, and affixes his or her initials to the
385 appropriate quality control records.

386
387 (ii) All pharmacy technicians and pharmacy technician trainees who compound sterile
388 preparations for administration to patients shall comply with the following:

389
390 (I) complete through completion of a single course, a minimum of 40 hours of instruction
391 and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be
392 obtained through completion of a course sponsored by an ACPE accredited provider which
393 provides 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this
394 subsection;

395
396 (II) complete a structured on-the-job didactic and experiential training program at this
397 pharmacy which provides 40 hours of instruction and experience in the areas listed in paragraph
398 (4)(D) of this subsection. Such training may not be transferred to another pharmacy unless the
399 pharmacies are under common ownership and control and use a common training program; and

400
401 (III) possess knowledge about:

402
403 (-a-) aseptic processing;

404

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

407
408 (-c-) chemical, pharmaceutical, and clinical properties of drugs;

409
410 (-d-) container, equipment, and closure system selection; and

411
412 (-e-) sterilization techniques.

413
414 (iii) Individuals enrolled in training programs accredited by the American Society of Health-
415 System Pharmacists may compound sterile preparations in a licensed pharmacy provided:

416
417 (I) the compounding occurs only during times the individual is assigned to a pharmacy as
418 a part of the experiential component of the American Society of Health-System Pharmacists
419 training program;

420
421 (II) the individual is under the direct supervision of and responsible to a pharmacist who
422 has completed training as specified in paragraph (2)(C) of this subsection; and

423
424 (III) the supervising pharmacist conducts in-process and final checks.

425
426 (iv) The required experiential portion of the training programs specified in this subparagraph
427 must be supervised by an individual who is actively engaged in performing sterile compounding,
428 is qualified and has completed training as specified in paragraph (2) or (3) of this subsection.

429
430 (v) In order to renew a registration as a pharmacy technician, during the previous registration
431 period, a pharmacy technician engaged in sterile compounding shall complete a minimum of:

432
433 (I) two hours of ACPE accredited continuing education relating to the areas listed in clause
434 (ii)(III) of this subparagraph if the pharmacy technician is engaged in compounding low and
435 medium risk sterile preparations; or

436
437 (II) four hours of ACPE accredited continuing education relating to the areas listed in clause
438 (ii)(III) of this subparagraph if pharmacy technician is engaged in compounding high risk sterile
439 preparations.

440
441 (4) Evaluation and testing requirements.

442
443 (A) All pharmacy personnel preparing sterile preparations shall be trained conscientiously and
444 skillfully by expert personnel through multimedia instructional sources and professional
445 publications in the theoretical principles and practical skills of aseptic manipulations, garbing
446 procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental
447 conditions, and cleaning and disinfection procedures before beginning to prepare compounded
448 sterile preparations.

449
450 (B) All pharmacy personnel shall perform didactic review and pass written and media-fill
451 testing of aseptic manipulative skills initially followed by:

452
453 (i) every 12 months for low- and medium-risk level compounding; and

454
455 (ii) every six months for high-risk level compounding.

456
457 (C) Pharmacy personnel who fail written tests or whose media-fill test vials result in gross
458 microbial colonization shall:

459
460 (i) be immediately re-instructed and re-evaluated by expert compounding personnel to
461 ensure correction of all aseptic practice deficiencies; and

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

464
465 (D) The didactic and experiential training shall include instruction, experience, and
466 demonstrated proficiency in the following areas:

467 (I) aseptic technique;

468 (II) critical area contamination factors;

469 (III) environmental monitoring;

470 (IV) structure and engineering controls related to facilities;

471 (V) equipment and supplies;

472 (VI) sterile preparation calculations and terminology;

473 (VII) sterile preparation compounding documentation;

474 (VIII) quality assurance procedures;

475 (IX) aseptic preparation procedures including proper gowning and gloving technique;

476 (X) handling of hazardous drugs, if applicable;

477 (XI) cleaning procedures; and

478 (XII) general conduct in the clean room.

479
480
481 (E) The aseptic technique of each person compounding or responsible for the direct
482 supervision of personnel compounding sterile preparations shall be observed and evaluated by
483 expert personnel as satisfactory through written and practical tests, and media-fill challenge
484 testing, and such evaluation documented.

485
486 (F) Media-fill tests must be conducted at each pharmacy where an individual compounds
487 sterile preparations. No preparation intended for patient use shall be compounded by an
488 individual until the on-site media-fill tests test indicates that the individual can competently
489 perform aseptic procedures, except that a pharmacist may temporarily compound sterile
490 preparations and supervise pharmacy technicians compounding sterile preparations without
491 media-fill tests provided the pharmacist completes the on-site media-fill tests within seven days
492 of commencing work at the pharmacy.

493
494 (G) Media-fill tests procedures for assessing the preparation of specific types of sterile
495 preparations shall be representative of the most challenging or stressful conditions encountered

506 by the pharmacy personnel being evaluated for each risk level and for sterilizing high-risk level
507 compounded sterile preparations.

508
509 (H) Media-fill challenge tests simulating high-risk level compounding shall be used to verify the
510 capability of the compounding environment and process to produce a sterile preparation.

511
512 (I) Commercially available sterile fluid culture media, such as Soybean–Casein Digest Medium
513 shall be able to promote exponential colonization of bacteria that are most likely to be
514 transmitted to compounding sterile preparations from the compounding personnel and
515 environment. Media-filled vials are generally incubated at 20 to 25 or at 30 to 35 for a minimum
516 of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled
517 containers should be incubated for at least 7 days at each temperature. Failure is indicated by
518 visible turbidity in the medium on or before 14 days.

519
520 (J) The pharmacist-in-charge shall ensure continuing competency of pharmacy personnel
521 through in-service education, training, and media-fill tests to supplement initial training.
522 Personnel competency shall be evaluated:

523
524 (i) during orientation and training prior to the regular performance of those tasks;

525
526 (ii) whenever the quality assurance program yields an unacceptable result;

527
528 (iii) whenever unacceptable techniques are observed; and

529
530 (iv) at least on an annual basis for low- and medium-risk level compounding, and every six
531 months for high-risk level compounding.

532
533 (K) The pharmacist-in-charge shall ensure that proper hand hygiene and garbing practices of
534 compounding personnel are evaluated prior to compounding sterile preparations intended for
535 patient use and whenever an aseptic media fill is performed.

536
537 (i) Sampling of compounding personnel glove fingertips shall be performed for all risk level
538 compounding.

539
540 (ii) All compounding personnel shall demonstrate competency in proper hand hygiene and
541 garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces,
542 routine disinfection of gloved hands).

543
544 (iii) Sterile contact agar plates shall be used to sample the gloved fingertips of
545 compounding personnel after garbing in order to assess garbing competency and after
546 completing the media-fill preparation (without applying sterile 70% IPA).

547
548 (iv) The visual observation shall be documented and maintained to provide a permanent
549 record and long-term assessment of personnel competency.

550
551 (v) All compounding personnel shall successfully complete an initial competency
552 evaluation and gloved fingertip/thumb sampling procedure no less than three times before
553 initially being allowed to compound sterile preparations for patient use. Immediately after the
554 compounding personnel completes the hand hygiene and garbing procedure (e.g., donning of
555 sterile gloves prior to any disinfection with sterile 70% IPA), the evaluator will collect a gloved
556 fingertip and thumb sample from both hands from the compounding personnel onto agar plates

557 by lightly pressing each fingertip into the agar. The plates will be incubated for the appropriate
558 incubation period and at the appropriate temperature. Re-evaluation of all compounding
559 personnel shall occur at least annually for compounding personnel who compound low and
560 medium risk level preparations and every six months for compounding personnel who
561 compound high risk level preparations.

562
563 (L) The pharmacist-in-charge shall ensure surface sampling shall be conducted in all ISO
564 classified areas on a periodic basis. Sampling shall be accomplished using contact plates at the
565 conclusion of compounding. The sample area shall be gently touched with the agar surface by
566 rolling the plate across the surface to be sampled.

567
568 (5) Documentation of Training. The pharmacy shall maintain a record of the training and
569 continuing education on each person who compounds sterile preparations. The record shall
570 contain, at a minimum, a written record of initial and in-service training, education, and the
571 results of written and practical testing and media-fill testing of pharmacy personnel. The record
572 shall be maintained and available for inspection by the board and contain the following
573 information:

574
575 (A) name of the person receiving the training or completing the testing or media-fill tests;

576
577 (B) date(s) of the training, testing, or media-fill challenge testing;

578
579 (C) general description of the topics covered in the training or testing or of the process
580 validated;

581
582 (D) name of the person supervising the training, testing, or media-fill challenge testing; and

583
584 (E) signature or initials of the person receiving the training or completing the testing or
585 media-fill challenge testing and the pharmacist-in-charge or other pharmacist employed by the
586 pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or
587 media-fill challenge testing of personnel.

588
589 (d) Operational Standards.

590
591 (1) General Requirements.

592
593 (A) Sterile preparations may be compounded:

594
595 (i) upon presentation of a practitioner's prescription drug or medication order based on a
596 valid pharmacist/patient/prescriber relationship;

597
598 (ii) in anticipation of future prescription drug or medication orders based on routine, regularly
599 observed prescribing patterns; or

600
601 (iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.

602
603 (B) Sterile compounding in anticipation of future prescription drug or medication orders must
604 be based upon a history of receiving valid prescriptions issued within an established
605 pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional
606 judgment the quantity prepared is stable for the anticipated shelf time.

607

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

610
611 (ii) Documentation of the criteria used to determine the stability for the anticipated shelf time
612 must be maintained and be available for inspection.

613
614 (iii) Any preparation compounded in anticipation of future prescription drug or medication
615 orders shall be labeled. Such label shall contain:

616
617 (I) name and strength of the compounded preparation or list of the active ingredients and
618 strengths;

619
620 (II) facility's lot number;

621
622 (III) beyond-use date as determined by the pharmacist using appropriate documented
623 criteria as outlined in paragraph (6)(G) of this subsection;

624
625 (IV) quantity or amount in the container;

626
627 (V) appropriate ancillary instructions, such as storage instructions or cautionary
628 statements, including hazardous drug warning labels where appropriate; and

629
630 (VI) device-specific instructions, where appropriate.

631
632 (C) Commercially available products may be compounded for dispensing to individual
633 patients or for office use provided the following conditions are met:

634
635 (i) the commercial product is not reasonably available from normal distribution channels in a
636 timely manner to meet patient's needs;

637
638 (ii) the pharmacy maintains documentation that the product is not reasonably available due
639 to a drug shortage or unavailability from the manufacturer; and

640
641 (iii) the prescribing practitioner has requested that the drug be compounded as described in
642 subparagraph (D) of this paragraph.

643
644 (D) A pharmacy may not compound preparations that are essentially copies of commercially
645 available products (e.g., the preparation is dispensed in a strength that is only slightly different
646 from a commercially available product) unless the prescribing practitioner specifically orders the
647 strength or dosage form and specifies why the patient needs the particular strength or dosage
648 form of the preparation or why the preparation for office use is needed in the particular strength
649 or dosage form of the preparation. The prescribing practitioner shall provide documentation of a
650 patient specific medical need and the preparation produces a clinically significant therapeutic
651 response (e.g. the physician requests an alternate preparation due to hypersensitivity to
652 excipients or preservative in the FDA-approved product, or the physician requests an effective
653 alternate dosage form) or if the drug product is not commercially available. The unavailability of
654 such drug product must be documented prior to compounding. The methodology for
655 documenting unavailability includes maintaining a copy of the wholesaler's notification showing
656 back-ordered, discontinued, or out-of-stock items. This documentation must be available in
657 hard-copy or electronic format for inspection by the board.

658

659 (E) A pharmacy may enter into an agreement to compound and dispense
660 prescription/medication orders for another pharmacy provided the pharmacy complies with the
661 provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).
662

663 (F) Compounding pharmacies/pharmacists may advertise and promote the fact that they
664 provide sterile prescription compounding services, which may include specific drug preparations
665 and classes of drugs.
666

667 (G) A pharmacy may not compound veterinary preparations for use in food producing animals
668 except in accordance with federal guidelines.
669

670 (2) Microbial Contamination Risk Levels. Risk Levels for sterile compounded preparations shall
671 be as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF
672 and as listed below.
673

674 (A) Low-risk level compounded sterile preparations.
675

676 (i) Low-Risk conditions. Low-risk level compounded sterile preparations are those
677 compounded under all of the following conditions.
678

679 (I) The compounded sterile preparations are compounded with aseptic manipulations
680 entirely within ISO Class 5 or better air quality using only sterile ingredients, products,
681 components, and devices.
682

683 (II) The compounding involves only transfer, measuring, and mixing manipulations using
684 not more than three commercially manufactured packages of sterile products and not more than
685 two entries into any one sterile container or package (e.g., bag, vial) of sterile product or
686 administration container/device to prepare the compounded sterile preparation.
687

688 (III) Manipulations are limited to aseptically opening ampuls, penetrating disinfected
689 stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile
690 syringes to sterile administration devices, package containers of other sterile products, and
691 containers for storage and dispensing.
692

693 (IV) For a low-risk preparation, in the absence of direct sterility testing results or
694 appropriate information sources that justify different limits, the storage periods may not exceed
695 the following periods: before administration the compounded sterile preparation is stored
696 properly and are exposed for not more than 48 hours at controlled room temperature, for not
697 more than 14 days if stored at a cold temperature, and for 45 days if stored in a frozen state
698 between minus 25 degrees Celsius and minus 10 degrees Celsius. For delayed activation
699 device systems, the storage period begins when the device is activated.
700

701 (ii) Examples of Low-Risk Compounding. Examples of low-risk compounding include the
702 following.
703

704 (I) Single volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials
705 using sterile syringes with sterile needles, other administration devices, and other sterile
706 containers. The solution content of ampules shall be passed through a sterile filter to remove
707 any particles.
708

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

712
713 (B) Low-Risk Level compounded sterile preparations with 12-hour or less beyond-use date.
714 Low-risk level compounded sterile preparations are those compounded pursuant to a
715 physician's order for a specific patient under all of the following conditions.

716
717 (i) The compounded sterile preparations are compounded in compounding aseptic isolator
718 or compounding aseptic containment isolator that does not meet the requirements described in
719 paragraph (6)(A)(ii)(II) of this subsection relating to Low and Medium Risk Preparations or the
720 compounded sterile preparations are compounded in laminar airflow workbench or a biological
721 safety cabinet that cannot be located within an ISO Class 7 buffer area.

722
723 (ii) The primary engineering control device shall be certified and maintain ISO Class 5 for
724 exposure of critical sites and shall be located in a segregated compounding area restricted to
725 sterile compounding activities that minimizes the risk of contamination of the compounded
726 sterile preparation.

727
728 (iii) The segregated compounding area shall not be in a location that has unsealed windows
729 or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites,
730 warehouses, or food preparation.

731
732 (iv) For a low-risk preparation compounded as described in clauses (i) - (iii) of this
733 subparagraph, administration of such compounded sterile preparations must commence within
734 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is
735 less.

736
737 (C) Medium-risk level compounded sterile preparations.

738
739 (i) Medium-Risk Conditions. Medium-risk level compounded sterile preparations, are those
740 compounded aseptically under low-risk conditions and one or more of the following conditions
741 exists.

742
743 (I) Multiple individual or small doses of sterile products are combined or pooled to prepare
744 a compounded sterile preparation that will be administered either to multiple patients or to one
745 patient on multiple occasions.

746
747 (II) The compounding process includes complex aseptic manipulations other than the
748 single-volume transfer.

749
750 (III) The compounding process requires unusually long duration, such as that required to
751 complete the dissolution or homogenous mixing (e.g., reconstitution of intravenous
752 immunoglobulin or other intravenous protein products).

753
754 (IV) The compounded sterile preparations do not contain broad spectrum bacteriostatic
755 substances and they are administered over several days (e.g., an externally worn infusion
756 device).

757
758 (V) For a medium-risk preparation, in the absence of direct sterility testing results the
759 beyond use dates may not exceed the following time periods: before administration, the

760 compounded sterile preparations are properly stored and are exposed for not more than 30
761 hours at controlled room temperature, for not more than 9 days at a cold temperature, and for
762 45 days in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius.

763
764 (ii) Examples of medium-risk compounding. Examples of medium-risk compounding include
765 the following.

766
767 (I) Compounding of total parenteral nutrition fluids using a manual or automated device
768 during which there are multiple injections, detachments, and attachments of nutrient source
769 products to the device or machine to deliver all nutritional components to a final sterile
770 container.

771
772 (II) Filling of reservoirs of injection and infusion devices with more than three sterile drug
773 products and evacuations of air from those reservoirs before the filled device is dispensed.

774
775 (III) Filling of reservoirs of injection and infusion devices with volumes of sterile drug
776 solutions that will be administered over several days at ambient temperatures between 25 and
777 40 degrees Celsius (77 and 104 degrees Fahrenheit).

778
779 (IV) Transfer of volumes from multiple ampuls or vials into a single, final sterile container or
780 product.

781
782 (D) High-risk level compounded sterile preparations.

783
784 (i) High-risk Conditions. High-risk level (i) compounded sterile preparations are those
785 compounded under any of the following conditions.

786
787 (I) Non-sterile ingredients, including manufactured products not intended for sterile routes
788 of administration (e.g., oral) are incorporated or a non-sterile device is employed before terminal
789 sterilization.

790
791 (II) Any of the following are exposed to air quality worse than ISO Class 5 for more than 1
792 hour:

793
794 (-a-) sterile contents of commercially manufactured products;
795 (-b-) CSPs that lack effective antimicrobial preservatives; and
796 (-c-) sterile surfaces of devices and containers for the preparation, transfer, sterilization,
797 and packaging of CSPs.

798
799 (III) Compounding personnel are improperly garbed and gloved.

800
801 (IV) Non-sterile water-containing preparations are exposed no more than 6 hours before
802 being sterilized.

803
804 (V) It is assumed, and not verified by examination of labeling and documentation from
805 suppliers or by direct determination, that the chemical purity and content strength of ingredients
806 meet their original or compendial specifications in unopened or in opened packages of bulk
807 ingredients.

808
809 (VI) For a sterilized high-risk level preparation, in the absence of passing a sterility test, the
810 storage periods cannot exceed the following time periods: before administration, the

811 compounded sterile preparations are properly stored and are exposed for not more than 24
812 hours at controlled room temperature, for not more than 3 days at a cold temperature, and for
813 45 days in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius.
814

815 (VII) All non-sterile measuring, mixing, and purifying devices are rinsed thoroughly with
816 sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for
817 high-risk compounding. All high-risk compounded sterile solutions subjected to terminal
818 sterilization are prefiltered by passing through a filter with a nominal pore size not larger than
819 1.2 micron preceding or during filling into their final containers to remove particulate matter.
820 Sterilization of high-risk level compounded sterile preparations by filtration shall be performed
821 with a sterile 0.2 micrometer or 0.22 micrometer nominal pore size filter entirely within an ISO
822 Class 5 or superior air quality environment.
823

824 (ii) Examples of high-risk compounding. Examples of high-risk compounding include the
825 following.
826

827 (I) Dissolving non-sterile bulk drug powders to make solutions, which will be terminally
828 sterilized.
829

830 (II) Exposing the sterile ingredients and components used to prepare and package
831 compounded sterile preparations to room air quality worse than ISO Class 5 for more than one
832 hour.
833

834 (III) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is
835 performed.
836

837 (IV) Assuming, without appropriate evidence or direct determination, that packages of bulk
838 ingredients contain at least 95% by weight of their active chemical moiety and have not been
839 contaminated or adulterated between uses.
840

841 (3) Immediate Use Compounded Sterile Preparations. For the purpose of emergency or
842 immediate patient care, such situations may include cardiopulmonary resuscitation, emergency
843 room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the
844 compounded sterile preparation under low-risk level conditions would subject the patient to
845 additional risk due to delays in therapy. Compounded sterile preparations are exempted from
846 the requirements described in this paragraph for low-risk level compounded sterile preparations
847 when all of the following criteria are met.
848

849 (A) Only simple aseptic measuring and transfer manipulations are performed with not more
850 than three sterile non-hazardous commercial drug and diagnostic radiopharmaceutical drug
851 products, including an infusion or diluent solution, from the manufacturers' original containers
852 and not more than two entries into any one container or package of sterile infusion solution or
853 administration container/device.
854

855 (B) Unless required for the preparation, the compounding procedure occurs continuously
856 without delays or interruptions and does not exceed 1 hour.
857

858 (C) During preparation, aseptic technique is followed and, if not immediately administered, the
859 finished compounded sterile preparation is under continuous supervision to minimize the
860 potential for contact with nonsterile surfaces, introduction of particulate matter of biological

861 fluids, mix-ups with other compounded sterile preparations, and direct contact of outside
862 surfaces.

863
864 (D) Administration begins not later than one hour following the completion of preparing the
865 compounded sterile preparation.

866
867 (E) When the compounded sterile preparations is not administered by the person who
868 prepared it, or its administration is not witnessed by the person who prepared it, the
869 compounded sterile preparation shall bear a label listing patient identification information such
870 as name and identification number(s), the names and amounts of all ingredients, the name or
871 initials of the person who prepared the compounded sterile preparation, and the exact 1-hour
872 beyond-use time and date.

873
874 (F) If administration has not begun within one hour following the completion of preparing the
875 compounded sterile preparation, the compounded sterile preparation is promptly and safely
876 discarded. Immediate use compounded sterile preparations shall not be stored for later use.

877
878 (G) Hazardous drugs shall not be prepared as immediate use compounded sterile
879 preparations.

880
881 (4) Single-dose and multiple dose containers.

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

885
886 (B) Single-dose containers, including single-dose large volume parenteral solutions and
887 single-dose vials, exposed to ISO Class 5 or cleaner air may be used up to six hours after initial
888 needle puncture.

889
890 (C) Opened single-dose fusion sealed containers shall not be stored for any time period.

891
892 (D) Multiple-dose containers may be used up to 28 days after initial needle puncture unless
893 otherwise specified by the manufacturer.

894
895 (5) Library. In addition to the library requirements of the pharmacy's specific license
896 classification, a pharmacy shall maintain current or updated copies in hard-copy or electronic
897 format of each of the following:

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

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

903 (C) the United States Pharmacopeia/National Formulary containing USP Chapter 71, Sterility
904 Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding—Nonsterile
905 Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile
906 Preparations, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.

907
908 (6) Environment. Compounding facilities shall be physically designed and environmentally
909 controlled to minimize airborne contamination from contacting critical sites.

910
911 (A) Low and Medium Risk Preparations.

912
913 (i) A pharmacy that prepares low- and medium-risk preparations shall have a clean room for
914 the compounding of sterile preparations that is constructed to minimize the opportunities for
915 particulate and microbial contamination. The clean room shall:

916
917 (I) be clean, well lit, and of sufficient size to support sterile compounding activities;

918
919 (II) be maintained at a comfortable temperature (e.g., 20 degrees Celsius or cooler)
920 allowing compounding personnel to perform flawlessly when attired in the required aseptic
921 compounding garb;

922
923 (III) be used only for the compounding of sterile preparations;

924
925 (IV) be designed such that hand sanitizing and gowning occurs outside the buffer area but
926 allows hands-free access by compounding personnel to the buffer area;

927
928 (V) have non-porous and washable floors or floor covering to enable regular disinfection;

929
930 (VI) be ventilated in a manner to avoid disruption from the HVAC system and room cross-
931 drafts;

932
933 (VII) have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth,
934 impervious, free from cracks and crevices (e.g., coved), non-shedding and resistant to damage
935 by disinfectant agents;

936
937 (VIII) have junctures of ceilings to walls coved or caulked to avoid cracks and crevices;

938
939 (IX) have drugs and supplies stored on shelving areas above the floor to permit adequate
940 floor cleaning;

941
942 (X) contain only the appropriate compounding supplies and not be used for bulk storage for
943 supplies and materials. Objects that shed particles shall not be brought into the clean room;

944
945 (XI) contain an ante-area that provides at least an ISO class 8 air quality and contains a
946 sink with hot and cold running water that enables hands-free use with a closed system of soap
947 dispensing to minimize the risk of extrinsic contamination; and

948
949 (XII) contain a buffer area designed to maintain at least ISO Class 7 conditions for 0.5- μ m
950 and larger particles under dynamic working conditions. The following is applicable for the buffer
951 area.

952
953 (-a-) There shall be some demarcation designation that delineates the ante-area from the
954 buffer area. The demarcation shall be such that it does not create conditions that could
955 adversely affect the cleanliness of the area.

956
957 (-b-) The buffer area shall be segregated from surrounding, unclassified spaces to reduce
958 the risk of contaminants being blown, dragged, or otherwise introduced into the filtered
959 unidirectional airflow environment, and this segregation should be continuously monitored.

960

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

964
965 (-d-) The buffer area shall not contain sources of water (i.e., sinks) or floor drains.

966
967 (ii) The pharmacy shall prepare sterile preparations in a primary engineering control device,
968 such as a laminar air flow hood, biological safety cabinet, compounding aseptic isolator,
969 compounding aseptic containment isolator which is capable of maintaining at least ISO Class 5
970 conditions for 0.5-µm particles while compounding sterile preparations.

971
972 (I) The primary engineering control shall:

973
974 (-a-) be located in the buffer area and placed in the buffer area in a manner as to avoid
975 conditions that could adversely affect its operation such as strong air currents from opened
976 doors, personnel traffic, or air streams from the heating, ventilating and air condition system.

977
978 (-b-) be certified by a qualified independent contractor according to the International
979 Organization of Standardization (ISO) Classification of Particulate Matter in Room Air (ISO
980 14644-1) for operational efficiency at least every six months and whenever the device or room is
981 relocated or altered or major service to the facility is performed, in accordance with the
982 manufacturer's specifications;

983
984 (-c-) have pre-filters inspected periodically and replaced as needed, in accordance with
985 written policies and procedures and the manufacturer's specification, and the inspection and/or
986 replacement date documented; and

987
988 (-d-) be located in a buffer area that has a minimum differential positive pressure of 0.02
989 to 0.05 inches water column.

990
991 (II) The compounding aseptic isolator or compounding aseptic containment isolator must
992 be placed in an ISO Class 7 buffer area unless the isolator meets all of the following conditions.

993
994 (-a-) The isolator must provide isolation from the room and maintain ISO Class 5 during
995 dynamic operating conditions including transferring ingredients, components, and devices into
996 and out of the isolator and during preparation of compounded sterile preparations.

997
998 (-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical
999 exposure site must maintain ISO Class 5 levels during compounding operations.

1000
1001 (-c-) The pharmacy shall maintain documentation from the manufacturer that the isolator
1002 meets this standard when located in worse than ISO Class 7 environments.

1003
1004 (B) High-risk Preparations.

1005
1006 (i) In addition to the requirements in subparagraph (A) of this paragraph, when high-risk
1007 preparations are compounded, the primary engineering control shall be located in a buffer area
1008 that provides a physical separation, through the use of walls, doors and pass-throughs and has
1009 a minimum differential positive pressure of 0.02 to 0.05 inches water column.

1010

1011 (ii) Presterilization procedures for high-risk level compounded sterile preparations, such as
1012 weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.
1013
1014 (C) Automated compounding device. If automated compounding devices are used, the
1015 pharmacy shall have a method to calibrate and verify the accuracy of automated compounding
1016 devices used in aseptic processing and document the calibration and verification on a daily
1017 basis, based on the manufacturer's recommendations, and review the results at least weekly.
1018
1019 (D) Hazardous drugs. If the preparation is hazardous, the following is also applicable.
1020
1021 (i) General.
1022
1023 (I) Hazardous drugs shall be prepared only under conditions that protect personnel during
1024 preparation and storage.
1025
1026 (II) Hazardous drugs shall be stored separately from other inventory in a manner to prevent
1027 contamination and personnel exposure.
1028
1029 (III) All personnel involved in the compounding of hazardous drugs shall wear appropriate
1030 protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or
1031 dedicated shoes, and appropriate gloving at all times when handling hazardous drugs, including
1032 receiving, distribution, stocking, inventorying, preparation, for administration and disposal.
1033
1034 (IV) Appropriate safety and containment techniques for compounding hazardous drugs
1035 shall be used in conjunction with aseptic techniques required for preparing sterile preparations.
1036
1037 (V) Disposal of hazardous waste shall comply with all applicable local, state, and federal
1038 requirements.
1039
1040 (VI) Prepared doses of hazardous drugs must be dispensed, labeled with proper
1041 precautions inside and outside, and distributed in a manner to minimize patient contact with
1042 hazardous agents.
1043
1044 (ii) Primary engineering control device. Hazardous drugs shall be prepared in a Class II or III
1045 vertical flow biological safety cabinet or compounding aseptic containment isolator located in an
1046 ISO Class 7 area that is physically separated from other preparation areas. The area for
1047 preparation of sterile chemotherapeutic preparations shall:
1048
1049 (I) have not less than 0.01 inches water column negative pressure to the adjacent positive
1050 pressure ISO Class 7 or better ante-area; and
1051
1052 (II) have a pressure indicator that can be readily monitored for correct room pressurization.
1053
1054 (iii) Facilities that prepare a low volume of hazardous drugs. Pharmacies that prepare a low
1055 volume of hazardous drugs, are not required to comply with the provisions of clause (ii) of this
1056 subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g.,
1057 closed-system vial transfer device within a BSC or CACI that is located in a non-negative
1058 pressure room).
1059
1060 (E) Cleaning and disinfecting the sterile compounding areas. The following cleaning and
1061 disinfecting practices and frequencies apply to direct and contiguous compounding areas, which

1062 include ISO Class 5 compounding areas for exposure of critical sites as well as buffer areas,
1063 ante-areas, and segregated compounding areas.

1064
1065 (i) The pharmacist-in-charge is responsible for developing written procedures for cleaning
1066 and disinfecting the direct and contiguous compounding areas and assuring the procedures are
1067 followed.

1068
1069 (ii) These procedures shall be conducted at the beginning of each work shift, before each
1070 batch preparation is started, every 30 minutes during continuous compounding of individual
1071 compounded sterile preparations, when there are spills, and when surface contamination is
1072 known or suspected from procedural breaches.

1073
1074 (iii) Before compounding is performed, all items shall be removed from the direct and
1075 contiguous compounding areas and all surfaces are cleaned by removing loose material and
1076 residue from spills, followed by an application of a residue-free disinfecting agent (e.g., IPA),
1077 which is allowed to dry before compounding begins.

1078
1079 (iv) Work surfaces in the ISO Class 7 buffer areas and ISO Class 8 ante-areas, as well as
1080 segregated compounding areas, shall be cleaned and disinfected at least daily. Dust and debris
1081 shall be removed when necessary from storage sites for compounding ingredients and supplies
1082 using a method that does not degrade the ISO Class 7 or 8 air quality.

1083
1084 (v) Floors in the buffer area, ante-area, and segregated compounding area are cleaned by
1085 mopping with a cleaning and disinfecting agent at least once daily when no aseptic operations
1086 are in progress. Mopping shall be performed by trained personnel using approved agents and
1087 procedures described in the written SOPs. It is incumbent on compounding personnel to ensure
1088 that such cleaning is performed properly.

1089
1090 (vi) In the buffer area, ante-area, and segregated compounding area, walls, ceilings, and
1091 shelving shall be cleaned and disinfected monthly. Cleaning and disinfecting agents shall be
1092 used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic
1093 residues.

1094
1095 (viii) All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, and
1096 dedicated to use in the buffer area, ante-area, and segregated compounding areas and shall not
1097 be removed from these areas except for disposal. Floor mops may be used in both the buffer
1098 area and ant-are, but only in that order. If cleaning materials are reused, procedures shall be
1099 developed that ensure that the effectiveness of the cleaning device is maintained and that
1100 repeated use does not add to the bio-burden of the area being cleaned.

1101
1102 (ix) Supplies and equipment removed from shipping cartons must be wiped with a
1103 disinfecting agent, such as sterile IPA. After the disinfectant is sprayed or wiped on a surface to
1104 be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be
1105 used for compounding purposes. However, if sterile supplies are received in sealed pouches,
1106 the pouches may be removed as the supplies are introduced into the ISO Class 5 area without
1107 the need to disinfect the individual sterile supply items. No shipping or other external cartons
1108 may be taken into the buffer area or segregated compounding area.

1109
1110 (x) Storage shelving emptied of all supplies, walls, and ceilings are cleaned and disinfected
1111 at planned intervals, monthly, if not more frequently.

1112

1113 (xi) Cleaning must be done by personnel trained in appropriate cleaning techniques.
1114
1115 (xii) Proper documentation and frequency of cleaning must be maintained and shall contain
1116 the following:

- 1117
- 1118 (I) date and time of cleaning;
- 1119 (II) type of cleaning performed; and
- 1120 (III) name of individual who performed the cleaning.
- 1121

1122 (F) Security requirements. The pharmacist-in-charge may authorize personnel to gain access
1123 to that area of the pharmacy containing dispensed sterile preparations, in the absence of the
1124 pharmacist, for the purpose of retrieving dispensed prescriptions to deliver to patients. If the
1125 pharmacy allows such after-hours access, the area containing the dispensed sterile
1126 preparations shall be an enclosed and lockable area separate from the area containing
1127 undispensed prescription drugs. A list of the authorized personnel having such access shall be
1128 in the pharmacy's policy and procedure manual.

1129
1130 (G) Storage requirements and beyond-use dating.

1131
1132 (i) Storage requirements. All drugs shall be stored at the proper temperature and conditions,
1133 as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).

1134
1135 (ii) Beyond-use dating.

1136
1137 (I) Beyond-use dates for compounded sterile preparations shall be assigned based on
1138 professional experience, which shall include careful interpretation of appropriate information
1139 sources for the same or similar formulations.

1140
1141 (II) Beyond-use dates for compounded sterile preparations that are prepared strictly in
1142 accordance with manufacturers' product labeling must be those specified in that labeling, or
1143 from appropriate literature sources or direct testing.

1144
1145 (III) Beyond-use dates for compounded sterile preparations that lack justification from
1146 either appropriate literature sources or by direct testing evidence shall be assigned as described
1147 in Chapter 795, in Stability Criteria and Beyond-Use Dating under Pharmaceutical
1148 Compounding-Nonsterile Preparations of the USP/NF.

1149
1150 (IV) When assigning a beyond-use date, compounding personnel shall consult and apply
1151 drug-specific and general stability documentation and literature where available, and they
1152 should consider the nature of the drug and its degradation mechanism, the container in which it
1153 is packaged, the expected storage conditions, and the intended duration of therapy.

1154
1155 (V) The sterility and storage and stability beyond-use date for attached and activated
1156 container pairs of drug products for intravascular administration shall be applied as indicated by
1157 the manufacturer.

1158
1159 (7) Equipment and supplies. Pharmacies compounding sterile preparations shall have the
1160 following equipment and supplies:

1161
1162 (A) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure
1163 that proper storage requirements are met, if sterile preparations are stored in the refrigerator;

1164
1165 (B) a calibrated system or device to monitor the temperature where bulk chemicals are
1166 stored;
1167
1168 (C) a temperature-sensing mechanism suitably placed in the controlled temperature storage
1169 space to reflect accurately the true temperature;
1170
1171 (D) if applicable, a Class A prescription balance, or analytical balance and weights. Such
1172 balance shall be properly maintained and subject to periodic inspection by the Texas State
1173 Board of Pharmacy;
1174
1175 (E) equipment and utensils necessary for the proper compounding of sterile preparations.
1176 Such equipment and utensils used in the compounding process shall be:
1177
1178 (i) of appropriate design, appropriate capacity, and be operated within designed operational
1179 limits;
1180
1181 (ii) of suitable composition so that surfaces that contact components, in-process material, or
1182 drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity,
1183 strength, quality, or purity of the drug preparation beyond the desired result;
1184
1185 (iii) cleaned and sanitized immediately prior to and after each use; and
1186
1187 (iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;
1188
1189 (F) appropriate disposal containers for used needles, syringes, etc., and if applicable,
1190 hazardous waste from the preparation of hazardous drugs and/or biohazardous waste;
1191
1192 (G) appropriate packaging or delivery containers to maintain proper storage conditions for
1193 sterile preparations;
1194
1195 (H) infusion devices, if applicable; and
1196
1197 (I) all necessary supplies, including:
1198
1199 (i) disposable needles, syringes, and other supplies for aseptic mixing;
1200
1201 (ii) disinfectant cleaning solutions;
1202
1203 (iii) hand washing agents with bactericidal action;
1204
1205 (iv) disposable, lint free towels or wipes;
1206
1207 (v) appropriate filters and filtration equipment;
1208
1209 (vi) hazardous spill kits, if applicable; and
1210
1211 (vii) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as
1212 applicable.
1213
1214 (8) Labeling.

1215
1216 (A) Prescription drug or medication orders. In addition to the labeling requirements for the
1217 pharmacy's specific license classification, the label dispensed or distributed pursuant to a
1218 prescription drug or medication order shall contain the following:
1219
1220 (i) the generic name(s) or the official name(s) of the principal active ingredient(s) of the
1221 compounded sterile preparation;
1222
1223 (ii) for outpatient prescription orders only, a statement that the compounded sterile
1224 preparation has been compounded by the pharmacy. (An auxiliary label may be used on the
1225 container to meet this requirement);
1226
1227 (iii) a beyond-use date. The beyond-use date shall be determined as outlined in Chapter
1228 797, Pharmacy Compounding--Sterile Preparations of the USP/NF, and paragraph (7)(G) of this
1229 subsection;
1230
1231 (B) Batch. If the sterile preparation is compounded in a batch, the following shall also be
1232 included on the batch label:
1233
1234 (i) unique lot number assigned to the batch;
1235
1236 (ii) quantity;
1237
1238 (iii) appropriate ancillary instructions, such as storage instructions or cautionary statements,
1239 including hazardous drug warning labels where appropriate; and
1240
1241 (iv) device-specific instructions, where appropriate.
1242
1243 (C) Pharmacy bulk package. The label of a pharmacy bulk package shall:
1244
1245 (i) state prominently "Pharmacy Bulk Package--Not for Direct Infusion;"
1246
1247 (ii) contain or refer to information on proper techniques to help ensure safe use of the
1248 preparation; and
1249
1250 (iii) bear a statement limiting the time frame in which the container may be used once it has
1251 been entered, provided it is held under the labeled storage conditions.
1252
1253 (9) Written drug information for prescription drug orders only. Written information about the
1254 compounded preparation or its major active ingredient(s) shall be given to the patient at the time
1255 of dispensing a prescription drug order. A statement which indicates that the preparation was
1256 compounded by the pharmacy must be included in this written information. If there is no written
1257 information available, the patient shall be advised that the drug has been compounded and how
1258 to contact a pharmacist, and if appropriate, the prescriber, concerning the drug.
1259
1260 (10) Pharmaceutical Care Services. In addition to the pharmaceutical care requirements for the
1261 pharmacy's specific license classification, the following requirements for sterile preparations
1262 compounded pursuant to prescription drug orders must be met.
1263
1264 (A) Primary provider. There shall be a designated physician primarily responsible for the
1265 patient's medical care. There shall be a clear understanding between the physician, the patient,

1266 and the pharmacy of the responsibilities of each in the areas of the delivery of care, and the
1267 monitoring of the patient. This shall be documented in the patient medication record (PMR).
1268

1269 (B) Patient training. The pharmacist-in-charge shall develop policies to ensure that the patient
1270 and/or patient's caregiver receives information regarding drugs and their safe and appropriate
1271 use, including instruction when applicable, regarding:
1272

1273 (i) appropriate disposition of hazardous solutions and ancillary supplies;
1274

1275 (ii) proper disposition of controlled substances in the home;
1276

1277 (iii) self-administration of drugs, where appropriate;
1278

1279 (iv) emergency procedures, including how to contact an appropriate individual in the event of
1280 problems or emergencies related to drug therapy; and
1281

1282 (v) if the patient or patient's caregiver prepares sterile preparations in the home, the
1283 following additional information shall be provided:
1284

1285 (I) safeguards against microbial contamination, including aseptic techniques for
1286 compounding intravenous admixtures and aseptic techniques for injecting additives to premixed
1287 intravenous solutions;
1288

1289 (II) appropriate storage methods, including storage durations for sterile pharmaceuticals
1290 and expirations of self-mixed solutions;
1291

1292 (III) handling and disposition of premixed and self-mixed intravenous admixtures; and
1293

1294 (IV) proper disposition of intravenous admixture compounding supplies such as syringes,
1295 vials, ampules, and intravenous solution containers.
1296

1297 (C) Pharmacist-patient relationship. It is imperative that a pharmacist-patient relationship be
1298 established and maintained throughout the patient's course of therapy. This shall be
1299 documented in the patient's medication record (PMR).
1300

1301 (D) Patient monitoring. The pharmacist-in-charge shall develop policies to ensure that:
1302

1303 (i) the patient's response to drug therapy is monitored and conveyed to the appropriate
1304 health care provider;
1305

1306 (ii) the first dose of any new drug therapy is administered in the presence of an individual
1307 qualified to monitor for and respond to adverse drug reactions; and
1308

1309 (iii) reports of adverse events with a compounded sterile preparation are reviewed promptly
1310 and thoroughly to correct and prevent future occurrences.
1311

1312 (11) Drugs, components, and materials used in sterile compounding.
1313

1314 (A) Drugs used in sterile compounding shall be a USP/NF grade substances manufactured in
1315 an FDA-registered facility.
1316

1317 (B) If USP/NF grade substances are not available shall be of a chemical grade in one of the
1318 following categories:

- 1319 (i) Chemically Pure (CP);
1320
1321 (ii) Analytical Reagent (AR);
1322
1323 (iii) American Chemical Society (ACS); or
1324
1325 (iv) Food Chemical Codex.
1326

1327 (C) If a drug, component or material is not purchased from a FDA-registered facility, the
1328 pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the
1329 supplier and the pharmacist shall compare the monograph of drugs in a similar class to the
1330 Certificate of Analysis.
1331

1332 (D) All components shall:

- 1333 (i) be manufactured in an FDA-registered facility; or
1334
1335 (ii) in the professional judgment of the pharmacist, be of high quality and obtained from
1336 acceptable and reliable alternative sources; and
1337
1338 (iii) stored in properly labeled containers in a clean, dry area, under proper temperatures.
1339

1340 (E) Drug preparation containers and closures shall not be reactive, additive, or absorptive so
1341 as to alter the safety, identity, strength, quality, or purity of the compounded drug preparation
1342 beyond the desired result.
1343

1344 (F) Components, drug preparation containers, and closures shall be rotated so that the oldest
1345 stock is used first.
1346

1347 (G) Container closure systems shall provide adequate protection against foreseeable external
1348 factors in storage and use that can cause deterioration or contamination of the compounded
1349 drug preparation.
1350

1351 (H) A pharmacy may not compound a preparation that contains ingredients appearing on a
1352 federal Food and Drug Administration list of drug products withdrawn or removed from the
1353 market for safety reasons.
1354

1355 (12) Compounding process.

1356 (A) Standard operating procedures (SOPs). All significant procedures performed in the
1357 compounding area shall be covered by written SOPs designed to ensure accountability,
1358 accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall
1359 be developed and implemented for:
1360

- 1361 (i) the facility;
1362
1363 (ii) equipment;
1364
1365
1366
1367

- 1368 (iii) personnel;
- 1369
- 1370 (iv) preparation evaluation;
- 1371
- 1372 (v) quality assurance;
- 1373
- 1374 (vi) preparation recall;
- 1375
- 1376 (vii) packaging; and
- 1377
- 1378 (viii) storage of compounded sterile preparations.
- 1379

1380 (B) USP/NF. Any compounded formulation with an official monograph in the USP/NF shall be
1381 compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

1382 (C) Personnel Cleansing and Garbing.

1383

1384

1385 (i) Any person with an apparent illness or open lesion, including rashes, sunburn, weeping
1386 sores, conjunctivitis, and active respiratory infection, that may adversely affect the safety or
1387 quality of a drug preparation being compounded shall be excluded from working in ISO Class 5
1388 and ISO Class 7 compounding areas until the condition is remedied.

1389

1390 (ii) Before entering the buffer area, compounding personnel must remove the following:

1391

1392 (I) personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters,
1393 vests);

1394

1395 (II) all cosmetics, because they shed flakes and particles; and

1396

1397 (III) all hand, wrist, and other body jewelry or piercings (e.g., earrings, lip or eyebrow
1398 piercings) that can interfere with the effectiveness of personal protective equipment (e.g., fit of
1399 gloves and cuffs of sleeves).

1400

1401 (iii) The wearing of artificial nails or extenders is prohibited while working in the sterile
1402 compounding environment. Natural nails shall be kept neat and trimmed.

1403

1404 (iv) Personnel shall don personal protective equipment and perform hand hygiene in an
1405 order that proceeds from the dirtiest to the cleanest activities as follows:

1406

1407 (I) Activities considered the dirtiest include donning of dedicated shoes or shoe covers,
1408 head and facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye
1409 shield. Eye shields are optional unless working with irritants like germicidal disinfecting agents
1410 or when preparing hazardous drugs.

1411

1412 (II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face
1413 masks, personnel shall perform a hand hygiene procedure by removing debris from underneath
1414 fingernails using a nail cleaner under running warm water followed by vigorous hand washing.
1415 Personnel shall begin washing arms at the hands and continue washing to elbows for at least
1416 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in
1417 the ante-area. Hands and forearms to the elbows shall be completely dried using lint-free
1418 disposable towels, an electronic hands-free hand dryer, or a HEPA filtered hands dryer.

1419
1420 (III) After completion of hand washing, personnel shall don clean non-shedding gowns with
1421 sleeves that fit snugly around the wrists and enclosed at the neck.

1422
1423 (IV) Once inside the buffer area or segregated compounding area, and prior to donning
1424 sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless
1425 alcohol-based surgical hand scrub with persistent activity following manufacturers'
1426 recommendations. Hands shall be allowed to dry thoroughly before donning sterile gloves.

1427
1428 (V) Sterile gloves that form a continuous barrier with the gown shall be the last item
1429 donned before compounding begins. Routine application of sterile 70% IPA shall occur
1430 throughout the compounding day and whenever nonsterile surfaces are touched.

1431
1432 (v) When compounding personnel shall temporarily exit the ISO Class 7 environment during a
1433 work shift, the exterior gown, if not visibly soiled, may be removed and retained in the ISO Class
1434 8 ante-area, to be re-donned during that same work shift only. However, shoe covers, hair and
1435 facial hair covers, face mask/eye shield, and gloves shall be replaced with new ones before re-
1436 entering the ISO Class 7 clean environment along with performing proper hand hygiene.

1437
1438 (vi) During high-risk compounding activities that precede terminal sterilization, such as
1439 weighing and mixing of nonsterile ingredients, compounding personnel shall be garbed and
1440 gloved the same as when performing compounding in an ISO Class 5 environment. Properly
1441 garbed and gloved compounding personnel who are exposed to air quality that is either known
1442 or suspected to be worse than ISO Class 7 shall re-garb personal protective equipment along
1443 with washing their hands properly, performing antiseptic hand cleansing with a waterless
1444 alcohol-based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7
1445 buffer area.

1446
1447 (vii) When compounding aseptic isolators or compounding aseptic containment isolators are
1448 the source of the ISO Class 5 environment, the compounding personnel should follow the
1449 requirements as specified in this subparagraph, unless the isolator manufacturer can provide
1450 written documentation based on validated environmental testing that any components of
1451 personal protective equipment or cleansing are not required.

1452
1453 (13) Quality Assurance.

1454
1455 (A) Initial Formula Validation. Prior to routine compounding of a sterile preparation, a
1456 pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding
1457 a preparation that is sterile and that contains the stated amount of active ingredient(s).

1458
1459 (i) Low risk preparations.

1460
1461 (I) Quality assurance practices include, but are not limited to the following:

1462
1463 (-a-) Routine disinfection and air quality testing of the direct compounding environment to
1464 minimize microbial surface contamination and maintain ISO Class 5 air quality.

1465
1466 (-b-) Visual confirmation that compounding personnel are properly donning and wearing
1467 appropriate items and types of protective garments and goggles.

1468

1469 (-c-) Review of all orders and packages of ingredients to ensure that the correct identity
1470 and amounts of ingredients were compounded.

1471
1472 (-d-) Visual inspection of compounded sterile preparations to ensure the absence of
1473 particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy
1474 and thoroughness of labeling.

1475
1476 (II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at
1477 least annually by each person authorized to compound in a low-risk level under conditions that
1478 closely simulate the most challenging or stressful conditions encountered during compounding
1479 of low-risk level sterile preparations. Once begun, this test is completed without interruption
1480 within an ISO Class 5 air quality environment. Three sets of four 5-milliliter aliquots of sterile
1481 Soybean--Casein Digest Medium are transferred with the same sterile 10-milliliter syringe and
1482 vented needle combination into separate sealed, empty, sterile 30-milliliter clear vials (i.e., four
1483 5-milliliter aliquots into each of three 30-milliliter vials). Sterile adhesive seals are aseptically
1484 affixed to the rubber closures on the three filled vials. The vials are incubated within a range of
1485 20 - 35 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the
1486 medium on or before 14 days. The media-fill test must include a positive-control sample.

1487
1488 (ii) Medium risk preparations.

1489
1490 (I) Quality assurance procedures for medium-risk level compounded sterile preparations
1491 include all those for low-risk level compounded sterile preparations, as well as a more
1492 challenging media-fill test passed annually, or more frequently.

1493
1494 (II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at
1495 least annually under conditions that closely simulate the most challenging or stressful conditions
1496 encountered during compounding. This test is completed without interruption within an ISO
1497 Class 5 air quality environment. Six 100-milliliter aliquots of sterile Soybean--Casein Digest
1498 Medium are aseptically transferred by gravity through separate tubing sets into separate
1499 evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile
1500 10-milliliter syringe and 18-gauge needle combination is used to exchange two 5-milliliter
1501 aliquots of medium from one container to the other container in the pair. For example, after a 5-
1502 milliliter aliquot from the first container is added to the second container in the pair, the second
1503 container is agitated for 10 seconds, then a 5-milliliter aliquot is removed and returned to the
1504 first container in the pair. The first container is then agitated for 10 seconds, and the next 5-
1505 milliliter aliquot is transferred from it back to the second container in the pair. Following the two
1506 5-milliliter aliquot exchanges in each pair of containers, a 5-milliliter aliquot of medium from each
1507 container is aseptically injected into a sealed, empty, sterile 10-milliliter clear vial, using a sterile
1508 10-milliliter syringe and vented needle. Sterile adhesive seals are aseptically affixed to the
1509 rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35
1510 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the medium
1511 on or before 14 days. The media-fill test must include a positive-control sample.

1512
1513 (iii) High risk preparations.

1514
1515 (I) Procedures for high-risk level compounded sterile preparations include all those for low-
1516 risk level compounded sterile preparations. In addition, a media-fill test that represents high-risk
1517 level compounding is performed twice a year by each person authorized to compound high-risk
1518 level compounded sterile preparations.

1519

1520 (II) Example of a Media-Fill Test Procedure Compounded Sterile Preparations Sterilized by
1521 Filtration. This test, or an equivalent test, is performed under conditions that closely simulate the
1522 most challenging or stressful conditions encountered when compounding high-risk level
1523 compounded sterile preparations. Note: Sterility tests for autoclaved compounded sterile
1524 preparations are not required unless they are prepared in batches of more than 25 units. This
1525 test is completed without interruption in the following sequence:
1526

1527 (-a-) Dissolve 3 grams of nonsterile commercially available Soybean--Casein Digest
1528 Medium in 100 milliliters of non-bacteriostatic water to make a 3% nonsterile solution.
1529

1530 (-b-) Draw 25 milliliters of the medium into each of three 30-milliliter sterile syringes.
1531 Transfer 5 milliliters from each syringe into separate sterile 10-milliliter vials. These vials are the
1532 positive controls to generate exponential microbial growth, which is indicated by visible turbidity
1533 upon incubation.
1534

1535 (-c-) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron
1536 porosity filter unit and a 20-gauge needle to each syringe. Inject the next 10 milliliters from each
1537 syringe into three separate 10-milliliter sterile vials. Repeat the process for three more vials.
1538 Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at
1539 20 to 35 degrees Celsius for a minimum of 14 days. Inspect for microbial growth over 14 days
1540 as described in Chapter 797 Pharmaceutical Compounding--Sterile Preparations, of the
1541 USP/NF.
1542

1543 (B) Finished preparation release checks and tests.
1544

1545 (i) All high-risk level compounded sterile preparations that are prepared in groups of more
1546 than 25 identical individual single-dose packages (such as ampuls, bags, syringes, and vials), or
1547 in multiple dose vials for administration to multiple patients, or are exposed longer than 12 hours
1548 at 2 - 8 degrees Celsius and longer than six hours at warmer than 8 degrees Celsius before
1549 they are sterilized shall be tested to ensure they are sterile and do not contain excessive
1550 bacterial endotoxins as specified in Chapter 71, Sterility Tests of the USP/NF before being
1551 dispensed or administered.
1552

1553 (ii) All compounded sterile preparations that are intended to be solutions must be visually
1554 examined for the presence of particulate matter and not administered or dispensed when such
1555 matter is observed.
1556

1557 (iii) The prescription drug and medication orders, written compounding procedure,
1558 preparation records, and expended materials used to make compounded sterile preparations at
1559 all contamination risk levels shall be inspected for accuracy of correct identities and amounts of
1560 ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical
1561 appearance before they are dispensed or administered.
1562

1563 (C) Viable and nonviable environmental sampling testing. Environmental sampling shall occur,
1564 at a minimum, every six months as part of a comprehensive quality management program and
1565 under any of the following conditions:
1566

1567 (i) as part of the commissioning and certification of new facilities and equipment;
1568

1569 (ii) following any servicing of facilities and equipment;
1570
1571

1571 (iii) as part of the re-certification of facilities and equipment;

1572

1573 (iv) in response to identified problems with end products or staff technique; or

1574

1575 (v) in response to issues with compounded sterile preparations, observed compounding
1576 personnel work practices, or patient-related infections (where the compounded sterile
1577 preparation is being considered as a potential source of the infection).

1578

1579 (D) Total particle counts. Certification that each ISO classified area (e.g., ISO Class 5, 7, and
1580 8), is within established guidelines shall be performed no less than every six months and
1581 whenever the equipment is relocated or the physical structure of the buffer area or ante-area
1582 has been altered. All certification records shall be maintained and reviewed to ensure that the
1583 controlled environments comply with the proper air cleanliness, room pressures, and air
1584 changes per hour. Testing shall be performed by qualified operators using current, state-of-the-
1585 art equipment. with results of the following:

1586

1587 (i) ISO Class 5 – not more than 3520 particles 0.5 µm and larger size per cubic meter of air;

1588 (ii) ISO Class 7 – not more than 352,000 particles of 0.5 µm and larger size per cubic meter
1589 of air for any buffer area; and

1590 (iii) ISO Class 8 – not more than 3,520,000 particles of 0.5 µm and larger size per cubic
1591 meter of air for any ante-area.

1592

1593 (E) Pressure differential monitoring. A pressure gauge or velocity meter shall be installed to
1594 monitor the pressure differential or airflow between the buffer area and the ante-area and
1595 between the ante-area and the general environment outside the compounding area. The results
1596 shall be reviewed and documented on a log at least every work shift (minimum frequency shall
1597 be at least daily) or by a continuous recording device. The pressure between the ISO Class 7
1598 and the general pharmacy area shall not be less than 0.02 inch water column.

1599

1600 (F) Sampling plan. An appropriate environmental sampling plan shall be developed for
1601 airborne viable particles based on a risk assessment of compounding activities performed.
1602 Selected sampling sites shall include locations within each ISO Class 5 environment and in the
1603 ISO Class 7 and 8 areas and in the segregated compounding areas at greatest risk of
1604 contamination. The plan shall include sample location, method of collection, frequency of
1605 sampling, volume of air sampled, and time of day as related to activity in the compounding area
1606 and action levels.

1607

1608 (G) Viable air sampling. Evaluation of airborne microorganisms using volumetric collection
1609 methods in the controlled air environments shall be performed by properly trained individuals for
1610 all compounding risk levels. For low-, medium-, and high-risk level compounding, air sampling
1611 shall be performed at locations that are prone to contamination during compounding activities
1612 and during other activities such as staging, labeling, gowning, and cleaning. Locations shall
1613 include zones of air backwash turbulence within the laminar airflow workbench and other areas
1614 where air backwash turbulence may enter the compounding area. For low-risk level
1615 compounded sterile preparations within 12-hour or less beyond-use-date prepared in a primary
1616 engineering control that maintains an ISO Class 5, air sampling shall be performed at locations
1617 inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class
1618 5 environment during the certification of the primary engineering control.

1619

1620 (H) Air sampling frequency and process. Air sampling shall be performed at least every 6
1621 months as a part of the re-certification of facilities and equipment. A sufficient volume of air

1622 shall be sampled and the manufacturer's guidelines for use of the electronic air sampling
1623 equipment followed. At the end of the designated sampling or exposure period for air sampling
1624 activities, the microbial growth media plates are recovered and their covers secured and they
1625 are inverted and incubated at a temperature and for a time period conducive to multiplication of
1626 microorganisms. Sampling data shall be collected and reviewed on a periodic basis as a means
1627 of evaluating the overall control of the compounding environment. If an activity consistently
1628 shows elevated levels of microbial growth, competent microbiology personnel shall be
1629 consulted.

1630
1631 (I) Compounding accuracy checks. Written procedures for double-checking compounding
1632 accuracy shall be followed for every compounded sterile preparation during preparation and
1633 immediately prior to release, including label accuracy and the accuracy of the addition of all
1634 drug products or ingredients used to prepare the finished preparation and their volumes or
1635 quantities. At each step of the compounding process, the pharmacist shall ensure that
1636 components used in compounding are accurately weighed, measured, or subdivided as
1637 appropriate to conform to the formula being prepared.

1638
1639 (14) Quality control.

1640
1641 (A) Quality control procedures. The pharmacy shall follow established quality control
1642 procedures to monitor the compounding environment and quality of compounded drug
1643 preparations for conformity with the quality indicators established for the preparation. When
1644 developing these procedures, pharmacy personnel shall consider the provisions of USP
1645 Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical
1646 Compounding—Nonsterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical
1647 Compounding--Sterile Preparations, Chapter 1075, Good Compounding Practices, and Chapter
1648 1160, Pharmaceutical Calculations in Prescription Compounding, and USP Chapter 1163,
1649 Quality Assurance in Pharmaceutical Compounding of the current USP/NF. Such procedures
1650 shall be documented and be available for inspection.

1651
1652 (B) Verification of compounding accuracy and sterility.

1653
1654 (i) The accuracy of identities, concentrations, amounts, and purities of ingredients in
1655 compounded sterile preparations shall be confirmed by reviewing labels on packages, observing
1656 and documenting correct measurements with approved and correctly standardized devices, and
1657 reviewing information in labeling and certificates of analysis provided by suppliers.

1658
1659 (ii) If the correct identity, purity, strength, and sterility of ingredients and components of
1660 compounded sterile preparations cannot be confirmed such ingredients and components shall
1661 be discarded immediately.

1662
1663 (iii) If individual ingredients, such as bulk drug substances, are not labeled with expiration
1664 dates, when the drug substances are stable indefinitely in their commercial packages under
1665 labeled storage conditions, such ingredients may gain or lose moisture during storage and use
1666 and shall require testing to determine the correct amount to weigh for accurate content of active
1667 chemical moieties in compounded sterile preparations.

1668
1669 (e) Records. Any testing, cleaning, procedures, or other activities required in this subsection
1670 shall be documented and such documentation shall be maintained by the pharmacy.

1671
1672 (1) Maintenance of records. Every record required under this section must be:

1673
1674 (A) kept by the pharmacy and be available, for at least two years for inspecting and copying
1675 by the board or its representative and to other authorized local, state, or federal law
1676 enforcement agencies; and
1677

1678 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
1679 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,
1680 the requested records must be provided in an electronic format. Failure to provide the records
1681 set out in this section, either on site or within 72 hours, constitutes prima facie evidence of
1682 failure to keep and maintain records in violation of the Act.
1683

1684 (2) Compounding records.

1685
1686 (A) Compounding pursuant to patient specific prescription drug orders. Compounding records
1687 for all compounded preparations shall be maintained by the pharmacy electronically or manually
1688 as part of the prescription drug or medication order, formula record, formula book, or
1689 compounding log and shall include:

1690 (i) the date of preparation;

1691
1692 (ii) a complete formula, including methodology and necessary equipment which includes the
1693 brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name
1694 and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of
1695 each;
1696

1697 (iii) signature or initials of the pharmacist or pharmacy technician or pharmacy technician
1698 trainee performing the compounding;

1699 (iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians
1700 or pharmacy technician trainees and conducting in-process and finals checks of compounded
1701 pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the
1702 compounding function;

1703 (v) the quantity in units of finished preparation or amount of raw materials;

1704 (vi) the container used and the number of units prepared; and

1705 (vii) a reference to the location of the following documentation which may be maintained with
1706 other records, such as quality control records:

1707 (I) the criteria used to determine the beyond-use date; and

1708 (II) documentation of performance of quality control procedures.
1709

1710 (B) Compounding records when batch compounding or compounding in anticipation of future
1711 prescription drug or medication orders.

1712 (i) Master work sheet. A master work sheet shall be developed and approved by a
1713 pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work
1714 sheet shall be used as the preparation work sheet from which each batch is prepared and on
1715
1716
1717
1718
1719
1720
1721
1722

1723 which all documentation for that batch occurs. The master work sheet shall contain at a
1724 minimum:

- 1725 (I) the formula;
- 1726 (II) the components;
- 1727 (III) the compounding directions;
- 1728 (IV) a sample label;
- 1729 (V) evaluation and testing requirements;
- 1730 (VI) specific equipment used during preparation; and
- 1731 (VII) storage requirements.

1732 (ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall
1733 document the following:

- 1734 (I) identity of all solutions and ingredients and their corresponding amounts,
1735 concentrations, or volumes;
- 1736 (II) lot number for each component;
- 1737 (III) component manufacturer/distributor or suitable identifying number;
- 1738 (IV) container specifications (e.g., syringe, pump cassette);
- 1739 (V) unique lot or control number assigned to batch;
- 1740 (VI) expiration date of batch-prepared preparations;
- 1741 (VII) date of preparation;
- 1742 (VIII) name, initials, or electronic signature of the person(s) involved in the preparation;
- 1743 (IX) name, initials, or electronic signature of the responsible pharmacist;
- 1744 (X) finished preparation evaluation and testing specifications, if applicable; and
- 1745 (XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.

1746 (f) Office Use Compounding and Distribution of Sterile Compounded Preparations

1747 (1) General.

1748 (A) A pharmacy may compound, dispense, deliver, and distribute a compounded sterile
1749 preparation as specified in subchapter D, Texas Pharmacy Act Chapter 562.

1750

1773 (B) A Class A-S pharmacy is not required to register or be licensed under Chapter 431, Health
1774 and Safety Code, to distribute sterile compounded preparations to a Class C or Class C-S
1775 pharmacy.
1776

1777 (C) A Class C-S pharmacy is not required to register or be licensed under Chapter 431,
1778 Health and Safety Code, to distribute sterile compounded preparations that the Class C-S
1779 pharmacy has compounded for other Class C or Class C-S pharmacies under common
1780 ownership.

1781 (D) To compound and deliver a compounded preparation under this subsection, a pharmacy
1782 must:

1783
1784 (i) verify the source of the raw materials to be used in a compounded drug;

1785
1786 (ii) comply with applicable United States Pharmacopoeia guidelines, including the testing
1787 requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No.
1788 104-191);

1789
1790 (iii) enter into a written agreement with a practitioner for the practitioner's office use of a
1791 compounded preparation;

1792
1793 (iv) comply with all applicable competency and accrediting standards as determined by the
1794 board; and

1795
1796 (v) comply with the provisions of this subsection.
1797

1798 (2) Written Agreement. A pharmacy that provides sterile compounded preparations to
1799 practitioners for office use or to another pharmacy shall enter into a written agreement with the
1800 practitioner or pharmacy. The written agreement shall:

1801
1802 (A) address acceptable standards of practice for a compounding pharmacy and a practitioner
1803 and receiving pharmacy that enter into the agreement including a statement that the
1804 compounded drugs may only be administered to the patient and may not be dispensed to the
1805 patient or sold to any other person or entity except to a veterinarian as authorized by §563.054
1806 of the Act;

1807
1808 (B) require the practitioner or receiving pharmacy to include on a patient's chart, medication
1809 order or medication administration record the lot number and beyond-use date of a
1810 compounded preparation administered to a patient;

1811
1812 (C) describe the scope of services to be performed by the pharmacy and practitioner or
1813 receiving pharmacy, including a statement of the process for:

1814
1815 (i) a patient to report an adverse reaction or submit a complaint; and

1816
1817 (ii) the pharmacy to recall batches of compounded preparations.
1818

1819 (3) Recordkeeping.

1820
1821 (A) Maintenance of Records.
1822

1823 (i) Records of orders and distribution of sterile compounded preparations to a practitioner for
1824 office use or to an institutional pharmacy for administration to a patient shall:

1825
1826 (I) be kept by the pharmacy and be available, for at least two years from the date of the
1827 record, for inspecting and copying by the board or its representative and to other authorized
1828 local, state, or federal law enforcement agencies;

1829
1830 (II) maintained separately from the records of preparations dispensed pursuant to a
1831 prescription or medication order; and

1832
1833 (III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
1834 Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in
1835 an electronic format, the requested records must be provided in an electronic format. Failure to
1836 provide the records set out in this subsection, either on site or within 72 hours for whatever
1837 reason, constitutes prima facie evidence of failure to keep and maintain records.

1838
1839 (ii) Records may be maintained in an alternative data retention system, such as a data
1840 processing system or direct imaging system provided the data processing system is capable of
1841 producing a hard copy of the record upon the request of the board, its representative, or other
1842 authorized local, state, or federal law enforcement or regulatory agencies.

1843
1844 (B) Orders. The pharmacy shall maintain a record of all sterile compounded preparations
1845 ordered by a practitioner for office use or by an institutional pharmacy for administration to a
1846 patient. The record shall include the following information:

1847
1848 (i) date of the order;

1849
1850 (ii) name, address, and phone number of the practitioner who ordered the preparation and if
1851 applicable, the name, address and phone number of the institutional pharmacy ordering the
1852 preparation; and

1853
1854 (iii) name, strength, and quantity of the preparation ordered.

1855
1856 (C) Distributions. The pharmacy shall maintain a record of all sterile compounded
1857 preparations distributed pursuant to an order to a practitioner for office use or by an institutional
1858 pharmacy for administration to a patient. The record shall include the following information:

1859
1860 (i) date the preparation was compounded;

1861
1862 (ii) date the preparation was distributed;

1863
1864 (iii) name, strength and quantity in each container of the preparation;

1865
1866 (iv) pharmacy's lot number;

1867
1868 (v) quantity of containers shipped; and

1869
1870 (vi) name, address, and phone number of the practitioner or institutional pharmacy to whom
1871 the preparation is distributed.

1872
1873 (D) Audit Trail.

1874
1875 (i) The pharmacy shall store the order and distribution records of preparations for all sterile
1876 compounded preparations ordered by and or distributed to a practitioner for office use or by a
1877 Class S pharmacy for administration to a patient in such a manner as to be able to provide an
1878 audit trail for all orders and distributions of any of the following during a specified time period.
1879
1880 (I) any strength and dosage form of a preparation (by either brand or generic name or
1881 both);
1882
1883 (II) any ingredient;
1884
1885 (III) any lot number;
1886
1887 (IV) any practitioner;
1888
1889 (V) any facility; and
1890
1891 (VI) any pharmacy, if applicable.
1892
1893 (ii) The audit trail shall contain the following information:
1894
1895 (I) date of order and date of the distribution;
1896
1897 (II) practitioner's name, address, and name of the institutional pharmacy, if applicable;
1898
1899 (III) name, strength and quantity of the preparation in each container of the preparation;
1900
1901 (IV) name and quantity of each active ingredient;
1902
1903 (V) quantity of containers distributed; and
1904
1905 (VI) pharmacy's lot number;
1906
1907 (4) Labeling. The pharmacy shall affix a label to the preparation containing the following
1908 information:
1909
1910 (A) name, address, and phone number of the compounding pharmacy;
1911
1912 (B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation
1913 is distributed to a veterinarian the statement: "Compounded Preparation";
1914
1915 (C) name and strength of the preparation or list of the active ingredients and strengths;
1916
1917 (D) pharmacy's lot number;
1918
1919 (E) beyond-use date as determined by the pharmacist using appropriate documented criteria;
1920
1921 (F) quantity or amount in the container;
1922
1923 (G) appropriate ancillary instructions, such as storage instructions or cautionary statements,
1924 including hazardous drug warning labels where appropriate; and

1925
1926 (H) device-specific instructions, where appropriate.
1927
1928 (g) Recall Procedures.
1929
1930 (1) The pharmacy shall have written procedures for the recall of any compounded sterile
1931 preparation provided to a patient, to a practitioner for office use, or a pharmacy for
1932 administration. Written procedures shall include, but not be limited to the requirements as
1933 specified in paragraph (3) of this subsection.
1934
1935 (2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by
1936 the pharmacy upon identification of a potential or confirmed harm to a patient.
1937
1938 (3) In the event of a recall, the pharmacist-in-charge shall ensure that:
1939
1940 (A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is
1941 notified, in writing, of the recall;
1942
1943 (B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;
1944
1945 (C) the board is notified of the recall, in writing, not later than 24 hours after the recall is
1946 issued;
1947
1948 (D) if the preparation is distributed for office use, the Texas Department of State Health
1949 Services, Drugs and Medical Devices Group, is notified of the recall, in writing;
1950
1951 (E) the preparation is quarantined; and
1952
1953 (F) the pharmacy keeps a written record of the recall including all actions taken to notify all
1954 parties and steps taken to ensure corrective measures.
1955
1956 (4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if
1957 there is potential for or confirmed harm to a patient.
1958
1959 (5) A pharmacy that compounds sterile preparations shall notify the board immediately of any
1960 adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially
1961 attributable to a sterile preparation compounded by the pharmacy.

AN ACT

relating to the licensing and inspection of certain out-of-state pharmacies by the Texas State Board of Pharmacy; authorizing fees.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter B, Chapter 556, Occupations Code, is amended by adding Section 556.0551 to read as follows:

Sec. 556.0551. INSPECTION OF LICENSED NONRESIDENT PHARMACY.

(a) The board may inspect a nonresident pharmacy licensed by the board that compounds sterile preparations as necessary to ensure compliance with the safety standards and other requirements of this subtitle and board rules.

(b) A nonresident pharmacy shall reimburse the board for all expenses, including travel, incurred by the board in inspecting the pharmacy as provided by Subsection (a).

SECTION 2. Subsection (b), Section 560.001, Occupations Code, is amended to read as follows:

(b) A pharmacy located in another state may not ship, mail, or deliver to this state a prescription drug or device dispensed under a prescription drug order, or dispensed or delivered as authorized by Subchapter D, Chapter 562, [~~to a resident of this state~~] unless the pharmacy is licensed by the board or is exempt under Section 560.004.

SECTION 3. Section 560.052, Occupations Code, is amended by amending Subsections (b) and (c) and adding Subsections (g) and (h) to read as follows:

(b) To qualify for a pharmacy license, an applicant must submit to the board:

(1) a license fee set by the board, except as provided by Subsection (d); and

(2) a completed application that:

(A) is on a form prescribed by the board;

(B) is given under oath; and

(C) includes a statement of:

(i) the ownership;

(ii) the location of the pharmacy;

(iii) the license number of each pharmacist who is employed by the pharmacy, if the pharmacy is located in this state, or who is licensed to practice pharmacy in this state, if the pharmacy is located in another state [~~a Class E pharmacy~~];

(iv) the license number of the pharmacist-in-charge; and

(v) any other information the board determines necessary.

(c) A pharmacy located in another state that applies for a license [~~To qualify for a Class E pharmacy license, an applicant~~], in addition to satisfying the other requirements of this chapter,

must provide to the board:

(1) evidence that the applicant holds a pharmacy license, registration, or permit in good standing issued by the state in which the pharmacy is located;

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

(3) evidence of the applicant's ability to provide to the board a record of a prescription drug order dispensed or delivered as authorized by Subchapter D, Chapter 562, by the applicant to a resident of or practitioner in this state not later than 72 hours after the time the board requests the record;

(4) an affidavit by the pharmacist-in-charge that states that the pharmacist has read and understands the laws and rules relating to the applicable license [~~a Class E pharmacy~~];

(5) proof of creditworthiness; [~~and~~]

(6) an inspection report issued:

(A) not more than two years before the date the license application is received; and

(B) by the pharmacy licensing board in the state of the pharmacy's physical location, except as provided by Subsection (f); and

(7) any other information the board determines necessary.

(g) A license may not be issued to a pharmacy that compounds

sterile preparations unless the pharmacy has been inspected by the board to ensure the pharmacy meets the safety standards and other requirements of this subtitle and board rules.

(h) The board may accept, as satisfying the inspection requirement in Subsection (g) for a pharmacy located in another state, an inspection report issued by the pharmacy licensing board in the state in which the pharmacy is located if:

(1) the board determines that the other state has comparable standards and regulations applicable to pharmacies, including standards and regulations related to health and safety; and

(2) the pharmacy provides to the board any requested documentation related to the inspection.

SECTION 4. Chapter 561, Occupations Code, is amended by adding Section 561.0032 to read as follows:

Sec. 561.0032. ADDITIONAL RENEWAL REQUIREMENT FOR COMPOUNDING PHARMACY. (a) In addition to the renewal requirements under Section 561.003, a pharmacy that compounds sterile preparations may not renew a pharmacy license unless the pharmacy:

(1) has been inspected as provided by board rule; and

(2) if the pharmacy is located in another state, has reimbursed the board for all expenses, including travel, incurred by the board in inspecting the pharmacy during the term of the expiring license.

(b) The board may accept, as satisfying the inspection requirement in Subsection (a) for a pharmacy located in another state, an inspection report issued by the pharmacy licensing board in the state in which the pharmacy is located if:

(1) the board determines that the other state has comparable standards and regulations applicable to pharmacies, including standards and regulations related to health and safety; and

(2) the pharmacy provides to the board any requested documentation related to the inspection.

SECTION 5. Subsection (a), Section 562.106, Occupations Code, is amended to read as follows:

(a) A pharmacy shall report in writing to the board not later than the 10th day after the date of:

(1) a permanent closing of the pharmacy;

(2) a change of ownership of the pharmacy;

(3) a change of location of the pharmacy;

(4) a change of the person designated as the pharmacist-in-charge of the pharmacy;

(5) a sale or transfer of any controlled substance or dangerous drug as a result of the permanent closing or change of ownership of the pharmacy;

(6) any matter or occurrence that the board requires by rule to be reported;

(7) as determined by the board, an out-of-state purchase of any controlled substance;

(8) a final order against the pharmacy license holder by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state [~~a Class E pharmacy~~]; or

(9) a final order against a pharmacist who is designated as the pharmacist-in-charge of the pharmacy by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state [~~a Class E pharmacy~~].

SECTION 6. Subchapter D, Chapter 562, Occupations Code, is amended by adding Section 562.156 to read as follows:

Sec. 562.156. COMPOUNDED STERILE PREPARATION; NOTICE TO BOARD. (a) A pharmacy may not compound and dispense a sterile preparation unless the pharmacy holds a license as required by board rule.

(b) A pharmacy that compounds a sterile preparation shall notify the board:

(1) immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy;
and

(2) not later than 24 hours after the pharmacy issues a recall for a sterile preparation compounded by the pharmacy.

SECTION 7. Section 565.003, Occupations Code, is amended to read as follows:

Sec. 565.003. ADDITIONAL GROUNDS FOR DISCIPLINE REGARDING APPLICANT FOR OR HOLDER OF NONRESIDENT [~~CLASS E~~] PHARMACY LICENSE.

[~~(b)~~] Unless compliance would violate the pharmacy or drug statutes or rules in the state in which the pharmacy is located the board may discipline an applicant for or the holder of a nonresident [~~Class E~~] pharmacy license if the board finds that the applicant or license holder has failed to comply with:

- (1) Section 481.074 or 481.075, Health and Safety Code;
- (2) Texas substitution requirements regarding:

(A) the practitioner's directions concerning generic substitution;

(B) the patient's right to refuse generic substitution; or

(C) notification to the patient of the patient's right to refuse substitution;

(3) any board rule relating to providing drug information to the patient or the patient's agent in written form or by telephone; or

(4) any board rule adopted under Section 554.051(a) and determined by the board to be applicable under Section 554.051(b).

SECTION 8. Section 565.053, Occupations Code, is amended to read as follows:

Sec. 565.053. DISCIPLINE OF NONRESIDENT [~~CLASS E~~] PHARMACY; NOTICE TO RESIDENT STATE. The board shall give notice of a disciplinary action by the board against a license [~~the~~] holder located in another state [~~of a Class E pharmacy license~~] to the regulatory or licensing agency of the state in which the pharmacy is located.

SECTION 9. The heading to Section 565.054, Occupations Code, is amended to read as follows:

Sec. 565.054. SERVICE OF PROCESS ON NONRESIDENT [~~CLASS E~~] PHARMACY.

SECTION 10. Subsection (a), Section 565.054, Occupations Code, is amended to read as follows:

(a) Service of process on a nonresident [~~Class E~~] pharmacy under Section 565.058 or 566.051 or for disciplinary action taken by the board under Section 565.061 shall be on the owner and pharmacist-in-charge of the pharmacy, as designated on the pharmacy's license application.

SECTION 11. Not later than March 1, 2014, the Texas State Board of Pharmacy shall adopt rules necessary to implement the changes in law made by this Act.

SECTION 12. Section 560.052, Occupations Code, as amended by this Act, applies only to an application for a pharmacy license submitted to the Texas State Board of Pharmacy on or after the effective date of this Act. An application for a license submitted

before the effective date of this Act is governed by the law in effect on the date the application was submitted, and the former law is continued in effect for that purpose.

SECTION 13. Section 561.0032, Occupations Code, as added by this Act, applies only to the renewal of a pharmacy license that expires on or after the effective date of this Act. A license that expires before the effective date of this Act is governed by the law in effect on the date the license expired, and the former law is continued in effect for that purpose.

SECTION 14. This Act takes effect September 1, 2013.

President of the Senate

Speaker of the House

I hereby certify that S.B. No. 1100 passed the Senate on May 1, 2013, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

I hereby certify that S.B. No. 1100 passed the House on May 22, 2013, by the following vote: Yeas 143, Nays 5, two present not voting.

Chief Clerk of the House

Approved:

Date

Governor

1
2 **TITLE 22 EXAMINING BOARDS**
3 **PART 15 TEXAS STATE BOARD OF PHARMACY**
4 **CHAPTER 291 PHARMACIES**
5 **SUBCHAPTER B COMMUNITY PHARMACY (CLASS A)**

6
7 **§291.33 Operational Standards**

8
9 (a) Licensing requirements.

10
11 (1) – (8) (No change.)

12
13 (9) A Class A pharmacy engaged in the compounding of non-sterile preparations shall comply
14 with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile
15 Preparations).

16
17 (10) Prior to June 1, 2014, a [A] Class A pharmacy engaged in the compounding of sterile
18 preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies
19 Compounding Sterile Preparations).

20
21 **(11) Effective June 1, 2014, a Class A pharmacy shall not compound sterile preparations**
22 **unless the pharmacy has applied and obtained a Class A-S pharmacy license.**

23
24 **(12) [(14)]** A Class A pharmacy engaged in the provision of remote pharmacy services,
25 including storage and dispensing of prescription drugs, shall comply with the provisions of
26 §291.121 of this title (relating to Remote Pharmacy Services).

27
28 **(13) [(12)]** Class A pharmacy engaged in centralized prescription dispensing and/or prescription
29 drug or medication order processing shall comply with the provisions of §291.123 of this title
30 (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of
31 this title (relating to Centralized Prescription Dispensing).

32
33 (c) – (i) (No change.)
34
35

36 **§291.36 Pharmacies Compounding Sterile Preparations (Class A-S)**

37
38 **Licensing requirements. A pharmacy engaged in the compounding of sterile**
39 **preparations shall be designated as a Class A-S pharmacy.**

40
41 **(1) A Class A-S pharmacy shall register annually or biennially with the board on a**
42 **pharmacy license application provided by the board, following the procedures as**
43 **specified in §291.1 of this title (relating to Pharmacy License Application). A Class A-S**
44 **license may not be issued unless the pharmacy has been inspected by the board to**
45 **ensure the pharmacy meets the requirements as specified in §291.133 of this chapter**
46 **(relating to Pharmacies Compounding Sterile Preparations).**

47
48 **(2) A Class A-S pharmacy may not renew a pharmacy license unless the pharmacy has**
49 **been inspected by the board within the last renewal period.**
50

51 (3) A Class A-S pharmacy which changes ownership shall notify the board within ten
52 days of the change of ownership and apply for a new and separate license as specified in
53 §291.3 of this title (relating to Required Notifications).

54
55 (4) A Class A-S pharmacy which changes location and/or name shall notify the board
56 within ten days of the change and file for an amended license as specified in §291.3 of
57 this title.

58
59 (5) A Class A-S pharmacy owned by a partnership or corporation which changes
60 managing officers shall notify the board in writing of the names of the new managing
61 officers within ten days of the change, following the procedures as specified in §291.3 of
62 this title.

63
64 (6) A Class A-S pharmacy shall notify the board in writing within ten days of closing,
65 following the procedures as specified in §291.5 of this title (relating to Closing a
66 Pharmacy).

67
68 (7) A separate license is required for each principal place of business and only one
69 pharmacy license may be issued to a specific location.

70
71 (8) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
72 charged for the issuance and renewal of a license and the issuance of an amended
73 license.

74
75 (9) A Class A-S pharmacy which would otherwise be required to be licensed under the
76 Act, §560.051(a)(1) concerning Community Pharmacy (Class A) is required to comply
77 with the provisions of §291.31 of this subchapter (relating to Definitions), §291.32 of this
78 subchapter (relating to Personnel), §291.33 of this subchapter (relating to Operational
79 Standards), §291.34 of this subchapter (relating to Records), §291.35 of this subchapter
80 (relating to Official Prescription Records), and §291.133 of this title (relating to
81 Pharmacies Compounding Sterile Preparations).

82
83 (10) A Class A-S pharmacy engaged in the compounding of non-sterile preparations
84 shall comply with the provisions of §291.131 of this title (relating to Pharmacies
85 Compounding Non-Sterile Preparations).

86
87 (11) A Class A-S pharmacy engaged in the provision of remote pharmacy services,
88 including storage and dispensing of prescription drugs, shall comply with the provisions
89 of §291.121 of this title (relating to Remote Pharmacy Services).

90
91 (12) A Class A-S pharmacy engaged in centralized prescription dispensing and/or
92 prescription drug or medication order processing shall comply with the provisions of
93 §291.123 of this title (relating to Centralized Prescription Drug or Medication Order
94 Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).
95

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER C NUCLEAR PHARMACY (CLASS B)

5
6 **§291.54 Operational Standards**

7
8 (a) Licensing requirements.

9
10 (1) – (10) (No change.)

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

15
16 (12) **Prior to June 1, 2014, a [A]-Class B [~~nuclear~~] pharmacy engaged in the compounding of**
17 **sterile non-radioactive preparations shall comply with the provisions of §291.133 of this title**
18 **(relating to Pharmacies Compounding Sterile Preparations).**

19
20 **(13) Effective June 1, 2014, a Class B pharmacy shall not compound sterile preparations**
21 **unless the pharmacy has applied and obtained a Class B-S pharmacy license.**

22
23 (b) – (i) (No change.)

24
25
26 **§291.56 Pharmacies Compounding Sterile Preparations (Class B-S)**

27
28 **Licensing requirements. A pharmacy engaged in the compounding of sterile**
29 **preparations shall be designated as a Class B-S pharmacy.**

30
31 **(1) It is unlawful for a person to provide radioactive drug services unless such provision**
32 **is performed by a person licensed to act as an authorized nuclear pharmacist, as defined**
33 **by the board, or is a person acting under the direct supervision of an authorized nuclear**
34 **pharmacist acting in accordance with the Act and its rules, and the regulations of the**
35 **Texas Department of State Health Services, Radiation Control Program. Subsection (a) of**
36 **this section does not apply to:**

37 **(A) a licensed practitioner or his or her designated agent for administration to his or**
38 **her patient, provided no person may receive, possess, use, transfer, own, acquire, or**
39 **dispose of radiopharmaceuticals except as authorized in a specific or a general license**
40 **as provided in accordance with the requirements of the Texas Department of State Health**
41 **Services, Radiation Control Program, Texas Administrative Code, Title 25, Part 1,**
42 **Subchapter F, §289.252 relating to Licensing of Radioactive Material, or the Act;**

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

47
48 **(2) An applicant for a Class B-S pharmacy shall provide evidence to the board of the**
49 **possession of a Texas Department of State Health Services radioactive material license**
50 **or proof of application for a radioactive material license.**

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

58
59 (4) A Class B-S pharmacy may not renew a pharmacy license unless the pharmacy has
60 been inspected by the board within the last renewal period.

61
62 (5) A Class B-S pharmacy which changes ownership shall notify the board within ten
63 days of the change of ownership and apply for a new and separate license as specified in
64 §291.3 of this title (relating to Required Notifications).

65
66 (6) A Class B-S pharmacy which changes location and/or name shall notify the board
67 within ten days of the change and file for an amended license as specified in §291.3 of
68 this title.

69
70 (7) A Class B-S pharmacy owned by a partnership or corporation which changes
71 managing officers shall notify the board in writing of the names of the new managing
72 officers within ten days of the change, following the procedures as specified in §291.3 of
73 this title.

74
75 (8) A Class B-S pharmacy shall notify the board in writing within ten days of closing,
76 following the procedures as specified in §291.5 of this title (relating to Closing a
77 Pharmacy).

78
79 (9) A separate license is required for each principal place of business and only one
80 pharmacy license may be issued to a specific location.

81
82 (10) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
83 charged for the issuance and renewal of a license and the issuance of an amended
84 license.

85
86 (11) A Class B-S pharmacy which would otherwise be required to be licensed under the
87 Act, §560.051(a)(1) concerning Community Pharmacy (Class A) is required to comply
88 with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title
89 (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of
90 this title (relating to Records), and §291.35 of this title (relating to Official Prescription
91 Records), and §291.133 of this title (relating to Pharmacies Compounding Sterile
92 Preparations).

93
94 (12) A Class B-S pharmacy engaged in the compounding of non-sterile preparations
95 shall comply with the provisions of §291.131 of this title (relating to Pharmacies
96 Compounding Non-Sterile Preparations).

97
98 (13) A Class B-S pharmacy engaged in the provision of remote pharmacy services,
99 including storage and dispensing of prescription drugs, shall comply with the provisions
100 of §291.121 of this title (relating to Remote Pharmacy Services).

102 (14) A Class B-S pharmacy engaged in centralized prescription dispensing and/or
103 prescription drug or medication order processing shall comply with the provisions of
104 §291.123 of this title (relating to Centralized Prescription Drug or Medication Order
105 Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).
106

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER D INSTITUTIONAL PHARMACY (CLASS C)

5
6 **§291.74 Operational Standards**
7

8 (a) Licensing requirements.

9
10 (1) – (9) (No change.)

11
12 (10) A Class C ~~[(Institutional)]~~ pharmacy engaged in the compounding of non-sterile
13 preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies
14 Compounding Non-sterile Preparations).

15
16 (11) **Prior to June 1, 2014, a** [A] Class C ~~[(Institutional)]~~ pharmacy engaged in the
17 compounding of sterile preparations shall comply with the provisions of §291.133 of this title
18 (relating to Pharmacies Compounding Sterile Preparations).

19
20 **(12) Effective June 1, 2014, a Class C pharmacy shall not compound sterile preparations**
21 **unless the pharmacy has applied and obtained a Class C-S pharmacy.**

22
23 **(13)** ~~[(12)]~~ A Class C ~~[(Institutional)]~~ pharmacy engaged in the provision of remote pharmacy
24 services, including storage and dispensing of prescription drugs, shall comply with the
25 provisions of §291.121 of this title (relating to Remote Pharmacy Services).

26
27 **(14)** ~~[(13)]~~ A Class C ~~[(Institutional)]~~ pharmacy engaged in centralized prescription dispensing
28 and/or prescription drug or medication order processing shall comply with the provisions of
29 §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing)
30 and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

31
32 **(15)** ~~[(14)]~~ A Class C ~~[(Institutional)]~~ pharmacy with an ongoing clinical pharmacy program that
33 proposes to allow a pharmacy technician to verify the accuracy of work performed by another
34 pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a
35 patient admitted to the hospital if the patient's orders have previously been reviewed and
36 approved by a pharmacist shall make application to the board as follows.

37
38 (A) The pharmacist-in-charge must submit an application on a form provided by the board,
39 containing the following information:

40
41 (i) name, address, and pharmacy license number;

42
43 (ii) name and license number of the pharmacist-in-charge;

44
45 (iii) name and registration numbers of the pharmacy technicians;

46
47 (iv) anticipated date the pharmacy plans to begin allowing a pharmacy technician to verify
48 the accuracy of work performed by another pharmacy technician;

49
50 (v) documentation that the pharmacy has an ongoing clinical pharmacy program; and
51

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

53
54 (B) The pharmacy may not allow a pharmacy technician to check the work of another
55 pharmacy technician until the board has reviewed and approved the application and issued an
56 amended license to the pharmacy.

57
58 (C) Every two years, in connection with the application for renewal of the pharmacy license,
59 the pharmacy shall provide updated documentation that the pharmacy continues to have an
60 ongoing clinical pharmacy program as specified in subparagraph (A)(v) of this paragraph.

61
62 **(16)** ~~[(15)]~~ A rural hospital that wishes to allow a pharmacy technician to perform the duties
63 specified in §291.73(e)(2)(D) of this title (relating to Personnel), shall make application to the
64 board as follows.

65
66 ~~[(A) For an initial applications prior to September 1, 2010, the pharmacist-in-charge must~~
67 ~~submit a letter to the board containing the following information:~~

68
69 ~~—(i) name, address, and pharmacy license number;~~

70
71 ~~—(ii) name and license number of the pharmacist-in-charge;~~

72
73 ~~—(iii) name and registration number of the pharmacy technicians;~~

74
75 ~~—(iv) a statement indicating that pharmacy technicians will be performing the duties specified~~
76 ~~in §291.73(e)(2)(D) of this title; and~~

77
78 ~~—(v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural~~
79 ~~hospital is either:~~

80
81 ~~—(I) located in a county with a population of 50,000 or less as defined by the United States~~
82 ~~Census Bureau in the most recent U.S. census; or~~

83
84 ~~—(II) designated by the Centers for Medicare and Medicaid Services as a critical access~~
85 ~~hospital, rural referral center, or sole community hospital.]~~

86
87 **(A)** ~~[(B) After September 1, 2010 and prior]~~ **Prior** to allowing a pharmacy technician to perform
88 the duties specified in §291.73(e)(2)(D) of this title, the pharmacist-in-charge must submit an
89 application on a form provided by the board, containing the following information:

90
91 (i) name, address, and pharmacy license number;

92
93 (ii) name and license number of the pharmacist-in-charge;

94
95 (iii) name and registration number of the pharmacy technicians;

96
97 (iv) proposed date the pharmacy wishes to start allowing pharmacy technicians to perform
98 the duties specified in §291.73(e)(2)(D) of this title;

99
100 (v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural
101 hospital is either:

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

105
106 (II) designated by the Centers for Medicare and Medicaid Services as a critical access
107 hospital, rural referral center, or sole community hospital; and

108
109 (vi) any other information specified on the application.

110
111 **(B)** ~~[(C)]~~ A rural hospital ~~[that makes application after September 1, 2010]~~ may not allow a
112 pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title until the
113 board has reviewed and approved the application and issued an amended license to the
114 pharmacy.

115
116 **(C)** ~~[(C)]~~ Every two years in conjunction with the application for renewal of the pharmacy license,
117 the pharmacist-in-charge shall update the application for pharmacy technicians to perform the
118 duties specified in §291.73(e)(2)(D) of this title.

119
120 (b) – (j) (No change.)

121
122 **§291.76 Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center**

123
124 (a) – (c) (No change.)

125
126 (d) Operational standards.

127
128 (1) Licensing requirements.

129
130 (A) – (I) (No change.)

131
132 (J) An ASC pharmacy engaged in the compounding of non-sterile preparations shall comply
133 with the provisions of §291.131 of this title.

134
135 (K) **Prior to June 1, 2014, an [An]** ASC pharmacy engaged in the compounding of sterile
136 preparations shall comply with the provisions of §291.133 of this title.

137
138 **(L) Effective June 1, 2014, an ASC pharmacy must discontinue compounding sterile**
139 **preparations and shall be licensed as a Class C-S pharmacy.**

140
141 **(M)** ~~[(L)]~~ An ASC pharmacy engaged in the provision of remote pharmacy services, including
142 storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of
143 this title (relating to Remote Pharmacy Services).

144
145 **(N)** ~~[(M)]~~ An ASC pharmacy engaged in centralized prescription dispensing and/or
146 prescription drug or medication order processing shall comply with the provisions of §291.123 of
147 this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or
148 §291.125 of this title (relating to Centralized Prescription Dispensing).

149
150 (2) – (9) (No change.)

151
152 (e) (No change.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

206
207 (10) A Class C-S pharmacy, licensed under the Act, §560.051(a)(3), which also operates
208 another type of pharmacy which would otherwise be required to be licensed under the
209 Act, §560.051(a)(1) (Community Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear
210 Pharmacy (Class B)), is not required to secure a license for the such other type of
211 pharmacy; provided, however, such licensee is required to comply with the provisions of
212 §291.31 of this subchapter (relating to Definitions), §291.32 of this subchapter (relating to
213 Personnel), §291.33 of this subchapter (relating to Operational Standards), §291.34 of this
214 subchapter (relating to Records), and §291.35 of this subchapter (relating to Official
215 Prescription Records), contained in Community Pharmacy (Class A), or §291.51 of this
216 title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title
217 (relating to Personnel), §291.54 of this title (relating to Operational Standards), and
218 §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the
219 extent such sections are applicable to the operation of the pharmacy.

220
221 (11) A Class C-S pharmacy engaged in the compounding of non-sterile preparations
222 shall comply with the provisions of §291.131 of this title (relating to Pharmacies
223 Compounding Non-sterile Preparations).

224
225 (12) A Class C-S pharmacy engaged in the provision of remote pharmacy services,
226 including storage and dispensing of prescription drugs, shall comply with the provisions
227 of §291.121 of this title (relating to Remote Pharmacy Services).

228
229 (13) A Class C-S pharmacy engaged in centralized prescription dispensing and/or
230 prescription drug or medication order processing shall comply with the provisions of
231 §291.123 of this title (relating to Central Prescription Drug or Medication Order
232 Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

233
234 (14) A Class C-S pharmacy with an ongoing clinical pharmacy program that proposes to
235 allow a pharmacy technician to verify the accuracy of work performed by another
236 pharmacy technician relating to the filling of floor stock and unit dose distribution
237 systems for a patient admitted to the hospital if the patient's orders have previously been
238 reviewed and approved by a pharmacist shall make application to the board as follows.

239
240 (A) The pharmacist-in-charge must submit an application on a form provided by the
241 board, containing the following information:

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

244
245 (ii) name and license number of the pharmacist-in-charge;

246
247 (iii) name and registration numbers of the pharmacy technicians;

248
249 (iv) anticipated date the pharmacy plans to begin allowing a pharmacy technician to
250 verify the accuracy of work performed by another pharmacy technician;

251
252 (v) documentation that the pharmacy has an ongoing clinical pharmacy program; and

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

255
256 (B) The pharmacy may not allow a pharmacy technician to check the work of another
257 pharmacy technician until the board has reviewed and approved the application and
258 issued an amended license to the pharmacy.

259
260 (C) Every two years, in connection with the application for renewal of the pharmacy
261 license, the pharmacy shall provide updated documentation that the pharmacy continues
262 to have an ongoing clinical pharmacy program as specified in subparagraph (A)(v) of this
263 paragraph.

264
265 (15) A rural hospital that wishes to allow a pharmacy technician to perform the duties
266 specified in §291.73(e)(2)(D) of this title (relating to Personnel), shall make application to
267 the board as follows.

268
269 (A) Prior to allowing a pharmacy technician to perform the duties specified in
270 §291.73(e)(2)(D) of this title, the pharmacist-in-charge must submit an application on a
271 form provided by the board, containing the following information:

272
273 (i) name, address, and pharmacy license number;

274
275 (ii) name and license number of the pharmacist-in-charge;

276
277 (iii) name and registration number of the pharmacy technicians;

278
279 (iv) proposed date the pharmacy wishes to start allowing pharmacy technicians to
280 perform the duties specified in §291.73(e)(2)(D) of this title;

281
282 (v) documentation that the hospital is a rural hospital with 75 or fewer beds and that
283 the rural hospital is either:

284
285 (I) located in a county with a population of 50,000 or less as defined by the United
286 States Census Bureau in the most recent U.S. census; or

287
288 (II) designated by the Centers for Medicare and Medicaid Services as a critical
289 access hospital, rural referral center, or sole community hospital; and

290
291 (vi) any other information specified on the application.

292
293 (B) A rural hospital may not allow a pharmacy technician to perform the duties
294 specified in §291.73(e)(2)(D) of this title until the board has reviewed and approved the
295 application and issued an amended license to the pharmacy.

296
297 (C) Every two years in conjunction with the application for renewal of the pharmacy
298 license, the pharmacist-in-charge shall update the application for pharmacy technicians
299 to perform the duties specified in §291.73(e)(2)(D) of this title.

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER F NON-RESIDENT PHARMACY (CLASS E)

5
6 **§291.104 Operational Standards**

7
8 (a) Licensing requirements.

9
10 (1) – (12) (No change.)

11
12 (13) A Class E [~~Non-Resident~~] pharmacy engaged in the compounding of non-sterile
13 preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies
14 Compounding Non-Sterile Preparations).

15
16 (14) **Prior to June 1, 2014, a** [A] Class E [~~Non-Resident~~] pharmacy engaged in the
17 compounding of sterile preparations shall comply with the provisions of §291.133 of this title
18 (relating to Pharmacies Compounding Sterile Preparations).

19
20 **(15) Effective June 1, 2014, a Class E pharmacy shall not compound sterile preparations**
21 **unless the pharmacy has applied and obtained a Class E-S pharmacy.**

22
23 (b) – (f) (No change.)

24
25
26 **§291.106 Pharmacies Compounding Sterile Preparations (Class E-S)**

27
28 **Licensing requirements. A pharmacy engaged in the compounding of sterile**
29 **preparations shall be licensed as a Class E-S pharmacy.**

30
31 **(1) A Class E-S pharmacy shall register with the board on a pharmacy license application**
32 **provided by the board, following the procedures specified in §291.1 of this title (relating**
33 **to Pharmacy License Application).**

34
35 **(2) A Class E-S license may not be issued unless the pharmacy has been inspected by**
36 **the board or its designee to ensure the pharmacy meets the requirements as specified in**
37 **§291.133 of this title (relating to Pharmacies Compounding Sterile Preparations). A**
38 **Class E-S pharmacy shall reimburse the board for all expenses, including travel, related**
39 **to the inspection of the Class E-S pharmacy.**

40
41 **(3) On initial application, the pharmacy shall follow the procedures specified in §291.1 of**
42 **this title (relating to Pharmacy License Application) and then provide the following**
43 **additional information specified in §560.052(c) and (f) of the Act (relating to**
44 **Qualifications):**

45
46 **(A) evidence that the applicant holds a pharmacy license, registration, or permit issued**
47 **by the state in which the pharmacy is located;**

48
49 **(B) the name of the owner and pharmacist-in-charge of the pharmacy for service of**
50 **process;**

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

55
56 (D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read
57 and understands the laws and rules relating to a Class E pharmacy; and

58
59 (E) proof of creditworthiness.

60
61 (4) A Class E-S pharmacy may not renew a pharmacy license unless the pharmacy
62 has been inspected by the board or its designee within the last 2 years.

63
64 (5) A Class E-S pharmacy which changes ownership shall notify the board within ten
65 days of the change of ownership and apply for a new and separate license as specified in
66 §291.3 of this title (relating to Required Notifications).

67
68 (6) A Class E-S pharmacy which changes location and/or name shall notify the board
69 within ten days of the change and file for an amended license as specified in §291.3 of
70 this title.

71
72 (7) A Class E-S pharmacy owned by a partnership or corporation which changes
73 managing officers shall notify the board in writing of the names of the new managing
74 officers within ten days of the change, following the procedures in §291.3 of this title.

75
76 (8) A Class E-S pharmacy shall notify the board in writing within ten days of closing.

77
78 (9) A separate license is required for each principal place of business and only one
79 pharmacy license may be issued to a specific location.

80
81 (10) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
82 charged for the issuance and renewal of a license and the issuance of an amended
83 license.

84
85 (11) The board may grant an exemption from the licensing requirements of this Act on
86 the application of a pharmacy located in a state of the United States other than this state
87 that restricts its dispensing of prescription drugs or devices to residents of this state to
88 isolated transactions.

89
90 (12) A Class E-S pharmacy engaged in the centralized dispensing of prescription drug
91 or medication orders shall comply with the provisions of §291.125 of this title (relating to
92 Centralized Prescription Dispensing).

93
94 (13) A Class E-S pharmacy engaged in central processing of prescription drug or
95 medication orders shall comply with the provisions of §291.123 of this title (relating to
96 Central Prescription or Medication Order Processing).

97
98 (14) A Class E-S pharmacy engaged in the compounding of non-sterile preparations
99 shall comply with the provisions of §291.131 of this title (relating to Pharmacies
100 Compounding Non-Sterile Preparations).

102 **(15) A Class E-S pharmacy engaged in the compounding of sterile preparations shall**
103 **comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding**
104 **Sterile Preparations).**

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(a) Purpose. Pharmacies compounding sterile preparations, prepackaging pharmaceutical products, and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:</p> <p>(1) compounding of sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies;</p> <p>(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile preparation in a Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies to a practitioner's office for office use by the practitioner;</p> <p>(3) compounding and distribution of compounded sterile preparations by a Class A (Community) pharmacy for a Class C (Institutional) pharmacy; and</p> <p>(4) compounding of sterile preparations by a Class C (Institutional) pharmacy and the distribution of the compounded preparations to other Class C (Institutional) pharmacies under common ownership.</p> <p>(b) Definitions. In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.</p> <p>(1) ACPE--Accreditation Council for Pharmacy Education.</p> <p>(2) Airborne particulate cleanliness class--The level of cleanliness specified by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For example:</p>	<p>(a) Purpose. Pharmacies compounding sterile preparations, prepackaging pharmaceutical products, and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:</p> <p>(1) compounding of sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A-S, Class B-S, Class C-S, and Class E-S pharmacies;</p> <p>(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile preparation in Class A-S, Class B-S, Class C-S, and Class E-S pharmacies to a practitioner's office for office use by the practitioner;</p> <p>(3) compounding and distribution of compounded sterile preparations by a Class A-S pharmacy for a Class C-S pharmacy; and</p> <p>(4) compounding of sterile preparations by a Class C-S pharmacy and the distribution of the compounded preparations to other Class C or Class C-S pharmacies under common ownership.</p> <p>(b) Definitions. In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.</p> <p>(1) ACPE--Accreditation Council for Pharmacy Education.</p> <p>(2) Airborne particulate cleanliness class--The level of cleanliness specified by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For example:</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(A) ISO Class 5 (formerly Class 100) is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100 particles 0.5 microns in diameter per cubic foot of air);</p> <p>(B) ISO Class 7 (formerly Class 10,000) is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 10,000 particles 0.5 microns in diameter per cubic foot of air); and</p> <p>(C) ISO Class 8 (formerly Class 100,000) is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100,000 particles 0.5 microns in diameter per cubic foot of air).</p> <p>(3) Ancillary supplies--Supplies necessary for the preparation and administration of compounded sterile preparations.</p> <p>(4) Anteroom--An ISO Class 8 or better area where personnel may perform hand hygiene and garbing procedures, staging of components, order entry, labeling, and other high-particulate generating activities. It is also a transition area that:</p> <p>(A) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas; and</p> <p>(B) reduces the need for the heating, ventilating and air conditioning (HVAC) control system to respond to large disturbances.</p> <p>(5) Aseptic Processing--The technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during preparation.</p> <p>(6) Automated compounding device--An automated device that compounds, measures, and/or packages a specified quantity of</p>	<p>(A) ISO Class 5 (formerly Class 100) is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100 particles 0.5 microns in diameter per cubic foot of air);</p> <p>(B) ISO Class 7 (formerly Class 10,000) is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 10,000 particles 0.5 microns in diameter per cubic foot of air); and</p> <p>(C) ISO Class 8 (formerly Class 100,000) is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100,000 particles 0.5 microns in diameter per cubic foot of air).</p> <p>(3) Ancillary supplies--Supplies necessary for the preparation and administration of compounded sterile preparations.</p> <p>(4) Ante-area--An ISO Class 8 or better area where personnel may perform hand hygiene and garbing procedures, staging of components, order entry, labeling, and other high-particulate generating activities. It is also a transition area that:</p> <p>(A) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas; and</p> <p>(B) reduces the need for the heating, ventilating and air conditioning (HVAC) control system to respond to large disturbances.</p> <p>(5) Aseptic Processing-- A mode of processing pharmaceutical and medical preparations that involves the separate sterilization of the preparation and of the package (containers–closures or packaging material for medical devices) and the transfer of the preparation into the container and its closure under at least ISO Class 5 conditions.</p> <p>(6) Automated compounding device--An automated device that compounds, measures, and/or packages a specified quantity of</p>

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<p>individual components in a predetermined sequence for a designated sterile preparation.</p> <p>(7) Batch--A specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation cycle.</p> <p>(8) Batch preparation compounding--Compounding of multiple sterile preparation units, in a single discrete process, by the same individual(s), carried out during one limited time period. Batch preparation/compounding does not include the preparation of multiple sterile preparation units pursuant to patient specific medication orders.</p> <p>(9) Beyond-use date--The date or time after which the compounded sterile preparation shall not be stored or transported or begin to be administered to a patient. The beyond-use date is determined from the date or time the preparation is compounded.</p> <p>(10) Biological Safety Cabinet, Class II--A ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered exhausted air for environmental protection.</p> <p>(11) Buffer Area, Buffer or Core Room, Buffer or Clean Room Areas, Buffer Room Area, Buffer or Clean Area, or Buffer Zone--An ISO Class 7 area where the primary engineering control area is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.</p> <p>(12) Clean room or controlled area--A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.</p>	<p>individual components in a predetermined sequence for a designated sterile preparation.</p> <p>(7) Batch--A specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation cycle.</p> <p>(8) Batch preparation compounding--Compounding of multiple sterile preparation units, in a single discrete process, by the same individual(s), carried out during one limited time period. Batch preparation/compounding does not include the preparation of multiple sterile preparation units pursuant to patient specific medication orders.</p> <p>(9) Beyond-use date--The date or time after which the compounded sterile preparation shall not be stored or transported or begin to be administered to a patient. The beyond-use date is determined from the date or time the preparation is compounded.</p> <p>(10) Biological Safety Cabinet, Class II--A ventilated cabinet for personnel, product or preparation, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered exhausted air for environmental protection.</p> <p>(11) Buffer Area--An ISO Class 7 area where the primary engineering control area is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.</p> <p>(12) Clean room--A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(13) Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.</p> <p>(14) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:</p> <p>(A) as the result of a practitioner's prescription drug or medication order based on the practitioner-patient-pharmacist relationship in the course of professional practice;</p> <p>(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;</p> <p>(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or</p> <p>(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.</p> <p>(15) Compounding Aseptic Isolator--A form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment shall not occur unless it has first passed through a microbial retentive filter (HEPA minimum).</p> <p>(16) Compounding Aseptic Containment Isolator--A compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing</p>	<p>(13) Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.</p> <p>(14) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:</p> <p>(A) as the result of a practitioner's prescription drug or medication order based on the practitioner-patient-pharmacist relationship in the course of professional practice;</p> <p>(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;</p> <p>(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or</p> <p>(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.</p> <p>(15) Compounding Aseptic Isolator--A form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment shall not occur unless it has first passed through a microbial retentive filter (HEPA minimum).</p> <p>(16) Compounding Aseptic Containment Isolator--A compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing</p>

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<p>airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.</p> <p>(17) Critical Area--A critical area is an ISO Class 5 environment.</p> <p>(18) Critical Sites--Sterile ingredients of compounded sterile preparations and locations on devices and components used to prepare, package, and transfer compounded sterile preparations that provide opportunity for exposure to contamination.</p> <p>(19) Cytotoxic--A pharmaceutical that has the capability of killing living cells.</p> <p>(20) Device--An instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner.</p> <p>(21) Direct Compounding Area--A critical area within the ISO Class 5 primary engineering control where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.</p> <p>(22) Disinfectant--A disinfectant is an agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial spores. It refers to substances applied to inanimate objects.</p> <p>(23) First Air--The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.</p>	<p>airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.</p> <p>(17) Critical Area—An ISO Class 5 environment.</p> <p>(18) Critical Sites-- A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.</p> <p>(19) Device--An instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner.</p> <p>(20) Direct Compounding Area--A critical area within the ISO Class 5 primary engineering control where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.</p> <p>(21) Disinfectant—An agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.</p> <p>(22) First Air--The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.</p> <p>(23) Hazardous Drugs—Drugs that, studies in animals or humans indicate exposure to the drugs, have a potential for causing cancer, development or reproductive toxicity, or harm to organs.</p>

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<p>(24) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).</p> <p>(25) HVAC--Heating, ventilation, and air conditioning.</p> <p>(26) Immediate use--A sterile preparation that is not prepared according to USP 797 standards (i.e. outside the pharmacy and most likely not by pharmacy personnel) which shall be stored for no longer than one hour after completion of the preparation.</p> <p>(27) IPA--Isopropyl alcohol (2-propanol).</p> <p>(28) Media-Fill Test--A media-fill test is used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as Soybean--Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding. The issues to consider in the development of a media-fill test are the following: media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.</p> <p>(29) Multiple-Dose Container--A multiple-unit container for articles or preparations intended for potential administration only and usually contains antimicrobial preservatives. The beyond-use date for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.</p>	<p>(24) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).</p> <p>(25) HVAC--Heating, ventilation, and air conditioning.</p> <p>(26) Immediate use--A sterile preparation that is not prepared according to USP 797 standards (i.e. outside the pharmacy and most likely not by pharmacy personnel) which shall be stored for no longer than one hour after completion of the preparation.</p> <p>(27) IPA--Isopropyl alcohol (2-propanol).</p> <p>(28) Labeling—All labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term “label” designates that part of the labeling on the immediate container.</p> <p>(29) Media-Fill Test--A test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as Soybean--Casein Digest Medium is substituted for the actual drug preparation to simulate admixture compounding. The issues to consider in the development of a media-fill test are the following: media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.</p> <p>(30) Multiple-Dose Container--A multiple-unit container for articles or preparations intended for potential administration only and usually contains antimicrobial preservatives. The beyond-use date for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.</p>

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<p>(30) Negative Pressure Room--A room that is at a lower pressure compared to adjacent spaces and, therefore, the net flow of air is into the room.</p> <p>(31) Office use--The administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 562 of the Act, or for administration or provision by a veterinarian in accordance with §563.054 of the Act.</p> <p>(32) Pharmacy Bulk Package--A container of a sterile preparation for potential use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).</p> <p>(33) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original container into unit dose packaging or a multiple dose container for distribution within a facility licensed as a Class C pharmacy or to other pharmacies under common ownership for distribution within those facilities. The term as defined does not prohibit the prepackaging of drug products for use within other pharmacy classes.</p> <p>(34) Preparation or Compounded Sterile Preparation--A sterile admixture compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber.</p> <p>(35) Primary Engineering Control--A device or room that provides an ISO Class 5 environment for the exposure of critical sites when</p>	<p>(31) Negative Pressure Room--A room that is at a lower pressure compared to adjacent spaces and, therefore, the net flow of air is into the room.</p> <p>(32) Office use--The administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 562 of the Act, or for administration or provision by a veterinarian in accordance with §563.054 of the Act.</p> <p>(33) Pharmacy Bulk Package--A container of a sterile preparation for potential use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).</p> <p>(34) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original container into unit dose packaging or a multiple dose container for distribution within a facility licensed as a Class C pharmacy or to other pharmacies under common ownership for distribution within those facilities. The term as defined does not prohibit the prepackaging of drug products for use within other pharmacy classes.</p> <p>(35) Preparation or Compounded Sterile Preparation--A sterile admixture compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber. The components of the preparation may or may not be sterile products.</p> <p>(36) Primary Engineering Control--A device or room that provides an ISO Class 5 environment for the exposure of critical sites when</p>

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<p>compounding sterile preparations. Such devices include, but may not be limited to, laminar airflow workbenches, biological safety cabinets, and compounding aseptic isolators and compounding aseptic containment isolators.</p> <p>(36) Product--A product is a commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.</p> <p>(37) Positive Control--A quality assurance sample prepared to test positive for microbial growth.</p> <p>(38) Positive Pressure Room--A room that is at a higher pressure compared to adjacent spaces and, therefore, the net airflow is out of the room.</p> <p>(39) Quality assurance--The set of activities used to ensure that the process used in the preparation of sterile drug preparations lead to preparations that meet predetermined standards of quality.</p> <p>(40) Quality control--The set of testing activities used to determine that the ingredients, components (e.g., containers), and final compounded sterile preparations prepared meet predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.</p> <p>(41) Reasonable quantity--An amount of a compounded drug that:</p> <p>(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office or facility before the beyond use date of the drug;</p> <p>(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and</p> <p>(C) for any practitioner and all practitioners as a whole, is not greater</p>	<p>compounding sterile preparations. Such devices include, but may not be limited to, laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators.</p> <p>(37) Product--A commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.</p> <p>(38) Positive Control--A quality assurance sample prepared to test positive for microbial growth.</p> <p>(39) Positive Pressure Room--A room that is at a higher pressure compared to adjacent spaces and, therefore, the net airflow is out of the room.</p> <p>(40) Quality assurance--The set of activities used to ensure that the process used in the preparation of sterile drug preparations lead to preparations that meet predetermined standards of quality.</p> <p>(41) Quality control--The set of testing activities used to determine that the ingredients, components (e.g., containers), and final compounded sterile preparations prepared meet predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.</p> <p>(42) Reasonable quantity--An amount of a compounded drug that:</p> <p>(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office or facility before the beyond use date of the drug;</p> <p>(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and</p> <p>(C) for any practitioner and all practitioners as a whole, is not greater</p>

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<p>than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.</p> <p>(42) Segregated Compounding Area--A designated space, either a demarcated area or room, that is restricted to preparing low-risk level compounded sterile preparations with 12-hour or less beyond-use date. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of compounded sterile preparations and shall be void of activities and materials that are extraneous to sterile compounding.</p> <p>(43) Single-dose container--A container intended for a single use, other than single-dose vials and single-dose large volume potential solutions. Examples of single-dose containers include pre-filled syringes, cartridges, and fusion-sealed containers without preservatives.</p> <p>(44) Single-dose vial--A vial intended for a single use. Exceptions to this definition would be single dose vials routinely used to compound total potential nutrition (TPN) preparations (e.g., sodium chloride, sodium acetate, sodium phosphate, potassium chloride, potassium acetate, potassium phosphate, calcium gluconate, magnesium sulfate, multivitamin for injection, multi-trace elements, ascorbic acid, folic acid, heparin, phytonadione, l-carnitine, cysteine, selenium, injectable zinc).</p> <p>(45) Single-dose large volume parenteral solution--Large volume parenteral solutions (i.e., containers of solution of at least 1000 mL) routinely used for compounding sterile TPN preparations or for batch compounding (e.g., sterile water for injection (SWFI); 5%, 10%, and 70% dextrose in SWFI; 0.9% sodium chloride; 0.45% sodium chloride; 5% dextrose/0.9% sodium chloride; 5% dextrose/0.45% sodium chloride).</p> <p>(46) SOPs--Standard operating procedures.</p>	<p>than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.</p> <p>(43) Segregated Compounding Area--A designated space, either a demarcated area or room, that is restricted to preparing low-risk level compounded sterile preparations with 12-hour or less beyond-use date. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of compounded sterile preparations and shall be void of activities and materials that are extraneous to sterile compounding.</p> <p>(44) Single-dose container—A single-unit container for articles or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include pre-filled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.</p> <p>(45) SOPs--Standard operating procedures.</p> <p>(46) Sterilizing Grade Membranes— Membranes that are documented to retain 100% of a culture of 107 microorganisms of a strain of</p>

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<p>(47) Terminal Sterilization--The application of a lethal process, e.g., steam under pressure or autoclaving, to sealed final preparation containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10⁶, i.e., or a probability of less than one in one million of a non-sterile unit.</p> <p>(48) Unidirectional Flow--An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.</p> <p>(49) USP/NF--The current edition of the United States Pharmacopeia/National Formulary.</p> <p>(c) Personnel.</p> <p>(1) Pharmacist-in-charge.</p> <p>(A) General. The pharmacy shall have a pharmacist-in-charge in compliance with the specific license classification of the pharmacy.</p> <p>(B) Responsibilities. In addition to the responsibilities for the specific class of pharmacy, the pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning the compounding of sterile preparations:</p> <p>(i) developing a system to ensure that all pharmacy personnel responsible for compounding and/or supervising the compounding of sterile preparations within the pharmacy receive appropriate education and training and competency evaluation;</p>	<p>Brevundimonas (Pseudomonas) diminuta per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22-µm or 0.2-µm nominal pore size, depending on the manufacturer's practice.</p> <p>(47) Sterilization by Filtration— Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.</p> <p>(48) Terminal Sterilization--The application of a lethal process, e.g., steam under pressure or autoclaving, to sealed final preparation containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10⁻⁶ or a probability of less than one in one million of a non-sterile unit.</p> <p>(49) Unidirectional Flow--An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.</p> <p>(50) USP/NF--The current edition of the United States Pharmacopeia/National Formulary.</p> <p>(c) Personnel.</p> <p>(1) Pharmacist-in-charge.</p> <p>(A) General. The pharmacy shall have a pharmacist-in-charge in compliance with the specific license classification of the pharmacy.</p> <p>(B) Responsibilities. In addition to the responsibilities for the specific class of pharmacy, the pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning the compounding of sterile preparations:</p> <p>(i) developing a system to ensure that all pharmacy personnel responsible for compounding and/or supervising the compounding of sterile preparations within the pharmacy receive appropriate education and training and competency evaluation;</p>

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<p>(ii) determining that all personnel involved in compounding sterile preparations obtain continuing education appropriate for the type of compounding done by the personnel;</p> <p>(iii) supervising a system to ensure appropriate procurement of drugs and devices and storage of all pharmaceutical materials including pharmaceuticals, components used in the compounding of sterile preparations, and drug delivery devices;</p> <p>(iv) ensuring that the equipment used in compounding is properly maintained;</p> <p>(v) developing a system for the disposal and distribution of drugs from the pharmacy;</p> <p>(vi) developing a system for bulk compounding or batch preparation of drugs;</p> <p>(vii) developing a system for the compounding, sterility assurance, quality assurance, and quality control of sterile preparations; and</p> <p>(viii) if applicable, ensuring that the pharmacy has a system to dispose of hazardous waste in a manner so as not to endanger the public health.</p> <p>(2) Pharmacists. Special requirements for compounding sterile preparations.</p> <p>(A) All pharmacists engaged in compounding sterile preparations shall:</p> <p>(i) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised; and</p> <p>(ii) obtain continuing education appropriate for the type of</p>	<p>(ii) determining that all personnel involved in compounding sterile preparations obtain continuing education appropriate for the type of compounding done by the personnel;</p> <p>(iii) supervising a system to ensure appropriate procurement of drugs and devices and storage of all pharmaceutical materials including pharmaceuticals, components used in the compounding of sterile preparations, and drug delivery devices;</p> <p>(iv) ensuring that the equipment used in compounding is properly maintained;</p> <p>(v) developing a system for the disposal and distribution of drugs from the pharmacy;</p> <p>(vi) developing a system for bulk compounding or batch preparation of drugs;</p> <p>(vii) developing a system for the compounding, sterility assurance, quality assurance, and quality control of sterile preparations; and</p> <p>(viii) if applicable, ensuring that the pharmacy has a system to dispose of hazardous waste in a manner so as not to endanger the public health.</p> <p>(2) Pharmacists.</p> <p>(A) General.</p> <p>(i) A pharmacist is responsible for ensuring that compounded sterile preparations are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.</p> <p>(ii) A pharmacist shall inspect and approve all components, drug preparation containers, closures, labeling, and any other materials involved in the compounding process.</p>

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<p>compounding done by the pharmacist.</p> <p>(B) A pharmacist shall inspect and approve all components, drug preparation containers, closures, labeling, and any other materials involved in the compounding process.</p> <p>(C) A pharmacist shall review all compounding records for accuracy and conduct in-process and final checks to ensure that errors have not occurred in the compounding process.</p> <p>(D) A pharmacist is responsible for the proper maintenance, cleanliness, and use of all equipment used in the compounding process.</p> <p>(E) A pharmacist shall be accessible at all times to respond to patients' and other health professionals' questions and needs. Such access may be through a telephone or pager which is answered 24 hours a day.</p> <p>(3) Pharmacy technicians and pharmacy technician trainees. Pharmacy technicians and pharmacy technician trainees may compound sterile preparations provided the pharmacy technicians and/or pharmacy technician trainees:</p> <p>(A) have completed the education and training specified in paragraph (4) of this subsection; and</p> <p>(B) are supervised by a pharmacist who has completed the training specified in paragraph (4) of this subsection, conducts in-process and final checks, and affixes his or her initials to the appropriate quality control records.</p> <p>(4) Special education, training, and evaluation requirements for pharmacy personnel compounding or responsible for the direct supervision of pharmacy personnel compounding sterile preparations.</p> <p>(A) General.</p>	<p>(iii) A pharmacist shall review all compounding records for accuracy and conduct in-process and final checks and verification of calculations to ensure that errors have not occurred in the compounding process.</p> <p>(iv) A pharmacist is responsible for ensuring the proper maintenance, cleanliness, and use of all equipment used in the compounding process.</p> <p>(v) A pharmacist shall be accessible at all times, 24 hours a day, to respond to patients' and other health professionals' questions and needs.</p> <p>(B) Initial training and continuing education.</p> <p>(i) All pharmacists who compound sterile preparations or supervise pharmacy technicians and pharmacy technician trainees compounding sterile preparations shall comply with the following:</p> <p>(I) complete through a single course, a minimum of 20 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE accredited provider which provides 20 hours of instruction and experience in the areas listed in paragraph (4)(D);</p> <p>(II) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides 20 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and</p> <p>(III) possess knowledge about:</p> <p>(-a-) aseptic processing;</p>

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<p>(i) All pharmacy personnel preparing sterile preparations shall receive didactic and experiential training and competency evaluation through demonstration, testing (written and practical) as outlined by the pharmacist-in-charge and described in the policy and procedure or training manual. Such training shall include instruction and experience in the following areas:</p> <ul style="list-style-type: none"> (I) aseptic technique; (II) critical area contamination factors; (III) environmental monitoring; (IV) structure and engineering controls related to facilities; (V) equipment and supplies; (VI) sterile preparation calculations and terminology; (VII) sterile preparation compounding documentation; (VIII) quality assurance procedures; (IX) aseptic preparation procedures including proper gowning and gloving technique; (X) handling of cytotoxic and hazardous drugs, if applicable; and (XI) general conduct in the controlled area. <p>(ii) The aseptic technique of each person compounding or responsible for the direct supervision of personnel compounding sterile preparations shall be observed and evaluated as satisfactory through written and practical tests, and media-fill challenge testing, and such evaluation documented.</p> <p>(iii) Although media-fill tests may be incorporated into the</p>	<p>(-b-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;</p> <p>(-c-) chemical, pharmaceutical, and clinical properties of drugs;</p> <p>(-d-) container, equipment, and closure system selection; and</p> <p>(-e-) sterilization techniques.</p> <p>(ii) The required experiential portion of the training programs specified in this subparagraph must be supervised by an individual who is actively engaged in performing sterile compounding and is qualified and has completed training as specified in paragraph (2) or (3) of this subsection.</p> <p>(iii) In order to renew a license to practice pharmacy, during the previous licensure period, a pharmacist engaged in sterile compounding shall complete a minimum of:</p> <ul style="list-style-type: none"> (I) two hours of ACPE-accredited continuing education relating to the areas listed in clause (i)(II) of this subparagraph if the pharmacist is engaged in compounding low and medium risk sterile preparations; or (II) four hours of ACPE-accredited continuing education relating to the areas listed in clause (i)(II) of this subparagraph if the pharmacist is engaged in compounding high risk sterile preparations. <p>(3) Pharmacy technicians and pharmacy technician trainees.</p> <ul style="list-style-type: none"> (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training). (B) Initial training and continuing education. <p>(i) Pharmacy technicians and pharmacy technician trainees may</p>

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<p>experiential portion of a training program, media-fill tests must be conducted at each pharmacy where an individual compounds sterile preparations. No preparation intended for patient use shall be compounded by an individual until the on-site media-fill tests test indicates that the individual can competently perform aseptic procedures, except that a pharmacist may temporarily compound sterile preparations and supervise pharmacy technicians compounding sterile preparations without media-fill tests provided the pharmacist:</p> <p>(I) has completed a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE accredited provider which provides 20 hours of instruction and experience in the areas listed in this subparagraph; and</p> <p>(II) completes the on-site media-fill tests within seven days of commencing work at the pharmacy.</p> <p>(iv) Media-fill tests procedures for assessing the preparation of specific types of sterile preparations shall be representative of all types of manipulations, products, risk levels, and batch sizes that personnel preparing that type of sterile preparation are likely to encounter.</p> <p>(v) The pharmacist-in-charge shall ensure continuing competency of pharmacy personnel through in-service education, training, and media-fill tests to supplement initial training. Personnel competency shall be evaluated:</p> <p>(I) during orientation and training prior to the regular performance of those tasks;</p> <p>(II) whenever the quality assurance program yields an unacceptable result;</p> <p>(III) whenever unacceptable techniques are observed; and</p> <p>(IV) at least on an annual basis for low- and medium-risk level compounding, and every six months for high-risk level compounding.</p>	<p>compound sterile preparations provided the pharmacy technicians and/or pharmacy technician trainees are supervised by a pharmacist who has completed the training specified in paragraph (4)(D) of this subsection, conducts in-process and final checks, and affixes his or her initials to the appropriate quality control records.</p> <p>(ii) All pharmacy technicians and pharmacy technician trainees who compound sterile preparations for administration to patients shall comply with the following:</p> <p>(I) complete through completion of a single course, a minimum of 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a course sponsored by an ACPE accredited provider which provides 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection;</p> <p>(II) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and</p> <p>(III) possess knowledge about:</p> <p>(-a-) aseptic processing;</p> <p>(-b-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;</p> <p>(-c-) chemical, pharmaceutical, and clinical properties of drugs;</p> <p>(-d-) container, equipment, and closure system selection; and</p> <p>(-e-) sterilization techniques.</p>

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<p>(B) Pharmacists.</p> <p>(i) All pharmacists who compound sterile preparations for administration to patients or supervise pharmacy technicians and pharmacy technician trainees compounding sterile preparations shall:</p> <p>(I) complete through a single course, a minimum of 20 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph. Such training may be obtained through:</p> <p>(-a-) completion of a structured on-the-job didactic and experiential training program at this pharmacy which provides 20 hours of instruction and experience in the areas listed in paragraph (1) of this subsection. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; or</p> <p>(-b-) completion of a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE accredited provider which provides 20 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph.</p> <p>(II) possess knowledge about:</p> <p>(-a-) aseptic processing;</p> <p>(-b-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;</p> <p>(-c-) chemical, pharmaceutical, and clinical properties of drugs;</p> <p>(-d-) container, equipment, and closure system selection; and</p> <p>(-e-) sterilization techniques.</p>	<p>(iii) Individuals enrolled in training programs accredited by the American Society of Health-System Pharmacists may compound sterile preparations in a licensed pharmacy provided:</p> <p>(I) the compounding occurs only during times the individual is assigned to a pharmacy as a part of the experiential component of the American Society of Health-System Pharmacists training program;</p> <p>(II) the individual is under the direct supervision of and responsible to a pharmacist who has completed training as specified in paragraph (2)(C) of this subsection; and</p> <p>(III) the supervising pharmacist conducts in-process and final checks.</p> <p>(iv) The required experiential portion of the training programs specified in this subparagraph must be supervised by an individual who is actively engaged in performing sterile compounding, is qualified and has completed training as specified in paragraph (2) or (3) of this subsection.</p> <p>(v) In order to renew a registration as a pharmacy technician, during the previous registration period, a pharmacy technician engaged in sterile compounding shall complete a minimum of:</p> <p>(I) two hours of ACPE accredited continuing education relating to the areas listed in clause (ii)(III) of this subparagraph if the pharmacy technician is engaged in compounding low and medium risk sterile preparations; or</p> <p>(II) four hours of ACPE accredited continuing education relating to the areas listed in clause (ii)(III) of this subparagraph if pharmacy technician is engaged in compounding high risk sterile preparations.</p> <p>(4) Evaluation and testing requirements.</p>

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<p>(ii) The required experiential portion of the training programs specified in this subparagraph must be supervised by an individual who has already completed training as specified in subparagraph (B) or (C) of this paragraph.</p> <p>(C) Pharmacy technicians and pharmacy technician trainees. In addition to specific qualifications for registration, all pharmacy technicians and pharmacy technician trainees who compound sterile preparations for administration to patients shall:</p> <p>(i) have initial training obtained either through completion of:</p> <p>(I) a single course, a minimum of 40 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph. Such training may be obtained through:</p> <p>(-a-) completion of a structured on-the-job didactic and experiential training program at this pharmacy which provides 40 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; or</p> <p>(-b-) completion of a course sponsored by an ACPE accredited provider which provides 40 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph; or</p> <p>(II) a training program which is accredited by the American Society of Health-System Pharmacists. Individuals enrolled in training programs accredited by the American Society of Health-System Pharmacists may compound sterile preparations in a licensed pharmacy provided:</p> <p>(-a-) the compounding occurs only during times the individual is assigned to a pharmacy as a part of the experiential component of the American Society of Health-System Pharmacists training program;</p> <p>(-b-) the individual is under the direct supervision of and</p>	<p>(A) All pharmacy personnel preparing sterile preparations shall be trained conscientiously and skillfully by expert personnel through multimedia instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations, garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures before beginning to prepare compounded sterile preparations.</p> <p>(B) All pharmacy personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially followed by:</p> <p>(i) every 12 months for low- and medium-risk level compounding; and</p> <p>(ii) every six months for high-risk level compounding.</p> <p>(C) Pharmacy personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall:</p> <p>(i) be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies; and</p> <p>(ii) not be allowed to compound sterile preparations for patient use until passing results are achieved.</p> <p>(D) The didactic and experiential training shall include instruction, experience, and demonstrated proficiency in the following areas:</p> <p>(I) aseptic technique;</p> <p>(II) critical area contamination factors;</p> <p>(III) environmental monitoring;</p> <p>(IV) structure and engineering controls related to facilities;</p>

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<p>responsible to a pharmacist who has completed training as specified in subparagraph (B) of this paragraph; and</p> <p>(-c-) the supervising pharmacist conducts in-process and final checks.</p> <p>(ii) acquire the required experiential portion of the training programs specified in this subparagraph under the supervision of an individual who has already completed training as specified in subparagraph (B) or (C) of this paragraph.</p>	<p>(V) equipment and supplies;</p> <p>(VI) sterile preparation calculations and terminology;</p> <p>(VII) sterile preparation compounding documentation;</p> <p>(VIII) quality assurance procedures;</p> <p>(IX) aseptic preparation procedures including proper gowning and gloving technique;</p> <p>(X) handling of hazardous drugs, if applicable;</p> <p>(XI) cleaning procedures; and</p> <p>(XII) general conduct in the clean room.</p> <p>(E) The aseptic technique of each person compounding or responsible for the direct supervision of personnel compounding sterile preparations shall be observed and evaluated by expert personnel as satisfactory through written and practical tests, and media-fill challenge testing, and such evaluation documented.</p> <p>(F) Media-fill tests must be conducted at each pharmacy where an individual compounds sterile preparations. No preparation intended for patient use shall be compounded by an individual until the on-site media-fill tests test indicates that the individual can competently perform aseptic procedures, except that a pharmacist may temporarily compound sterile preparations and supervise pharmacy technicians compounding sterile preparations without media-fill tests provided the pharmacist completes the on-site media-fill tests within seven days of commencing work at the pharmacy.</p> <p>(G) Media-fill tests procedures for assessing the preparation of specific types of sterile preparations shall be representative of the most challenging or stressful conditions encountered by the pharmacy personnel being evaluated for each risk level and for sterilizing high-risk</p>

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	<p>level compounded sterile preparations.</p> <p>(H) Media-fill challenge tests simulating high-risk level compounding shall be used to verify the capability of the compounding environment and process to produce a sterile preparation.</p> <p>(I) Commercially available sterile fluid culture media, such as Soybean–Casein Digest Medium shall be able to promote exponential colonization of bacteria that are most likely to be transmitted to compounding sterile preparations from the compounding personnel and environment. Media-filled vials are generally incubated at 20 to 25 or at 30 to 35 for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature. Failure is indicated by visible turbidity in the medium on or before 14 days.</p> <p>(J) The pharmacist-in-charge shall ensure continuing competency of pharmacy personnel through in-service education, training, and media-fill tests to supplement initial training. Personnel competency shall be evaluated:</p> <ul style="list-style-type: none"> (i) during orientation and training prior to the regular performance of those tasks; (ii) whenever the quality assurance program yields an unacceptable result; (iii) whenever unacceptable techniques are observed; and (iv) at least on an annual basis for low- and medium-risk level compounding, and every six months for high-risk level compounding. <p>(K) The pharmacist-in-charge shall ensure that proper hand hygiene and garbing practices of compounding personnel are evaluated prior to compounding sterile preparations intended for patient use and whenever an aseptic media fill is performed.</p>

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	<p>(i) Sampling of compounding personnel glove fingertips shall be performed for all risk level compounding.</p> <p>(ii) All compounding personnel shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands).</p> <p>(iii) Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing in order to assess garbing competency and after completing the media-fill preparation (without applying sterile 70% IPA).</p> <p>(iv) The visual observation shall be documented and maintained to provide a permanent record and long-term assessment of personnel competency.</p> <p>(v) All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure no less than three times before initially being allowed to compound sterile preparations for patient use. Immediately after the compounding personnel completes the hand hygiene and garbing procedure (e.g., donning of sterile gloves prior to any disinfection with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands from the compounding personnel onto agar plates by lightly pressing each fingertip into the agar. The plates will be incubated for the appropriate incubation period and at the appropriate temperature. Re-evaluation of all compounding personnel shall occur at least annually for compounding personnel who compound low and medium risk level preparations and every six months for compounding personnel who compound high risk level preparations.</p> <p>(L) The pharmacist-in-charge shall ensure surface sampling shall be conducted in all ISO classified areas on a periodic basis. Sampling shall be accomplished using contact plates at the conclusion of compounding. The sample area shall be gently touched with the agar surface by rolling the plate across the surface to be sampled.</p>

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<p>(D) Documentation of Training. The pharmacy shall maintain a record on each person who compounds sterile preparations. The record shall contain, at a minimum, a written record of initial and in-service training, education, and the results of written and practical testing and media-fill testing of pharmacy personnel. The record shall be maintained and contain the following information:</p> <p>(i) name of the person receiving the training or completing the testing or media-fill tests;</p> <p>(ii) date(s) of the training, testing, or media-fill challenge testing;</p> <p>(iii) general description of the topics covered in the training or testing or of the process validated;</p> <p>(iv) name of the person supervising the training, testing, or media-fill challenge testing; and</p> <p>(v) signature or initials of the person receiving the training or completing the testing or media-fill challenge testing and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or media-fill challenge testing of personnel.</p> <p>(d) Operational Standards.</p> <p>(1) General Requirements.</p> <p>(A) Sterile preparations may be compounded in licensed pharmacies:</p> <p>(i) upon presentation of a practitioner's prescription drug or medication order based on a valid pharmacist/patient/prescriber relationship;</p> <p>(ii) in anticipation of future prescription drug or medication orders</p>	<p>(5) Documentation of Training. The pharmacy shall maintain a record of the training and continuing education on each person who compounds sterile preparations. The record shall contain, at a minimum, a written record of initial and in-service training, education, and the results of written and practical testing and media-fill testing of pharmacy personnel. The record shall be maintained and available for inspection by the board and contain the following information:</p> <p>(A) name of the person receiving the training or completing the testing or media-fill tests;</p> <p>(B) date(s) of the training, testing, or media-fill challenge testing;</p> <p>(C) general description of the topics covered in the training or testing or of the process validated;</p> <p>(D) name of the person supervising the training, testing, or media-fill challenge testing; and</p> <p>(E) signature or initials of the person receiving the training or completing the testing or media-fill challenge testing and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or media-fill challenge testing of personnel.</p> <p>(d) Operational Standards.</p> <p>(1) General Requirements.</p> <p>(A) Sterile preparations may be compounded:</p> <p>(i) upon presentation of a practitioner's prescription drug or medication order based on a valid pharmacist/patient/prescriber relationship;</p> <p>(ii) in anticipation of future prescription drug or medication orders</p>

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<p>based on routine, regularly observed prescribing patterns; or</p> <p>(iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.</p> <p>(B) Sterile compounding in anticipation of future prescription drug or medication orders must be based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared is stable for the anticipated shelf time.</p> <p>(i) The pharmacist's professional judgment shall be based on the criteria used to determine a beyond-use date outlined in paragraph (5)(G) of this subsection.</p> <p>(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time must be maintained and be available for inspection.</p> <p>(iii) Any preparation compounded in anticipation of future prescription drug or medication orders shall be labeled. Such label shall contain:</p> <p>(I) name and strength of the compounded preparation or list of the active ingredients and strengths;</p> <p>(II) facility's lot number;</p> <p>(III) beyond-use date as determined by the pharmacist using appropriate documented criteria as outlined in paragraph (5)(G) of this subsection;</p> <p>(IV) quantity or amount in the container;</p> <p>(V) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and</p>	<p>based on routine, regularly observed prescribing patterns; or</p> <p>(iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.</p> <p>(B) Sterile compounding in anticipation of future prescription drug or medication orders must be based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared is stable for the anticipated shelf time.</p> <p>(i) The pharmacist's professional judgment shall be based on the criteria used to determine a beyond-use date outlined in paragraph (6)(G) of this subsection.</p> <p>(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time must be maintained and be available for inspection.</p> <p>(iii) Any preparation compounded in anticipation of future prescription drug or medication orders shall be labeled. Such label shall contain:</p> <p>(I) name and strength of the compounded preparation or list of the active ingredients and strengths;</p> <p>(II) facility's lot number;</p> <p>(III) beyond-use date as determined by the pharmacist using appropriate documented criteria as outlined in paragraph (6)(G) of this subsection;</p> <p>(IV) quantity or amount in the container;</p> <p>(V) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and</p>

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<p>(VI) device-specific instructions, where appropriate.</p> <p>(C) Commercially available products may be compounded for dispensing to individual patients provided the following conditions are met:</p> <p>(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet patient's needs;</p> <p>(ii) the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and</p> <p>(iii) the prescribing practitioner has requested that the drug be compounded as described in subparagraph (D) of this paragraph.</p> <p>(D) A pharmacy may not compound preparations that are essentially copies of commercially available products (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product) unless the prescribing practitioner specifically orders the strength or dosage form and specifies why the patient needs the particular strength or dosage form of the preparation. The prescribing practitioner shall provide documentation of a patient specific medical need and the preparation produces a clinically significant therapeutic response (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The methodology for documenting unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered, discontinued, or out-of-stock items. This documentation must be available in hard-copy or electronic format for inspection by the board.</p> <p>(E) A pharmacy may enter into an agreement to compound and</p>	<p>(VI) device-specific instructions, where appropriate.</p> <p>(C) Commercially available products may be compounded for dispensing to individual patients or for office use provided the following conditions are met:</p> <p>(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet patient's needs;</p> <p>(ii) the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and</p> <p>(iii) the prescribing practitioner has requested that the drug be compounded as described in subparagraph (D) of this paragraph.</p> <p>(D) A pharmacy may not compound preparations that are essentially copies of commercially available products (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product) unless the prescribing practitioner specifically orders the strength or dosage form and specifies why the patient needs the particular strength or dosage form of the preparation or why the preparation for office use is needed in the particular strength or dosage form of the preparation. The prescribing practitioner shall provide documentation of a patient specific medical need and the preparation produces a clinically significant therapeutic response (e.g. the physician requests an alternate preparation due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The methodology for documenting unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered, discontinued, or out-of-stock items. This documentation must be available in hard-copy or electronic format for inspection by the board.</p> <p>(E) A pharmacy may enter into an agreement to compound and</p>

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<p>dispense prescription/medication orders for another pharmacy provided the pharmacy complies with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).</p> <p>(F) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide sterile prescription compounding services, which may include specific drug preparations and classes of drugs.</p> <p>(G) A pharmacy may not compound veterinary preparations for use in food producing animals except in accordance with federal guidelines.</p> <p>(2) Microbial Contamination Risk Levels. Risk Levels for sterile compounded preparations shall be as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF and as listed below.</p> <p>(A) Low-risk level compounded sterile preparations.</p> <p>(i) Low-Risk conditions. Low-risk level compounded sterile preparations are those compounded under all of the following conditions.</p> <p>(I) The compounded sterile preparations are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices.</p> <p>(II) The compounding involves only transfer, measuring, and mixing manipulations with closed or sealed packaging systems that are preformed promptly and attentively.</p> <p>(III) Manipulations are limited to aseptically opening ampuls, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices and packages of other sterile products.</p>	<p>dispense prescription/medication orders for another pharmacy provided the pharmacy complies with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).</p> <p>(F) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide sterile prescription compounding services, which may include specific drug preparations and classes of drugs.</p> <p>(G) A pharmacy may not compound veterinary preparations for use in food producing animals except in accordance with federal guidelines.</p> <p>(2) Microbial Contamination Risk Levels. Risk Levels for sterile compounded preparations shall be as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF and as listed below.</p> <p>(A) Low-risk level compounded sterile preparations.</p> <p>(i) Low-Risk conditions. Low-risk level compounded sterile preparations are those compounded under all of the following conditions.</p> <p>(I) The compounded sterile preparations are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices.</p> <p>(II) The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the compounded sterile preparation.</p> <p>(III) Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and</p>

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<p>(IV) For a low-risk preparation, in the absence of direct sterility testing results or appropriate information sources that justify different limits, the storage periods may not exceed the following periods: before administration, 48 hours at controlled room temperature, for not more than 14 days if stored at a cold temperature, and for 45 days if stored in a frozen state at minus 20 degrees Celsius or colder). For delayed activation device systems, the storage period begins when the device is activated.</p> <p>(ii) Examples of Low-Risk Compounding. Examples of low-risk compounding include the following.</p> <p>(I) Single volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampules shall be passed through a sterile filter to remove any glass particles.</p> <p>(II) Manually measuring and mixing no more than three manufactured products to compound drug admixtures.</p> <p>(B) Low-Risk Level compounded sterile preparations with 12-hour or less beyond-use date. Low-risk level compounded sterile preparations are those compounded pursuant to a physician's order for a specific patient under all of the following conditions.</p> <p>(i) The compounded sterile preparations are compounded in compounding aseptic isolator or compounding aseptic containment isolator that does not meet the requirements described in paragraph (5)(A)(ii)(II) of this subsection relating to Low and Medium Risk Preparations or the compounded sterile preparations are compounded in laminar airflow workbench or a biological safety cabinet that cannot be located within an ISO Class 7 buffer area.</p>	<p>containers for storage and dispensing.</p> <p>(IV) For a low-risk preparation, in the absence of direct sterility testing results or appropriate information sources that justify different limits, the storage periods may not exceed the following periods: before administration the compounded sterile preparation is stored properly and are exposed for not more than 48 hours at controlled room temperature, for not more than 14 days if stored at a cold temperature, and for 45 days if stored in a frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius. For delayed activation device systems, the storage period begins when the device is activated.</p> <p>(ii) Examples of Low-Risk Compounding. Examples of low-risk compounding include the following.</p> <p>(I) Single volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampules shall be passed through a sterile filter to remove any particles.</p> <p>(II) Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluent solution to compound drug admixtures and nutritional solutions.</p> <p>(B) Low-Risk Level compounded sterile preparations with 12-hour or less beyond-use date. Low-risk level compounded sterile preparations are those compounded pursuant to a physician's order for a specific patient under all of the following conditions.</p> <p>(i) The compounded sterile preparations are compounded in compounding aseptic isolator or compounding aseptic containment isolator that does not meet the requirements described in paragraph (6)(A)(ii)(II) of this subsection relating to Low and Medium Risk Preparations or the compounded sterile preparations are compounded in laminar airflow workbench or a biological safety cabinet that cannot be located within an ISO Class 7 buffer area.</p>

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<p>(ii) The primary engineering control device is located in a segregated compounding area restricted to sterile compounding activities that minimizes the risk of contamination of the compounded sterile preparation.</p> <p>(iii) The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, or that is adjacent to construction sites, warehouses, or food preparation.</p> <p>(iv) For a low-risk preparation compounded as described in clauses (i) - (iii) of this subparagraph, administration of such compounded sterile preparations must commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less.</p> <p>(C) Medium-risk level compounded sterile preparations.</p> <p>(i) Medium-Risk Conditions. Medium-risk level compounded sterile preparations, are those compounded aseptically under low-risk conditions and one or more of the following conditions exists.</p> <p>(I) Multiple individual or small doses of sterile products are combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions.</p> <p>(II) The compounding process includes complex aseptic manipulations other than the single-volume transfer.</p> <p>(III) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogenous mixing (e.g., reconstitution of intravenous immunoglobulin or other intravenous protein products).</p> <p>(IV) The compounded sterile preparations do not contain broad</p>	<p>(ii) The primary engineering control device shall be certified and maintain ISO Class 5 for exposure of critical sites and shall be located in a segregated compounding area restricted to sterile compounding activities that minimizes the risk of contamination of the compounded sterile preparation.</p> <p>(iii) The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation.</p> <p>(iv) For a low-risk preparation compounded as described in clauses (i) - (iii) of this subparagraph, administration of such compounded sterile preparations must commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less.</p> <p>(C) Medium-risk level compounded sterile preparations.</p> <p>(i) Medium-Risk Conditions. Medium-risk level compounded sterile preparations, are those compounded aseptically under low-risk conditions and one or more of the following conditions exists.</p> <p>(I) Multiple individual or small doses of sterile products are combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions.</p> <p>(II) The compounding process includes complex aseptic manipulations other than the single-volume transfer.</p> <p>(III) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogenous mixing (e.g., reconstitution of intravenous immunoglobulin or other intravenous protein products).</p> <p>(IV) The compounded sterile preparations do not contain broad</p>

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<p>spectrum bacteriostatic substances and they are administered over several days (e.g., an externally worn infusion device).</p> <p>(V) For a medium-risk preparation, in the absence of direct sterility testing results or appropriate information sources that justify different limits the beyond use dates may not exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 30 hours at controlled room temperature, for not more than 9 days at a cold temperature, and for 45 days in solid frozen state at minus 20 degrees Celsius or colder.</p> <p>(ii) Examples of medium-risk compounding. Examples of medium-risk compounding include the following.</p> <p>(I) Compounding of total parenteral nutrition fluids using a manual or automated device during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.</p> <p>(II) Filling of reservoirs of injection and infusion devices with multiple sterile drug products and evacuations of air from those reservoirs before the filled device is dispensed.</p> <p>(III) Filling of reservoirs of injection and infusion devices with volumes of sterile drug solutions that will be administered over several days at ambient temperatures between 25 and 40 degrees Celsius (77 and 104 degrees Fahrenheit).</p> <p>(IV) Transfer of volumes from multiple ampuls or vials into a single, final sterile container or product.</p> <p>(D) High-risk level compounded sterile preparations.</p> <p>(i) High-risk Conditions. High-risk level compounded sterile preparations are those compounded under any of the following conditions.</p>	<p>spectrum bacteriostatic substances and they are administered over several days (e.g., an externally worn infusion device).</p> <p>(V) For a medium-risk preparation, in the absence of direct sterility testing results the beyond use dates may not exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 30 hours at controlled room temperature, for not more than 9 days at a cold temperature, and for 45 days in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius.</p> <p>(ii) Examples of medium-risk compounding. Examples of medium-risk compounding include the following.</p> <p>(I) Compounding of total parenteral nutrition fluids using a manual or automated device during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.</p> <p>(II) Filling of reservoirs of injection and infusion devices with more than three sterile drug products and evacuations of air from those reservoirs before the filled device is dispensed.</p> <p>(III) Filling of reservoirs of injection and infusion devices with volumes of sterile drug solutions that will be administered over several days at ambient temperatures between 25 and 40 degrees Celsius (77 and 104 degrees Fahrenheit).</p> <p>(IV) Transfer of volumes from multiple ampuls or vials into a single, final sterile container or product.</p> <p>(D) High-risk level compounded sterile preparations.</p> <p>(i) High-risk Conditions. High-risk level compounded sterile preparations are those compounded under any of the following conditions.</p>

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<p>(I) Non-sterile ingredients, including manufactured products are incorporated or a non-sterile device is employed before terminal sterilization.</p> <p>(II) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior to ISO Class 5. This includes storage in environments inferior to ISO Class 5 of opened or partially used packages of manufactured sterile products that lack antimicrobial preservatives.</p> <p>(III) Non-sterile preparations are exposed no more than 6 hours before being sterilized.</p> <p>(IV) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.</p> <p>(V) For a high-risk preparation, in the absence of direct sterility testing results or appropriate information sources that justify different limits, the storage periods cannot exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 24 hours at controlled room temperature, for not more than 3 days at a cold temperature, and for 45 days in solid frozen state at minus 20 degrees or colder.</p> <p>(VI) All non-sterile measuring, mixing, and purifying equipment is rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for high-risk compounding while assuring cleanliness. All high-risk compounded sterile aqueous solutions subjected to terminal sterilization are passed through a filter with a</p>	<p>(I) Non-sterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral) are incorporated or a non-sterile device is employed before terminal sterilization.</p> <p>(II) Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour:</p> <ul style="list-style-type: none"> (-a-) sterile contents of commercially manufactured products; (-b-) CSPs that lack effective antimicrobial preservatives; and (-c-) sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs. <p>(III) Compounding personnel are improperly garbed and gloved.</p> <p>(IV) Non-sterile water-containing preparations are exposed no more than 6 hours before being sterilized.</p> <p>(V) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.</p> <p>(VI) For a sterilized high-risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 24 hours at controlled room temperature, for not more than 3 days at a cold temperature, and for 45 days in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius.</p> <p>(VII) All non-sterile measuring, mixing, and purifying devices are rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for high-risk compounding. All high-risk compounded sterile solutions subjected to terminal sterilization are prefiltered by passing through a filter with a nominal pore size not</p>

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<p>nominal porosity not larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter. Sterilization of high-risk level compounded sterile preparations by filtration shall be performed entirely within an ISO Class 5 or superior air quality environment.</p> <p>(ii) Examples of high-risk compounding. Examples of high-risk compounding include the following.</p> <p>(I) Dissolving non-sterile bulk drug powders to make solutions, which will be terminally sterilized.</p> <p>(II) Exposing the sterile ingredients and components used to prepare and package compounded sterile preparations to room air quality worse than ISO Class 5.</p> <p>(III) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is performed.</p> <p>(IV) Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.</p> <p>(3) Immediate Use Compounded Sterile Preparations. For the purpose of emergency or immediate patient care, such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the compounded sterile preparation under low-risk level conditions would subject the patient to additional risk due to delays in therapy. Compounded sterile preparations are exempted from the requirements described in this paragraph for low-risk, medium-risk, and high-risk level compounded sterile preparations when all of the following criteria are met.</p> <p>(A) Only simple aseptic measuring and transfer manipulations are performed with not more than three sterile non-hazardous commercial</p>	<p>larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter. Sterilization of high-risk level compounded sterile preparations by filtration shall be performed with a sterile 0.2 micrometer or 0.22 micrometer nominal pore size filter entirely within an ISO Class 5 or superior air quality environment.</p> <p>(ii) Examples of high-risk compounding. Examples of high-risk compounding include the following.</p> <p>(I) Dissolving non-sterile bulk drug powders to make solutions, which will be terminally sterilized.</p> <p>(II) Exposing the sterile ingredients and components used to prepare and package compounded sterile preparations to room air quality worse than ISO Class 5 for more than one hour.</p> <p>(III) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is performed.</p> <p>(IV) Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.</p> <p>(3) Immediate Use Compounded Sterile Preparations. For the purpose of emergency or immediate patient care, such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the compounded sterile preparation under low-risk level conditions would subject the patient to additional risk due to delays in therapy. Compounded sterile preparations are exempted from the requirements described in this paragraph for low-risk level compounded sterile preparations when all of the following criteria are met.</p> <p>(A) Only simple aseptic measuring and transfer manipulations are performed with not more than three sterile non-hazardous commercial</p>

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<p>drug and diagnostic radiopharmaceutical drug products, including an infusion or diluent solution.</p> <p>(B) Unless required for the preparation, the preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour.</p> <p>(C) Administration begins not later than one hour following the completion of preparing the compounded sterile preparation.</p> <p>(D) When the compounded sterile preparations is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the compounded sterile preparation shall bear a label listing patient identification information such as name and identification number(s), the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact 1-hour beyond-use time and date.</p> <p>(E) If administration has not begun within one hour following the completion of preparing the compounded sterile preparation, the compounded sterile preparation is promptly and safely discarded. Immediate use compounded sterile preparations shall not be stored for later use.</p> <p>(F) Cytotoxic drugs shall not be prepared as immediate use compounded sterile preparations.</p>	<p>drug and diagnostic radiopharmaceutical drug products, including an infusion or diluent solution, from the manufacturers' original containers and not more than two entries into any one container or package of sterile infusion solution or administration container/device.</p> <p>(B) Unless required for the preparation, the compounding procedure occurs continuously without delays or interruptions and does not exceed 1 hour.</p> <p>(C) During preparation, aseptic technique is followed and, if not immediately administered, the finished compounded sterile preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter of biological fluids, mix-ups with other compounded sterile preparations, and direct contact of outside surfaces.</p> <p>(D) Administration begins not later than one hour following the completion of preparing the compounded sterile preparation.</p> <p>(E) When the compounded sterile preparations is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the compounded sterile preparation shall bear a label listing patient identification information such as name and identification number(s), the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact 1-hour beyond-use time and date.</p> <p>(F) If administration has not begun within one hour following the completion of preparing the compounded sterile preparation, the compounded sterile preparation is promptly and safely discarded. Immediate use compounded sterile preparations shall not be stored for later use.</p> <p>(G) Hazardous drugs shall not be prepared as immediate use compounded sterile preparations.</p> <p>(4) Single-dose and multiple dose containers. (A) Opened or needle punctured single-dose containers, such as bags</p>

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<p>(4) Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain current or updated copies in hard-copy or electronic format of each of the following:</p> <p>(A) a reference text on injectable drug preparations, such as Handbook on Injectable Drug Products;</p> <p>(B) a specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy, e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs; and</p> <p>(C) the United States Pharmacopeia/National Formulary or the USP Pharmacist's Pharmacopeia containing USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations.</p> <p>(5) Environment. Compounding facilities shall be physically designed and environmentally controlled to minimize airborne contamination of critical sites.</p>	<p>bottles, syringes, and vials of sterile products shall be used within one hour if opened in worse than ISO Class 5 air quality. Any remaining contents must be discarded.</p> <p>(B) Single-dose containers, including single-dose large volume parenteral solutions and single-dose vials, exposed to ISO Class 5 or cleaner air may be used up to six hours after initial needle puncture.</p> <p>(C) Opened single-dose fusion sealed containers shall not be stored for any time period.</p> <p>(D) Multiple-dose containers may be used up to 28 days after initial needle puncture unless otherwise specified by the manufacturer.</p> <p>(5) Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain current or updated copies in hard-copy or electronic format of each of the following:</p> <p>(A) a reference text on injectable drug preparations, such as Handbook on Injectable Drug Products;</p> <p>(B) a specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy, e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs; and</p> <p>(C) the United States Pharmacopeia/National Formulary containing USP Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding—Nonsterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.</p> <p>(6) Environment. Compounding facilities shall be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.</p>

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<p>(A) Low and Medium Risk Preparations.</p> <p>(i) A pharmacy that prepares low- and medium-risk preparations shall have a clean room/controlled area for the compounding of sterile preparations that is constructed to minimize the opportunities for particulate and microbial contamination. The clean room/controlled area shall:</p> <p>(I) be clean, well lit, and of sufficient size to support sterile compounding activities;</p> <p>(II) be used only for the compounding of sterile preparations;</p> <p>(III) be designed such that hand sanitizing and gowning occurs outside the buffer area but allows hands-free access by compounding personnel to the buffer room/area;</p> <p>(IV) have non-porous and washable floors or floor covering to enable regular disinfection;</p> <p>(V) be ventilated in a manner to avoid disruption from the HVAC system and room cross-drafts;</p> <p>(VI) have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices (e.g., coved), nonshedding and resistant to damage by disinfectant agents;</p> <p>(VII) have junctures of ceilings to walls coved or caulked to avoid cracks and crevices;</p> <p>(VIII) have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning;</p>	<p>(A) Low and Medium Risk Preparations.</p> <p>(i) A pharmacy that prepares low- and medium-risk preparations shall have a clean room for the compounding of sterile preparations that is constructed to minimize the opportunities for particulate and microbial contamination. The clean room shall:</p> <p>(I) be clean, well lit, and of sufficient size to support sterile compounding activities;</p> <p>(II) be maintained at a comfortable temperature (e.g., 20 degrees Celsius or cooler) allowing compounding personnel to perform flawlessly when attired in the required aseptic compounding garb;</p> <p>(III) be used only for the compounding of sterile preparations;</p> <p>(IV) be designed such that hand sanitizing and gowning occurs outside the buffer area but allows hands-free access by compounding personnel to the buffer area;</p> <p>(V) have non-porous and washable floors or floor covering to enable regular disinfection;</p> <p>(VI) be ventilated in a manner to avoid disruption from the HVAC system and room cross-drafts;</p> <p>(VII) have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices (e.g., coved), non-shedding and resistant to damage by disinfectant agents;</p> <p>(VIII) have junctures of ceilings to walls coved or caulked to avoid cracks and crevices;</p> <p>(IX) have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning;</p>

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<p>(IX) contain only the appropriate compounding supplies and not be used for bulk storage for supplies and materials. Objects that shed particles shall not be brought into the controlled area;</p> <p>(X) contain an anteroom/ante-zone that provides at least an ISO class 8 air quality and may contain a sink that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination; and</p> <p>(XI) contain a buffer zone or buffer room designed to maintain at least ISO Class 7 conditions. The following is applicable for the buffer area.</p> <p>(-a-) There shall be some demarcation designation that delineates the anteroom or area from the buffer area. The demarcation shall be such that it does not create conditions that could adversely affect the cleanliness of the area.</p> <p>(-b-) The buffer area shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation should be continuously monitored.</p> <p>(-c-) A buffer zone that is not physically separated from the anteroom shall employ the principle of displacement airflow as defined in Chapter 797, Pharmaceutical Compounding--Sterile Preparations, of the USP/NF, with limited access to personnel.</p> <p>(-d-) The buffer area shall not contain sources of water (i.e., sinks) or floor drains.</p> <p>(ii) The pharmacy shall prepare sterile pharmaceuticals in a primary engineering control device, such as a laminar air flow hood, biological safety cabinet, compounding aseptic isolator, compounding aseptic containment isolator which is capable of maintaining at least ISO Class 5 conditions during normal activity.</p>	<p>(X) contain only the appropriate compounding supplies and not be used for bulk storage for supplies and materials. Objects that shed particles shall not be brought into the clean room;</p> <p>(XI) contain an ante-area that provides at least an ISO class 8 air quality and contains a sink with hot and cold running water that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination; and</p> <p>(XII) contain a buffer area designed to maintain at least ISO Class 7 conditions for 0.5-µm and larger particles under dynamic working conditions. The following is applicable for the buffer area.</p> <p>(-a-) There shall be some demarcation designation that delineates the ante-area from the buffer area. The demarcation shall be such that it does not create conditions that could adversely affect the cleanliness of the area.</p> <p>(-b-) The buffer area shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation should be continuously monitored.</p> <p>(-c-) A buffer area that is not physically separated from the ante-area shall employ the principle of displacement airflow as defined in Chapter 797, Pharmaceutical Compounding--Sterile Preparations, of the USP/NF, with limited access to personnel.</p> <p>(-d-) The buffer area shall not contain sources of water (i.e., sinks) or floor drains.</p> <p>(ii) The pharmacy shall prepare sterile preparations in a primary engineering control device, such as a laminar air flow hood, biological safety cabinet, compounding aseptic isolator, compounding aseptic containment isolator which is capable of maintaining at least ISO Class 5 conditions for 0.5-µm particles while compounding sterile preparations.</p>

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<p>(I) The primary engineering control shall:</p> <p>(-a-) be located in the buffer area or room and placed in the buffer area in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system.</p> <p>(-b-) be certified by an independent contractor according to the International Organization of Standardization (ISO) Classification of Particulate Matter in Room Air (ISO 14644-1) for operational efficiency at least every six months and when it is relocated, in accordance with the manufacturer's specifications; and</p> <p>(-c-) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specification, and the inspection and/or replacement date documented.</p> <p>(II) The compounding aseptic isolator or compounding aseptic containment isolator must be placed in an ISO Class 7 buffer area unless the isolator meets all of the following conditions.</p> <p>(-a-) The isolator must provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations.</p> <p>(-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site must maintain ISO Class 5 levels during compounding operations.</p> <p>(-c-) The pharmacy shall maintain documentation from the manufacturer that the isolator meets this standard when located in worse</p>	<p>(I) The primary engineering control shall:</p> <p>(-a-) be located in the buffer area and placed in the buffer area in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system.</p> <p>(-b-) be certified by a qualified independent contractor according to the International Organization of Standardization (ISO) Classification of Particulate Matter in Room Air (ISO 14644-1) for operational efficiency at least every six months and whenever the device or room is relocated or altered or major service to the facility is performed, in accordance with the manufacturer's specifications;</p> <p>(-c-) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specification, and the inspection and/or replacement date documented; and</p> <p>(-d-) be located in a buffer area that has a minimum differential positive pressure of 0.02 to 0.05 inches water column.</p> <p>(II) The compounding aseptic isolator or compounding aseptic containment isolator must be placed in an ISO Class 7 buffer area unless the isolator meets all of the following conditions.</p> <p>(-a-) The isolator must provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations.</p> <p>(-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site must maintain ISO Class 5 levels during compounding operations.</p> <p>(-c-) The pharmacy shall maintain documentation from the manufacturer that the isolator meets this standard when located in worse</p>

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<p>than ISO Class 7 environments.</p> <p>(B) High-risk Preparations. In addition to the requirements in subparagraph (A) of this paragraph, when high-risk preparations are compounded, the primary engineering control shall be located in a buffer room that provides a physical separation, through the use of walls, doors and pass-throughs and has a minimum differential positive pressure of 0.02 to 0.05 inches water column.</p> <p>(C) Automated compounding device. If automated compounding devices are used, the pharmacy shall have a method to calibrate and verify the accuracy of automated compounding devices used in aseptic processing and document the calibration and verification on a routine basis, based on the manufacturer's recommendations.</p> <p>(D) Cytotoxic drugs. If the preparation is cytotoxic, the following is also applicable.</p> <p>(i) General.</p> <p>(I) All personnel involved in the compounding of cytotoxic products shall wear appropriate protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and</p>	<p>than ISO Class 7 environments.</p> <p>(B) High-risk Preparations.</p> <p>(i) In addition to the requirements in subparagraph (A) of this paragraph, when high-risk preparations are compounded, the primary engineering control shall be located in a buffer area that provides a physical separation, through the use of walls, doors and pass-throughs and has a minimum differential positive pressure of 0.02 to 0.05 inches water column.</p> <p>(ii) Presterilization procedures for high-risk level compounded sterile preparations, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.</p> <p>(C) Automated compounding device. If automated compounding devices are used, the pharmacy shall have a method to calibrate and verify the accuracy of automated compounding devices used in aseptic processing and document the calibration and verification on a daily basis, based on the manufacturer's recommendations, and review the results at least weekly.</p> <p>(D) Hazardous drugs. If the preparation is hazardous, the following is also applicable.</p> <p>(i) General.</p> <p>(I) Hazardous drugs shall be prepared only under conditions that protect personnel during preparation and storage.</p> <p>(II) Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure.</p> <p>(III) All personnel involved in the compounding of hazardous drugs shall wear appropriate protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and appropriate gloving at all times when handling hazardous drugs,</p>

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<p>appropriate gloving.</p> <p>(II) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with aseptic techniques required for preparing sterile preparations.</p> <p>(III) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.</p> <p>(IV) Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and distributed in a manner to minimize patient contact with cytotoxic agents.</p> <p>(ii) Primary engineering control device. Cytotoxic drugs shall be prepared in a Class II or III vertical flow biological safety cabinet or compounding aseptic containment isolator located in an ISO Class 7 area that is physically separated from other preparation areas. The area for preparation of sterile chemotherapeutic preparations shall:</p> <p>(I) have not less than 0.01 inches water column negative pressure to the adjacent positive pressure ISO Class 7 or better anteroom; and</p> <p>(II) have a pressure indicator that can be readily monitored for correct room pressurization.</p> <p>(iii) Facilities that prepare a low volume of cytotoxic drugs. Pharmacies that prepare a low volume of cytotoxic drugs, are not required to comply with the provisions of clause (ii) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., closed-system vial transfer device within a BSC or CACI that is located in a non-negative pressure room).</p> <p>(E) Cleaning and disinfecting the sterile compounding areas. The following cleaning and disinfecting practices and frequencies apply to direct and contiguous compounding areas, which include ISO Class 5 compounding areas for exposure of critical sites as well as buffer rooms,</p>	<p>including receiving, distribution, stocking, inventorying, preparation, for administration and disposal.</p> <p>(IV) Appropriate safety and containment techniques for compounding hazardous drugs shall be used in conjunction with aseptic techniques required for preparing sterile preparations.</p> <p>(V) Disposal of hazardous waste shall comply with all applicable local, state, and federal requirements.</p> <p>(VI) Prepared doses of hazardous drugs must be dispensed, labeled with proper precautions inside and outside, and distributed in a manner to minimize patient contact with hazardous agents.</p> <p>(ii) Primary engineering control device. Hazardous drugs shall be prepared in a Class II or III vertical flow biological safety cabinet or compounding aseptic containment isolator located in an ISO Class 7 area that is physically separated from other preparation areas. The area for preparation of sterile chemotherapeutic preparations shall:</p> <p>(I) have not less than 0.01 inches water column negative pressure to the adjacent positive pressure ISO Class 7 or better ante-area; and</p> <p>(II) have a pressure indicator that can be readily monitored for correct room pressurization.</p> <p>(iii) Facilities that prepare a low volume of hazardous drugs. Pharmacies that prepare a low volume of hazardous drugs, are not required to comply with the provisions of clause (ii) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., closed-system vial transfer device within a BSC or CACI that is located in a non-negative pressure room).</p> <p>(E) Cleaning and disinfecting the sterile compounding areas. The following cleaning and disinfecting practices and frequencies apply to direct and contiguous compounding areas, which include ISO Class 5 compounding areas for exposure of critical sites as well as buffer areas,</p>

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<p>anterooms, and ante-areas.</p> <p>(i) The pharmacist-in-charge is responsible for developing written procedures for cleaning and disinfecting the direct and contiguous compounding areas and assuring the procedures are followed.</p> <p>(ii) These procedures shall be conducted prior to and after each work shift (at a minimum of every 12 hours while the pharmacy is open) and when there are spills or environmental quality breaches.</p> <p>(iii) Before compounding is performed, all items are removed from the direct and contiguous compounding areas and all surfaces are cleaned of loose material and residue from spills, followed by an application of a residue-free disinfecting agent (e.g., IPA), that is left on for a time sufficient to exert its antimicrobial effect.</p> <p>(iv) Work surfaces near the direct and contiguous compounding areas in the buffer or clean area are cleaned of loose material and residue from spills, followed by an application of a residue-free disinfecting agent that is left on for a time sufficient to exert its antimicrobial effect.</p> <p>(v) Floors in the buffer or clean area are cleaned by mopping at least once daily when no aseptic operations are in progress preceding from the buffer or clean room area to the anteroom area.</p> <p>(vi) In the anteroom area, walls, ceilings, and shelving shall be cleaned monthly.</p>	<p>ante-areas, and segregated compounding areas.</p> <p>(i) The pharmacist-in-charge is responsible for developing written procedures for cleaning and disinfecting the direct and contiguous compounding areas and assuring the procedures are followed.</p> <p>(ii) These procedures shall be conducted at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding of individual compounded sterile preparations, when there are spills, and when surface contamination is known or suspected from procedural breaches.</p> <p>(iii) Before compounding is performed, all items shall be removed from the direct and contiguous compounding areas and all surfaces are cleaned by removing loose material and residue from spills, followed by an application of a residue-free disinfecting agent (e.g., IPA), which is allowed to dry before compounding begins.</p> <p>(iv) Work surfaces in the ISO Class 7 buffer areas and ISO Class 8 ante-areas, as well as segregated compounding areas, shall be cleaned and disinfected at least daily. Dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 air quality.</p> <p>(v) Floors in the buffer area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent at least once daily when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs. It is incumbent on compounding personnel to ensure that such cleaning is performed properly.</p> <p>(vi) In the buffer area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly. Cleaning and disinfecting agents shall be used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues.</p>

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<p>(vii) Supplies and equipment removed from shipping cartons must be wiped with a disinfecting agent, such as IPA. However, if supplies are received in sealed pouches, the pouches may be removed as the supplies are introduced into the buffer or clean area without the need to disinfect the individual supply items. No shipping or other external cartons may be taken into the buffer or clean area.</p> <p>(viii) Storage shelving, emptied of all supplies, walls, and ceilings are cleaned and disinfected at planned intervals, monthly, if not more frequently.</p> <p>(F) Security requirements. The pharmacy may authorize personnel to gain access to that area of the pharmacy containing dispensed sterile preparations, in the absence of the pharmacist, for the purpose of retrieving dispensed prescriptions to deliver to patients. If the pharmacy</p>	<p>(viii) All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer area and ant-are, but only in that order. If cleaning materials are reused, procedures shall be developed that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bio-burden of the area being cleaned.</p> <p>(ix) Supplies and equipment removed from shipping cartons must be wiped with a disinfecting agent, such as sterile IPA. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes. However, if sterile supplies are received in sealed pouches, the pouches may be removed as the supplies are introduced into the ISO Class 5 area without the need to disinfect the individual sterile supply items. No shipping or other external cartons may be taken into the buffer area or segregated compounding area.</p> <p>(x) Storage shelving emptied of all supplies, walls, and ceilings are cleaned and disinfected at planned intervals, monthly, if not more frequently.</p> <p>(xi) Cleaning must be done by personnel trained in appropriate cleaning techniques.</p> <p>(xii) Proper documentation and frequency of cleaning must be maintained and shall contain the following:</p> <ul style="list-style-type: none"> (I) date and time of cleaning; (II) type of cleaning performed; and (III) name of individual who performed the cleaning. <p>(F) Security requirements. The pharmacist-in-charge may authorize personnel to gain access to that area of the pharmacy containing dispensed sterile preparations, in the absence of the pharmacist, for the purpose of retrieving dispensed prescriptions to deliver to patients. If the</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>allows such after-hours access, the area containing the dispensed sterile pharmaceuticals shall be an enclosed and lockable area separate from the area containing undispensed prescription drugs. A list of the authorized personnel having such access shall be in the pharmacy's policy and procedure manual.</p> <p>(G) Storage requirements and beyond-use dating.</p> <p>(i) Storage requirements. All drugs shall be stored at the proper temperature and conditions, as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).</p> <p>(ii) Beyond-use dating.</p> <p>(I) Beyond-use dates for compounded sterile preparations shall be assigned based on professional experience, which shall include careful interpretation of appropriate information sources for the same or similar formulations.</p> <p>(II) Beyond-use dates for compounded sterile preparations that are prepared strictly in accordance with manufacturers' product labeling must be those specified in that labeling, or from appropriate literature sources or direct testing.</p> <p>(III) Beyond-use dates for compounded sterile preparations that lack justification from either appropriate literature sources or by direct testing evidence must be assigned as described in Chapter 797, Pharmaceutical Compounding--Sterile Preparations of the USP/NF.</p>	<p>pharmacy allows such after-hours access, the area containing the dispensed sterile preparations shall be an enclosed and lockable area separate from the area containing undispensed prescription drugs. A list of the authorized personnel having such access shall be in the pharmacy's policy and procedure manual.</p> <p>(G) Storage requirements and beyond-use dating.</p> <p>(i) Storage requirements. All drugs shall be stored at the proper temperature and conditions, as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).</p> <p>(ii) Beyond-use dating.</p> <p>(I) Beyond-use dates for compounded sterile preparations shall be assigned based on professional experience, which shall include careful interpretation of appropriate information sources for the same or similar formulations.</p> <p>(II) Beyond-use dates for compounded sterile preparations that are prepared strictly in accordance with manufacturers' product labeling must be those specified in that labeling, or from appropriate literature sources or direct testing.</p> <p>(III) Beyond-use dates for compounded sterile preparations that lack justification from either appropriate literature sources or by direct testing evidence shall be assigned as described in Chapter 795, in Stability Criteria and Beyond-Use Dating under Pharmaceutical Compounding-Nonsterile Preparations of the USP/NF.</p> <p>(IV) When assigning a beyond-use date, compounding personnel shall consult and apply drug-specific and general stability documentation and literature where available, and they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy.</p>

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<p>(6) Equipment and supplies. Pharmacies compounding sterile preparations shall have the following equipment and supplies:</p> <p>(A) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure that proper storage requirements are met, if sterile pharmaceuticals are stored in the refrigerator;</p> <p>(B) a calibrated system or device to monitor the temperature where bulk chemicals are stored;</p> <p>(C) if applicable, a Class A prescription balance, or analytical balance and weights. Such balance shall be properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy;</p> <p>(D) equipment and utensils necessary for the proper compounding of sterile preparations. Such equipment and utensils used in the compounding process shall be:</p> <p>(i) of appropriate design, appropriate capacity, and be operated within designed operational limits;</p> <p>(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug preparation beyond the desired result;</p> <p>(iii) cleaned and sanitized immediately prior to and after each use; and</p>	<p>(V) The sterility and storage and stability beyond-use date for attached and activated container pairs of drug products for intravascular administration shall be applied as indicated by the manufacturer.</p> <p>(7) Equipment and supplies. Pharmacies compounding sterile preparations shall have the following equipment and supplies:</p> <p>(A) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure that proper storage requirements are met, if sterile preparations are stored in the refrigerator;</p> <p>(B) a calibrated system or device to monitor the temperature where bulk chemicals are stored;</p> <p>(C) a temperature-sensing mechanism suitably placed in the controlled temperature storage space to reflect accurately the true temperature;</p> <p>(D) if applicable, a Class A prescription balance, or analytical balance and weights. Such balance shall be properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy;</p> <p>(E) equipment and utensils necessary for the proper compounding of sterile preparations. Such equipment and utensils used in the compounding process shall be:</p> <p>(i) of appropriate design, appropriate capacity, and be operated within designed operational limits;</p> <p>(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug preparation beyond the desired result;</p> <p>(iii) cleaned and sanitized immediately prior to and after each use; and</p>

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<p>(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;</p> <p>(E) appropriate disposal containers for used needles, syringes, etc., and if applicable, hazardous waste from the preparation of hazardous drugs and/or biohazardous waste;</p> <p>(F) appropriate packaging or delivery containers to maintain proper storage conditions for sterile preparations;</p> <p>(G) infusion devices, if applicable; and</p> <p>(H) all necessary supplies, including:</p> <p>(i) disposable needles, syringes, and other supplies for aseptic mixing;</p> <p>(ii) disinfectant cleaning solutions;</p> <p>(iii) hand washing agents with bactericidal action;</p> <p>(iv) disposable, lint free towels or wipes;</p> <p>(v) appropriate filters and filtration equipment;</p> <p>(vi) cytotoxic spill kits, if applicable; and</p> <p>(vii) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.</p> <p>(7) Labeling.</p> <p>(A) Prescription drug or medication orders. In addition to the labeling requirements for the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following.</p>	<p>(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;</p> <p>(F) appropriate disposal containers for used needles, syringes, etc., and if applicable, hazardous waste from the preparation of hazardous drugs and/or biohazardous waste;</p> <p>(G) appropriate packaging or delivery containers to maintain proper storage conditions for sterile preparations;</p> <p>(H) infusion devices, if applicable; and</p> <p>(I) all necessary supplies, including:</p> <p>(i) disposable needles, syringes, and other supplies for aseptic mixing;</p> <p>(ii) disinfectant cleaning solutions;</p> <p>(iii) hand washing agents with bactericidal action;</p> <p>(iv) disposable, lint free towels or wipes;</p> <p>(v) appropriate filters and filtration equipment;</p> <p>(vi) hazardous spill kits, if applicable; and</p> <p>(vii) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.</p> <p>(8) Labeling.</p> <p>(A) Prescription drug or medication orders. In addition to the labeling requirements for the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following:</p>

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<p>(i) The generic name(s) or the official name(s) of the principal active ingredient(s) of the compounded sterile preparation.</p> <p>(ii) For outpatient prescription orders only, a statement that the compounded sterile preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement).</p> <p>(iii) A beyond-use date. The beyond-use date shall be determined as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF, and paragraph (4) of this subsection.</p> <p>(B) Batch. If the sterile pharmaceutical is compounded in a batch, the following shall also be included on the batch label.</p> <p>(i) unique lot number assigned to the batch;</p> <p>(ii) quantity;</p> <p>(iii) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and</p> <p>(iv) device-specific instructions, where appropriate.</p> <p>(C) Pharmacy bulk package. The label of a pharmacy bulk package shall:</p> <p>(i) state prominently "Pharmacy Bulk Package--Not for Direct Infusion;"</p> <p>(ii) contain or refer to information on proper techniques to help ensure safe use of the preparation; and</p> <p>(iii) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.</p>	<p>(i) the generic name(s) or the official name(s) of the principal active ingredient(s) of the compounded sterile preparation;</p> <p>(ii) for outpatient prescription orders only, a statement that the compounded sterile preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement);</p> <p>(iii) a beyond-use date. The beyond-use date shall be determined as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF, and paragraph (7)(G) of this subsection;</p> <p>(B) Batch. If the sterile preparation is compounded in a batch, the following shall also be included on the batch label:</p> <p>(i) unique lot number assigned to the batch;</p> <p>(ii) quantity;</p> <p>(iii) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and</p> <p>(iv) device-specific instructions, where appropriate.</p> <p>(C) Pharmacy bulk package. The label of a pharmacy bulk package shall:</p> <p>(i) state prominently "Pharmacy Bulk Package--Not for Direct Infusion;"</p> <p>(ii) contain or refer to information on proper techniques to help ensure safe use of the preparation; and</p> <p>(iii) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(8) Written drug information for prescription drug orders only. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing a prescription drug order. A statement which indicates that the preparation was compounded by the pharmacy must be included in this written information. If there is no written information available, the patient shall be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate, the prescriber, concerning the drug.</p> <p>(9) Pharmaceutical Care Services. In addition to the pharmaceutical care requirements for the pharmacy's specific license classification, the following requirements for sterile preparations compounded pursuant to prescription drug orders must be met.</p> <p>(A) Primary provider. There shall be a designated physician primarily responsible for the patient's medical care. There shall be a clear understanding between the physician, the patient, and the pharmacy of the responsibilities of each in the areas of the delivery of care, and the monitoring of the patient. This shall be documented in the patient medication record (PMR).</p> <p>(B) Patient training. The pharmacist-in-charge shall develop policies to ensure that the patient and/or patient's caregiver receives information regarding drugs and their safe and appropriate use, including instruction when applicable, regarding:</p> <ul style="list-style-type: none"> (i) appropriate disposition of hazardous solutions and ancillary supplies; (ii) proper disposition of controlled substances in the home; (iii) self-administration of drugs, where appropriate; (iv) emergency procedures, including how to contact an appropriate individual in the event of problems or emergencies related to drug therapy; and 	<p>(9) Written drug information for prescription drug orders only. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing a prescription drug order. A statement which indicates that the preparation was compounded by the pharmacy must be included in this written information. If there is no written information available, the patient shall be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate, the prescriber, concerning the drug.</p> <p>(10) Pharmaceutical Care Services. In addition to the pharmaceutical care requirements for the pharmacy's specific license classification, the following requirements for sterile preparations compounded pursuant to prescription drug orders must be met.</p> <p>(A) Primary provider. There shall be a designated physician primarily responsible for the patient's medical care. There shall be a clear understanding between the physician, the patient, and the pharmacy of the responsibilities of each in the areas of the delivery of care, and the monitoring of the patient. This shall be documented in the patient medication record (PMR).</p> <p>(B) Patient training. The pharmacist-in-charge shall develop policies to ensure that the patient and/or patient's caregiver receives information regarding drugs and their safe and appropriate use, including instruction when applicable, regarding:</p> <ul style="list-style-type: none"> (i) appropriate disposition of hazardous solutions and ancillary supplies; (ii) proper disposition of controlled substances in the home; (iii) self-administration of drugs, where appropriate; (iv) emergency procedures, including how to contact an appropriate individual in the event of problems or emergencies related to drug therapy; and

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(v) if the patient or patient's caregiver prepares sterile preparations in the home, the following additional information shall be provided:</p> <p>(I) safeguards against microbial contamination, including aseptic techniques for compounding intravenous admixtures and aseptic techniques for injecting additives to premixed intravenous solutions;</p> <p>(II) appropriate storage methods, including storage durations for sterile pharmaceuticals and expirations of self-mixed solutions;</p> <p>(III) handling and disposition of premixed and self-mixed intravenous admixtures; and</p> <p>(IV) proper disposition of intravenous admixture compounding supplies such as syringes, vials, ampules, and intravenous solution containers.</p> <p>(C) Pharmacist-patient relationship. It is imperative that a pharmacist-patient relationship be established and maintained throughout the patient's course of therapy. This shall be documented in the patient's medication record (PMR).</p> <p>(D) Patient monitoring. The pharmacist-in-charge shall develop policies to ensure that:</p> <p>(i) the patient's response to drug therapy is monitored and conveyed to the appropriate health care provider; and</p> <p>(ii) the first dose of any new drug therapy is administered in the presence of an individual qualified to monitor for and respond to adverse drug reactions.</p>	<p>(v) if the patient or patient's caregiver prepares sterile preparations in the home, the following additional information shall be provided:</p> <p>(I) safeguards against microbial contamination, including aseptic techniques for compounding intravenous admixtures and aseptic techniques for injecting additives to premixed intravenous solutions;</p> <p>(II) appropriate storage methods, including storage durations for sterile pharmaceuticals and expirations of self-mixed solutions;</p> <p>(III) handling and disposition of premixed and self-mixed intravenous admixtures; and</p> <p>(IV) proper disposition of intravenous admixture compounding supplies such as syringes, vials, ampules, and intravenous solution containers.</p> <p>(C) Pharmacist-patient relationship. It is imperative that a pharmacist-patient relationship be established and maintained throughout the patient's course of therapy. This shall be documented in the patient's medication record (PMR).</p> <p>(D) Patient monitoring. The pharmacist-in-charge shall develop policies to ensure that:</p> <p>(i) the patient's response to drug therapy is monitored and conveyed to the appropriate health care provider;</p> <p>(ii) the first dose of any new drug therapy is administered in the presence of an individual qualified to monitor for and respond to adverse drug reactions; and</p> <p>(iii) reports of adverse events with a compounded sterile preparation are reviewed promptly and thoroughly to correct and prevent future occurrences.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(10) Drugs, components, and materials used in sterile compounding.</p> <p>(A) Drugs used in sterile compounding shall be a USP/NF grade substances manufactured in an FDA-registered facility.</p> <p>(B) If USP/NF grade substances are not available shall be of a chemical grade in one of the following categories:</p> <ul style="list-style-type: none"> (i) Chemically Pure (CP); (ii) Analytical Reagent (AR); (iii) American Chemical Society (ACS); or (iv) Food Chemical Codex. <p>(C) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.</p> <p>(D) All components shall:</p> <ul style="list-style-type: none"> (i) be manufactured in an FDA-registered facility; or (ii) in the professional judgment of the pharmacist, be of high quality and obtained from acceptable and reliable alternative sources; and (iii) stored in properly labeled containers in a clean, dry area, under proper temperatures. <p>(E) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug preparation beyond the desired result.</p> <p>(F) Components, drug preparation containers, and closures shall be</p>	<p>(11) Drugs, components, and materials used in sterile compounding.</p> <p>(A) Drugs used in sterile compounding shall be a USP/NF grade substances manufactured in an FDA-registered facility.</p> <p>(B) If USP/NF grade substances are not available shall be of a chemical grade in one of the following categories:</p> <ul style="list-style-type: none"> (i) Chemically Pure (CP); (ii) Analytical Reagent (AR); (iii) American Chemical Society (ACS); or (iv) Food Chemical Codex. <p>(C) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.</p> <p>(D) All components shall:</p> <ul style="list-style-type: none"> (i) be manufactured in an FDA-registered facility; or (ii) in the professional judgment of the pharmacist, be of high quality and obtained from acceptable and reliable alternative sources; and (iii) stored in properly labeled containers in a clean, dry area, under proper temperatures. <p>(E) Drug preparation containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug preparation beyond the desired result.</p> <p>(F) Components, drug preparation containers, and closures shall be</p>

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<p>rotated so that the oldest stock is used first.</p> <p>(G) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug preparation.</p> <p>(H) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.</p> <p>(11) Compounding process.</p> <p>(A) Standard operating procedures (SOPs). All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed for:</p> <ul style="list-style-type: none"> (i) the facility; (ii) equipment; (iii) personnel; (iv) preparation evaluation; (v) quality assurance; (vi) preparation recall; (vii) packaging; and (viii) storage of compounded sterile preparations. <p>(B) USP/NF. Any compounded formulation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.</p>	<p>rotated so that the oldest stock is used first.</p> <p>(G) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug preparation.</p> <p>(H) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.</p> <p>(12) Compounding process.</p> <p>(A) Standard operating procedures (SOPs). All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed and implemented for:</p> <ul style="list-style-type: none"> (i) the facility; (ii) equipment; (iii) personnel; (iv) preparation evaluation; (v) quality assurance; (vi) preparation recall; (vii) packaging; and (viii) storage of compounded sterile preparations. <p>(B) USP/NF. Any compounded formulation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(C) Personnel Cleansing and Garbing.</p> <p>(i) Any person with an apparent illness or open lesion that may adversely affect the safety or quality of a drug preparation being compounded shall be excluded from direct contact with components, drug preparation containers, closures, any materials involved in the compounding process, and drug products until the condition is corrected.</p> <p>(ii) Before entering the clean area, compounding personnel must remove the following:</p> <p>(I) personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests);</p> <p>(II) all cosmetics, because they shed flakes and particles; and</p> <p>(III) all hand, wrist, and other body jewelry.</p> <p>(iii) The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment.</p> <p>(iv) Personnel must don personal protective equipment and perform hand hygiene in an order that proceeds from the dirtiest to the cleanest activities as follows:</p> <p>(I) Activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye shield. Eye shields are optional unless working with irritants like germicidal disinfecting agents.</p>	<p>(C) Personnel Cleansing and Garbing.</p> <p>(i) Any person with an apparent illness or open lesion, including rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infection, that may adversely affect the safety or quality of a drug preparation being compounded shall be excluded from working in ISO Class 5 and ISO Class 7 compounding areas until the condition is remedied.</p> <p>(ii) Before entering the buffer area, compounding personnel must remove the following:</p> <p>(I) personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests);</p> <p>(II) all cosmetics, because they shed flakes and particles; and</p> <p>(III) all hand, wrist, and other body jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of personal protective equipment (e.g., fit of gloves and cuffs of sleeves).</p> <p>(iii) The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed.</p> <p>(iv) Personnel shall don personal protective equipment and perform hand hygiene in an order that proceeds from the dirtiest to the cleanest activities as follows:</p> <p>(I) Activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye shield. Eye shields are optional unless working with irritants like germicidal disinfecting agents or when preparing hazardous drugs.</p>

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<p>(II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, personnel shall perform a hand hygiene procedure by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Personnel shall begin washing arms at the hands and continue washing to elbows for at least 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in the anteroom/ante-area.</p> <p>(III) After completion of hand washing, personnel shall don clean non-shedding gowns with sleeves that fit snugly around the wrists.</p> <p>(IV) Gloves that form a continuous barrier with the gown shall be the last item donned before compounding begins.</p> <p>(V) Gloves, either those which are sterile or have been disinfected by applying 70% IPA or appropriate disinfectant to all contact surface areas and allowed to dry, that form a continuous barrier with the gown shall be the last item donned before compounding begins. Routine application of 70% IPA shall occur throughout the compounding day and whenever nonsterile surfaces are touched.</p> <p>(VI) When compounding personnel must temporarily exit the ISO Class 7 environment during a work shift, the exterior gown, if not visibly soiled, may be removed and retained in the ISO Class 8 anteroom/ante-area, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face mask/eye shield, and gloves</p>	<p>(II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, personnel shall perform a hand hygiene procedure by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Personnel shall begin washing arms at the hands and continue washing to elbows for at least 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in the ante-area. Hands and forearms to the elbows shall be completely dried using lint-free disposable towels, an electronic hands-free hand dryer, or a HEPA filtered hands dryer.</p> <p>(III) After completion of hand washing, personnel shall don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclosed at the neck.</p> <p>(IV) Once inside the buffer area or segregated compounding area, and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations. Hands shall be allowed to dry thoroughly before donning sterile gloves.</p> <p>(V) Sterile gloves that form a continuous barrier with the gown shall be the last item donned before compounding begins. Routine application of sterile 70% IPA shall occur throughout the compounding day and whenever nonsterile surfaces are touched.</p> <p>(v) When compounding personnel shall temporarily exit the ISO Class 7 environment during a work shift, the exterior gown, if not visibly soiled, may be removed and retained in the ISO Class 8 ante-area, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face mask/eye shield, and gloves shall be</p>

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<p>must be replaced with new ones before re-entering the ISO Class 7 clean environment along with performing proper hand hygiene.</p> <p>(D) At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.</p> <p>(12) Quality Assurance.</p> <p>(A) Initial Formula Validation. Prior to routine compounding of a sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a product that is sterile and that contains the stated amount of active ingredient(s).</p> <p>(i) Low risk preparations.</p> <p>(I) Quality assurance practices include, but are not limited to the following:</p>	<p>replaced with new ones before re-entering the ISO Class 7 clean environment along with performing proper hand hygiene.</p> <p>(vi) During high-risk compounding activities that precede terminal sterilization, such as weighing and mixing of nonsterile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 environment. Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 shall re-garb personal protective equipment along with washing their hands properly, performing antiseptic hand cleansing with a waterless alcohol-based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7 buffer area.</p> <p>(vii) When compounding aseptic isolators or compounding aseptic containment isolators are the source of the ISO Class 5 environment, the compounding personnel should follow the requirements as specified in this subparagraph, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any components of personal protective equipment or cleansing are not required.</p> <p>(13) Quality Assurance.</p> <p>(A) Initial Formula Validation. Prior to routine compounding of a sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a preparation that is sterile and that contains the stated amount of active ingredient(s).</p> <p>(i) Low risk preparations.</p> <p>(I) Quality assurance practices include, but are not limited to the following:</p>

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<p>(-a-) Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality.</p> <p>(-b-) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments and goggles.</p> <p>(-c-) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.</p> <p>(-d-) Visual inspection of compounded sterile preparations to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.</p> <p>(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually by each person authorized to compound in a low-risk level under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low-risk level sterile produce. Once begun, this test is completed without interruption within an ISO Class 5 air quality environment. Three sets of four 5-milliliter aliquots of sterile Soybean--Casein Digest Medium are transferred with the same sterile 10-milliliter syringe and vented needle combination into separate sealed, empty, sterile 30-milliliter clear vials (i.e., four 5-milliliter aliquots into each of three 30-milliliter vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.</p> <p>(ii) Medium risk preparations.</p> <p>(I) Quality assurance procedures for medium-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations, as well as a more challenging media-</p>	<p>(-a-) Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality.</p> <p>(-b-) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments and goggles.</p> <p>(-c-) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.</p> <p>(-d-) Visual inspection of compounded sterile preparations to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.</p> <p>(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually by each person authorized to compound in a low-risk level under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low-risk level sterile preparations. Once begun, this test is completed without interruption within an ISO Class 5 air quality environment. Three sets of four 5-milliliter aliquots of sterile Soybean--Casein Digest Medium are transferred with the same sterile 10-milliliter syringe and vented needle combination into separate sealed, empty, sterile 30-milliliter clear vials (i.e., four 5-milliliter aliquots into each of three 30-milliliter vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.</p> <p>(ii) Medium risk preparations.</p> <p>(I) Quality assurance procedures for medium-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations, as well as a more challenging media-</p>

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<p>fill test passed annually, or more frequently.</p> <p>(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. This test is completed without interruption within an ISO Class 5 air quality environment. Six 100-milliliter aliquots of sterile Soybean--Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-milliliter syringe and 18-gauge needle combination is used to exchange two 5-milliliter aliquots of medium from one container to the other container in the pair. For example, after a 5-milliliter aliquot from the first container is added to the second container in the pair, the second container is agitated for 10 seconds, then a 5-milliliter aliquot is removed and returned to the first container in the pair. The first container is then agitated for 10 seconds, and the next 5-milliliter aliquot is transferred from it back to the second container in the pair. Following the two 5-milliliter aliquot exchanges in each pair of containers, a 5-milliliter aliquot of medium from each container is aseptically injected into a sealed, empty, sterile 10-milliliter clear vial, using a sterile 10-milliliter syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.</p> <p>(iii) High risk preparations.</p> <p>(I) Procedures for high-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations. In addition, a media-fill test that represents high-risk level compounding is performed twice a year by each person authorized to compound high-risk level compounded sterile preparations.</p> <p>(II) Example of a Media-Fill Test Procedure Compounded Sterile Preparations Sterilized by Filtration. This test, or an equivalent test, is</p>	<p>fill test passed annually, or more frequently.</p> <p>(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. This test is completed without interruption within an ISO Class 5 air quality environment. Six 100-milliliter aliquots of sterile Soybean--Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-milliliter syringe and 18-gauge needle combination is used to exchange two 5-milliliter aliquots of medium from one container to the other container in the pair. For example, after a 5-milliliter aliquot from the first container is added to the second container in the pair, the second container is agitated for 10 seconds, then a 5-milliliter aliquot is removed and returned to the first container in the pair. The first container is then agitated for 10 seconds, and the next 5-milliliter aliquot is transferred from it back to the second container in the pair. Following the two 5-milliliter aliquot exchanges in each pair of containers, a 5-milliliter aliquot of medium from each container is aseptically injected into a sealed, empty, sterile 10-milliliter clear vial, using a sterile 10-milliliter syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.</p> <p>(iii) High risk preparations.</p> <p>(I) Procedures for high-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations. In addition, a media-fill test that represents high-risk level compounding is performed twice a year by each person authorized to compound high-risk level compounded sterile preparations.</p> <p>(II) Example of a Media-Fill Test Procedure Compounded Sterile Preparations Sterilized by Filtration. This test, or an equivalent test, is</p>

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<p>performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level compounded sterile preparations. Note: Sterility tests for autoclaved compounded sterile preparations are not required unless they are prepared in batches of more than 25 units. This test is completed without interruption in the following sequence:</p> <p>(-a-) Dissolve 3 grams of nonsterile commercially available Soybean--Casein Digest Medium in 100 milliliters of non-bacteriostatic water to make a 3% nonsterile solution.</p> <p>(-b-) Draw 25 milliliters of the medium into each of three 30-milliliter sterile syringes. Transfer 5 milliliters from each syringe into separate sterile 10-milliliter vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.</p> <p>(-c-) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron porosity filter unit and a 20-gauge needle to each syringe. Inject the next 10 milliliters from each syringe into three separate 10-milliliter sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20 to 35 degrees Celsius. Inspect for microbial growth over 14 days as described in Chapter 797 Pharmaceutical Compounding--Sterile Preparations, of the USP/NF.</p> <p>(B) Finished preparation release checks and tests.</p> <p>(i) High-risk level compounded sterile preparations. All high-risk level compounded sterile preparations that are prepared in groups of more than 25 identical individual single-dose packages (such as ampuls, bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than 12 hours at 2 - 8 degrees Celsius (36 - 46 degrees Fahrenheit) and longer than six hours at warmer than 8 degrees Celsius (46 degrees Fahrenheit) before they are sterilized shall be tested to ensure they are sterile and do not contain</p>	<p>performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level compounded sterile preparations. Note: Sterility tests for autoclaved compounded sterile preparations are not required unless they are prepared in batches of more than 25 units. This test is completed without interruption in the following sequence:</p> <p>(-a-) Dissolve 3 grams of nonsterile commercially available Soybean--Casein Digest Medium in 100 milliliters of non-bacteriostatic water to make a 3% nonsterile solution.</p> <p>(-b-) Draw 25 milliliters of the medium into each of three 30-milliliter sterile syringes. Transfer 5 milliliters from each syringe into separate sterile 10-milliliter vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.</p> <p>(-c-) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron porosity filter unit and a 20-gauge needle to each syringe. Inject the next 10 milliliters from each syringe into three separate 10-milliliter sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20 to 35 degrees Celsius for a minimum of 14 days. Inspect for microbial growth over 14 days as described in Chapter 797 Pharmaceutical Compounding--Sterile Preparations, of the USP/NF.</p> <p>(B) Finished preparation release checks and tests.</p> <p>(i) All high-risk level compounded sterile preparations that are prepared in groups of more than 25 identical individual single-dose packages (such as ampuls, bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than 12 hours at 2 - 8 degrees Celsius and longer than six hours at warmer than 8 degrees Celsius before they are sterilized shall be tested to ensure they are sterile and do not contain excessive bacterial endotoxins as specified in Chapter 71, Sterility Tests of the USP/NF</p>

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<p>excessive bacterial endotoxins as specified in Chapter 71, Sterility Tests of the USP/NF.</p> <p>(ii) All compounded sterile preparations that are intended to be solutions must be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed.</p> <p>(iii) The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded sterile preparations at all contamination risk levels shall be inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.</p>	<p>before being dispensed or administered.</p> <p>(ii) All compounded sterile preparations that are intended to be solutions must be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed.</p> <p>(iii) The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded sterile preparations at all contamination risk levels shall be inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are dispensed or administered.</p> <p>(C) Viable and nonviable environmental sampling testing. Environmental sampling shall occur, at a minimum, every six months as part of a comprehensive quality management program and under any of the following conditions:</p> <p>(i) as part of the commissioning and certification of new facilities and equipment;</p> <p>(ii) following any servicing of facilities and equipment;</p> <p>(iii) as part of the re-certification of facilities and equipment;</p> <p>(iv) in response to identified problems with end products or staff technique; or</p> <p>(v) in response to issues with compounded sterile preparations, observed compounding personnel work practices, or patient-related infections (where the compounded sterile preparation is being considered as a potential source of the infection).</p> <p>(D) Total particle counts. Certification that each ISO classified area (e.g., ISO Class 5, 7, and 8), is within established guidelines shall be</p>

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	<p>performed no less than every six months and whenever the equipment is relocated or the physical structure of the buffer area or ante-area has been altered. All certification records shall be maintained and reviewed to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and air changes per hour. Testing shall be performed by qualified operators using current, state-of-the-art equipment. with results of the following:</p> <ul style="list-style-type: none"> (i) ISO Class 5 – not more than 3520 particles 0.5 µm and larger size per cubic meter of air; (ii) ISO Class 7 – not more than 352,000 particles of 0.5 µm and larger size per cubic meter of air for any buffer area; and (iii) ISO Class 8 – not more than 3,520,000 particles of 0.5 µm and larger size per cubic meter of air for any ante-area. <p>(E) Pressure differential monitoring. A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 and the general pharmacy area shall not be less than 0.02 inch water column.</p> <p>(F) Sampling plan. An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas and in the segregated compounding areas at greatest risk of contamination. The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.</p> <p>(G) Viable air sampling. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments shall be performed by properly trained individuals for all compounding risk levels. For low-, medium-, and high-risk level compounding, air sampling shall</p>

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<p>(13) Quality control.</p>	<p>be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning. Locations shall include zones of air backwash turbulence within the laminar airflow workbench and other areas where air backwash turbulence may enter the compounding area. For low-risk level compounded sterile preparations within 12-hour or less beyond-use-date prepared in a primary engineering control that maintains an ISO Class 5, air sampling shall be performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class 5 environment during the certification of the primary engineering control.</p> <p>(H) Air sampling frequency and process. Air sampling shall be performed at least every 6 months as a part of the re-certification of facilities and equipment. A sufficient volume of air shall be sampled and the manufacturer’s guidelines for use of the electronic air sampling equipment followed. At the end of the designated sampling or exposure period for air sampling activities, the microbial growth media plates are recovered and their covers secured and they are inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.</p> <p>(I) Compounding accuracy checks. Written procedures for double-checking compounding accuracy shall be followed for every compounded sterile preparation during preparation and immediately prior to release, including label accuracy and the accuracy of the addition of all drug products or ingredients used to prepare the finished preparation and their volumes or quantities. At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.</p> <p>(14) Quality control.</p>

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<p>(A) Quality control procedures. The pharmacy shall follow established quality control procedures to monitor the compounding environment and quality of compounded drug preparations for conformity with the quality indicators established for the preparation. When developing these procedures, pharmacy personnel shall consider the provisions of Chapter 797, Pharmaceutical Compounding--Sterile Preparations, Chapter 1075, Good Compounding Practices, and Chapter 1160, Pharmaceutical Calculations in Prescription Compounding of the current USP/NF. Such procedures shall be documented and be available for inspection.</p> <p>(B) Verification of compounding accuracy and sterility.</p> <p>(i) The accuracy of identities, concentrations, amounts, and purities of ingredients in compounded sterile preparations shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.</p> <p>(ii) If the correct identify, purity, strength, and sterility of ingredients and components of compounded sterile preparations cannot be confirmed such ingredients and components shall be discarded immediately.</p> <p>(iii) If individual ingredients, such as bulk drug substances, are not labeled with expiration dates, when the drug substances are stable indefinitely in their commercial packages under labeled storage conditions, such ingredients may gain or lose moisture during storage and use and shall require testing to determine the correct amount to weigh for accurate content of active chemical moieties in compounded sterile preparations.</p>	<p>(A) Quality control procedures. The pharmacy shall follow established quality control procedures to monitor the compounding environment and quality of compounded drug preparations for conformity with the quality indicators established for the preparation. When developing these procedures, pharmacy personnel shall consider the provisions of USP Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding—Nonsterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations, Chapter 1075, Good Compounding Practices, and Chapter 1160, Pharmaceutical Calculations in Prescription Compounding, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding of the current USP/NF. Such procedures shall be documented and be available for inspection.</p> <p>(B) Verification of compounding accuracy and sterility.</p> <p>(i) The accuracy of identities, concentrations, amounts, and purities of ingredients in compounded sterile preparations shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.</p> <p>(ii) If the correct identity, purity, strength, and sterility of ingredients and components of compounded sterile preparations cannot be confirmed such ingredients and components shall be discarded immediately.</p> <p>(iii) If individual ingredients, such as bulk drug substances, are not labeled with expiration dates, when the drug substances are stable indefinitely in their commercial packages under labeled storage conditions, such ingredients may gain or lose moisture during storage and use and shall require testing to determine the correct amount to weigh for accurate content of active chemical moieties in compounded sterile preparations.</p>

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<p>(e) Records.</p> <p>(1) Maintenance of records. Every record required under this section must be:</p> <p>(A) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and</p> <p>(B) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.</p> <p>(2) Compounding records.</p> <p>(A) Compounding pursuant to patient specific prescription drug orders. Compounding records for all compounded pharmaceuticals shall be maintained by the pharmacy electronically or manually as part of the prescription drug or medication order, formula record, formula book, or compounding log and shall include:</p> <p>(i) the date of preparation;</p> <p>(ii) a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of each;</p> <p>(iii) signature or initials of the pharmacist or pharmacy technician or</p>	<p>(e) Records. Any testing, cleaning, procedures, or other activities required in this subsection shall be documented and such documentation shall be maintained by the pharmacy.</p> <p>(1) Maintenance of records. Every record required under this section must be:</p> <p>(A) kept by the pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and</p> <p>(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.</p> <p>(2) Compounding records.</p> <p>(A) Compounding pursuant to patient specific prescription drug orders. Compounding records for all compounded preparations shall be maintained by the pharmacy electronically or manually as part of the prescription drug or medication order, formula record, formula book, or compounding log and shall include:</p> <p>(i) the date of preparation;</p> <p>(ii) a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of each;</p> <p>(iii) signature or initials of the pharmacist or pharmacy technician or</p>

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<p>pharmacy technician trainee performing the compounding;</p> <p>(iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting in-process and finals checks of compounded pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the compounding function;</p> <p>(v) the quantity in units of finished products or amount of raw materials;</p> <p>(vi) the container used and the number of units prepared; and</p> <p>(vii) a reference to the location of the following documentation which may be maintained with other records, such as quality control records:</p> <p>(I) the criteria used to determine the beyond-use date; and</p> <p>(II) documentation of performance of quality control procedures.</p> <p>(B) Compounding records when batch compounding or compounding in anticipation of future prescription drug or medication orders.</p> <p>(i) Master work sheet. A master work sheet shall be developed and approved by a pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work sheet shall be used as the preparation work sheet from which each batch is prepared and on which all documentation for that batch occurs. The master work sheet shall contain at a minimum:</p> <p>(I) the formula;</p> <p>(II) the components;</p> <p>(III) the compounding directions;</p> <p>(IV) a sample label;</p>	<p>pharmacy technician trainee performing the compounding;</p> <p>(iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting in-process and finals checks of compounded pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the compounding function;</p> <p>(v) the quantity in units of finished preparation or amount of raw materials;</p> <p>(vi) the container used and the number of units prepared; and</p> <p>(vii) a reference to the location of the following documentation which may be maintained with other records, such as quality control records:</p> <p>(I) the criteria used to determine the beyond-use date; and</p> <p>(II) documentation of performance of quality control procedures.</p> <p>(B) Compounding records when batch compounding or compounding in anticipation of future prescription drug or medication orders.</p> <p>(i) Master work sheet. A master work sheet shall be developed and approved by a pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work sheet shall be used as the preparation work sheet from which each batch is prepared and on which all documentation for that batch occurs. The master work sheet shall contain at a minimum:</p> <p>(I) the formula;</p> <p>(II) the components;</p> <p>(III) the compounding directions;</p> <p>(IV) a sample label;</p>

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<p>(V) evaluation and testing requirements;</p> <p>(VI) specific equipment used during preparation; and</p> <p>(VII) storage requirements.</p> <p>(ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall document the following:</p> <p>(I) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;</p> <p>(II) lot number for each component;</p> <p>(III) component manufacturer/distributor or suitable identifying number;</p> <p>(IV) container specifications (e.g., syringe, pump cassette);</p> <p>(V) unique lot or control number assigned to batch;</p> <p>(VI) expiration date of batch-prepared preparations;</p> <p>(VII) date of preparation;</p> <p>(VIII) name, initials, or electronic signature of the person(s) involved in the preparation;</p> <p>(IX) name, initials, or electronic signature of the responsible pharmacist;</p> <p>(X) finished preparation evaluation and testing specifications, if applicable; and</p> <p>(XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.</p>	<p>(V) evaluation and testing requirements;</p> <p>(VI) specific equipment used during preparation; and</p> <p>(VII) storage requirements.</p> <p>(ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall document the following:</p> <p>(I) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;</p> <p>(II) lot number for each component;</p> <p>(III) component manufacturer/distributor or suitable identifying number;</p> <p>(IV) container specifications (e.g., syringe, pump cassette);</p> <p>(V) unique lot or control number assigned to batch;</p> <p>(VI) expiration date of batch-prepared preparations;</p> <p>(VII) date of preparation;</p> <p>(VIII) name, initials, or electronic signature of the person(s) involved in the preparation;</p> <p>(IX) name, initials, or electronic signature of the responsible pharmacist;</p> <p>(X) finished preparation evaluation and testing specifications, if applicable; and</p> <p>(XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.</p>

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<p>(f) Office Use Compounding and Distribution of Compounded Preparations to Class C Pharmacies or Veterinarians in Accordance with §563.054 of the Act.</p> <p>(1) General.</p> <p>(A) A pharmacy may dispense and deliver a reasonable quantity of a compounded preparation to a practitioner for office use by the practitioner in accordance with this subsection.</p> <p>(B) A Class A (Community) pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations to a Class C (Institutional) pharmacy.</p> <p>(C) A Class C (Institutional) pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations that the Class C pharmacy has compounded for other Class C pharmacies under common ownership.</p> <p>(D) To dispense and deliver a compounded preparation under this subsection, a pharmacy must:</p> <p>(i) verify the source of the raw materials to be used in a compounded drug;</p> <p>(ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);</p> <p>(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;</p> <p>(iv) comply with all applicable competency and accrediting standards as determined by the board; and</p>	<p>(f) Office Use Compounding and Distribution of Sterile Compounded Preparations</p> <p>(1) General.</p> <p>(A) A pharmacy may compound, dispense, deliver, and distribute a compounded sterile preparation as specified in subchapter D, Texas Pharmacy Act Chapter 562.</p> <p>(B) A Class A-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations to a Class C or Class C-S pharmacy.</p> <p>(C) A Class C-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations that the Class C-S pharmacy has compounded for other Class C or Class C-S pharmacies under common ownership.</p> <p>(D) To compound and deliver a compounded preparation under this subsection, a pharmacy must:</p> <p>(i) verify the source of the raw materials to be used in a compounded drug;</p> <p>(ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);</p> <p>(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;</p> <p>(iv) comply with all applicable competency and accrediting standards as determined by the board; and</p>

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<p>(v) comply with the provisions of this subsection.</p> <p>(2) Written Agreement. A pharmacy that provides sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:</p> <p>(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded drugs may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except as authorized by §563.054 of the Act;</p> <p>(B) require the practitioner or receiving pharmacy to include on a patient's chart, medication order or medication administration record the lot number and beyond-use date of a compounded preparation administered to a patient;</p> <p>(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:</p> <p>(i) a patient to report an adverse reaction or submit a complaint; and</p> <p>(ii) the pharmacy to recall batches of compounded preparations.</p> <p>(3) Recordkeeping.</p> <p>(A) Maintenance of Records.</p> <p>(i) Records of orders and distribution of sterile compounded preparations to a practitioner for office use or to a Class C pharmacy for administration to a patient shall:</p> <p>(l) be kept by the pharmacy and be available, for at least two years from the date of the record, for inspecting and copying by the board or</p>	<p>(v) comply with the provisions of this subsection.</p> <p>(2) Written Agreement. A pharmacy that provides sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:</p> <p>(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded drugs may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except to a veterinarian as authorized by §563.054 of the Act;</p> <p>(B) require the practitioner or receiving pharmacy to include on a patient's chart, medication order or medication administration record the lot number and beyond-use date of a compounded preparation administered to a patient;</p> <p>(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:</p> <p>(i) a patient to report an adverse reaction or submit a complaint; and</p> <p>(ii) the pharmacy to recall batches of compounded preparations.</p> <p>(3) Recordkeeping.</p> <p>(A) Maintenance of Records.</p> <p>(i) Records of orders and distribution of sterile compounded preparations to a practitioner for office use or to an institutional pharmacy for administration to a patient shall:</p> <p>(l) be kept by the pharmacy and be available, for at least two years from the date of the record, for inspecting and copying by the board or</p>

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<p>its representative and to other authorized local, state, or federal law enforcement agencies;</p> <p>(II) maintained separately from the records of products dispensed pursuant to a prescription or medication order; and</p> <p>(III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.</p> <p>(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.</p> <p>(B) Orders. The pharmacy shall maintain a record of all sterile compounded preparations ordered by a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:</p> <p>(i) date of the order;</p> <p>(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the Class C Pharmacy ordering the preparation; and</p> <p>(iii) name, strength, and quantity of the preparation ordered.</p> <p>(C) Distributions. The pharmacy shall maintain a record of all sterile compounded preparations distributed pursuant to an order to a</p>	<p>its representative and to other authorized local, state, or federal law enforcement agencies;</p> <p>(II) maintained separately from the records of preparations dispensed pursuant to a prescription or medication order; and</p> <p>(III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.</p> <p>(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.</p> <p>(B) Orders. The pharmacy shall maintain a record of all sterile compounded preparations ordered by a practitioner for office use or by an institutional pharmacy for administration to a patient. The record shall include the following information:</p> <p>(i) date of the order;</p> <p>(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the institutional pharmacy ordering the preparation; and</p> <p>(iii) name, strength, and quantity of the preparation ordered.</p> <p>(C) Distributions. The pharmacy shall maintain a record of all sterile compounded preparations distributed pursuant to an order to a practitioner for office use or by an institutional pharmacy for</p>

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<p>practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:</p> <ul style="list-style-type: none"> (i) date the preparation was compounded; (ii) date the preparation was distributed; (iii) name, strength and quantity in each container of the preparation; (iv) pharmacy's lot number; (v) quantity of containers shipped; and (vi) name, address, and phone number of the practitioner or Class C Pharmacy to whom the preparation is distributed. <p>(D) Audit Trail.</p> <p>(i) The pharmacy shall store the order and distribution records of preparations for all sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a Class C pharmacy for administration to a patient in such a manner as to be able to provide a audit trail for all orders and distributions of any of the following during a specified time period.</p> <ul style="list-style-type: none"> (I) any strength and dosage form of a preparation (by either brand or generic name or both); (II) any ingredient; (III) any lot number; (IV) any practitioner; (V) any facility; and (VI) any pharmacy, if applicable. 	<p>administration to a patient. The record shall include the following information:</p> <ul style="list-style-type: none"> (i) date the preparation was compounded; (ii) date the preparation was distributed; (iii) name, strength and quantity in each container of the preparation; (iv) pharmacy's lot number; (v) quantity of containers shipped; and (vi) name, address, and phone number of the practitioner or institutional pharmacy to whom the preparation is distributed. <p>(D) Audit Trail.</p> <p>(i) The pharmacy shall store the order and distribution records of preparations for all sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a Class S pharmacy for administration to a patient in such a manner as to be able to provide an audit trail for all orders and distributions of any of the following during a specified time period.</p> <ul style="list-style-type: none"> (I) any strength and dosage form of a preparation (by either brand or generic name or both); (II) any ingredient; (III) any lot number; (IV) any practitioner; (V) any facility; and (VI) any pharmacy, if applicable.

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<p>(ii) The audit trail shall contain the following information:</p> <p>(I) date of order and date of the distribution;</p> <p>(II) practitioner's name, address, and name of the Class C pharmacy, if applicable;</p> <p>(III) name, strength and quantity of the preparation in each container of the preparation;</p> <p>(IV) name and quantity of each active ingredient;</p> <p>(V) quantity of containers distributed; and</p> <p>(VI) pharmacy's lot number;</p> <p>(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:</p> <p>(A) name, address, and phone number of the compounding pharmacy;</p> <p>(B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";</p> <p>(C) name and strength of the preparation or list of the active ingredients and strengths;</p> <p>(D) pharmacy's lot number;</p> <p>(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;</p> <p>(F) quantity or amount in the container;</p>	<p>(ii) The audit trail shall contain the following information:</p> <p>(I) date of order and date of the distribution;</p> <p>(II) practitioner's name, address, and name of the institutional pharmacy, if applicable;</p> <p>(III) name, strength and quantity of the preparation in each container of the preparation;</p> <p>(IV) name and quantity of each active ingredient;</p> <p>(V) quantity of containers distributed; and</p> <p>(VI) pharmacy's lot number;</p> <p>(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:</p> <p>(A) name, address, and phone number of the compounding pharmacy;</p> <p>(B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";</p> <p>(C) name and strength of the preparation or list of the active ingredients and strengths;</p> <p>(D) pharmacy's lot number;</p> <p>(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;</p> <p>(F) quantity or amount in the container;</p>

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<p>(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and</p> <p>(H) device-specific instructions, where appropriate.</p> <p>(g) Recall Procedures.</p> <p>(1) The pharmacy shall have written procedures for the recall of any compounded sterile preparation provided to a patient, to a practitioner for office use, or a pharmacy for administration. Written procedures shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.</p> <p>(2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.</p> <p>(3) In the event of a recall, the pharmacist-in-charge shall ensure that:</p> <p>(A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;</p> <p>(B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;</p> <p>(C) if the preparation is prepared as a batch, the board is notified of the recall, in writing;</p> <p>(D) if the preparation is distributed for office use, the Texas Department of State Health Services, Drugs and Medical Devices Group, is notified of the recall, in writing;</p> <p>(E) the preparation is quarantined; and</p> <p>(F) the pharmacy keeps a written record of the recall including all actions taken to notify all parties and steps taken to ensure corrective</p>	<p>(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and</p> <p>(H) device-specific instructions, where appropriate.</p> <p>(g) Recall Procedures.</p> <p>(1) The pharmacy shall have written procedures for the recall of any compounded sterile preparation provided to a patient, to a practitioner for office use, or a pharmacy for administration. Written procedures shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.</p> <p>(2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.</p> <p>(3) In the event of a recall, the pharmacist-in-charge shall ensure that:</p> <p>(A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;</p> <p>(B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;</p> <p>(C) the board is notified of the recall, in writing, not later than 24 hours after the recall is issued;</p> <p>(D) if the preparation is distributed for office use, the Texas Department of State Health Services, Drugs and Medical Devices Group, is notified of the recall, in writing;</p> <p>(E) the preparation is quarantined; and</p> <p>(F) the pharmacy keeps a written record of the recall including all actions taken to notify all parties and steps taken to ensure corrective</p>

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<p>measures.</p> <p>(4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if there is potential for or confirmed harm to a patient.</p>	<p>measures.</p> <p>(4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if there is potential for or confirmed harm to a patient.</p> <p>(5) A pharmacy that compounds sterile preparations shall notify the board immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy.</p>