

RULE REVIEW ANALYSIS

Introduction: **THIS RULE REVIEW IS SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED REVIEW**

Short Title: Services Provided by Pharmacies

Rule Number: Chapter 291, Subchapter G (§§291.120-291.121, 291.123, 291.125, 291.127, 291.129, 291.131, 291.133)

Statutory Authority: Government Code, §2001.039, added by Acts 1999, 76th Legislature, Chapter 1499, Article 1, Section 1.11.

Background: Review of these sections follow the Board's rule review plan.

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

5
6 **§291.120 General**
7

8 (a) Purpose. This subchapter applies to all classes of pharmacies except as otherwise noted.
9

10 (b) Definitions.

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12 (1) The Texas Pharmacy Act or Act--Subtitle J, other than Chapter 567, Occupations Code, as
13 amended.

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15 (2) Board--The Texas State Board of Pharmacy.
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17 **§291.121 Remote Pharmacy Services**
18

19 (a) Remote pharmacy services using automated pharmacy systems.
20

21 (1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy
22 services by a Class A or Class C pharmacy in a facility that is not at the same location as the
23 Class A or Class C pharmacy through an automated pharmacy system as outlined in §562.109
24 of the Texas Pharmacy Act.

25
26 (2) Definitions. The following words and terms, when used in this section, shall have the
27 following meanings, unless the context clearly indicates otherwise. All other words and terms
28 shall have the meanings defined in the Act.

29
30 (A) Automated pharmacy system--A mechanical system that dispenses prescription drugs
31 and maintains related transaction information.
32

33 (B) Remote site--A facility not located at the same location as a Class A or Class C
34 pharmacy, at which remote pharmacy services are provided using an automated pharmacy
35 dispensing system.
36

37 (C) Repackaging--The act of repackaging and relabeling quantities of drug products from a
38 manufacturer's original commercial container, or quantities of unit dosed drugs, into another
39 cartridge or container for dispensing by a pharmacist using an automated pharmacy system.
40

41 (D) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy
42 (Class C) providing remote pharmacy services.
43

44 (E) Remote pharmacy service--The provision of pharmacy services, including the storage and
45 dispensing of prescription drugs, in remote sites.
46

47 (F) Unit dose--An amount of a drug packaged in a dosage form ready for administration to a
48 particular patient, by the prescribed route at the prescribed time, and properly labeled with
49 name, strength, and expiration date of the drug.
50

51 (3) General requirements.
52

53 (A) A provider pharmacy may provide remote pharmacy services using an automated
54 pharmacy system to a jail or prison operated by or for the State of Texas, a jail or prison
55 operated by local government or a healthcare facility regulated under Chapter 142, 242, 247, or
56 252, Health and Safety Code, provided drugs are administered by a licensed healthcare
57 professional working in the jail, prison, or healthcare facility.
58

59 (B) A provider pharmacy may only provide remote pharmacy services using an automated
60 pharmacy system to inpatients of the remote site.
61

62 (C) A provider pharmacy may provide remote pharmacy services at more than one remote
63 site.
64

65 (D) Before providing remote pharmacy services, the automated pharmacy system at the
66 remote site must be tested by the provider pharmacy and found to dispense accurately. The
67 provider pharmacy shall make the results of such testing available to the board upon request.
68

69 (E) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required
70 to comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel,
71 Operational Standards, and Records for Class A (Community) Pharmacies) and this section.
72

73 (F) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy
74 operations involving the automated pharmacy system located at the remote site including
75 supervision of the automated pharmacy system and compliance with this section.
76

77 (G) A pharmacist from the provider pharmacy shall be accessible at all times to respond to
78 patient's or other health professionals' questions and needs pertaining to drugs dispensed
79 through the use of the automated pharmacy system. Such access may be through a 24 hour
80 pager service or telephone which is answered 24 hours a day.
81

82 (4) Operational standards.
83

84 (A) Application for permission to provide pharmacy services using an automated pharmacy
85 system.
86

87 (i) A Class A or Class C Pharmacy shall make application to the board to provide remote
88 pharmacy services using an automated pharmacy system. The application shall contain an
89 affidavit with the notarized signatures of the pharmacist-in-charge, and the medical director or
90 the person responsible for the on-site operation of the facility (e.g., administrator, chief operating
91 officer, owner, chief executive officer), and include the following:
92

93 (I) the name, address, and license number of the provider pharmacy;
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95 (II) name and address of the facility where the remote pharmacy services will be provided;
96

97 (III) a statement indicating that the provider pharmacy and the facility have entered into a
98 written contract or agreement which outlines the services to be provided and the responsibilities
99 and accountabilities of each party in fulfilling the terms of the contract or agreement in
100 compliance with federal and state laws and regulations; and

101
102 (IV) documentation that the automated pharmacy system is located where medications are
103 administered by license healthcare professionals and is:

104
105 (-a-) a facility regulated under Chapter 142, 242, 247, or 252, Health and Safety Code; or
106

107 (-b-) a jail or prison, operated by the State of Texas or local government.
108

109 (ii) Such application shall be resubmitted every two years in conjunction with the application
110 for renewal of the provider pharmacy's license. The renewal petition shall contain the
111 documentation required in clause (i) of this subparagraph except the notarized signature of the
112 medical director or the person responsible for the on-site operation of the facility (e.g.,
113 administrator, chief operating officer, owner, chief executive officer) is not required.
114

115 (iii) Upon approval of the application, the provider pharmacy will be sent a certificate which
116 must be displayed at the remote site.
117

118 (B) Notification requirements.
119

120 (i) A provider pharmacy shall notify the board in writing within ten days of a change of
121 location, discontinuance of service, or closure of:

122 (I) a remote site where an automated pharmacy system is operated by the pharmacy; or
123

124 (II) a remote pharmacy service at a remote site.
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126 (ii) A provider pharmacy shall comply with appropriate federal and state controlled
127 substance registrations for each remote site if controlled substances are maintained within an
128 automated pharmacy system at the facility.
129

130 (C) Environment/Security.
131

132 (i) A provider pharmacy shall only store drugs at a remote site within an automated
133 pharmacy system which is locked by key, combination or other mechanical or electronic means
134 so as to prohibit access by unauthorized personnel.
135

136 (ii) An automated pharmacy system shall be under the continuous supervision of a provider
137 pharmacy pharmacist. To qualify as continuous supervision, the pharmacist is not required to be
138 physically present at the site of the automated pharmacy system if the system is supervised
139 electronically by a pharmacist.
140

141 (iii) Automated pharmacy systems shall have adequate security and procedures to:
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143 (I) comply with federal and state laws and regulations; and
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145 (II) maintain patient confidentiality.
146

147 (iv) Access to the automated pharmacy system shall be limited to pharmacists or personnel
148 who:
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150

151 (I) are designated in writing by the pharmacist-in-charge; and

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153 (II) have completed documented training concerning their duties associated with the
154 automated pharmacy system.

155

156 (v) Drugs shall be stored in compliance with the provisions of §291.15 of this title (relating to
157 Storage of Drugs) and §291.33(f)(2) of this title including the requirements for temperature and
158 handling of outdated drugs.

159

160 (D) Prescription dispensing and delivery.

161

162 (i) Drugs shall only be dispensed at a remote site through an automated pharmacy system
163 after receipt of an original prescription drug order by a pharmacist at the provider pharmacy in a
164 manner authorized by §291.34(b) of this title.

165

166 (ii) A pharmacist at the provider pharmacy shall control all operations of the automated
167 pharmacy system and approve the release of the initial dose of a prescription drug order.
168 Subsequent doses from an approved prescription drug order may be removed from the
169 automated medication system after this initial approval. Any change made in the prescription
170 drug order shall require a new approval by a pharmacist to release the drug.

171

172 (iii) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified
173 in §291.33(c) of this title prior to releasing a prescription drug order to the automated pharmacy
174 system.

175

176 (iv) Drugs dispensed by the provider pharmacy through an automated pharmacy system
177 shall comply with the labeling or labeling alternatives specified in §291.33(c) of this title.

178

179 (v) An automated pharmacy system used to meet the emergency medication needs for
180 residents of a remote site must comply with the requirements for emergency medication kits in
181 subsection (b) of this section.

182

183 (E) Drugs.

184

185 (i) Drugs for use in an automated pharmacy system shall be packaged in the original
186 manufacturer's container or be prepackaged in the provider pharmacy and labeled in
187 compliance with the board's prepackaging requirements for the class of pharmacy.

188

189 (ii) Drugs dispensed from the automated pharmacy system may be returned to the
190 pharmacy for reuse provided the drugs are in sealed, tamper evident packaging which has not
191 been opened.

192

193 (F) Stocking an automated pharmacy system.

194

195 (i) Stocking of drugs in an automated pharmacy system shall be completed by a pharmacist,
196 pharmacy technician, or pharmacy technician trainee under the direct supervision of a
197 pharmacist, except as provided in clause (ii) of this subparagraph.

198

199 (ii) If the automated pharmacy system uses removable cartridges or containers to hold
200 drugs, the prepackaging of the cartridges or containers shall occur at the provider pharmacy

201 unless provided by an FDA approved repackager. The prepackaged cartridges or containers
202 may be sent to the remote site to be loaded into the machine by personnel designated by the
203 pharmacist-in-charge provided:

204 (I) a pharmacist verifies the cartridge or container has been properly filled and labeled;

205
206 (II) the individual cartridges or containers are transported to the remote site in a secure,
207 tamper-evident container; and
208

209 (III) the automated pharmacy system uses bar-coding, microchip, or other technologies to
210 ensure that the containers are accurately loaded in the automated pharmacy system.
211

212 (iii) All drugs to be stocked in the automated pharmacy system shall be delivered to the
213 remote site by the provider pharmacy.
214

215 (G) Quality assurance program. A pharmacy that provides pharmacy services through an
216 automated pharmacy system at a remote site shall operate according to a written program for
217 quality assurance of the automated pharmacy system which:
218

219 (i) requires continuous supervision of the automated pharmacy system; and
220

221 (ii) establishes mechanisms and procedures to routinely test the accuracy of the automated
222 pharmacy system at a minimum of every six months and whenever any upgrade or change is
223 made to the system and documents each such activity.
224

225 (H) Policies and procedures of operation.

226 (i) A pharmacy that provides pharmacy services through an automated pharmacy system at
227 a remote site shall operate according to written policies and procedures. The policy and
228 procedure manual shall include, but not be limited to, the following:
229

230 (I) a current list of the name and address of the pharmacist-in-charge and personnel
231 designated by the pharmacist-in-charge to have access to the drugs stored in the automated
232 pharmacy system;
233

234 (II) duties which may only be performed by a pharmacist;
235

236 (III) a copy of the portion of the written contract or agreement between the pharmacy and
237 the facility which outlines the services to be provided and the responsibilities and
238 accountabilities of each party relating to the operation of the automated pharmacy system in
239 fulfilling the terms of the contract in compliance with federal and state laws and regulations;
240

241 (IV) date of last review/revision of the policy and procedure manual; and
242

243 (V) policies and procedures for:
244

245 (-a-) security;
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247 (-b-) operation of the automated pharmacy system;
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251 (-c-) preventative maintenance of the automated pharmacy system;

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253 (-d-) sanitation;

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255 (-e-) storage of drugs;

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257 (-f-) dispensing;

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259 (-g-) supervision;

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261 (-h-) drug procurement;

262

263 (-i-) receiving of drugs;

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265 (-j-) delivery of drugs; and

266

267 (-k-) recordkeeping.

268

269 (ii) A pharmacy that provides pharmacy services through an automated pharmacy system at
270 a remote site shall, at least annually, review its written policies and procedures, revise them if
271 necessary, and document the review.

272

273 (iii) A pharmacy providing remote pharmacy services using an automated pharmacy system
274 shall maintain a written plan for recovery from an event which interrupts the ability of the
275 automated pharmacy system to dispense prescription drugs. The written plan for recovery shall
276 include:

277

278 (I) planning and preparation for maintaining pharmacy services when an automated
279 pharmacy system is experiencing downtime;

280

281 (II) procedures for response when an automated pharmacy system is experiencing
282 downtime; and

283

284 (III) procedures for the maintenance and testing of the written plan for recovery.

285

286 (5) Records.

287

288 (A) Maintenance of records.

289

290 (i) Every record required under this section must be:

291

292 (I) kept by the provider pharmacy and be available, for at least two years for inspecting and
293 copying by the board or its representative and to other authorized local, state, or federal law
294 enforcement agencies; and

295

296 (II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent
297 of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
298 format, the requested records must be provided in an electronic format if specifically requested
299 by the board or its representative. Failure to provide the records set out in this section, either on

300 site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records
301 in violation of the Act.

302
303 (ii) The provider pharmacy shall maintain original prescription drug orders for drugs
304 dispensed from an automated pharmacy system in compliance with §291.34(b) of this title.
305

306 (iii) if prescription drug records are maintained in a data processing system, the system shall
307 have a workable (electronic) data retention system which can produce a separate audit trail of
308 drug usage by the provider pharmacy and each remote site for the preceding two years as
309 specified in §291.34(e) of this title.

310
311 (B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this
312 title.

313
314 (C) Records of dispensing. Dispensing records for a prescription drug order shall be
315 maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.
316

317 (D) Transaction information.

318
319 (i) The automated pharmacy system shall electronically record all transactions involving
320 drugs stored in, removed, or dispensed from the system.

321
322 (ii) Records of dispensing from an automated pharmacy system for a patient shall be
323 maintained by the providing pharmacy and include the:

- 324
325 (I) identity of the system accessed;
326
327 (II) identification of the individual accessing the system;
328
329 (III) date of transaction;
330
331 (IV) name, strength, dosage form, and quantity of drug accessed; and
332
333 (V) name of the patient for whom the drug was accessed.

334
335 (iii) Records of stocking or removal from an automated pharmacy system shall be
336 maintained by the pharmacy and include the:

- 337
338 (I) date;
339
340 (II) name, strength, dosage form, and quantity of drug stocked or removed;
341
342 (III) name, initials, or identification code of the person stocking or removing drugs from the
343 system;
344
345 (IV) name, initials, or identification code of the pharmacist who checks and verifies that the
346 system has been accurately filled;

347
348 (E) Patient medication records. Patient medication records shall be created and maintained
349 by the provider pharmacy in the manner required by §291.34(c) of this title.

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(F) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the records of the provider pharmacy and from any other remote site's records; and

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title (relating to Inventory Requirements for All Classes of Pharmacies) that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs of the provider pharmacy.

(b) Remote pharmacy services using emergency medication kits.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an emergency medication kit as outlined in §562.108 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this subsection, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and maintains related transaction information.

(B) Emergency medication kits--Controlled substances and dangerous drugs maintained by a provider pharmacy to meet the emergency medication needs of a resident:

(i) at an institution licensed under Chapter 242 or 252, Health and Safety Code; or

(ii) at an institution licensed under Chapter 242, Health and Safety Code and that is a veterans home as defined by the §164.002, Natural Resources Code, if the provider pharmacy is a United States Department of Veterans Affairs pharmacy or another federally operated pharmacy.

(C) Remote site--A facility not located at the same location as a Class A, Class C, Class E pharmacy or a United States Department of Affairs pharmacy or another federally operated pharmacy, at which remote pharmacy services are provided using an emergency medication kit.

399 (D) Prepackaging--The act of repackaging and relabeling quantities of drug products from a
400 manufacturer's original commercial container, or quantities of unit dosed drugs, into another
401 cartridge or container for dispensing by a pharmacist using an emergency medication kit.
402

403 (E) Provider pharmacy--The community pharmacy (Class A), the institutional pharmacy
404 (Class C), the non-resident (Class E) pharmacy located not more than 20 miles from an
405 institution licensed under Chapter 242 or 252, Health and Safety Code, or the United States
406 Department of Veterans Affairs pharmacy or another federally operated pharmacy providing
407 remote pharmacy services.
408

409 (F) Remote pharmacy service--The provision of pharmacy services, including the storage and
410 dispensing of prescription drugs, in remote sites.
411

412 (3) General requirements.
413

414 (A) A provider pharmacy may provide remote pharmacy services using an emergency
415 medication kit to an institution regulated under Chapter 242, or 252, Health and Safety Code.
416

417 (B) A provider pharmacy may provide remote pharmacy services at more than one remote
418 site.
419

420 (C) A provider pharmacy shall not place an emergency medication kit in a remote site which
421 already has a kit from another provider pharmacy except as provided by paragraph (4)(B)(iii) of
422 this subsection.
423

424 (D) A provider pharmacy which is licensed as an institutional (Class C) or a non-resident
425 (Class E) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title
426 and this section.
427

428 (E) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy
429 operations involving the emergency medication kit located at the remote site including
430 supervision of the emergency medication kit and compliance with this section.
431

432 (4) Operational standards.
433

434 (A) Application for permission to provide pharmacy services using an emergency medication
435 kit.
436

437 (i) A Class A, Class C, or Class E Pharmacy shall make application to the board to provide
438 remote pharmacy services using an emergency medication kit. The application shall contain an
439 affidavit with the notarized signatures of the pharmacist-in-charge, and the medical director or
440 the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief
441 executive officer, chief operating officer), and include the following:
442

443 (I) the name, address, and license number of the provider pharmacy;
444

445 (II) name and address of the healthcare facility where the remote pharmacy services will be
446 provided;
447

448 (III) a statement indicating that the provider pharmacy and the healthcare facility have
449 entered into a written contract or agreement which outlines the services to be provided and the
450 responsibilities and accountabilities of each party in fulfilling the terms of the contract or
451 agreement in compliance with federal and state laws and regulations;

452
453 (IV) documentation that the emergency medication kit is located in a facility regulated
454 under Chapter 242, or 252, Health and Safety Code; and

455
456 (V) if applicable, documentation that the emergency kit is located in a facility that is not
457 more than 20 miles from the Class E pharmacy providing the emergency kit.

458
459 (ii) Such application shall be resubmitted every two years in conjunction with the application
460 for renewal of the provider pharmacy's license. The renewal petition shall contain the
461 documentation required in clause (i) of this subparagraph except the notarized signature of the
462 medical director or the person responsible for the on-site operation of the facility (e.g.,
463 administrator, owner, chief executive officer, chief operating officer) is not required.

464
465 (iii) Upon approval of the application, the provider pharmacy will be sent a certificate which
466 must be displayed at the remote site.

467
468 (B) Notification requirements.

469
470 (i) A provider pharmacy shall notify the board in writing within ten days of a change of
471 location, discontinuance of service, or closure of:

472
473 (I) a remote site where an emergency medication kit is operated by the pharmacy; or

474
475 (II) a remote pharmacy service at a remote site.

476
477 (ii) A provider pharmacy shall comply with appropriate federal and state controlled
478 substance registrations for each remote site if controlled substances are maintained within an
479 emergency medication kit at the facility.

480
481 (iii) If more than one provider pharmacy provides an emergency kit to a remote site, the
482 provider pharmacies must enter into a written agreement as to the emergency medications
483 supplied by each pharmacy. The provider pharmacies shall not duplicate drugs stored in the
484 emergency medication kits. The written agreement shall include reasons why an additional
485 pharmacy is required to meet the emergency medication needs of the residents of the
486 institution.

487
488 (C) Environment/Security.

489
490 (i) Emergency medication kits shall have adequate security and procedures to:

491
492 (I) prohibit unauthorized access;

493
494 (II) comply with federal and state laws and regulations; and

495
496 (III) maintain patient confidentiality.

497

498 (ii) Access to the emergency medication kit shall be limited to pharmacists and licensed
499 healthcare personnel employed by the facility.

500
501 (iii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of
502 this title including the requirements for temperature and handling outdated drugs.

503
504 (D) Prescription dispensing and delivery.

505
506 (i) Drugs in the emergency medication kit shall be accessed for administration to meet the
507 emergency medication needs of a resident of the remote site pursuant to an order from a
508 practitioner. The prescription drug order for the drugs used from the emergency medication kit
509 shall be forwarded to the provider pharmacy in a manner authorized by §291.34(b) of this title.

510
511 (ii) The remote site shall notify the provider pharmacy of each entry into an emergency
512 medication kit. Such notification shall meet the requirements of paragraph (5)(D)(ii) of this
513 subsection.

514
515 (E) Drugs.

516
517 (i) The contents of an emergency medication kit:

518
519 (I) may consist of dangerous drugs and controlled substances; and

520
521 (II) shall be determined by the consultant pharmacist, pharmacist-in-charge of the provider
522 pharmacy, medical director, and the director of nurses and limited to those drugs necessary to
523 meet the resident's emergency medication needs. For the purpose of this subsection, this shall
524 mean a situation in which a drug cannot be supplied by a pharmacy within a reasonable time
525 period.

526
527 (ii) When deciding on the drugs to be placed in the emergency medication kit, the consultant
528 pharmacist, pharmacist-in-charge of the provider pharmacy, medical director, and the director of
529 nurses must determine, select, and record a prudent number of drugs for potential emergency
530 incidents based on:

531
532 (I) clinical criteria applicable to each facility's demographics;

533
534 (II) the facility's census; and

535
536 (III) the facility's healthcare environment.

537
538 (iii) A current list of the drugs stored in each remote site's emergency medication kit shall be
539 maintained by the provider pharmacy and a copy kept with the emergency medication kit.

540
541 (iv) An automated pharmacy system may be used as an emergency medication kit provided
542 the system limits emergency access to only those drugs approved for the emergency
543 medication kit.

544
545 (v) Drugs for use in an emergency medication kit shall be packaged in the original
546 manufacturer's container or prepackaged in the provider pharmacy and labeled in compliance
547 with the board's prepackaging requirements for the class of pharmacy.

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(F) Stocking emergency medication kits.

(i) Stocking of drugs in an emergency medication kit shall be completed at the provider pharmacy or remote site by a pharmacist, pharmacy technician, or pharmacy technician trainee under the direct supervision of a pharmacist, except as provided in clause (ii) of this subparagraph.

(ii) If the emergency medication kit is an automated pharmacy system which uses bar-coding, microchip, or other technologies to ensure that the containers or unit dose drugs are accurately loaded, the prepackaging of the containers or unit dose drugs shall occur at the provider pharmacy unless provided by a FDA approved repackager. The prepackaged containers or unit dose drugs may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(I) a pharmacist verifies the container or unit dose drug has been properly filled and labeled;

(II) the individual containers or unit dose drugs are transported to the remote site in a secure, tamper-evident container; and

(III) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure that the containers or unit dose drugs are accurately loaded in the automated pharmacy system.

(iii) All drugs to be stocked in the emergency medication kit shall be delivered to the remote site by the provider pharmacy.

(G) Policies and procedures of operation.

(i) A provider pharmacy that provides pharmacy services through an emergency medication kit at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) duties which may only be performed by a pharmacist;

(II) a copy of the written contract or agreement between the pharmacy and the facility which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

(III) date of last review/revision of the policy and procedure manual; and

(IV) policies and procedures for:

(-a-) security;

(-b-) operation of the emergency medication kit;

597 (-c-) preventative maintenance of the automated pharmacy system if the emergency
598 medication kit is an automated pharmacy system;

599
600 (-d-) sanitation;

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602 (-e-) storage of drugs;

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604 (-f-) dispensing;

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606 (-g-) supervision;

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608 (-h-) drug procurement;

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610 (-i-) receiving of drugs;

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612 (-j-) delivery of drugs; and

613
614 (-k-) recordkeeping.

615
616 (ii) A pharmacy that provides pharmacy services through an emergency medication kit at a
617 remote site shall, at least annually, review its written policies and procedures, revise them if
618 necessary, and document the review.

619
620 (iii) A pharmacy providing remote pharmacy services using an emergency medication kit
621 which is an automated pharmacy system shall maintain a written plan for recovery from an
622 event which interrupts the ability of the automated pharmacy system to provide emergency
623 medications. The written plan for recovery shall include:

624
625 (I) planning and preparation for maintaining pharmacy services when an automated
626 pharmacy system is experiencing downtime;

627
628 (II) procedures for response when an automated pharmacy system is experiencing
629 downtime; and

630
631 (III) procedures for the maintenance and testing of the written plan for recovery.

632
633 (5) Records.

634
635 (A) Maintenance of records.

636
637 (i) Every record required under this section must be:

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639 (I) kept by the provider pharmacy and be available, for at least two years for inspecting and
640 copying by the board or its representative and to other authorized local, state, or federal law
641 enforcement agencies; and

642
643 (II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent
644 of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
645 format, the requested records must be provided in an electronic format if specifically requested
646 by the board or its representative. Failure to provide the records set out in this section, either on

647 site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records
648 in violation of the Act.

649
650 (ii) The provider pharmacy shall maintain original prescription drug orders for drugs
651 dispensed from an emergency medication kit in compliance with §291.34(b) of this title.
652

653 (B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this
654 title.

655
656 (C) Records of dispensing. Dispensing records for a prescription drug order shall be
657 maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.
658

659 (D) Transaction information.

660
661 (i) A prescription drug order shall be maintained by the provider pharmacy as the record of
662 removal of a drug from an emergency medication kit for administration to a patient.
663

664 (ii) The remote site shall notify the provider pharmacy electronically or in writing of each
665 entry into an emergency medication kit. Such notification may be included on the prescription
666 drug order or a separate document and shall include the name, strength, and quantity of the
667 drug removed, the time of removal, and the name of the person removing the drug.
668

669 (iii) A separate record of stocking, removal, or dispensing for administration from an
670 emergency medication kit shall be maintained by the pharmacy and include the:

671
672 (I) date;

673
674 (II) name, strength, dosage form, and quantity of drug stocked, removed, or dispensed for
675 administration;

676
677 (III) name, initials, or identification code of the person stocking, removing, or dispensing for
678 administration, drugs from the system;

679
680 (IV) name, initials, or identification code of the pharmacist who checks and verifies that the
681 system has been accurately filled; and
682

683 (V) unique prescription number assigned to the prescription drug order when the drug is
684 administered to the patient.
685

686 (E) Inventory.

687
688 (i) A provider pharmacy shall:

689
690 (I) keep a record of all drugs sent to and returned from a remote site separate from the
691 records of the provider pharmacy and from any other remote site's records; and
692

693 (II) keep a perpetual inventory of controlled substances and other drugs required to be
694 inventoried under §291.17 of this title, that are received and dispensed or distributed from each
695 remote site.
696

697 (ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at
698 each remote site. The following is applicable to this inventory.

699
700 (I) The inventory of each remote site and the provider pharmacy shall be taken on the
701 same day.

702
703 (II) The inventory of each remote site shall be included with, but listed separately from, the
704 drugs of other remote sites and separately from the drugs of the provider pharmacy.

705
706 (c) Remote pharmacy services using telepharmacy systems.

707
708 (1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy
709 services by a Class A or Class C pharmacy in a healthcare facility that is not at the same
710 location as a Class A or Class C pharmacy through a telepharmacy system as outlined in
711 §562.110 of the Texas Pharmacy Act.

712
713 (2) Definitions. The following words and terms, when used in this section, shall have the
714 following meanings, unless the context clearly indicates otherwise. All other words and terms
715 shall have the meanings defined in the Act or §291.31 of this title.

716
717 (A) Prepackaging--The act of repackaging and relabeling quantities of drug products from a
718 manufacturer's original commercial container into a prescription container for dispensing by a
719 pharmacist to the ultimate consumer.

720
721 (B) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy
722 (Class C) providing remote pharmacy services.

723
724 (C) Remote site--a facility not located at the same location as a Class A or Class C
725 pharmacy, at which remote pharmacy services are provided using a telepharmacy dispensing
726 system.

727
728 (D) Remote pharmacy service--The provision of pharmacy services, including the storage and
729 dispensing of prescription drugs, drug regimen review, and patient counseling, at a remote site.

730
731 (E) Still image capture--A specific image captured electronically from a video or other image
732 capture device.

733
734 (F) Store and forward--A video or still image record which is saved electronically for future
735 review.

736
737 (G) Telepharmacy system--A system that monitors the dispensing of prescription drugs and
738 provides for related drug use review and patient counseling services by an electronic method
739 which shall include the use of the following types of technology:

740
741 (i) audio and video;

742
743 (ii) still image capture; and

744
745 (iii) store and forward.

746

747 (H) Unit-of-use--A sufficient quantity of a drug for one normal course of therapy as
748 determined by the pharmacist-in-charge and the prescribing practitioner(s) at the healthcare
749 facility.

750

751 (3) General requirements.

752

753 (A) A provider pharmacy may provide remote pharmacy services using a telepharmacy
754 system to:

755

756 (i) a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended;

757

758 (ii) a health center as defined by 42 U.S.C. Section 254b, as amended; or

759

760 (iii) healthcare facility located in a medically underserved area as defined by state or federal
761 law.

762

763 (B) A provider pharmacy may not provide remote pharmacy services if a Class A
764 (Community) or Class C (Institutional) pharmacy that dispenses prescription drug orders to out-
765 patients is located in the same community. For the purposes of this subsection a community is
766 defined as:

767

768 (i) the census tract in which the remote site is located, if the remote site is located in a
769 Metropolitan Statistical Area (MSA) as defined by the United States Census Bureau in the most
770 recent U.S. Census; or

771

772 (ii) within 10 miles of the remote site, if the remote site is not located in a MSA.

773

774 (C) The provider pharmacy shall have sufficient pharmacists on duty such that each
775 pharmacist may supervise no more than three remote sites that are simultaneously open to
776 provide services. An exception to the supervision limit may be granted by the board in situations
777 where the provider has documented a need for a pharmacist to supervise additional remote
778 sites and has demonstrated that appropriate safeguards are in place to assure proper
779 supervision of each remote site.

780

781 (D) Before providing remote pharmacy service, the telepharmacy system at the off-site facility
782 must be tested by the provider pharmacy and found to operate properly. The provider pharmacy
783 shall make the results of such testing available to the board upon request.

784

785 (E) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required
786 to comply with the provisions of §§291.31 - 291.34 of this title and this section.

787

788 (F) The pharmacist-in-charge of the provider pharmacy is responsible for all operations at the
789 remote site including supervision of the telepharmacy system and compliance with this section.

790

791 (4) Operational standards.

792

793 (A) Application to provide pharmacy services using a telepharmacy system.

794

795 (i) A Class A or class C Pharmacy shall make application to the board to provide remote
796 pharmacy services using a telepharmacy system. The application shall contain an affidavit with

797 the notarized signatures of pharmacist-in-charge, and the medical director or the person
798 responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive
799 officer, chief operating officer), and include the following:

800

801 (I) the name, address, and license number of the provider pharmacy;

802

803 (II) name and address of the healthcare facility where the remote pharmacy services will be
804 provided;

805

806 (III) a statement indicating that the provider pharmacy and the healthcare facility have
807 entered into a written contract or agreement which outlines the services to be provided and the
808 responsibilities and accountabilities of each party in fulfilling the terms of the contract or
809 agreement in compliance with federal and state laws and regulations;

810

811 (IV) documentation that the healthcare facility is:

812

813 (-a-) a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended;

814

815 (-b-) a health center as defined by 42 U.S.C. Section 254b, as amended; or

816

817 (-c-) located in a medically underserved area as defined by state or federal law; and

818

819 (V) documentation that a Class A (Community) or Class C (Institutional) Pharmacy that
820 dispenses prescriptions drug orders to out-patients is not located within the community, as
821 defined in paragraph (3)(B) of this subsection, where the remote site is located.

822

823 (ii) Such application shall be resubmitted every two years in conjunction with the renewal of
824 the provider pharmacy's license. The renewal application shall contain the documentation
825 required in clause (i) of this subparagraph except the notarized signature of the medical director
826 or the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief
827 executive officer, chief operating officer) is not required.

828

829 (iii) On approval of the application, the provider pharmacy will be sent a registration
830 certificate, which must be displayed at the remote site.

831

832 (B) Notification requirements.

833

834 (i) A provider pharmacy shall notify the board in writing within ten days of a change of
835 location, discontinuance of service, or closure of:

836

837 (I) a remote site where a telepharmacy system is operated by the pharmacy; or

838

839 (II) a remote pharmacy service at a remote site.

840

841 (ii) A provider pharmacy shall comply with appropriate federal and state controlled
842 substance registrations for each remote site, if controlled substances are maintained.

843

844 (C) Environment/Security.

845

846 (i) A remote site shall be under the continuous supervision of a provider pharmacy
847 pharmacist at all times the site is open to provide pharmacy services. To qualify as continuous
848 supervision, the pharmacist is not required to be physically present at the remote site and shall
849 supervise electronically through the use of the following types of technology:

850
851 (I) audio and video;

852
853 (II) still image capture; and

854
855 (III) store and forward.

856
857 (ii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of
858 this title including the requirements for temperature and handling of outdated drugs.

859
860 (iii) Drugs for use in the telepharmacy system shall be stored in an area that is:

861
862 (I) separate from any other drugs used by the healthcare facility; and

863
864 (II) locked by key, combination or other mechanical or electronic means, so as to prohibit
865 access by unauthorized personnel.

866
867 (iv) Access to the area where drugs are stored at the remote site and operation of the
868 telepharmacy system shall be limited to pharmacists employed by the provider pharmacy or
869 personnel who:

870
871 (I) are licensed healthcare providers pharmacy technicians or pharmacy technician
872 trainees;

873
874 (II) are designated in writing by the pharmacist-in-charge; and

875
876 (III) have completed documented training concerning their duties associated with the
877 telepharmacy pharmacy system.

878
879 (v) Remote sites shall have adequate security and procedures to:

880
881 (I) comply with federal and state laws and regulations; and

882
883 (II) maintain patient confidentiality.

884
885 (vi) The provider pharmacy shall have procedures that specify that drugs may only be
886 delivered to the remote site by the provider pharmacy and shall:

887
888 (I) be shipped in a sealed container with a list of drugs delivered;

889
890 (II) signed for on receipt by an employee of the healthcare facility;

891
892 (III) be quarantined in a locked area, if personnel designated to receive the drugs by the
893 pharmacist-in-charge is not available; and

894

895 (IV) be checked by personnel designated by the pharmacist-in-charge to verify that drugs
896 sent by the provider pharmacy were actually received. The designated person who checks the
897 order shall document the verification by signing and dating the list of drugs delivered.
898

899 (D) Prescription dispensing and delivery.
900

901 (i) Drugs shall only be dispensed at the remote site through a telepharmacy system after
902 receipt of an original prescription drug order by a pharmacist at the provider pharmacy in the
903 manner authorized by §291.34(b) of this title.
904

905 (ii) Drugs may be dispensed by the provider pharmacy through a telepharmacy system at a
906 remote site only in unit-of-use containers that are:
907

908 (I) prepackaged in suitable containers at the provider pharmacy and appropriately labeled
909 as specified in §291.33(c)(6) of this title; or
910

911 (II) in original manufacturer's containers.
912

913 (iii) The following duties shall be performed only by a pharmacist at the provider pharmacy:
914

915 (I) receiving an oral prescription drug order;
916

917 (II) interpret the prescription drug order;
918

919 (III) verify the accuracy of prescription data entry;
920

921 (IV) select the drug product;
922

923 (V) interpret the patient's medication record and conduct a drug regimen review as
924 specified in clause (iv) of this subparagraph;
925

926 (VI) authorize the telepharmacy system to print a prescription label at the remote site as
927 specified in clause (v) of this subparagraph;
928

929 (VII) perform the final check of the dispensed prescription as specified in clause (vi) of this
930 subparagraph to ensure that the prescription drug order has been dispensed accurately as
931 prescribed;
932

933 (VIII) counsel the patient as specified clause (vii) of this subparagraph.
934

935 (iv) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified
936 in §291.33(c) of this title prior to delivery of the dispensed prescription to the patient or patient's
937 agent.
938

939 (v) The dispensed prescription shall be labeled at the remote site with the information
940 specified in §291.33(c) of this title except that:
941

942 (I) the label shall contain both the name, address, and phone number of the provider
943 pharmacy and the name and address of the remote site; and
944

945 (II) the unique identification number of the prescription on the label shall in some manner
946 identify the remote site which dispensed the prescription using a telepharmacy system.

947
948 (vi) A pharmacist at the provider pharmacy shall perform the final check of the dispensed
949 prescription before delivery to the patient to ensure that the prescription has been dispensed
950 accurately as prescribed. This final check shall be accomplished through a visual check using
951 electronic methods.

952
953 (vii) A pharmacist at the provider pharmacy shall counsel the patient or patient's agent as
954 specified in §291.33(c) of this title. This counseling may be performed using electronic methods.
955 Non-pharmacist personnel may not ask questions of a patient or patient's agent which are
956 intended to screen and/or limit interaction with the pharmacist.

957
958 (viii) If the remote site has direct access to the provider pharmacy's data processing system,
959 only a pharmacist, pharmacy technician, or pharmacy technician trainee may enter prescription
960 information into the data processing system. The original prescription shall be sent to the
961 provider pharmacy and a pharmacist shall verify the accuracy of the data entry.

962
963 (ix) Drugs which require reconstitution through the addition of a specified amount of water
964 may be dispensed by the remote site only if a pharmacy technician, pharmacy technician
965 trainee, or licensed healthcare provider reconstitutes the product.

966
967 (E) Quality assurance program. A pharmacy that provides pharmacy services through a
968 telepharmacy system at a remote site shall operate according to a written program for quality
969 assurance of the telepharmacy system which:

970
971 (i) requires continuous supervision of the telepharmacy system at all times the site is open
972 to provide pharmacy services; and

973
974 (ii) establishes mechanisms and procedures to routinely test the operation of the
975 telepharmacy system at a minimum of every six months and whenever any upgrade or change
976 is made to the system and documents each such activity.

977
978 (F) Policies and procedures.

979
980 (i) A pharmacy that provides pharmacy services through a telepharmacy system at a remote
981 site shall operate according to written policies and procedures. The policy and procedure
982 manual shall include, but not be limited to, the following:

983
984 (I) a current list of the name and address of the pharmacist-in-charge and personnel
985 designated by the pharmacist-in-charge to have:

986
987 (-a-) have access to the area where drugs are stored at the remote site; and

988
989 (-b-) operate the telepharmacy system;

990
991 (II) duties which may only be performed by a pharmacist;

992
993 (III) a copy of the written contract or agreement between the provider pharmacy and the
994 healthcare facility which outlines the services to be provided and the responsibilities and

995 accountabilities of each party in fulfilling the terms of the contract or agreement in compliance
996 with federal and state laws and regulations;

997
998 (IV) date of last review/revision of policy and procedure manual; and
999

1000 (V) policies and procedures for:

1001
1002 (-a-) security;

1003
1004 (-b-) operation of the telepharmacy system;

1005
1006 (-c-) sanitation;

1007
1008 (-d-) storage of drugs;

1009
1010 (-e-) dispensing;

1011
1012 (-f-) supervision;

1013
1014 (-g-) drug and/or device procurement;

1015
1016 (-h-) receiving of drugs and/or devices;

1017
1018 (-i-) delivery of drugs and/or devices; and

1019
1020 (-j-) recordkeeping

1021
1022 (ii) A pharmacy that provides pharmacy services through a telepharmacy system at a
1023 remote site shall, at least annually, review its written policies and procedures, revise them if
1024 necessary, and document the review.

1025
1026 (iii) A pharmacy providing remote pharmacy services through a telepharmacy system shall
1027 maintain a written plan for recovery from an event which interrupts the ability of a pharmacist to
1028 electronically supervise the telepharmacy system and the dispensing of prescription drugs at the
1029 remote site. The written plan for recovery shall include:

1030
1031 (I) a statement that prescription drugs shall not be dispensed at the remote site, if a
1032 pharmacist is not able to electronically supervise the telepharmacy system and the dispensing
1033 of prescription drugs;

1034
1035 (II) procedures for response when a telepharmacy system is experiencing downtime; and

1036
1037 (III) procedures for the maintenance and testing of the written plan for recovery.

1038
1039 (5) Records.

1040
1041 (A) Maintenance of records.

1042
1043 (i) Every record required under this section must be:

1044

1045 (I) kept by the provider pharmacy and be available, for at least two years for inspecting and
1046 copying by the board or its representative and to other authorized local, state, or federal law
1047 enforcement agencies; and
1048

1049 (II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent
1050 of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
1051 format, the requested records must be provided in an electronic format if specifically requested
1052 by the board or its representative. Failure to provide the records set out in this section, either on
1053 site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records
1054 in violation of the Act.

1055
1056 (ii) The provider pharmacy shall maintain original prescription drug orders for medications
1057 dispensed from a remote site using a telepharmacy system in the manner required by
1058 §291.34(b) of this title.
1059

1060 (iii) If prescription drug records are maintained in a data processing system, the system shall
1061 have a workable (electronic) data retention system which can produce a separate audit trail of
1062 drug usage by the provider pharmacy and by each remote site for the preceding two years as
1063 specified in §291.34(e) of this title.
1064

1065 (B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this
1066 title.
1067

1068 (C) Patient medication records. Patient medication records shall be created and maintained
1069 at the provider pharmacy in the manner required by §291.34(c) of this title.
1070

1071 (D) Inventory.
1072

1073 (i) A provider pharmacy shall:
1074

1075 (I) keep a record of all drugs sent to and returned from a remote site separate from the
1076 records of the provider pharmacy and from any other remote site's records;
1077

1078 (II) keep a perpetual inventory of controlled substances and other drugs required to be
1079 inventoried under §291.17 of this title, that are received and dispensed or distributed from each
1080 remote site.
1081

1082 (ii) As specified in §291.17 of this title. A provider pharmacy shall conduct an inventory at
1083 each remote site. The following is applicable to this inventory.
1084

1085 (I) The inventory of each remote site and the provider pharmacy shall be taken on the
1086 same day.
1087

1088 (II) The inventory of each remote site shall be included with, but listed separately from, the
1089 drugs of other remote sites and separately from the drugs at the provider pharmacy.
1090

1091 **§291.123 Central Prescription Drug or Medication Order Processing**
1092

1093 (a) Purpose.
1094

1095 (1) The purpose of this section is to provide standards for centralized prescription drug or
1096 medication order processing by a Class A (Community), Class C (Institutional), or Class E (Non-
1097 Resident) pharmacy.
1098

1099 (2) Any facility established for the purpose of processing prescription drug or medication drug
1100 orders shall be licensed as a Class A, Class C, or Class E pharmacy under the Act. However,
1101 nothing in this subsection shall prohibit an individual pharmacist employee who is licensed in
1102 Texas from remotely accessing the pharmacy's electronic data base from outside the pharmacy
1103 in order to process prescription or medication drug orders, provided the pharmacy establishes
1104 controls to protect the privacy and security of confidential records.
1105

1106 (b) Definitions. The following words and terms, when used in this section, shall have the
1107 following meanings, unless the context clearly indicates otherwise. Any term not defined in this
1108 section shall have the definition set out in the Act. Centralized prescription drug or medication
1109 order processing--the processing of a prescription drug or medication orders by a Class A,
1110 Class C, or Class E pharmacy on behalf of another pharmacy, a health care provider, or a
1111 payor. Centralized prescription drug or medication order processing does not include the
1112 dispensing of a prescription drug order but includes any of the following:
1113

- 1114 (1) receiving, interpreting, or clarifying prescription drug or medication drug orders;
1115
- 1116 (2) data entering and transferring of prescription drug or medication order information;
1117
- 1118 (3) performing drug regimen review;
1119
- 1120 (4) obtaining refill and substitution authorizations;
1121
- 1122 (5) interpreting clinical data for prior authorization for dispensing;
1123
- 1124 (6) performing therapeutic interventions; and
1125
- 1126 (7) providing drug information concerning a patient's prescription.
1127

1128 (c) Operational Standards.

1129 (1) General requirements.

1130 (A) A Class A, Class C, or Class E Pharmacy may outsource prescription drug or medication
1131 order processing to another Class A, Class C, or Class E pharmacy provided the pharmacies:
1132

1133 (i) have:
1134

1135 (I) the same owner; or
1136

1137 (II) entered into a written contract or agreement which outlines the services to be provided
1138 and the responsibilities and accountabilities of each pharmacy in compliance with federal and
1139 state laws and regulations; and
1140

1141 (ii) share a common electronic file or have appropriate technology to allow access to
1142 sufficient information necessary or required to process a non-dispensing function.
1143
1144

1145
1146 (B) A pharmacy that performs centralized prescription drug or medication order processing
1147 shall comply with the provisions applicable to the class of pharmacy contained in either
1148 §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational Standards,
1149 Records, and Official Prescription Requirements in Class A (Community) Pharmacies), or
1150 §§291.72 - 291.75 of this title (relating to Definitions, Personnel, Operational Standards, and
1151 Records in a Class C (Institutional) Pharmacy), or §§291.102 - 291.105 of this title (relating to
1152 Definitions, Personnel, Operational Standards, and Records in a Class E (Non-Resident)
1153 Pharmacy) to the extent applicable for the specific processing activity and this section including:

- 1154
- 1155 (i) duties which must be performed by a pharmacist; and
 - 1156
 - 1157 (ii) supervision requirements for pharmacy technicians and pharmacy technician trainees.
 - 1158
- 1159 (2) Notifications to patients.

1160
1161 (A) A pharmacy that outsources prescription drug or medication order processing to another
1162 pharmacy shall prior to outsourcing their prescription:

- 1163
- 1164 (i) notify patients that prescription processing may be outsourced to another pharmacy; and
 - 1165
 - 1166 (ii) give the name of that pharmacy; or if the pharmacy is part of a network of pharmacies
1167 under common ownership and any of the network pharmacies may process the prescription, the
1168 patient shall be notified of this fact. Such notification may be provided through a one-time written
1169 notice to the patient or through use of a sign in the pharmacy.
 - 1170

1171 (B) The provisions of this paragraph do not apply to patients in facilities where drugs are
1172 administered to patients by a person required to do so by the laws of the state (i.e., hospitals or
1173 nursing homes).

1174
1175 (3) Policy and Procedures. A policy and procedure manual as it relates to central processing
1176 shall be maintained at all pharmacies involved in central processing and be available for
1177 inspection. Each pharmacy is required to maintain only those portions of the policy and
1178 procedure manual that relate to that pharmacy's operations. The manual shall:

- 1179
- 1180 (A) outline the responsibilities of each of the pharmacies;
 - 1181
 - 1182 (B) include a list of the name, address, telephone numbers, and all license/registration
1183 numbers of the pharmacies involved in centralized prescription drug or medication order
1184 processing; and
 - 1185
 - 1186 (C) include policies and procedures for:
 - 1187
 - 1188 (i) protecting the confidentiality and integrity of patient information;
 - 1189
 - 1190 (ii) maintenance of appropriate records to identify the name(s), initials, or identification
1191 code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any
1192 processing;
 - 1193
 - 1194 (iii) complying with federal and state laws and regulations;

1195
1196 (iv) operating a continuous quality improvement program for pharmacy services designed to
1197 objectively and systematically monitor and evaluate the quality and appropriateness of patient
1198 care, pursue opportunities to improve patient care, and resolve identified problems; and
1199

1200 (v) annually reviewing the written policies and procedures and documenting such review.
1201

1202 (d) Records. All pharmacies shall maintain appropriate records which identify, by prescription
1203 drug or medication order, the name(s), initials, or identification code(s) of each pharmacist,
1204 pharmacy technician, or pharmacy technician trainee who performs a processing function for a
1205 prescription drug or medication order. Such records may be maintained:
1206

1207 (1) separately by each pharmacy and pharmacist; or
1208

1209 (2) in a common electronic file as long as the records are maintained in such a manner that the
1210 data processing system can produce a printout which lists the functions performed by each
1211 pharmacy and pharmacist.
1212

1213 **§291.125 Centralized Prescription Dispensing**
1214

1215 (a) Purpose. The purpose of this section is to provide standards for centralized prescription
1216 dispensing by a Class A (Community), Class C (Institutional) pharmacy, or Class E (Non-
1217 Resident) Pharmacy.
1218

1219 (b) Definitions. The following words and terms, when used in this section, shall have the
1220 following meanings, unless the context clearly indicates otherwise. Any term not defined in this
1221 section shall have the definition set out in the Act.
1222

1223 (1) Central fill pharmacy--a Class A, Class A-S, Class C, Class C-S, Class E, or Class E-S
1224 pharmacy that prepares prescription drug orders for dispensing pursuant to a valid prescription
1225 transmitted to the central fill pharmacy by an outsourcing pharmacy.
1226

1227 (2) Centralized prescription dispensing--the dispensing or refilling of a prescription drug order
1228 by a Class A, Class C, or Class E pharmacy at the request of another Class A or Class C
1229 pharmacy and the return of the dispensed prescriptions to the outsourcing pharmacy for delivery
1230 to the patient or patient's agent, or at the request of the outsourcing pharmacy for direct delivery
1231 to the patient.
1232

1233 (3) Outsourcing pharmacy--a Class A or Class C pharmacy that transmits a prescription drug
1234 order to a central fill pharmacy to be dispensed by the central fill pharmacy.
1235

1236 (c) Operational standards.
1237

1238 (1) General requirements.
1239

1240 (A) A Class A or Class C pharmacy may outsource prescription drug order dispensing to a
1241 central fill pharmacy provided the pharmacies:
1242

1243 (i) have:
1244

1245 (I) the same owner; or
1246
1247 (II) entered into a written contract or agreement which outlines the services to be provided
1248 and the responsibilities and accountabilities of each pharmacy in compliance with federal and
1249 state laws and regulations; and
1250
1251 (ii) share a common electronic file or have appropriate technology to allow access to
1252 sufficient information necessary or required to dispense or process a prescription drug order.
1253
1254 (B) The pharmacist-in-charge of the central fill pharmacy shall ensure that:
1255
1256 (i) the pharmacy maintains and uses adequate storage or shipment containers and shipping
1257 processes to ensure drug stability and potency. Such shipping processes shall include the use
1258 of appropriate packaging material and/or devices to ensure that the drug is maintained at an
1259 appropriate temperature range to maintain the integrity of the medication throughout the delivery
1260 process; and
1261
1262 (ii) the dispensed prescriptions are shipped in containers which are sealed in a manner as to
1263 show evidence of opening or tampering.
1264
1265 (C) A Class A or Class C central fill pharmacy shall comply with the provisions of §§291.31 -
1266 291.35 of this title (relating to Definitions, Personnel, Operational Standards, Records, and
1267 Official Prescription Requirements in Community Pharmacy (Class A) and this section.
1268
1269 (D) A Class E central fill pharmacy shall comply with §§291.101 - 291.105 of this title (relating
1270 to Purpose, Definitions, Personnel, Operational Standards, and Records in Non-resident
1271 Pharmacy (Class E) and this section.
1272
1273 (2) Notifications to patients.
1274
1275 (A) A pharmacy that outsources prescription dispensing to a central fill pharmacy shall:
1276
1277 (i) prior to outsourcing the prescription:
1278
1279 (I) notify patients that their prescription may be outsourced to a central fill pharmacy; and
1280
1281 (II) give the name of the central fill pharmacy or if the pharmacy is part of a network of
1282 pharmacies under common ownership and any of the network pharmacies may dispense the
1283 prescription, the patient shall be notified of this fact. Such notification may be provided through a
1284 one-time written notice to the patient or through use of a sign in the pharmacy; and
1285
1286 (ii) if the prescription is delivered directly to the patient by the central fill pharmacy and not
1287 returned to the outsourcing pharmacy, place on the prescription container or on a separate
1288 sheet delivered with the prescription container, in both English and Spanish, the local, and if
1289 applicable, the toll-free telephone number of the pharmacy and the statement: "Written
1290 information about this prescription has been provided for you. Please read this information
1291 before you take the medication. If you have questions concerning this prescription, a pharmacist
1292 is available during normal business hours to answer these questions at (insert the pharmacy's
1293 local and toll-free telephone numbers)."
1294

1295 (B) The provisions of this paragraph do not apply to patients in facilities where drugs are
1296 administered to patients by a person required to do so by the laws of the state (e.g., hospitals or
1297 nursing homes).
1298

1299 (3) Prescription Labeling. The central fill pharmacy shall place on the prescription label, the
1300 name and address of the outsourcing pharmacy and a unique identifier (i.e., the central fill
1301 pharmacy's DEA registration number or, if the pharmacy does not have a DEA registration
1302 number, the central fill pharmacy's Texas license number) indicating that the prescription was
1303 dispensed by the central fill pharmacy; and comply with all other labeling requirements in
1304 §291.33 of this title.
1305

1306 (4) Policies and Procedures. A policy and procedure manual as it relates to centralized
1307 dispensing shall be maintained at both pharmacies and be available for inspection. Each
1308 pharmacy is required to maintain only those portions of the policy and procedure manual that
1309 relate to that pharmacy's operations. The manual shall:
1310

1311 (A) outline the responsibilities of each of the pharmacies;

1312
1313 (B) include a list of the name, address, telephone numbers, and all license/registration
1314 numbers of the pharmacies involved in centralized prescription dispensing; and
1315

1316 (C) include policies and procedures for:
1317

1318 (i) notifying patients that their prescription may be outsourced to a central fill pharmacy for
1319 dispensing and providing the name of that pharmacy;

1320 (ii) protecting the confidentiality and integrity of patient information;

1321
1322 (iii) dispensing prescription drug orders when the dispensed order is not received or the
1323 patient comes in before the order is received;

1324 (iv) complying with federal and state laws and regulations;

1325
1326 (v) operating a continuous quality improvement program for pharmacy services designed to
1327 objectively and systematically monitor and evaluate the quality and appropriateness of patient
1328 care, pursue opportunities to improve patient care, and resolve identified problems; and
1329

1330 (vi) annually reviewing the written policies and procedures and documenting such review.
1331

1332 (d) Records.
1333

1334 (1) Records may be maintained in an alternative data retention system, such as a data
1335 processing system or direct imaging system provided:
1336

1337 (A) the records maintained in the alternative system contain all of the information required on
1338 the manual record; and
1339

1340 (B) the data processing system is capable of producing a hard copy of the record upon the
1341 request of the board, its representative, or other authorized local, state, or federal law
1342 enforcement or regulatory agencies.
1343
1344

1345
1346 (2) Each pharmacy shall comply with all the laws and rules relating to the maintenance of
1347 records and be able to produce an audit trail showing all prescriptions dispensed by the
1348 pharmacy.

1349
1350 (3) The outsourcing pharmacy shall maintain records which indicate the:
1351
1352 (A) date:
1353
1354 (i) the request for dispensing was transmitted to the central fill pharmacy; and
1355
1356 (ii) the dispensed prescription was received by the outsourcing pharmacy, including the
1357 method of delivery (e.g., private, common, or contract carrier) and the name of the person
1358 accepting delivery; and
1359
1360 (B) name, address, license number, and the unique identifier of the central fill pharmacy.

1361
1362 (4) The central fill pharmacy shall maintain records which indicate the:

1363
1364 (A) date the prescription was shipped to the outsourcing pharmacy or the patient;

1365
1366 (B) name and address where the prescription was shipped;

1367
1368 (C) method of delivery (e.g., private, common, or contract carrier); and

1369
1370 (D) name, address, and license number of the outsourcing pharmacy.

1371
1372 **§291.127 Emergency Remote Pharmacy License**

1373
1374 (a) Definitions. The following words and terms, when used in this section, shall have the
1375 following meanings, unless the context clearly indicates otherwise. All other words and terms
1376 shall have the meanings defined in the Act.

1377
1378 (1) Emergency remote pharmacy--A pharmacy not located at the same Texas location as a
1379 home pharmacy at which pharmacy services are provided during an emergency situation.

1380
1381 (2) Emergency situation--An emergency caused by a natural or manmade disaster or any other
1382 exceptional situation that causes an extraordinary demand for pharmacy services.

1383
1384 (3) Home pharmacy--A currently licensed Class A (Community), Class C (Institutional), or
1385 Class D (Clinic) pharmacy that is providing emergency pharmacy services through an
1386 emergency remote pharmacy.

1387
1388 (b) Emergency remote pharmacy license. In an emergency situation, the board may grant a
1389 holder of a Class A (Community), Class C (Institutional), or Class D (Clinic) pharmacy license,
1390 the authority to operate a pharmacy and provide pharmacy services at an alternate location.
1391 The following is applicable for the emergency remote pharmacy.

1392

1393 (1) The emergency remote pharmacy will not be issued a separate pharmacy license, but shall
1394 operate under the license of the home pharmacy. To qualify for an emergency remote pharmacy
1395 license, the applicant must submit an application including the following information:

1396
1397 (A) license number, name, address, and phone number of the home pharmacy;

1398
1399 (B) name, address, and phone number of the emergency remote pharmacy;

1400
1401 (C) name and Texas pharmacist license number of the pharmacist-in-charge of the home
1402 pharmacy and of the pharmacist-in-charge of the emergency remote pharmacy; and

1403
1404 (D) any other information required by the board.

1405
1406 (2) The board will notify the home pharmacy of the approval of an emergency remote
1407 pharmacy license.

1408
1409 (3) The emergency remote pharmacy license shall be valid for a period as determined by the
1410 board not to exceed six months. The executive director of the board, in his/her discretion, may
1411 renew the remote license for an additional six months, if the emergency situation still exists and
1412 the holder of the license shows good cause for emergency remote pharmacy to continue
1413 operation.

1414
1415 (4) The emergency remote pharmacy shall have a written contract or agreement with the home
1416 pharmacy which outlines the services to be provided and the responsibilities and
1417 accountabilities of the remote and home pharmacy in fulfilling the terms of the contract or
1418 agreement in compliance with federal and state laws and regulations.

1419
1420 (5) The home pharmacy shall designate a pharmacist to serve as the pharmacist-in-charge of
1421 the emergency remote pharmacy.

1422
1423 (6) The emergency remote pharmacy shall comply with the rules for the class of pharmacy
1424 under which the home pharmacy is licensed. A Class A pharmacy shall comply with the rules
1425 under Subchapter B of this chapter titled Community Pharmacy (Class A). A Class C pharmacy
1426 shall comply with the rules under Subchapter D of this chapter titled Institutional Pharmacy
1427 (Class C). A Class D pharmacy shall comply with the rules under Subchapter E of this chapter
1428 titled Clinic Pharmacy (Class D).

1429
1430 (7) The records of services provided at the emergency remote pharmacy shall be:

1431
1432 (A) kept by the home pharmacy and be available, for at least two years from the date of
1433 provision of the service, for inspecting and copying by the board or its representative and to
1434 other authorized local, state, or federal law enforcement agencies; and

1435
1436 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
1437 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,
1438 the requested records must be provided in an electronic format if specifically requested by the
1439 board or its representative. Failure to provide the records set out in this section, either on site or
1440 within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in
1441 violation of the Act.

1442

1443 **§291.129** **Satellite Pharmacy**

1444
1445 (a) Purpose. The purpose of this section is to create a new class of pharmacy for the provision
1446 of pharmacy services by a Class A or Class C pharmacy in a location that is not at the same
1447 location as a Class A or Class C pharmacy through a satellite pharmacy and to provide
1448 standards for the operation of this class of pharmacy established under §560.053 of the Texas
1449 Pharmacy Act.

1450
1451 (b) Definitions. The following words and terms, when used in the section, shall have the
1452 following meanings, unless the context clearly indicates otherwise. All other words and terms
1453 shall have the meanings defined in the Act or §291.31 of this title.

1454
1455 (1) Provider pharmacy--The Class A or Class C pharmacy providing satellite pharmacy
1456 services.

1457
1458 (2) Satellite pharmacy--A facility not located at the same location as a Class A or Class C
1459 pharmacy at which satellite pharmacy services are provided.

1460
1461 (3) Satellite pharmacy services--The provision of pharmacy services, including the storage and
1462 delivery of prescription drugs, in an alternate location.

1463
1464 (c) General requirements.

1465
1466 (1) A Class A or Class C provider pharmacy may establish a satellite pharmacy in a location
1467 that is not at the same location as a Class A or Class C pharmacy.

1468
1469 (2) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy
1470 operations involving the satellite pharmacy including supervision of satellite pharmacy personnel
1471 and compliance with this section.

1472
1473 (3) A satellite pharmacy may not store bulk drugs and may only store prescription medications
1474 that have been previously verified and dispensed by the provider pharmacy.

1475
1476 (4) A Class C pharmacy that is a provider pharmacy dispensing outpatient prescriptions for a
1477 satellite pharmacy shall comply with the provisions of §§291.31 - 291.34 of this title (relating to
1478 Definitions, Personnel, Operational Standards, and Records for Class A (Community)
1479 pharmacies) and this section.

1480
1481 (5) The provider pharmacy and the satellite pharmacy must have:

1482
1483 (A) the same owner; and

1484
1485 (B) share a common electronic file or have appropriate technology to allow access to
1486 sufficient information necessary or required to process a non-dispensing function.

1487
1488 (d) Personnel.

1489
1490 (1) All individuals working at the satellite pharmacy shall be employees of the provider
1491 pharmacy and must report their employment to the board as such.

1492

1493 (2) A satellite pharmacy shall have sufficient pharmacists on duty to operate the satellite
1494 pharmacy competently, safely, and adequately to meet the needs of the patients of the
1495 pharmacy.
1496

1497 (3) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and
1498 pharmacy technician trainees and for designating and delegating duties, other than those listed
1499 in paragraph (7) of this subsection, to pharmacy technicians and pharmacy technician trainees.
1500 Each pharmacist:
1501

1502 (A) shall verify the accuracy of all acts, tasks, and functions performed by pharmacy
1503 technicians and pharmacy technician trainees; and
1504

1505 (B) shall be responsible for any delegated act performed by pharmacy technicians and
1506 pharmacy technician trainees under his or her supervision.
1507

1508 (4) A pharmacist shall be physically present to directly supervise a pharmacy technician or
1509 pharmacy technician trainee who is entering prescription data into the data processing system.
1510 Each prescription entered into the data processing system shall be verified at the time of data
1511 entry.
1512

1513 (5) All pharmacists while on duty, shall be responsible for complying with all state and federal
1514 laws or rules governing the practice of pharmacy.
1515

1516 (6) A pharmacist shall ensure that the drug is dispensed and delivered safely and accurately
1517 as prescribed. A pharmacist shall ensure the safety and accuracy of the portion of the process
1518 the pharmacist is performing.
1519

1520 (7) Duties, in a satellite pharmacy, that may only be performed by a pharmacist are as follows:
1521

1522 (A) receiving oral prescription drug orders and reducing these orders to writing, either
1523 manually or electronically;
1524

1525 (B) interpreting or clarifying prescription drug orders;
1526

1527 (C) communicating to the patient or patient's agent information about the prescription drug or
1528 device which in the exercise of the pharmacist's professional judgment, the pharmacist deems
1529 significant, as specified in §291.33(c) of this title;
1530

1531 (D) communicating to the patient or the patient's agent on his or her request information
1532 concerning any prescription drugs dispensed to the patient by the pharmacy;
1533

1534 (E) assuring that a reasonable effort is made to obtain, record, and maintain patient
1535 medication records;
1536

1537 (F) interpreting patient medication records and performing drug regimen reviews; and
1538

1539 (G) performing a specific act of drug therapy management for a patient delegated to a
1540 pharmacist by a written protocol from a physician licensed in this state in compliance with the
1541 Medical Practice Act.
1542

1543 (8) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties
1544 listed in paragraph (7) of this subsection. However, a pharmacist may delegate to pharmacy
1545 technicians and pharmacy technician trainees any nonjudgmental technical duty associated with
1546 the preparation and distribution of prescription drugs provided:

1547

1548 (A) a pharmacist verifies the accuracy of all acts, tasks, and functions performed by
1549 pharmacy technicians and pharmacy technician trainees; and

1550

1551 (B) pharmacy technicians and pharmacy technician trainees are under the direct supervision
1552 of and responsible to a pharmacist.

1553

1554 (9) Pharmacy technicians and pharmacy technician trainees, in a satellite pharmacy, may
1555 perform only nonjudgmental technical duties associated with the preparation and distribution of
1556 prescription drugs as follows:

1557

1558 (A) initiating and receiving refill authorization requests;

1559

1560 (B) entering prescription data into a data processing system; and

1561

1562 (C) reconstituting medications.

1563

1564 (10) In a satellite pharmacy, the ratio of pharmacists to pharmacy technicians/pharmacy
1565 technician trainees may be 1:3, provided at least one of the three is a pharmacy technician and
1566 not a pharmacy technician trainee.

1567

1568 (11) All satellite pharmacy personnel shall wear identification tags or badges that bears the
1569 person's name and identifies him or her as a pharmacist, pharmacist intern, pharmacy
1570 technician, or pharmacy technician trainee.

1571

1572 (e) Operational requirements.

1573

1574 (1) Application for permission to provide satellite pharmacy services.

1575

1576 (A) A Class A or Class C pharmacy shall make application to the board to provide satellite
1577 pharmacy services. The application shall contain an affidavit with the notarized signatures of the
1578 pharmacist-in-charge and the person responsible for the on-site operation of the facility where
1579 the satellite pharmacy will be located and include the following:

1580

1581 (i) the name, address, and license number of the provider pharmacy;

1582

1583 (ii) the name and address of the facility where the satellite pharmacy will be located;

1584

1585 (iii) anticipated date of opening and hours of operation; and

1586

1587 (iv) copy of the lease agreement or if the location of the satellite pharmacy is owned by the
1588 applicant, a notarized statement certifying such location ownership.

1589

1590 (B) Such application shall be resubmitted every two years in conjunction with the application
1591 for renewal of the provider pharmacy's license. The renewal petition shall contain the
1592 documentation required in subparagraph (A) of this paragraph except the notarized signature of

1593 the person responsible for the on-site operation of the facility where the satellite pharmacy will
1594 be located.

1595
1596 (C) Upon approval of the application, the provider pharmacy will be sent a certificate which
1597 must be displayed at the satellite pharmacy.

1598
1599 (2) Notification requirements.

1600
1601 (A) A provider pharmacy shall notify the board in writing within ten days of a change of
1602 location, discontinuance of service, or closure of a satellite pharmacy that is operated by the
1603 pharmacy.

1604
1605 (B) A provider pharmacy shall comply with appropriate federal and state controlled substance
1606 registrations for each satellite pharmacy if controlled substances are maintained at the satellite
1607 pharmacy.

1608
1609 (3) Environment.

1610
1611 (A) The satellite pharmacy shall be arranged in an orderly fashion and kept clean. All required
1612 equipment shall be clean and in good operating condition.

1613
1614 (B) A satellite pharmacy shall contain an area which is suitable for confidential patient
1615 counseling.

1616
1617 (i) Such counseling area shall:

1618
1619 (I) be easily accessible to both patient and pharmacists and not allow patient access to
1620 prescription drugs;

1621
1622 (II) be designed to maintain the confidentiality and privacy of the pharmacist/patient
1623 communication.

1624
1625 (ii) In determining whether the area is suitable for confidential patient counseling and
1626 designed to maintain the confidentiality and privacy of the pharmacist/patient communication,
1627 the board may consider factors such as the following:

1628
1629 (I) the proximity of the counseling area to the check-out or cash register area;

1630
1631 (II) the volume of pedestrian traffic in and around the counseling area;

1632
1633 (III) the presence of walls or other barriers between the counseling area and other areas of
1634 the pharmacy; and

1635
1636 (IV) any evidence of confidential information being overheard by persons other than the
1637 patient or patient's agent or the pharmacist or agents of the pharmacist.

1638
1639 (C) The satellite pharmacy shall be properly lighted and ventilated.

1640
1641 (D) The temperature of the satellite pharmacy shall be maintained within a range compatible
1642 with the proper storage of drugs in compliance with the provisions of §291.15 of this title

1643 (relating to storage of drugs). The temperature of the refrigerator shall be maintained within a
1644 range compatible with the proper storage of drugs requiring refrigeration.

1645
1646 (E) Animals, including birds and reptiles, shall not be kept within the pharmacy and in
1647 immediately adjacent areas under the control of the pharmacy. This provision does not apply to
1648 fish in aquariums, guide dogs accompanying disabled persons, or animals for sale to the
1649 general public in a separate area that is inspected by local health jurisdictions.

1650
1651 (4) Security.

1652
1653 (A) A satellite pharmacy shall be under the continuous, physically present supervision of a
1654 pharmacist at all times the satellite pharmacy is open to provide pharmacy services.

1655
1656 (B) The satellite pharmacy shall be enclosed by walls, partitions or other means of floor-to-
1657 ceiling enclosure. In addition, to the security requirements outlined in §291.33(b)(2) of this title,
1658 satellite pharmacies shall have adequate security and procedures to

1659
1660 (i) prohibit unauthorized access;

1661
1662 (ii) comply with federal and state regulations; and

1663
1664 (iii) maintain patient confidentiality.

1665
1666 (C) Access to the satellite pharmacy shall be limited to pharmacists, pharmacy technicians,
1667 and pharmacy technician trainees employed by the provider pharmacy and who are designated
1668 in writing by the pharmacist-in-charge.

1669
1670 (D) The provider pharmacy shall have procedures that specify that prescriptions may only be
1671 delivered to the satellite pharmacy by the provider pharmacy and shall:

1672
1673 (i) be delivered in a sealed container with a list of the prescriptions delivered;

1674
1675 (ii) signed for on receipt by the pharmacist at the satellite pharmacy;

1676
1677 (iii) be checked by personnel designated by the pharmacist-in-charge to verify that the
1678 prescriptions sent by the provider pharmacy were actually received. The designated person who
1679 checks the order shall document the verification by signing and dating the list of prescriptions
1680 delivered.

1681
1682 (5) Prescription dispensing and delivery. A satellite pharmacy shall comply with the
1683 requirements outlines in §291.33(c) of this title with regard to prescription dispensing and
1684 delivery.

1685
1686 (6) Equipment and supplies. A satellite pharmacy shall have the following equipment and
1687 supplies:

1688
1689 (A) typewriter or comparable equipment;

1690
1691 (B) refrigerator, if storing drugs requiring refrigeration;

1692

1693 (C) metric-apothecary weight and measure conversion charts.
1694
1695 (7) Library. A reference library shall be maintained by the satellite pharmacy that includes the
1696 following in hard-copy or electronic format:
1697
1698 (A) current copies of the following:
1699
1700 (i) Texas Pharmacy Act and rules;
1701
1702 (ii) Texas Dangerous Drug Act and rules;
1703
1704 (iii) Texas Controlled Substances Act and rules; and
1705
1706 (iv) Federal Controlled Substances Act and rules (or official publication describing the
1707 requirements of the Federal Controlled Substances Act and rules);
1708
1709 (B) at least one current or updated reference from each of the following categories:
1710
1711 (i) patient information:
1712
1713 (I) United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient);
1714 or
1715
1716 (II) a reference text or information leaflets which provide patient information;
1717
1718 (ii) drug interactions: a reference text on drug interactions, such as Drug Interaction Facts. A
1719 separate reference is not required if other references maintained by the pharmacy contain drug
1720 interaction information including information needed to determine severity or significance of the
1721 interaction and appropriate recommendations or actions to be taken;
1722
1723 (iii) a general information reference text, such as:
1724
1725 (I) Facts and Comparisons with current supplements;
1726
1727 (II) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the
1728 Healthcare Provider);
1729
1730 (III) Clinical Pharmacology;
1731
1732 (IV) American Hospital Formulary Service with current supplements; or
1733
1734 (V) Remington's Pharmaceutical Sciences; and
1735
1736 (C) basic antidote information and the telephone number of the nearest Regional Poison
1737 Control Center.
1738
1739 (f) Records.
1740
1741 (1) Maintenance of records.
1742

1743 (A) Every record required to be kept and §291.34 of this title and under this section shall be;

1744

1745 (i) kept by the provider pharmacy and be available, for at least two years from the date of
1746 such inventory or record, for inspecting and copying by the board or its representative and to
1747 other authorized local, state, or federal law enforcement agencies; and
1748

1749 (ii) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent
1750 of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
1751 format, the requested records must be provided in an electronic format if specifically requested
1752 by the board or its representative. Failure to provide the records set out in this section, either on
1753 site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records
1754 in violation of the Act.
1755

1756 (B) Records, except when specifically required to be maintained in original or hard-copy form,
1757 may be maintained in an alternative data retention system, such as a data processing system or
1758 direct imaging system provided:
1759

1760 (i) the records maintained in the alternative system contain all of the information required on
1761 the manual record; and
1762

1763 (ii) the data processing system is capable of producing a hard copy of the record upon the
1764 request of the board, its representative, or other authorized local, state, or federal law
1765 enforcement or regulatory agencies.
1766

1767 (C) Prescription drug orders shall be maintained by the provider pharmacy in the manner
1768 required by §291.34(d) or (e) of this title.
1769

1770 (2) Prescriptions.

1771 (A) Prescription drug orders shall meet the requirements of §291.34(b) of this title.
1772

1773 (B) The provider pharmacy must maintain appropriate records to identify the name(s), initials,
1774 or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or
1775 pharmacy technician trainee who performed any processing at the satellite pharmacy.
1776
1777

1778 (C) A provider pharmacy shall keep a record of all prescriptions sent and returned between
1779 the pharmacies separate from the records of the provider pharmacy and from any other satellite
1780 pharmacy's records.
1781

1782 (D) A satellite pharmacy shall keep a record of all prescriptions received and returned
1783 between the pharmacies.
1784

1785 **§291.131 Pharmacies Compounding Non-Sterile Preparations**
1786

1787 (a) Purpose. Pharmacies compounding non-sterile preparations, prepackaging pharmaceutical
1788 products and distributing those products shall comply with all requirements for their specific
1789 license classification and this section. The purpose of this section is to provide standards for
1790 the:
1791

1792 (1) compounding of non-sterile preparations pursuant to a prescription or medication order for
1793 a patient from a practitioner in Class A (Community), Class C (Institutional), and Class E (Non-
1794 resident) pharmacies;

1795
1796 (2) compounding, dispensing, and delivery of a reasonable quantity of a compounded non-
1797 sterile preparation in a Class A (Community), Class C (Institutional), and Class E (Non-resident)
1798 pharmacies to a practitioner's office for office use by the practitioner;

1799
1800 (3) compounding and distribution of compounded non-sterile preparations by a Class A
1801 (Community) pharmacy for a Class C (Institutional) pharmacy; and

1802
1803 (4) compounding of non-sterile preparations by a Class C (Institutional) pharmacy and the
1804 distribution of the compounded preparations to other Class C (Institutional) pharmacies under
1805 common ownership.

1806
1807 (b) Definitions. In addition to the definitions for specific license classifications, the following
1808 words and terms, when used in this section, shall have the following meanings, unless the
1809 context clearly indicates otherwise.

1810
1811 (1) Beyond-use date--The date or time after which the compounded non-sterile preparation
1812 shall not be stored or transported or begin to be administered to a patient. The beyond-use date
1813 is determined from the date or time when the preparation was compounded.

1814
1815 (2) Component--Any ingredient intended for use in the compounding of a drug preparation,
1816 including those that may not appear in such preparation.

1817
1818 (3) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or
1819 device:

1820
1821 (A) as the result of a practitioner's prescription drug or medication order, based on the
1822 practitioner-patient-pharmacist relationship in the course of professional practice;

1823
1824 (B) for administration to a patient by a practitioner as the result of a practitioner's initiative
1825 based on the practitioner-patient-pharmacist relationship in the course of professional practice;

1826
1827 (C) in anticipation of prescription drug or medication orders based on routine, regularly
1828 observed prescribing patterns; or

1829
1830 (D) for or as an incident to research, teaching, or chemical analysis and not for sale or
1831 dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.

1832
1833 (4) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of
1834 105 degrees F (41 degrees C).

1835
1836 (5) Reasonable quantity--An amount of a compounded drug that:

1837
1838 (A) does not exceed the amount a practitioner anticipates may be used in the practitioner's
1839 office or facility before the beyond use date of the drug;

1840

1841 (B) is reasonable considering the intended use of the compounded drug and the nature of the
1842 practitioner's practice; and

1843
1844 (C) for any practitioner and all practitioners as a whole, is not greater than an amount the
1845 pharmacy is capable of compounding in compliance with pharmaceutical standards for identity,
1846 strength, quality, and purity of the compounded drug that are consistent with United States
1847 Pharmacopoeia guidelines and accreditation practices.

1848
1849 (6) SOPs--Standard operating procedures.

1850
1851 (7) USP/NF--The current edition of the United States Pharmacopoeia/National Formulary.

1852
1853 (c) Personnel.

1854
1855 (1) Pharmacist-in-charge. In addition to the responsibilities for the specific class of pharmacy,
1856 the pharmacist-in-charge shall have the responsibility for, at a minimum, the following
1857 concerning non-sterile compounding:

1858
1859 (A) determining that all personnel involved in non-sterile compounding possess the
1860 education, training, and proficiency necessary to properly and safely perform compounding
1861 duties undertaken or supervised;

1862
1863 (B) determining that all personnel involved in non-sterile compounding obtain continuing
1864 education appropriate for the type of compounding done by the personnel;

1865
1866 (C) assuring that the equipment used in compounding is properly maintained;

1867
1868 (D) maintaining an appropriate environment in areas where non-sterile compounding occurs;
1869 and

1870
1871 (E) assuring that effective quality control procedures are developed and followed.

1872
1873 (2) Pharmacists. Special requirements for non-sterile compounding.

1874
1875 (A) All pharmacists engaged in compounding shall:

1876
1877 (i) possess the education, training, and proficiency necessary to properly and safely perform
1878 compounding duties undertaken or supervised; and

1879
1880 (ii) obtain continuing education appropriate for the type of compounding done by the
1881 pharmacist.

1882
1883 (B) A pharmacist shall inspect and approve all components, drug product containers,
1884 closures, labeling, and any other materials involved in the compounding process.

1885
1886 (C) A pharmacist shall review all compounding records for accuracy and conduct in-process
1887 and final checks to ensure that errors have not occurred in the compounding process.

1888
1889 (D) A pharmacist is responsible for the proper maintenance, cleanliness, and use of all
1890 equipment used in the compounding process.

1891
1892 (3) Pharmacy technicians and pharmacy technician trainees. All pharmacy technicians and
1893 pharmacy technician trainees engaged in non-sterile compounding shall:
1894
1895 (A) possess the education, training, and proficiency necessary to properly and safely perform
1896 compounding duties undertaken;
1897
1898 (B) obtain continuing education appropriate for the type of compounding done by the
1899 pharmacy technician or pharmacy technician trainee; and
1900
1901 (C) perform compounding duties under the direct supervision of and responsible to a
1902 pharmacist.
1903
1904 (4) Training.
1905
1906 (A) All training activities shall be documented and covered by appropriate SOPs as outlined in
1907 subsection (d)(8)(A) of this section.
1908
1909 (B) All personnel involved in non-sterile compounding shall be well trained and must
1910 participate in continuing relevant training programs.
1911
1912 (d) Operational Standards.
1913
1914 (1) General requirements.
1915
1916 (A) Non-sterile drug preparations may be compounded in licensed pharmacies:
1917
1918 (i) upon presentation of a practitioner's prescription drug or medication order based on a
1919 valid pharmacist/patient/prescriber relationship;
1920
1921 (ii) in anticipation of future prescription drug or medication orders based on routine, regularly
1922 observed prescribing patterns; or
1923
1924 (iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.
1925
1926 (B) Non-sterile compounding in anticipation of future prescription drug or medication orders
1927 must be based upon a history of receiving valid prescriptions issued within an established
1928 pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional
1929 judgment the quantity prepared is stable for the anticipated shelf time.
1930
1931 (i) The pharmacist's professional judgment shall be based on the criteria used to determine
1932 a beyond-use date outlined in paragraph (5)(C) of this subsection.
1933
1934 (ii) Documentation of the criteria used to determine the stability for the anticipated shelf time
1935 must be maintained and be available for inspection.
1936
1937 (iii) Any preparation compounded in anticipation of future prescription drug or medication
1938 orders shall be labeled. Such label shall contain:
1939

1940 (I) name and strength of the compounded preparation or list of the active ingredients and
1941 strengths;

1942
1943 (II) facility's lot number;

1944
1945 (III) beyond-use date as determined by the pharmacist using appropriate documented
1946 criteria as outlined in paragraph (5)(C) of this subsection; and

1947
1948 (IV) quantity or amount in the container.

1949
1950 (C) Commercially available products may be compounded for dispensing to individual
1951 patients provided the following conditions are met:

1952
1953 (i) the commercial product is not reasonably available from normal distribution channels in a
1954 timely manner to meet patient's needs;

1955
1956 (ii) the pharmacy maintains documentation that the product is not reasonably available due
1957 to a drug shortage or unavailability from the manufacturer; and

1958
1959 (iii) the prescribing practitioner has requested that the drug be compounded as described in
1960 subparagraph (D) of this paragraph.

1961
1962 (D) A pharmacy may not compound preparations that are essentially copies of commercially
1963 available products (e.g., the preparation is dispensed in a strength that is only slightly different
1964 from a commercially available product) unless the prescribing practitioner specifically orders the
1965 strength or dosage form and specifies why the patient needs the particular strength or dosage
1966 form of the preparation. The prescribing practitioner shall provide documentation of a patient
1967 specific medical need and the preparation produces a clinically significant therapeutic response
1968 (e.g. the physician requests an alternate product due to hypersensitivity to excipients or
1969 preservative in the FDA-approved product, or the physician requests an effective alternate
1970 dosage form) or if the drug product is not commercially available. The unavailability of such drug
1971 product must be documented prior to compounding. The methodology for documenting
1972 unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered,
1973 discontinued, or out-of-stock items. This documentation must be available in hard-copy or
1974 electronic format for inspection by the board.

1975
1976 (E) A pharmacy may enter into an agreement to compound and dispense
1977 prescription/medication orders for another pharmacy provided the pharmacy complies with the
1978 provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

1979
1980 (F) Compounding pharmacies/pharmacists may advertise and promote the fact that they
1981 provide non-sterile prescription compounding services, which may include specific drug
1982 products and classes of drugs.

1983
1984 (G) A pharmacy may not compound veterinary preparations for use in food producing animals
1985 except in accordance with federal guidelines.

1986
1987 (H) A pharmacist may add flavoring to a prescription at the request of a patient, the patient's
1988 agent, or the prescriber. The pharmacist shall label the flavored prescription with a beyond-use-
1989 date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise

1990 documented. Documentation of beyond-use-dates longer than fourteen days shall be
1991 maintained by the pharmacy electronically or manually and made available to agents of the
1992 board on request. A pharmacist may not add flavoring to an over-the-counter product at the
1993 request of a patient or patient's agent unless the pharmacist obtains a prescription for the over-
1994 the-counter product from the patient's practitioner.

1995
1996 (2) Library. In addition to the library requirements of the pharmacy's specific license
1997 classification, a pharmacy shall maintain a current copy, in hard-copy or electronic format, of
1998 Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations.

1999
2000 (3) Environment.

2001
2002 (A) Pharmacies regularly engaging in compounding shall have a designated and adequate
2003 area for the safe and orderly compounding of non-sterile preparations, including the placement
2004 of equipment and materials. Pharmacies involved in occasional compounding shall prepare an
2005 area prior to each compounding activity which is adequate for safe and orderly compounding.

2006
2007 (B) Only personnel authorized by the responsible pharmacist shall be in the immediate
2008 vicinity of a drug compounding operation.

2009
2010 (C) A sink with hot and cold running water, exclusive of rest room facilities, shall be
2011 accessible to the compounding areas and be maintained in a sanitary condition. Supplies
2012 necessary for adequate washing shall be accessible in the immediate area of the sink and
2013 include:

2014
2015 (i) soap or detergent; and

2016
2017 (ii) air-driers or single-use towels.

2018
2019 (D) If drug products which require special precautions to prevent contamination, such as
2020 penicillin, are involved in a compounding operation, appropriate measures, including dedication
2021 of equipment for such operations or the meticulous cleaning of contaminated equipment prior to
2022 its use for the preparation of other drug products, must be used in order to prevent cross-
2023 contamination.

2024
2025 (4) Equipment and Supplies. The pharmacy shall:

2026
2027 (A) have a Class A prescription balance, or analytical balance and weights which shall be
2028 properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy;
2029 and

2030
2031 (B) have equipment and utensils necessary for the proper compounding of prescription drug
2032 or medication orders. Such equipment and utensils used in the compounding process shall be:

2033
2034 (i) of appropriate design and capacity, and be operated within designed operational limits;

2035
2036 (ii) of suitable composition so that surfaces that contact components, in-process material, or
2037 drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity,
2038 strength, quality, or purity of the drug product beyond the desired result;

2039

2040 (iii) cleaned and sanitized immediately prior and after to each use; and
2041
2042 (iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance.
2043
2044 (5) Labeling. In addition to the labeling requirements of the pharmacy's specific license
2045 classification, the label dispensed or distributed pursuant to a prescription drug or medication
2046 order shall contain the following.
2047
2048 (A) The generic name(s) or the official name(s) of the principal active ingredient(s) of the
2049 compounded preparation.
2050
2051 (B) A statement that the preparation has been compounded by the pharmacy. (An auxiliary
2052 label may be used on the container to meet this requirement).
2053
2054 (C) A beyond-use date after which the compounded preparation should not be used. The
2055 beyond-use date shall be determined as outlined in Chapter 795 of the USP/NF concerning
2056 Pharmacy Compounding Non-Sterile Preparations including the following:
2057
2058 (i) The pharmacist shall consider:
2059
2060 (I) physical and chemical properties of active ingredients;
2061
2062 (II) use of preservatives and/or stabilizing agents;
2063
2064 (III) dosage form;
2065
2066 (IV) storage containers and conditions; and
2067
2068 (V) scientific, laboratory, or reference data from a peer reviewed source and retained in the
2069 pharmacy. The reference data should follow the same preparation instructions for combining
2070 raw materials and packaged in a container with similar properties.
2071
2072 (ii) In the absence of stability information applicable for a specific drug or preparation, the
2073 following maximum beyond-use dates are to be used when the compounded preparation is
2074 packaged in tight, light-resistant containers and stored at controlled room temperatures.
2075
2076 (I) Nonaqueous liquids and solid formulations (Where the manufactured drug product is the
2077 source of active ingredient): 25% of the time remaining until the product's expiration date or 6
2078 months, whichever is earlier.
2079
2080 (II) Water-containing formulations (Prepared from ingredients in solid form): Not later than
2081 14 days when refrigerated between 2 - 8 degrees Celsius (36 - 46 degrees Fahrenheit).
2082
2083 (III) All other formulations: Intended duration of therapy or 30 days, whichever is earlier.
2084
2085 (iii) Beyond-use date limits may be exceeded when supported by valid scientific stability
2086 information for the specific compounded preparation.
2087
2088 (6) Written drug information. Written information about the compounded preparation or its
2089 major active ingredient(s) shall be given to the patient at the time of dispensing. A statement

2090 which indicates that the preparation was compounded by the pharmacy must be included in this
2091 written information. If there is no written information available, the patient should be advised that
2092 the drug has been compounded and how to contact a pharmacist, and if appropriate the
2093 prescriber, concerning the drug.

2094

2095 (7) Drugs, components, and materials used in non-sterile compounding.

2096

2097 (A) Drugs used in non-sterile compounding shall be a USP/NF grade substances
2098 manufactured in an FDA-registered facility.

2099

2100 (B) If USP/NF grade substances are not available, or when food, cosmetics, or other
2101 substances are, or must be used, the substance shall be of a chemical grade in one of the
2102 following categories:

2103

2104 (i) Chemically Pure (CP);

2105

2106 (ii) Analytical Reagent (AR); or

2107

2108 (iii) American Chemical Society (ACS); or

2109

2110 (iv) Food Chemical Codex; or

2111

2112 (C) If a drug, component or material is not purchased from a FDA-registered facility, the
2113 pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the
2114 supplier and the pharmacist shall compare the monograph of drugs in a similar class to the
2115 Certificate of Analysis.

2116

2117 (D) A manufactured drug product may be a source of active ingredient. Only manufactured
2118 drugs from containers labeled with a batch control number and a future expiration date are
2119 acceptable as a potential source of active ingredients. When compounding with manufactured
2120 drug products, the pharmacist must consider all ingredients present in the drug product relative
2121 to the intended use of the compounded preparation.

2122

2123 (E) All components shall be stored in properly labeled containers in a clean, dry area, under
2124 proper temperatures.

2125

2126 (F) Drug product containers and closures shall not be reactive, additive, or absorptive so as
2127 to alter the safety, identity, strength, quality, or purity of the compounded drug product beyond
2128 the desired result.

2129

2130 (G) Components, drug product containers, and closures shall be rotated so that the oldest
2131 stock is used first.

2132

2133 (H) Container closure systems shall provide adequate protection against foreseeable external
2134 factors in storage and use that can cause deterioration or contamination of the compounded
2135 drug product.

2136

2137 (I) A pharmacy may not compound a preparation that contains ingredients appearing on a
2138 federal Food and Drug Administration list of drug products withdrawn or removed from the
2139 market for safety reasons.

2140
2141 (8) Compounding process.
2142
2143 (A) All significant procedures performed in the compounding area shall be covered by written
2144 SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the
2145 compounding process. At a minimum, SOPs shall be developed for:
2146
2147 (i) the facility;
2148
2149 (ii) equipment;
2150
2151 (iii) personnel;
2152
2153 (iv) preparation evaluation;
2154
2155 (v) quality assurance;
2156
2157 (vi) preparation recall;
2158
2159 (vii) packaging; and
2160
2161 (viii) storage of compounded preparations.
2162
2163 (B) Any compounded preparation with an official monograph in the USP/NF shall be
2164 compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.
2165
2166 (C) Any person with an apparent illness or open lesion that may adversely affect the safety or
2167 quality of a drug product being compounded shall be excluded from direct contact with
2168 components, drug product containers, closures, any materials involved in the compounding
2169 process, and drug products until the condition is corrected.
2170
2171 (D) Personnel engaged in the compounding of drug preparations shall wear clean clothing
2172 appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons,
2173 hair nets, gowns, hand or arm coverings, or masks shall be worn as necessary to protect
2174 personnel from chemical exposure and drug preparations from contamination.
2175
2176 (E) At each step of the compounding process, the pharmacist shall ensure that components
2177 used in compounding are accurately weighed, measured, or subdivided as appropriate to
2178 conform to the formula being prepared.
2179
2180 (9) Quality Assurance.
2181
2182 (A) Initial formula validation. Prior to routine compounding of a non-sterile preparation, a
2183 pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding
2184 a product that contains the stated amount of active ingredient(s).
2185
2186 (B) Finished preparation checks. The prescription drug and medication orders, written
2187 compounding procedure, preparation records, and expended materials used to make
2188 compounded non-sterile preparations shall be inspected for accuracy of correct identities and

2189 amounts of ingredients, packaging, labeling, and expected physical appearance before the non-
2190 sterile preparations are dispensed.

2191
2192 (10) Quality Control.

2193
2194 (A) The pharmacy shall follow established quality control procedures to monitor the quality of
2195 compounded drug preparations for uniformity and consistency such as capsule weight
2196 variations, adequacy of mixing, clarity, or pH of solutions. When developing these procedures,
2197 pharmacy personnel shall consider the provisions of Chapter 795, concerning Pharmacy
2198 Compounding Non-Sterile Preparations, Chapter 1075, concerning Good Compounding
2199 Practices, and Chapter 1160, concerning Pharmaceutical Calculations in Prescription
2200 Compounding contained in the current USP/NF. Such procedures shall be documented and be
2201 available for inspection.

2202
2203 (B) Compounding procedures that are routinely performed, including batch compounding,
2204 shall be completed and verified according to written procedures. The act of verification of a
2205 compounding procedure involves checking to ensure that calculations, weighing and measuring,
2206 order of mixing, and compounding techniques were appropriate and accurately performed.

2207
2208 (C) Unless otherwise indicated or appropriate, compounded preparations are to be prepared
2209 to ensure that each preparation shall contain not less than 90.0 percent and not more than
2210 110.0 percent of the theoretically calculated and labeled quantity of active ingredient per unit
2211 weight or volume and not less than 90.0 percent and not more than 110.0 percent of the
2212 theoretically calculated weight or volume per unit of the preparation.

2213
2214 (e) Records.

2215
2216 (1) Maintenance of records. Every record required by this section shall be:

2217
2218 (A) kept by the pharmacy and be available, for at least two years for inspecting and copying
2219 by the board or its representative and to other authorized local, state, or federal law
2220 enforcement agencies; and

2221
2222 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
2223 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,
2224 the requested records must be provided in an electronic format. Failure to provide the records
2225 set out in this section, either on site or within 72 hours, constitutes prima facie evidence of
2226 failure to keep and maintain records in violation of the Act.

2227
2228 (2) Compounding records.

2229
2230 (A) Compounding pursuant to patient specific prescription drug or medication orders.
2231 Compounding records for all compounded preparations shall be maintained by the pharmacy
2232 electronically or manually as part of the prescription drug or medication order, formula record,
2233 formula book, or compounding log and shall include:

2234
2235 (i) the date of preparation;

2236

2237 (ii) a complete formula, including methodology and necessary equipment which includes the
2238 brand name(s) of the raw materials, or if no brand name, the generic name(s) and name(s) of
2239 the manufacturer(s) of the raw materials and the quantities of each;

2240
2241 (iii) signature or initials of the pharmacist or pharmacy technician or pharmacy technician
2242 trainee performing the compounding;

2243
2244 (iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians
2245 or pharmacy technician trainees and conducting in-process and final checks of compounded
2246 preparations if pharmacy technicians or pharmacy technician trainees perform the compounding
2247 function;

2248
2249 (v) the quantity in units of finished preparations or amount of raw materials;

2250
2251 (vi) the container used and the number of units prepared;

2252
2253 (vii) a reference to the location of the following documentation which may be maintained with
2254 other records, such as quality control records:

2255
2256 (I) the criteria used to determine the beyond-use date; and

2257
2258 (II) documentation of performance of quality control procedures. Documentation of the
2259 performance of quality control procedures is not required if the compounding process is done
2260 pursuant to a patient specific order and involves the mixing of two or more commercially
2261 available oral liquids or commercially available preparations when the final product is intended
2262 for external use.

2263
2264 (B) Compounding records when batch compounding or compounding in anticipation of future
2265 prescription drug or medication orders.

2266
2267 (i) Master work sheet. A master work sheet shall be developed and approved by a
2268 pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work
2269 sheet shall be used as the preparation work sheet from which each batch is prepared and on
2270 which all documentation for that batch occurs. The master work sheet shall contain at a
2271 minimum:

2272
2273 (I) the formula;

2274
2275 (II) the components;

2276
2277 (III) the compounding directions;

2278
2279 (IV) a sample label;

2280
2281 (V) evaluation and testing requirements;

2282
2283 (VI) specific equipment used during preparation; and

2284
2285 (VII) storage requirements.

2286

2287 (ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall
2288 document the following:

- 2289
2290 (I) identity of all solutions and ingredients and their corresponding amounts,
2291 concentrations, or volumes;
2292
2293 (II) lot number or each component;
2294
2295 (III) component manufacturer/distributor or suitable identifying number;
2296
2297 (IV) container specifications;
2298
2299 (V) unique lot or control number assigned to batch;
2300
2301 (VI) beyond use date of batch-prepared preparations;
2302
2303 (VII) date of preparation;
2304
2305 (VIII) name, initials, or electronic signature of the person(s) involved in the preparation;
2306
2307 (IX) name, initials, or electronic signature of the responsible pharmacist;
2308
2309 (X) finished preparation evaluation and testing specifications, if applicable; and
2310
2311 (XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.

2312
2313 (f) Office Use Compounding and Distribution of Compounded Preparations to Class C
2314 Pharmacies or Veterinarians in Accordance With §563.054 of the Act.

2315
2316 (1) General.

2317 (A) A pharmacy may dispense and deliver a reasonable quantity of a compounded
2318 preparation to a practitioner for office use by the practitioner in accordance with this subsection.
2319
2320

2321 (B) A Class A (Community) pharmacy is not required to register or be licensed under Chapter
2322 431, Health and Safety Code, to distribute non-sterile compounded preparations to a Class C
2323 (Institutional) pharmacy.
2324

2325 (C) A Class C (Institutional) pharmacy is not required to register or be licensed under Chapter
2326 431, Health and Safety Code, to distribute non-sterile compounded preparations that the Class
2327 C pharmacy has compounded for other Class C pharmacies under common ownership.
2328

2329 (D) To dispense and deliver a compounded preparation under this subsection, a pharmacy
2330 must:

2331
2332 (i) verify the source of the raw materials to be used in a compounded drug;
2333

2334 (ii) comply with applicable United States Pharmacopoeia guidelines, including the testing
2335 requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No.
2336 104-191);

2337
2338 (iii) enter into a written agreement with a practitioner for the practitioner's office use of a
2339 compounded preparation;
2340
2341 (iv) comply with all applicable competency and accrediting standards as determined by the
2342 board; and
2343
2344 (v) comply with the provisions of this subsection.
2345
2346 (2) Written Agreement. A pharmacy that provides non-sterile compounded preparations to
2347 practitioners for office use or to another pharmacy shall enter into a written agreement with the
2348 practitioner or pharmacy. The written agreement shall:
2349
2350 (A) address acceptable standards of practice for a compounding pharmacy and a practitioner
2351 and receiving pharmacy that enter into the agreement including a statement that the
2352 compounded preparations may only be administered to the patient and may not be dispensed to
2353 the patient or sold to any other person or entity except as authorized by §563.054 of the Act;
2354
2355 (B) require the practitioner or receiving pharmacy to include on a patient's chart, medication
2356 order, or medication administration record the lot number and beyond-use date of a
2357 compounded preparation administered to a patient; and
2358
2359 (C) describe the scope of services to be performed by the pharmacy and practitioner or
2360 receiving pharmacy, including a statement of the process for:
2361
2362 (i) a patient to report an adverse reaction or submit a complaint; and
2363
2364 (ii) the pharmacy to recall batches of compounded preparations.
2365
2366 (3) Recordkeeping.
2367
2368 (A) Maintenance of Records.
2369
2370 (i) Records of orders and distribution of non-sterile compounded preparations to a
2371 practitioner for office use or to a Class C (Institutional) pharmacy for administration to a patient
2372 shall:
2373
2374 (I) be kept by the pharmacy and be available, for at least two years from the date of the
2375 record, for inspecting and copying by the board or its representative and to other authorized
2376 local, state, or federal law enforcement agencies;
2377
2378 (II) maintained separately from the records of products dispensed pursuant to a
2379 prescription or medication order; and
2380
2381 (III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
2382 Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in
2383 an electronic format, the requested records must be provided in an electronic format. Failure to
2384 provide the records set out in this subsection, either on site or within 72 hours for whatever
2385 reason, constitutes prima facie evidence of failure to keep and maintain records.
2386

2387 (ii) Records may be maintained in an alternative data retention system, such as a data
2388 processing system or direct imaging system provided the data processing system is capable of
2389 producing a hard copy of the record upon the request of the board, its representative, or other
2390 authorized local, state, or federal law enforcement or regulatory agencies.

2391
2392 (B) Orders. The pharmacy shall maintain a record of all non-sterile compounded preparations
2393 ordered by a practitioner for office use or by a Class C pharmacy for administration to a patient.
2394 The record shall include the following information:

2395
2396 (i) date of the order;

2397
2398 (ii) name, address, and phone number of the practitioner who ordered the preparation and if
2399 applicable, the name, address and phone number of the Class C pharmacy ordering the
2400 preparation; and

2401
2402 (iii) name, strength, and quantity of the preparation ordered.

2403
2404 (C) Distributions. The pharmacy shall maintain a record of all non-sterile compounded
2405 preparations distributed pursuant to an order to a practitioner for office use or by a Class C
2406 pharmacy for administration to a patient. The record shall include the following information:

2407
2408 (i) date the preparation was compounded;

2409
2410 (ii) date the preparation was distributed;

2411
2412 (iii) name, strength and quantity in each container of the preparation;

2413
2414 (iv) pharmacy's lot number;

2415
2416 (v) quantity of containers shipped; and

2417
2418 (vi) name, address, and phone number of the practitioner or Class C pharmacy to whom the
2419 preparation is distributed.

2420
2421 (D) Audit Trail.

2422
2423 (i) The pharmacy shall store the order and distribution records of preparations for all non-
2424 sterile compounded preparations ordered by and or distributed to a practitioner for office use or
2425 by a Class C pharmacy for administration to a patient in such a manner as to be able to provide
2426 a audit trail for all orders and distributions of any of the following during a specified time period.

2427
2428 (I) any strength and dosage form of a preparation (by either brand or generic name or
2429 both);

2430
2431 (II) any ingredient;

2432
2433 (III) any lot number;

2434
2435 (IV) any practitioner;

2436

2437 (V) any facility; and
2438
2439 (VI) any pharmacy, if applicable.
2440
2441 (ii) The audit trail shall contain the following information:
2442
2443 (I) date of order and date of the distribution;
2444
2445 (II) practitioner's name, address, and name of the Class C pharmacy, if applicable;
2446
2447 (III) name, strength and quantity of the preparation in each container of the preparation;
2448
2449 (IV) name and quantity of each active ingredient;
2450
2451 (V) quantity of containers distributed; and
2452
2453 (VI) pharmacy's lot number;
2454
2455 (4) Labeling. The pharmacy shall affix a label to the preparation containing the following
2456 information:
2457
2458 (A) name, address, and phone number of the compounding pharmacy;
2459
2460 (B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation
2461 is distributed to a veterinarian the statement: "Compounded Preparation";
2462
2463 (C) name and strength of the preparation or list of the active ingredients and strengths;
2464
2465 (D) pharmacy's lot number;
2466
2467 (E) beyond-use date as determined by the pharmacist using appropriate documented criteria;
2468
2469 (F) quantity or amount in the container;
2470
2471 (G) appropriate ancillary instructions, such as storage instructions or cautionary statements,
2472 including hazardous drug warning labels where appropriate; and
2473
2474 (H) device-specific instructions, where appropriate.
2475
2476 (g) Recall Procedures.
2477
2478 (1) The pharmacy shall have written procedures for the recall of any compounded non-sterile
2479 preparations provided to a patient, to a practitioner for office use, or a pharmacy for
2480 administration. Written procedures shall include, but not be limited to the requirements as
2481 specified in paragraph (3) of this subsection.
2482
2483 (2) The pharmacy shall immediately initiate a recall of any non-sterile preparation compounded
2484 by the pharmacy upon identification of a potential or confirmed harm to a patient.
2485
2486 (3) In the event of a recall, the pharmacist-in-charge shall ensure that:

- 2487
2488 (A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is
2489 notified, in writing, of the recall;
2490
2491 (B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;
2492
2493 (C) if the preparation is prepared as a batch, the board is notified of the recall, in writing;
2494
2495 (D) if the preparation is distributed for office use, the Texas Department of State Health
2496 Services, Drugs and Medical Devices Group, is notified of the recall, in writing;
2497
2498 (E) the preparation is quarantined; and
2499
2500 (F) the pharmacy keeps a written record of the recall including all actions taken to notify all
2501 parties and steps taken to ensure corrective measures.
2502
2503 (4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if
2504 there is potential for or confirmed harm to a patient.
2505

2506 **§291.133 Pharmacies Compounding Sterile Preparations**
2507

- 2508 (a) Purpose. Pharmacies compounding sterile preparations, prepackaging pharmaceutical
2509 products, and distributing those products shall comply with all requirements for their specific
2510 license classification and this section. The purpose of this section is to provide standards for
2511 the:
2512
2513 (1) compounding of sterile preparations pursuant to a prescription or medication order for a
2514 patient from a practitioner in Class A-S, Class B, Class C-S, and Class E-S pharmacies;
2515
2516 (2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile
2517 preparation in Class A-S, Class B, Class C-S, and Class E-S pharmacies to a practitioner's
2518 office for office use by the practitioner;
2519
2520 (3) compounding and distribution of compounded sterile preparations by a Class A-S
2521 pharmacy for a Class C-S pharmacy; and
2522
2523 (4) compounding of sterile preparations by a Class C-S pharmacy and the distribution of the
2524 compounded preparations to other Class C or Class C-S pharmacies under common ownership.
2525
2526 (b) Definitions. In addition to the definitions for specific license classifications, the following
2527 words and terms, when used in this section, shall have the following meanings, unless the
2528 context clearly indicates otherwise.
2529
2530 (1) ACPE--Accreditation Council for Pharmacy Education.
2531
2532 (2) Airborne particulate cleanliness class--The level of cleanliness specified by the maximum
2533 allowable number of particles per cubic meter of air as specified in the International
2534 Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For
2535 example:
2536

2537 (A) ISO Class 5 (formerly Class 100) is an atmospheric environment that contains less than
2538 3,520 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100 particles
2539 0.5 microns in diameter per cubic foot of air);

2540
2541 (B) ISO Class 7 (formerly Class 10,000) is an atmospheric environment that contains less
2542 than 352,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 10,000
2543 particles 0.5 microns in diameter per cubic foot of air); and

2544
2545 (C) ISO Class 8 (formerly Class 100,000) is an atmospheric environment that contains less
2546 than 3,520,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as
2547 100,000 particles 0.5 microns in diameter per cubic foot of air).

2548
2549 (3) Ancillary supplies--Supplies necessary for the preparation and administration of
2550 compounded sterile preparations.

2551
2552 (4) Ante-area--An ISO Class 8 or better area where personnel may perform hand hygiene and
2553 garbing procedures, staging of components, order entry, labeling, and other high-particulate
2554 generating activities. It is also a transition area that:

2555
2556 (A) provides assurance that pressure relationships are constantly maintained so that air flows
2557 from clean to dirty areas; and

2558
2559 (B) reduces the need for the heating, ventilating and air conditioning (HVAC) control system
2560 to respond to large disturbances.

2561
2562 (5) Aseptic Processing--A mode of processing pharmaceutical and medical preparations that
2563 involves the separate sterilization of the preparation and of the package (containers-closures or
2564 packaging material for medical devices) and the transfer of the preparation into the container
2565 and its closure under at least ISO Class 5 conditions.

2566
2567 (6) Automated compounding device--An automated device that compounds, measures, and/or
2568 packages a specified quantity of individual components in a predetermined sequence for a
2569 designated sterile preparation.

2570
2571 (7) Batch--A specific quantity of a drug or other material that is intended to have uniform
2572 character and quality, within specified limits, and is produced during a single preparation cycle.

2573
2574 (8) Batch preparation compounding--Compounding of multiple sterile preparation units, in a
2575 single discrete process, by the same individual(s), carried out during one limited time period.
2576 Batch preparation/compounding does not include the preparation of multiple sterile preparation
2577 units pursuant to patient specific medication orders.

2578
2579 (9) Beyond-use date--The date or time after which the compounded sterile preparation shall
2580 not be stored or transported or begin to be administered to a patient. The beyond-use date is
2581 determined from the date or time the preparation is compounded.

2582
2583 (10) Biological Safety Cabinet, Class II--A ventilated cabinet for personnel, product or
2584 preparation, and environmental protection having an open front with inward airflow for personnel
2585 protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered
2586 exhausted air for environmental protection.

2587
2588 (11) Buffer Area--An ISO Class 7 or, if a Class B pharmacy, ISO Class 8 or better, area where
2589 the primary engineering control area is physically located. Activities that occur in this area
2590 include the preparation and staging of components and supplies used when compounding
2591 sterile preparations.
2592
2593 (12) Clean room--A room in which the concentration of airborne particles is controlled to meet
2594 a specified airborne particulate cleanliness class. Microorganisms in the environment are
2595 monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a
2596 specified cleanliness class.
2597
2598 (13) Component--Any ingredient intended for use in the compounding of a drug preparation,
2599 including those that may not appear in such preparation.
2600
2601 (14) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or
2602 device:
2603
2604 (A) as the result of a practitioner's prescription drug or medication order based on the
2605 practitioner-patient-pharmacist relationship in the course of professional practice;
2606
2607 (B) for administration to a patient by a practitioner as the result of a practitioner's initiative
2608 based on the practitioner-patient-pharmacist relationship in the course of professional practice;
2609
2610 (C) in anticipation of prescription drug or medication orders based on routine, regularly
2611 observed prescribing patterns; or
2612
2613 (D) for or as an incident to research, teaching, or chemical analysis and not for sale or
2614 dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.
2615
2616 (15) Compounding Aseptic Isolator--A form of barrier isolator specifically designed for
2617 compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic
2618 compounding environment within the isolator throughout the compounding and material transfer
2619 processes. Air exchange into the isolator from the surrounding environment shall not occur
2620 unless it has first passed through a microbial retentive filter (HEPA minimum).
2621
2622 (16) Compounding Aseptic Containment Isolator--A compounding aseptic isolator designed to
2623 provide worker protection from exposure to undesirable levels of airborne drug throughout the
2624 compounding and material transfer processes and to provide an aseptic environment for
2625 compounding sterile preparations. Air exchange with the surrounding environment should not
2626 occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system
2627 capable of containing airborne concentrations of the physical size and state of the drug being
2628 compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator
2629 should be appropriately removed by properly designed building ventilation.
2630
2631 (17) Compounding Personnel--A pharmacist, pharmacy technician, or pharmacy technician
2632 trainee who performs the actual compounding; a pharmacist who supervises pharmacy
2633 technicians or pharmacy technician trainees compounding sterile preparations, and a
2634 pharmacist who performs an intermediate or final verification of a compounded sterile
2635 preparation.
2636

- 2637 (18) Critical Area--An ISO Class 5 environment.
2638
- 2639 (19) Critical Sites--A location that includes any component or fluid pathway surfaces (e.g., vial
2640 septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed and
2641 at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and
2642 mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the
2643 critical site increases with the size of the openings and exposure time.
2644
- 2645 (20) Device--An instrument, apparatus, implement, machine, contrivance, implant, in-vitro
2646 reagent, or other similar or related article, including any component part or accessory, that is
2647 required under federal or state law to be ordered or prescribed by a practitioner.
2648
- 2649 (21) Direct Compounding Area--A critical area within the ISO Class 5 primary engineering
2650 control where critical sites are exposed to unidirectional HEPA-filtered air, also known as first
2651 air.
2652
- 2653 (22) Disinfectant--An agent that frees from infection, usually a chemical agent but sometimes a
2654 physical one, and that destroys disease-causing pathogens or other harmful microorganisms
2655 but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.
2656
- 2657 (23) First Air--The air exiting the HEPA filter in a unidirectional air stream that is essentially
2658 particle free.
2659
- 2660 (24) Hazardous Drugs--Drugs that, studies in animals or humans indicate exposure to the
2661 drugs, have a potential for causing cancer, development or reproductive toxicity, or harm to
2662 organs. For the purposes of this chapter, radiopharmaceuticals are not considered hazardous
2663 drugs.
2664
- 2665 (25) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum
2666 of 105 degrees F (41 degrees C).
2667
- 2668 (26) HVAC--Heating, ventilation, and air conditioning.
2669
- 2670 (27) Immediate use--A sterile preparation that is not prepared according to USP 797 standards
2671 (i.e., outside the pharmacy and most likely not by pharmacy personnel) which shall be stored for
2672 no longer than one hour after completion of the preparation.
2673
- 2674 (28) IPA--Isopropyl alcohol (2-propanol).
2675
- 2676 (29) Labeling--All labels and other written, printed, or graphic matter on an immediate
2677 container of an article or preparation or on, or in, any package or wrapper in which it is
2678 enclosed, except any outer shipping container. The term "label" designates that part of the
2679 labeling on the immediate container.
2680
- 2681 (30) Media-Fill Test--A test used to qualify aseptic technique of compounding personnel or
2682 processes and to ensure that the processes used are able to produce sterile preparation without
2683 microbial contamination. During this test, a microbiological growth medium such as Soybean-
2684 Casein Digest Medium is substituted for the actual drug preparation to simulate admixture
2685 compounding. The issues to consider in the development of a media-fill test are the following:

2686 media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection
2687 of filled units, documentation, interpretation of results, and possible corrective actions required.
2688

2689 (31) Multiple-Dose Container--A multiple-unit container for articles or preparations intended for
2690 potential administration only and usually contains antimicrobial preservatives. The beyond-use
2691 date for an opened or entered (e.g., needle-punctured) multiple-dose container with
2692 antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.
2693

2694 (32) Negative Pressure Room--A room that is at a lower pressure compared to adjacent
2695 spaces and, therefore, the net flow of air is into the room.
2696

2697 (33) Office use--The administration of a compounded drug to a patient by a practitioner in the
2698 practitioner's office or by the practitioner in a health care facility or treatment setting, including a
2699 hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 562 of the Act, or
2700 for administration or provision by a veterinarian in accordance with §563.054 of the Act.
2701

2702 (34) Pharmacy Bulk Package--A container of a sterile preparation for potential use that
2703 contains many single doses. The contents are intended for use in a pharmacy admixture
2704 program and are restricted to the preparation of admixtures for infusion or, through a sterile
2705 transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one
2706 time after constitution with a suitable sterile transfer device or dispensing set, which allows
2707 measured dispensing of the contents. The pharmacy bulk package is to be used only in a
2708 suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).
2709

2710 (35) Prepackaging--The act of repackaging and relabeling quantities of drug products from a
2711 manufacturer's original container into unit dose packaging or a multiple dose container for
2712 distribution within a facility licensed as a Class C pharmacy or to other pharmacies under
2713 common ownership for distribution within those facilities. The term as defined does not prohibit
2714 the prepackaging of drug products for use within other pharmacy classes.
2715

2716 (36) Preparation or Compounded Sterile Preparation--A sterile admixture compounded in a
2717 licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed
2718 prescriber. The components of the preparation may or may not be sterile products.
2719

2720 (37) Primary Engineering Control--A device or room that provides an ISO Class 5 environment
2721 for the exposure of critical sites when compounding sterile preparations. Such devices include,
2722 but may not be limited to, laminar airflow workbenches, biological safety cabinets, compounding
2723 aseptic isolators, and compounding aseptic containment isolators.
2724

2725 (38) Product--A commercially manufactured sterile drug or nutrient that has been evaluated for
2726 safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are accompanied
2727 by full prescribing information, which is commonly known as the FDA-approved manufacturer's
2728 labeling or product package insert.
2729

2730 (39) Positive Control--A quality assurance sample prepared to test positive for microbial
2731 growth.
2732

2733 (40) Quality assurance--The set of activities used to ensure that the process used in the
2734 preparation of sterile drug preparations lead to preparations that meet predetermined standards
2735 of quality.

- 2736
2737 (41) Quality control--The set of testing activities used to determine that the ingredients,
2738 components (e.g., containers), and final compounded sterile preparations prepared meet
2739 predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.
2740
2741 (42) Reasonable quantity--An amount of a compounded drug that:
2742
2743 (A) does not exceed the amount a practitioner anticipates may be used in the practitioner's
2744 office or facility before the beyond use date of the drug;
2745
2746 (B) is reasonable considering the intended use of the compounded drug and the nature of the
2747 practitioner's practice; and
2748
2749 (C) for any practitioner and all practitioners as a whole, is not greater than an amount the
2750 pharmacy is capable of compounding in compliance with pharmaceutical standards for identity,
2751 strength, quality, and purity of the compounded drug that are consistent with United States
2752 Pharmacopoeia guidelines and accreditation practices.
2753
2754 (43) Segregated Compounding Area--A designated space, either a demarcated area or room,
2755 that is restricted to preparing low-risk level compounded sterile preparations with 12-hour or less
2756 beyond-use date. Such area shall contain a device that provides unidirectional airflow of ISO
2757 Class 5 air quality for preparation of compounded sterile preparations and shall be void of
2758 activities and materials that are extraneous to sterile compounding.
2759
2760 (44) Single-dose container--A single-unit container for articles or preparations intended for
2761 parenteral administration only. It is intended for a single use. A single-dose container is labeled
2762 as such. Examples of single-dose containers include pre-filled syringes, cartridges, fusion-
2763 sealed containers, and closure-sealed containers when so labeled.
2764
2765 (45) SOPs--Standard operating procedures.
2766
2767 (46) Sterilizing Grade Membranes--Membranes that are documented to retain 100% of a
2768 culture of 10⁷ microorganisms of a strain of *Brevundimonas* (*Pseudomonas*) *diminuta* per
2769 square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such
2770 filter membranes are nominally at 0.22-micrometer or 0.2-micrometer nominal pore size,
2771 depending on the manufacturer's practice.
2772
2773 (47) Sterilization by Filtration--Passage of a fluid or solution through a sterilizing grade
2774 membrane to produce a sterile effluent.
2775
2776 (48) Terminal Sterilization--The application of a lethal process, e.g., steam under pressure or
2777 autoclaving, to sealed final preparation containers for the purpose of achieving a predetermined
2778 sterility assurance level of usually less than 10⁻⁶ or a probability of less than one in one million
2779 of a non-sterile unit.
2780
2781 (49) Unidirectional Flow--An airflow moving in a single direction in a robust and uniform
2782 manner and at sufficient speed to reproducibly sweep particles away from the critical processing
2783 or testing area.
2784
2785 (50) USP/NF--The current edition of the United States Pharmacopoeia/National Formulary.

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(c) Personnel.

(1) Pharmacist-in-charge.

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

(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:

(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;

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

(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;

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

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

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

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

(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.

(2) Pharmacists.

(A) General.

(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.

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

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

2835 (iv) A pharmacist shall review all compounding records for accuracy and conduct a final
2836 check.

2837
2838 (v) A pharmacist is responsible for ensuring the proper maintenance, cleanliness, and use of
2839 all equipment used in the compounding process.

2840
2841 (vi) A pharmacist shall be accessible at all times, 24 hours a day, to respond to patients' and
2842 other health professionals' questions and needs.

2843
2844 (B) Initial training and continuing education.

2845
2846 (i) All pharmacists who compound sterile preparations or supervise pharmacy technicians
2847 and pharmacy technician trainees compounding sterile preparations shall comply with the
2848 following:

2849
2850 (I) complete through a single course, a minimum of 20 hours of instruction and experience
2851 in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through
2852 completion of a recognized course in an accredited college of pharmacy or a course sponsored
2853 by an ACPE accredited provider;

2854
2855 (II) complete a structured on-the-job didactic and experiential training program at this
2856 pharmacy which provides sufficient hours of instruction and experience in the facility's sterile
2857 compounding processes and procedures. Such training may not be transferred to another
2858 pharmacy unless the pharmacies are under common ownership and control and use a common
2859 training program; and

2860
2861 (III) possess knowledge about:

2862
2863 (-a-) aseptic processing;

2864
2865 (-b-) quality control and quality assurance as related to environmental, component, and
2866 finished preparation release checks and tests;

2867
2868 (-c-) chemical, pharmaceutical, and clinical properties of drugs;

2869
2870 (-d-) container, equipment, and closure system selection; and

2871
2872 (-e-) sterilization techniques.

2873
2874 (ii) The required experiential portion of the training programs specified in this subparagraph
2875 must be supervised by an individual who is actively engaged in performing sterile compounding
2876 and is qualified and has completed training as specified in this paragraph or paragraph (3) of
2877 this subsection.

2878
2879 (iii) In order to renew a license to practice pharmacy, during the previous licensure period, a
2880 pharmacist engaged in sterile compounding shall complete a minimum of:

2881
2882 (I) two hours of ACPE-accredited continuing education relating to one or more of the areas
2883 listed in paragraph (4)(D) of this subsection if the pharmacist is engaged in compounding low
2884 and medium risk sterile preparations; or

2885
2886 (II) four hours of ACPE-accredited continuing education relating to one or more of the
2887 areas listed in paragraph (4)(D) of this subsection if the pharmacist is engaged in compounding
2888 high risk sterile preparations.

2889
2890 (3) Pharmacy technicians and pharmacy technician trainees.

2891
2892 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the
2893 training requirements specified in §297.6 of this title (relating to Pharmacy Technician and
2894 Pharmacy Technician Trainee Training).

2895
2896 (B) Initial training and continuing education.

2897
2898 (i) Pharmacy technicians and pharmacy technician trainees may compound sterile
2899 preparations provided the pharmacy technicians and/or pharmacy technician trainees are
2900 supervised by a pharmacist as specified in paragraph (2) of this subsection.

2901
2902 (ii) All pharmacy technicians and pharmacy technician trainees who compound sterile
2903 preparations for administration to patients shall:

2904
2905 (I) have initial training obtained either through completion of:

2906
2907 (-a-) a single course, a minimum of 40 hours of instruction and experience in the areas
2908 listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion
2909 of a course sponsored by an ACPE accredited provider which provides 40 hours of instruction
2910 and experience; or

2911
2912 (-b-) a training program which is accredited by the American Society of Health-System
2913 Pharmacists.

2914
2915 (II) and

2916
2917 (-a-) complete a structured on-the-job didactic and experiential training program at this
2918 pharmacy which provides sufficient hours of instruction and experience in the facility's sterile
2919 compounding processes and procedures. Such training may not be transferred to another
2920 pharmacy unless the pharmacies are under common ownership and control and use a common
2921 training program; and

2922
2923 (-b-) possess knowledge about:

2924
2925 (-1-) aseptic processing;

2926
2927 (-2-) quality control and quality assurance as related to environmental, component, and
2928 finished preparation release checks and tests;

2929
2930 (-3-) chemical, pharmaceutical, and clinical properties of drugs;

2931
2932 (-4-) container, equipment, and closure system selection; and

2933
2934 (-5-) sterilization techniques.

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

(I) 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;

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

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

(IV) supervising pharmacist conducts a final check.

(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) of this subsection or this paragraph.

(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:

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

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

(4) Evaluation and testing requirements.

(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.

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

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

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

2984 (C) Pharmacy personnel who fail written tests or whose media-fill test vials result in gross
2985 microbial colonization shall:

2986
2987 (i) be immediately re-instructed and re-evaluated by expert compounding personnel to
2988 ensure correction of all aseptic practice deficiencies; and

2989
2990 (ii) not be allowed to compound sterile preparations for patient use until passing results are
2991 achieved.

2992
2993 (D) The didactic and experiential training shall include instruction, experience, and
2994 demonstrated proficiency in the following areas:

- 2995 (i) aseptic technique;
- 2996
2997 (ii) critical area contamination factors;
- 2998
2999 (iii) environmental monitoring;
- 3000
3001 (iv) structure and engineering controls related to facilities;
- 3002
3003 (v) equipment and supplies;
- 3004
3005 (vi) sterile preparation calculations and terminology;
- 3006
3007 (vii) sterile preparation compounding documentation;
- 3008
3009 (viii) quality assurance procedures;
- 3010
3011 (ix) aseptic preparation procedures including proper gowning and gloving technique;
- 3012
3013 (x) handling of hazardous drugs, if applicable;
- 3014
3015 (xi) cleaning procedures; and
- 3016
3017 (xii) general conduct in the clean room.

3018
3019
3020 (E) The aseptic technique of each person compounding or responsible for the direct
3021 supervision of personnel compounding sterile preparations shall be observed and evaluated by
3022 expert personnel as satisfactory through written and practical tests, and challenge testing, and
3023 such evaluation documented. Compounding personnel shall not evaluate their own aseptic
3024 technique or results of their own media-fill challenge testing.

3025
3026 (F) Media-fill tests must be conducted at each pharmacy where an individual compounds low
3027 or medium risk sterile preparations. If pharmacies are under common ownership and control,
3028 the media-fill testing may be conducted at only one of the pharmacies provided each of the
3029 pharmacies are operated under equivalent policies and procedures and the testing is conducted
3030 under the most challenging or stressful conditions. In addition, each pharmacy must maintain
3031 documentation of the media-fill test. No preparation intended for patient use shall be
3032 compounded by an individual until the on-site media-fill tests indicate that the individual can
3033 competently perform aseptic procedures, except that a pharmacist may temporarily compound

3034 sterile preparations and supervise pharmacy technicians compounding sterile preparations
3035 without media-fill tests provided the pharmacist completes the on-site media-fill tests within
3036 seven days of commencing work at the pharmacy.

3037
3038 (G) Media-fill tests must be conducted at each pharmacy where an individual compounds
3039 high risk sterile preparations. No preparation intended for patient use shall be compounded by
3040 an individual until the on-site media-fill tests indicate that the individual can competently perform
3041 aseptic procedures, except that a pharmacist may temporarily compound sterile preparations
3042 and supervise pharmacy technicians compounding sterile preparations without media-fill tests
3043 provided the pharmacist completes the on-site media-fill tests within seven days of commencing
3044 work at the pharmacy.

3045
3046 (H) Media-fill tests procedures for assessing the preparation of specific types of sterile
3047 preparations shall be representative of the most challenging or stressful conditions encountered
3048 by the pharmacy personnel being evaluated and, if applicable, for sterilizing high-risk level
3049 compounded sterile preparations.

3050
3051 (I) Media-fill challenge tests simulating high-risk level compounding shall be used to verify the
3052 capability of the compounding environment and process to produce a sterile preparation.

3053
3054 (J) Commercially available sterile fluid culture media, such as Soybean-Casein Digest
3055 Medium shall be able to promote exponential colonization of bacteria that are most likely to be
3056 transmitted to compounding sterile preparations from the compounding personnel and
3057 environment. Media-filled vials are generally incubated at 20 to 25 degrees Celsius or at 30 to
3058 35 degrees Celsius for a minimum of 14 days. If two temperatures are used for incubation of
3059 media-filled samples, then these filled containers should be incubated for at least 7 days at each
3060 temperature. Failure is indicated by visible turbidity in the medium on or before 14 days.

3061
3062 (K) The pharmacist-in-charge shall ensure continuing competency of pharmacy personnel
3063 through in-service education, training, and media-fill tests to supplement initial training.
3064 Personnel competency shall be evaluated:

3065
3066 (i) during orientation and training prior to the regular performance of those tasks;

3067
3068 (ii) whenever the quality assurance program yields an unacceptable result;

3069
3070 (iii) whenever unacceptable techniques are observed; and

3071
3072 (iv) at least on an annual basis for low- and medium-risk level compounding, and every six
3073 months for high-risk level compounding.

3074
3075 (L) The pharmacist-in-charge shall ensure that proper hand hygiene and garbing practices of
3076 compounding personnel are evaluated prior to compounding, supervising, or verifying sterile
3077 preparations intended for patient use and whenever an aseptic media fill is performed.

3078
3079 (i) Sampling of compounding personnel glove fingertips shall be performed for all risk level
3080 compounding.

3081

3082 (ii) All compounding personnel shall demonstrate competency in proper hand hygiene and
3083 garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces,
3084 routine disinfection of gloved hands).

3085
3086 (iii) Sterile contact agar plates shall be used to sample the gloved fingertips of compounding
3087 personnel after garbing in order to assess garbing competency and after completing the media-
3088 fill preparation (without applying sterile 70% IPA).

3089
3090 (iv) The visual observation shall be documented and maintained to provide a permanent
3091 record and long-term assessment of personnel competency.

3092
3093 (v) All compounding personnel shall successfully complete an initial competency evaluation
3094 and gloved fingertip/thumb sampling procedure no less than three times before initially being
3095 allowed to compound sterile preparations for patient use. Immediately after the compounding
3096 personnel completes the hand hygiene and garbing procedure (i.e., after donning of sterile
3097 gloves and before any disinfecting with sterile 70% IPA), the evaluator will collect a gloved
3098 fingertip and thumb sample from both hands of the compounding personnel onto agar plates or
3099 media test paddles by having the individual lightly touching each fingertip onto the agar. The
3100 test plates or test paddles will be incubated for the appropriate incubation period and at the
3101 appropriate temperature. Results of the initial gloved fingertip evaluations shall indicate zero
3102 colony-forming units (0 CFU) growth on the agar plates or media test paddles, or the test shall
3103 be considered a failure. In the event of a failed gloved fingertip test, the evaluation shall be
3104 repeated until the individual can successfully don sterile gloves and pass the gloved fingertip
3105 evaluation, defined as zero CFUs growth. No preparation intended for patient use shall be
3106 compounded by an individual until the results of the initial gloved fingertip evaluation indicate
3107 that the individual can competently perform aseptic procedures except that a pharmacist may
3108 temporarily supervise pharmacy technicians compounding sterile preparations while waiting for
3109 the results of the evaluation for no more than three days.

3110
3111 (vi) Re-evaluation of all compounding personnel shall occur at least annually for
3112 compounding personnel who compound low and medium risk level preparations and every six
3113 months for compounding personnel who compound high risk level preparations. Results of
3114 gloved fingertip tests conducted immediately after compounding personnel complete a
3115 compounding procedure shall indicate no more than 3 CFUs growth, or the test shall be
3116 considered a failure, in which case, the evaluation shall be repeated until an acceptable test can
3117 be achieved (i.e., the results indicated no more than 3 CFUs growth).

3118
3119 (M) The pharmacist-in-charge shall ensure surface sampling shall be conducted in all ISO
3120 classified areas on a periodic basis. Sampling shall be accomplished using contact plates at the
3121 conclusion of compounding. The sample area shall be gently touched with the agar surface by
3122 rolling the plate across the surface to be sampled.

3123
3124 (5) Documentation of Training. The pharmacy shall maintain a record of the training and
3125 continuing education on each person who compounds sterile preparations. The record shall
3126 contain, at a minimum, a written record of initial and in-service training, education, and the
3127 results of written and practical testing and media-fill testing of pharmacy personnel. The record
3128 shall be maintained and available for inspection by the board and contain the following
3129 information:

3130
3131 (A) name of the person receiving the training or completing the testing or media-fill tests;

3132
3133 (B) date(s) of the training, testing, or media-fill challenge testing;
3134
3135 (C) general description of the topics covered in the training or testing or of the process
3136 validated;
3137
3138 (D) name of the person supervising the training, testing, or media-fill challenge testing; and
3139
3140 (E) signature or initials of the person receiving the training or completing the testing or media-
3141 fill challenge testing and the pharmacist-in-charge or other pharmacist employed by the
3142 pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or
3143 media-fill challenge testing of personnel.
3144
3145 (d) Operational Standards.
3146
3147 (1) General Requirements.
3148
3149 (A) Sterile preparations may be compounded:
3150
3151 (i) upon presentation of a practitioner's prescription drug or medication order based on a
3152 valid pharmacist/patient/prescriber relationship;
3153
3154 (ii) in anticipation of future prescription drug or medication orders based on routine, regularly
3155 observed prescribing patterns; or
3156
3157 (iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.
3158
3159 (B) Sterile compounding in anticipation of future prescription drug or medication orders must
3160 be based upon a history of receiving valid prescriptions issued within an established
3161 pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional
3162 judgment the quantity prepared is stable for the anticipated shelf time.
3163
3164 (i) The pharmacist's professional judgment shall be based on the criteria used to determine
3165 a beyond-use date outlined in paragraph (6)(G) of this subsection.
3166
3167 (ii) Documentation of the criteria used to determine the stability for the anticipated shelf time
3168 must be maintained and be available for inspection.
3169
3170 (iii) Any preparation compounded in anticipation of future prescription drug or medication
3171 orders shall be labeled. Such label shall contain:
3172
3173 (I) name and strength of the compounded preparation or list of the active ingredients and
3174 strengths;
3175
3176 (II) facility's lot number;
3177
3178 (III) beyond-use date as determined by the pharmacist using appropriate documented
3179 criteria as outlined in paragraph (6)(G) of this subsection;
3180
3181 (IV) quantity or amount in the container;

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

(VI) device-specific instructions, where appropriate.

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

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

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

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

(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 individual 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.

(E) A pharmacy may enter into an agreement to compound and 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).

(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.

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

(H) Compounded sterile preparations, including hazardous drugs and radiopharmaceuticals, shall be prepared only under conditions that protect the pharmacy personnel in the preparation and storage areas.

3230 (2) Microbial Contamination Risk Levels. Risk Levels for sterile compounded preparations shall
3231 be as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF
3232 and as listed in this paragraph.

3233
3234 (A) Low-risk level compounded sterile preparations.

3235
3236 (i) Low-Risk conditions. Low-risk level compounded sterile preparations are those
3237 compounded under all of the following conditions.

3238
3239 (I) The compounded sterile preparations are compounded with aseptic manipulations
3240 entirely within ISO Class 5 or better air quality using only sterile ingredients, products,
3241 components, and devices.

3242
3243 (II) The compounding involves only transfer, measuring, and mixing manipulations using
3244 not more than three commercially manufactured packages of sterile products and not more than
3245 two entries into any one sterile container or package (e.g., bag, vial) of sterile product or
3246 administration container/device to prepare the compounded sterile preparation.

3247
3248 (III) Manipulations are limited to aseptically opening ampuls, penetrating disinfected
3249 stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile
3250 syringes to sterile administration devices, package containers of other sterile products, and
3251 containers for storage and dispensing.

3252
3253 (IV) For a low-risk preparation, in the absence of passing a sterility test the storage periods
3254 cannot exceed the following periods: before administration the compounded sterile preparation
3255 is stored properly and are exposed for not more than 48 hours at controlled room temperature,
3256 for not more than 14 days if stored at a cold temperature, and for 45 days if stored in a frozen
3257 state between minus 25 degrees Celsius and minus 10 degrees Celsius. For delayed activation
3258 device systems, the storage period begins when the device is activated.

3259
3260 (ii) Examples of Low-Risk Compounding. Examples of low-risk compounding include the
3261 following.

3262
3263 (I) Single volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials
3264 using sterile syringes with sterile needles, other administration devices, and other sterile
3265 containers. The solution content of ampules shall be passed through a sterile filter to remove
3266 any particles.

3267
3268 (II) Simple aseptic measuring and transferring with not more than three packages of
3269 manufactured sterile products, including an infusion or diluent solution to compound drug
3270 admixtures and nutritional solutions.

3271
3272 (B) Low-Risk Level compounded sterile preparations with 12-hour or less beyond-use date.
3273 Low-risk level compounded sterile preparations are those compounded pursuant to a
3274 physician's order for a specific patient under all of the following conditions.

3275
3276 (i) The compounded sterile preparations are compounded in compounding aseptic isolator
3277 or compounding aseptic containment isolator that does not meet the requirements described in
3278 paragraph (7)(C) or (D) of this subsection (relating to Primary Engineering Control Device) or

3279 the compounded sterile preparations are compounded in laminar airflow workbench or a
3280 biological safety cabinet that cannot be located within the buffer area.

3281
3282 (ii) The primary engineering control device shall be certified and maintain ISO Class 5 for
3283 exposure of critical sites and shall be located in a segregated compounding area restricted to
3284 sterile compounding activities that minimizes the risk of contamination of the compounded
3285 sterile preparation.

3286
3287 (iii) The segregated compounding area shall not be in a location that has unsealed windows
3288 or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites,
3289 warehouses, or food preparation.

3290
3291 (iv) For a low-risk preparation compounded as described in clauses (i) - (iii) of this
3292 subparagraph, administration of such compounded sterile preparations must commence within
3293 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is
3294 less. However, the administration of sterile radiopharmaceuticals, with documented testing of
3295 chemical stability, may be administered beyond 12 hours of preparation.

3296
3297 (C) Medium-risk level compounded sterile preparations.

3298
3299 (i) Medium-Risk Conditions. Medium-risk level compounded sterile preparations, are those
3300 compounded aseptically under low-risk conditions and one or more of the following conditions
3301 exists.

3302
3303 (I) Multiple individual or small doses of sterile products are combined or pooled to prepare
3304 a compounded sterile preparation that will be administered either to multiple patients or to one
3305 patient on multiple occasions.

3306
3307 (II) The compounding process includes complex aseptic manipulations other than the
3308 single-volume transfer.

3309
3310 (III) The compounding process requires unusually long duration, such as that required to
3311 complete the dissolution or homogenous mixing (e.g., reconstitution of intravenous
3312 immunoglobulin or other intravenous protein products).

3313
3314 (IV) The compounded sterile preparations do not contain broad spectrum bacteriostatic
3315 substances and they are administered over several days (e.g., an externally worn infusion
3316 device).

3317
3318 (V) For a medium-risk preparation, in the absence of passing a sterility test the storage
3319 periods cannot exceed the following time periods: before administration, the compounded sterile
3320 preparations are properly stored and are exposed for not more than 30 hours at controlled room
3321 temperature, for not more than 9 days at a cold temperature, and for 45 days in solid frozen
3322 state between minus 25 degrees Celsius and minus 10 degrees Celsius.

3323
3324 (ii) Examples of medium-risk compounding. Examples of medium-risk compounding include
3325 the following.

3326
3327 (I) Compounding of total parenteral nutrition fluids using a manual or automated device
3328 during which there are multiple injections, detachments, and attachments of nutrient source

3329 products to the device or machine to deliver all nutritional components to a final sterile
3330 container.

3331
3332 (II) Filling of reservoirs of injection and infusion devices with more than three sterile drug
3333 products and evacuations of air from those reservoirs before the filled device is dispensed.
3334

3335 (III) Filling of reservoirs of injection and infusion devices with volumes of sterile drug
3336 solutions that will be administered over several days at ambient temperatures between 25 and
3337 40 degrees Celsius (77 and 104 degrees Fahrenheit).
3338

3339 (IV) Transfer of volumes from multiple ampuls or vials into a single, final sterile container or
3340 product.

3341
3342 (D) High-risk level compounded sterile preparations.
3343

3344 (i) High-risk Conditions. High-risk level compounded sterile preparations are those
3345 compounded under any of the following conditions.
3346

3347 (I) Non-sterile ingredients, including manufactured products not intended for sterile routes
3348 of administration (e.g., oral) are incorporated or a non-sterile device is employed before terminal
3349 sterilization.

3350
3351 (II) Any of the following are exposed to air quality worse than ISO Class 5 for more than 1
3352 hour:
3353

3354 (-a-) sterile contents of commercially manufactured products;
3355
3356 (-b-) CSPs that lack effective antimicrobial preservatives; and
3357
3358 (-c-) sterile surfaces of devices and containers for the preparation, transfer, sterilization,
3359 and packaging of CSPs.
3360

3361 (III) Compounding personnel are improperly garbed and gloved.
3362

3363 (IV) Non-sterile water-containing preparations are exposed no more than 6 hours before
3364 being sterilized.
3365

3366 (V) It is assumed, and not verified by examination of labeling and documentation from
3367 suppliers or by direct determination, that the chemical purity and content strength of ingredients
3368 meet their original or compendial specifications in unopened or in opened packages of bulk
3369 ingredients.
3370

3371 (VI) For a sterilized high-risk level preparation, in the absence of passing a sterility test, the
3372 storage periods cannot exceed the following time periods: before administration, the
3373 compounded sterile preparations are properly stored and are exposed for not more than 24
3374 hours at controlled room temperature, for not more than 3 days at a cold temperature, and for
3375 45 days in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius.
3376

3377 (VII) All non-sterile measuring, mixing, and purifying devices are rinsed thoroughly with
3378 sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for

3379 high-risk compounding. All high-risk compounded sterile solutions subjected to terminal
3380 sterilization are prefiltered by passing through a filter with a nominal pore size not larger than
3381 1.2 micron preceding or during filling into their final containers to remove particulate matter.
3382 Sterilization of high-risk level compounded sterile preparations by filtration shall be performed
3383 with a sterile 0.2 micrometer or 0.22 micrometer nominal pore size filter entirely within an ISO
3384 Class 5 or superior air quality environment.

3385
3386 (ii) Examples of high-risk compounding. Examples of high-risk compounding include the
3387 following.

3388
3389 (I) Dissolving non-sterile bulk drug powders to make solutions, which will be terminally
3390 sterilized.

3391
3392 (II) Exposing the sterile ingredients and components used to prepare and package
3393 compounded sterile preparations to room air quality worse than ISO Class 5 for more than one
3394 hour.

3395
3396 (III) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is
3397 performed.

3398
3399 (IV) Assuming, without appropriate evidence or direct determination, that packages of bulk
3400 ingredients contain at least 95% by weight of their active chemical moiety and have not been
3401 contaminated or adulterated between uses.

3402
3403 (3) Immediate Use Compounded Sterile Preparations. For the purpose of emergency or
3404 immediate patient care, such situations may include cardiopulmonary resuscitation, emergency
3405 room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the
3406 compounded sterile preparation under low-risk level conditions would subject the patient to
3407 additional risk due to delays in therapy. Compounded sterile preparations are exempted from
3408 the requirements described in this paragraph for low-risk level compounded sterile preparations
3409 when all of the following criteria are met.

3410
3411 (A) Only simple aseptic measuring and transfer manipulations are performed with not more
3412 than three sterile non-hazardous commercial drug and diagnostic radiopharmaceutical drug
3413 products, including an infusion or diluent solution, from the manufacturers' original containers
3414 and not more than two entries into any one container or package of sterile infusion solution or
3415 administration container/device.

3416
3417 (B) Unless required for the preparation, the compounding procedure occurs continuously
3418 without delays or interruptions and does not exceed 1 hour.

3419
3420 (C) During preparation, aseptic technique is followed and, if not immediately administered,
3421 the finished compounded sterile preparation is under continuous supervision to minimize the
3422 potential for contact with nonsterile surfaces, introduction of particulate matter of biological
3423 fluids, mix-ups with other compounded sterile preparations, and direct contact of outside
3424 surfaces.

3425
3426 (D) Administration begins not later than one hour following the completion of preparing the
3427 compounded sterile preparation.

3428

3429 (E) When the compounded sterile preparations is not administered by the person who
3430 prepared it, or its administration is not witnessed by the person who prepared it, the
3431 compounded sterile preparation shall bear a label listing patient identification information such
3432 as name and identification number(s), the names and amounts of all ingredients, the name or
3433 initials of the person who prepared the compounded sterile preparation, and the exact 1-hour
3434 beyond-use time and date.

3435
3436 (F) If administration has not begun within one hour following the completion of preparing the
3437 compounded sterile preparation, the compounded sterile preparation is promptly and safely
3438 discarded. Immediate use compounded sterile preparations shall not be stored for later use.

3439
3440 (G) Hazardous drugs shall not be prepared as immediate use compounded sterile
3441 preparations.

3442
3443 (4) Single-dose and multiple dose containers.

3444
3445 (A) Opened or needle punctured single-dose containers, such as bags bottles, syringes, and
3446 vials of sterile products shall be used within one hour if opened in worse than ISO Class 5 air
3447 quality. Any remaining contents must be discarded.

3448
3449 (B) Single-dose containers, including single-dose large volume parenteral solutions and
3450 single-dose vials, exposed to ISO Class 5 or cleaner air may be used up to six hours after initial
3451 needle puncture.

3452
3453 (C) Opened single-dose fusion sealed containers shall not be stored for any time period.

3454
3455 (D) Multiple-dose containers may be used up to 28 days after initial needle puncture unless
3456 otherwise specified by the manufacturer.

3457
3458 (5) Library. In addition to the library requirements of the pharmacy's specific license
3459 classification, a pharmacy shall maintain current or updated copies in hard-copy or electronic
3460 format of each of the following:

3461
3462 (A) a reference text on injectable drug preparations, such as Handbook on Injectable Drug
3463 Products;

3464
3465 (B) a specialty reference text appropriate for the scope of pharmacy services provided by the
3466 pharmacy, e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation
3467 of hazardous drugs; and

3468
3469 (C) the United States Pharmacopeia/National Formulary containing USP Chapter 71, Sterility
3470 Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding--Nonsterile
3471 Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile
3472 Preparations, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding; and

3473
3474 (D) any additional USP/NF chapters applicable to the practice of the pharmacy (e.g., USP
3475 Chapter 800, Hazardous Drugs--Handling in Healthcare Settings, USP Chapter 823, Positron
3476 Emission Tomography Drugs for Compounding, Investigational, and Research Uses).

3477

3478 (6) Environment. Compounding facilities shall be physically designed and environmentally
3479 controlled to minimize airborne contamination from contacting critical sites.

3480
3481 (A) Low and Medium Risk Preparations. A pharmacy that prepares low- and medium-risk
3482 preparations shall have a clean room for the compounding of sterile preparations that is
3483 constructed to minimize the opportunities for particulate and microbial contamination. The clean
3484 room shall:

3485
3486 (i) be clean, well lit, and of sufficient size to support sterile compounding activities;

3487
3488 (ii) be maintained at a temperature of 20 degrees Celsius or cooler and at a humidity below
3489 60%;

3490
3491 (iii) be used only for the compounding of sterile preparations;

3492
3493 (iv) be designed such that hand sanitizing and gowning occurs outside the buffer area but
3494 allows hands-free access by compounding personnel to the buffer area;

3495
3496 (v) have non-porous and washable floors or floor covering to enable regular disinfection;

3497
3498 (vi) be ventilated in a manner to avoid disruption from the HVAC system and room cross-
3499 drafts;

3500
3501 (vii) have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth,
3502 impervious, free from cracks and crevices (e.g., coved), non-shedding and resistant to damage
3503 by disinfectant agents;

3504
3505 (viii) have junctures of ceilings to walls coved or caulked to avoid cracks and crevices;

3506
3507 (ix) have drugs and supplies stored on shelving areas above the floor to permit adequate
3508 floor cleaning;

3509
3510 (x) contain only the appropriate compounding supplies and not be used for bulk storage for
3511 supplies and materials. Objects that shed particles shall not be brought into the clean room. A
3512 Class B pharmacy may use low-linting absorbent materials in the primary engineering control
3513 device;

3514
3515 (xi) contain an ante-area that contains a sink with hot and cold running water that enables
3516 hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic
3517 contamination. A Class B pharmacy may have a sink with hot and cold running water that
3518 enables hands-free use with a closed system of soap dispensing immediately outside the ante-
3519 area if antiseptic hand cleansing is performed using a waterless alcohol-based surgical hand
3520 scrub with persistent activity following manufacturers' recommendations once inside the ante-
3521 area; and

3522
3523 (xii) contain a buffer area. The following is applicable for the buffer area.

3524
3525 (l) There shall be some demarcation designation that delineates the ante-area from the
3526 buffer area. The demarcation shall be such that it does not create conditions that could
3527 adversely affect the cleanliness of the area.

3528
3529 (II) The buffer area shall be segregated from surrounding, unclassified spaces to reduce
3530 the risk of contaminants being blown, dragged, or otherwise introduced into the filtered
3531 unidirectional airflow environment, and this segregation should be continuously monitored.
3532
3533 (III) A buffer area that is not physically separated from the ante-area shall employ the
3534 principle of displacement airflow as defined in Chapter 797, Pharmaceutical Compounding--
3535 Sterile Preparations, of the USP/NF, with limited access to personnel.
3536
3537 (IV) The buffer area shall not contain sources of water (i.e., sinks) or floor drains other than
3538 distilled or sterile water introduced for facilitating the use of heat block wells for
3539 radiopharmaceuticals.
3540
3541 (B) High-risk Preparations.
3542
3543 (i) In addition to the requirements in subparagraph (A) of this paragraph, when high-risk
3544 preparations are compounded, the primary engineering control shall be located in a buffer area
3545 that provides a physical separation, through the use of walls, doors and pass-throughs and has
3546 a minimum differential positive pressure of 0.02 to 0.05 inches water column.
3547
3548 (ii) Presterilization procedures for high-risk level compounded sterile preparations, such as
3549 weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.
3550
3551 (C) Automated compounding device.
3552
3553 (i) General. If automated compounding devices are used, the pharmacy shall have a method
3554 to calibrate and verify the accuracy of automated compounding devices used in aseptic
3555 processing and document the calibration and verification on a daily basis, based on the
3556 manufacturer's recommendations, and review the results at least weekly.
3557
3558 (ii) Loading bulk drugs into automated compounding devices.
3559
3560 (I) Automated compounding device may be loaded with bulk drugs only by a pharmacist or
3561 by pharmacy technicians or pharmacy technician trainees under the direction and direct
3562 supervision of a pharmacist.
3563
3564 (II) The label of an automated compounding device container shall indicate the brand name
3565 and strength of the drug; or if no brand name, then the generic name, strength, and name of the
3566 manufacturer or distributor.
3567
3568 (III) Records of loading bulk drugs into an automated compounding device shall be
3569 maintained to show:
3570
3571 (-a-) name of the drug, strength, and dosage form;
3572
3573 (-b-) manufacturer or distributor;
3574
3575 (-c-) manufacturer's lot number;
3576
3577 (-d-) manufacturer's expiration date;

3578
3579 (-e-) quantity added to the automated compounding device;
3580
3581 (-f-) date of loading;
3582
3583 (-g-) name, initials, or electronic signature of the person loading the automated
3584 compounding device; and
3585
3586 (-h-) name, initials, or electronic signature of the responsible pharmacist.
3587
3588 (IV) The automated compounding device shall not be used until a pharmacist verifies that
3589 the system is properly loaded and affixes his or her signature or electronic signature to the
3590 record specified in subclause (III) of this clause.
3591
3592 (D) Hazardous drugs. If the preparation is hazardous, the following is also applicable.
3593
3594 (i) Hazardous drugs shall be prepared only under conditions that protect personnel during
3595 preparation and storage.
3596
3597 (ii) Hazardous drugs shall be stored separately from other inventory in a manner to prevent
3598 contamination and personnel exposure.
3599
3600 (iii) All personnel involved in the compounding of hazardous drugs shall wear appropriate
3601 protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or
3602 dedicated shoes, and appropriate gloving at all times when handling hazardous drugs, including
3603 receiving, distribution, stocking, inventorying, preparation, for administration and disposal.
3604
3605 (iv) Appropriate safety and containment techniques for compounding hazardous drugs shall
3606 be used in conjunction with aseptic techniques required for preparing sterile preparations.
3607
3608 (v) Disposal of hazardous waste shall comply with all applicable local, state, and federal
3609 requirements.
3610
3611 (vi) Prepared doses of hazardous drugs must be dispensed, labeled with proper precautions
3612 inside and outside, and distributed in a manner to minimize patient contact with hazardous
3613 agents.
3614
3615 (E) Blood-labeling procedures. When compounding activities require the manipulation of a
3616 patient's blood-derived material (e.g., radiolabeling a patient's or donor's white blood cells), the
3617 manipulations shall be performed in a ISO Class 5 biological safety cabinet located in a buffer
3618 area and shall be clearly separated from routine material-handling procedures and equipment
3619 used in preparation activities to avoid any cross-contamination. The preparations shall not
3620 require sterilization.
3621
3622 (F) Cleaning and disinfecting the sterile compounding areas. The following cleaning and
3623 disinfecting practices and frequencies apply to direct and contiguous compounding areas, which
3624 include ISO Class 5 compounding areas for exposure of critical sites as well as buffer areas,
3625 ante-areas, and segregated compounding areas.
3626

3627 (i) The pharmacist-in-charge is responsible for developing written procedures for cleaning
3628 and disinfecting the direct and contiguous compounding areas and assuring the procedures are
3629 followed.

3630
3631 (ii) These procedures shall be conducted at the beginning of each work shift, before each
3632 batch preparation is started, when there are spills, and when surface contamination is known or
3633 suspected resulting from procedural breaches, and every 30 minutes during continuous
3634 compounding of individual compounded sterile preparations, unless a particular compounding
3635 procedure requires more than 30 minutes to complete, in which case, the direct compounding
3636 area is to be cleaned immediately after the compounding activity is completed.

3637
3638 (iii) Before compounding is performed, all items shall be removed from the direct and
3639 contiguous compounding areas and all surfaces are cleaned by removing loose material and
3640 residue from spills, followed by an application of a residue-free disinfecting agent (e.g., IPA),
3641 which is allowed to dry before compounding begins. In a Class B pharmacy, objects used in
3642 preparing sterile radiopharmaceuticals (e.g., dose calibrator) which cannot be reasonably
3643 removed from the compounding area shall be sterilized with an application of a residue-free
3644 disinfection agent.

3645
3646 (iv) Work surfaces in the buffer areas and ante-areas, as well as segregated compounding
3647 areas, shall be cleaned and disinfected at least daily. Dust and debris shall be removed when
3648 necessary from storage sites for compounding ingredients and supplies using a method that
3649 does not degrade the ISO Class 7 or 8 air quality.

3650
3651 (v) Floors in the buffer area, ante-area, and segregated compounding area are cleaned by
3652 mopping with a cleaning and disinfecting agent at least once daily when no aseptic operations
3653 are in progress. Mopping shall be performed by trained personnel using approved agents and
3654 procedures described in the written SOPs. It is incumbent on compounding personnel to ensure
3655 that such cleaning is performed properly.

3656
3657 (vi) In the buffer area, ante-area, and segregated compounding area, walls, ceilings, and
3658 shelving shall be cleaned and disinfected monthly. Cleaning and disinfecting agents shall be
3659 used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic
3660 residues.

3661
3662 (vii) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding, and
3663 dedicated to use in the buffer area, ante-area, and segregated compounding areas and shall not
3664 be removed from these areas except for disposal. Floor mops may be used in both the buffer
3665 area and ante-area, but only in that order. If cleaning materials are reused, procedures shall be
3666 developed that ensure that the effectiveness of the cleaning device is maintained and that
3667 repeated use does not add to the bio-burden of the area being cleaned.

3668
3669 (viii) Supplies and equipment removed from shipping cartons must be wiped with a
3670 disinfecting agent, such as sterile IPA. After the disinfectant is sprayed or wiped on a surface to
3671 be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be
3672 used for compounding purposes. However, if sterile supplies are received in sealed pouches,
3673 the pouches may be removed as the supplies are introduced into the ISO Class 5 area without
3674 the need to disinfect the individual sterile supply items. No shipping or other external cartons
3675 may be taken into the buffer area or segregated compounding area.

3676

3677 (ix) Storage shelving emptied of all supplies, walls, and ceilings are cleaned and disinfected
3678 at planned intervals, monthly, if not more frequently.

3679
3680 (x) Cleaning must be done by personnel trained in appropriate cleaning techniques.

3681
3682 (xi) Proper documentation and frequency of cleaning must be maintained and shall contain
3683 the following:

3684
3685 (I) date and time of cleaning;

3686
3687 (II) type of cleaning performed; and

3688
3689 (III) name of individual who performed the cleaning.

3690
3691 (G) Security requirements. The pharmacist-in-charge may authorize personnel to gain access
3692 to that area of the pharmacy containing dispensed sterile preparations, in the absence of the
3693 pharmacist, for the purpose of retrieving dispensed prescriptions to deliver to patients. If the
3694 pharmacy allows such after-hours access, the area containing the dispensed sterile
3695 preparations shall be an enclosed and lockable area separate from the area containing
3696 undispensed prescription drugs. A list of the authorized personnel having such access shall be
3697 in the pharmacy's policy and procedure manual.

3698
3699 (H) Storage requirements and beyond-use dating.

3700
3701 (i) Storage requirements. All drugs shall be stored at the proper temperature and conditions,
3702 as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).

3703
3704 (ii) Beyond-use dating.

3705
3706 (I) Beyond-use dates for compounded sterile preparations shall be assigned based on
3707 professional experience, which shall include careful interpretation of appropriate information
3708 sources for the same or similar formulations.

3709
3710 (II) Beyond-use dates for compounded sterile preparations that are prepared strictly in
3711 accordance with manufacturers' product labeling must be those specified in that labeling, or
3712 from appropriate literature sources or direct testing.

3713
3714 (III) When assigning a beyond-use date, compounding personnel shall consult and apply
3715 drug-specific and general stability documentation and literature where available, and they
3716 should consider the nature of the drug and its degradation mechanism, the container in which it
3717 is packaged, the expected storage conditions, and the intended duration of therapy.

3718
3719 (IV) The sterility and storage and stability beyond-use date for attached and activated
3720 container pairs of drug products for intravascular administration shall be applied as indicated by
3721 the manufacturer.

3722
3723 (7) Primary engineering control device. The pharmacy shall prepare sterile preparations in a
3724 primary engineering control device (PEC), such as a laminar air flow hood, biological safety
3725 cabinet, compounding aseptic isolator (CAI), or compounding aseptic containment isolator

3726 (CACI) which is capable of maintaining at least ISO Class 5 conditions for 0.5 micrometer
3727 particles while compounding sterile preparations.

3728
3729 (A) Laminar air flow hood. If the pharmacy is using a laminar air flow hood as its PEC, the
3730 laminar air flow hood shall:

3731
3732 (i) be located in the buffer area and placed in the buffer area in a manner as to avoid
3733 conditions that could adversely affect its operation such as strong air currents from opened
3734 doors, personnel traffic, or air streams from the heating, ventilating and air condition system;

3735
3736 (ii) be certified by a qualified independent contractor according to the appropriate Controlled
3737 Environment Testing Association (CETA) standard (CAG-003-2006) for operational efficiency at
3738 least every six months and whenever the device or room is relocated or altered or major service
3739 to the facility is performed;

3740
3741 (iii) have pre-filters inspected periodically and replaced as needed, in accordance with
3742 written policies and procedures and the manufacturer's specification, and the inspection and/or
3743 replacement date documented; and

3744
3745 (iv) be located in a buffer area that has a minimum differential positive pressure of 0.02 to
3746 0.05 inches water column. A buffer area that is not physically separated from the ante-area shall
3747 employ the principle of displacement airflow as defined in Chapter 797, Pharmaceutical
3748 Compounding--Sterile Preparations, of the USP/NF, with limited access to personnel.

3749
3750 (B) Biological safety cabinet.

3751
3752 (i) If the pharmacy is using a biological safety cabinet as its PEC for the preparation of
3753 hazardous sterile compounded preparations, the biological safety cabinet shall be a Class II or
3754 III vertical flow biological safety cabinet located in an ISO Class 7 area that is physically
3755 separated from other preparation areas. The area for preparation of sterile chemotherapeutic
3756 preparations shall:

3757
3758 (I) have not less than 0.01 inches water column negative pressure to the adjacent positive
3759 pressure ISO Class 7 or better ante-area; and

3760
3761 (II) have a pressure indicator that can be readily monitored for correct room pressurization.

3762
3763 (ii) Pharmacies that prepare a low volume of hazardous drugs, are not required to comply
3764 with the provisions of clause (i) of this subparagraph if the pharmacy uses a device that
3765 provides two tiers of containment (e.g., closed-system vial transfer device within a BSC).

3766
3767 (iii) If the pharmacy is using a biological safety cabinet as its PEC for the preparation of non-
3768 hazardous sterile compounded preparations, the biological safety cabinet shall:

3769
3770 (I) be located in the buffer area and placed in the buffer area in a manner as to avoid
3771 conditions that could adversely affect its operation such as strong air currents from opened
3772 doors, personnel traffic, or air streams from the heating, ventilating and air condition system;

3773
3774 (II) be certified by a qualified independent contractor according to the International
3775 Organization of Standardization (ISO) Classification of Particulate Matter in Room Air (ISO

3776 14644-1) for operational efficiency at least every six months and whenever the device or room is
3777 relocated or altered or major service to the facility is performed, in accordance with the
3778 manufacturer's specifications and test procedures specified in the Institute of Environmental
3779 Sciences and Technology (IEST) document IEST-RP-CC002.3;

3780

3781 (III) have pre-filters inspected periodically and replaced as needed, in accordance with
3782 written policies and procedures and the manufacturer's specification, and the inspection and/or
3783 replacement date documented; and

3784

3785 (IV) be located in a buffer area that has a minimum differential positive pressure of 0.02 to
3786 0.05 inches water column.

3787

3788 (C) Compounding aseptic isolator.

3789

3790 (i) If the pharmacy is using a compounding aseptic isolator (CAI) as its PEC, the CAI shall
3791 provide unidirectional airflow within the main processing and antechambers, and be placed in an
3792 ISO Class 7 buffer area unless the isolator meets all of the following conditions:

3793

3794 (I) The isolator must provide isolation from the room and maintain ISO Class 5 during
3795 dynamic operating conditions including transferring ingredients, components, and devices into
3796 and out of the isolator and during preparation of compounded sterile preparations.

3797

3798 (II) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure
3799 site must maintain ISO Class 5 levels during compounding operations.

3800

3801 (III) The CAI must be validated according to CETA CAG-002-2006 standards.

3802

3803 (IV) The pharmacy shall maintain documentation from the manufacturer that the isolator
3804 meets this standard when located in worse than ISO Class 7 environments.

3805

3806 (ii) If the isolator meets the requirements in clause (i) of this subparagraph, the CAI may be
3807 placed in a non-ISO classified area of the pharmacy; however, the area shall be segregated
3808 from other areas of the pharmacy and shall:

3809

3810 (I) be clean, well lit, and of sufficient size;

3811

3812 (II) be used only for the compounding of low- and medium-risk, non-hazardous sterile
3813 preparations;

3814

3815 (III) be located in an area of the pharmacy with non-porous and washable floors or floor
3816 covering to enable regular disinfection; and

3817

3818 (IV) be an area in which the CAI is placed in a manner as to avoid conditions that could
3819 adversely affect its operation.

3820

3821 (iii) In addition to the requirements specified in clauses (i) and (ii) of this subparagraph, if the
3822 CAI is used in the compounding of high-risk non-hazardous preparations, the CAI shall be
3823 placed in an area or room with at least ISO 8 quality air so that high-risk powders weighed in at
3824 least ISO-8 air quality conditions, compounding utensils for measuring and other compounding

3825 equipment are not exposed to lesser air quality prior to the completion of compounding and
3826 packaging of the high-risk preparation.

3827
3828 (D) Compounding aseptic containment isolator.

3829
3830 (i) If the pharmacy is using a compounding aseptic containment isolator as its PEC for the
3831 preparation of low- and medium-risk hazardous drugs, the CACI shall be located in a separate
3832 room away from other areas of the pharmacy and shall:

3833
3834 (I) provide at least 0.01 inches water column negative pressure compared to the other
3835 areas of the pharmacy;

3836
3837 (II) provide unidirectional airflow within the main processing and antechambers, and be
3838 placed in an ISO Class 7 buffer area, unless the CACI meets all of the following conditions.

3839
3840 (-a-) The isolator must provide isolation from the room and maintain ISO Class 5 during
3841 dynamic operating conditions including transferring ingredients, components, and devices into
3842 and out of the isolator and during preparation of compounded sterile preparations.

3843
3844 (-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical
3845 exposure site must maintain ISO Class 5 levels during compounding operations.

3846
3847 (-c-) The CACI must be validated according to CETA CAG-002-2006 standards.

3848
3849 (-d-) The pharmacy shall maintain documentation from the manufacturer that the isolator
3850 meets this standard when located in worse than ISO Class 7 environments.

3851
3852 (ii) If the CACI meets all conditions specified in clause (i) of this subparagraph, the CACI
3853 shall not be located in the same room as a CAI, but shall be located in a separate room in the
3854 pharmacy, that is not required to maintain ISO classified air. The room in which the CACI is
3855 located shall provide a minimum of 0.01 inches water column negative pressure compared with
3856 the other areas of the pharmacy and shall meet the following requirements:

3857
3858 (I) be clean, well lit, and of sufficient size;

3859
3860 (II) be maintained at a temperature of 20 degrees Celsius or cooler and a humidity below
3861 60%;

3862
3863 (III) be used only for the compounding of hazardous sterile preparations;

3864
3865 (IV) be located in an area of the pharmacy with walls, ceilings, floors, fixtures, shelving,
3866 counters, and cabinets that are smooth, impervious, free from cracks and crevices, non-
3867 shedding and resistant to damage by disinfectant agents; and

3868
3869 (V) have non-porous and washable floors or floor covering to enable regular disinfection.

3870
3871 (iii) If the CACI is used in the compounding of high-risk hazardous preparations, the CACI
3872 shall be placed in an area or room with at least ISO 8 quality air so that high-risk powders,
3873 weighed in at least ISO-8 air quality conditions, are not exposed to lesser air quality prior to the
3874 completion of compounding and packaging of the high-risk preparation.

3875
3876 (iv) Pharmacies that prepare a low volume of hazardous drugs, are not required to comply
3877 with the provisions of clauses (i) and (iii) of this subparagraph if the pharmacy uses a device
3878 that provides two tiers of containment (e.g., CACI that is located in a non-negative pressure
3879 room).

3880
3881 (8) Additional Equipment and Supplies. Pharmacies compounding sterile preparations shall
3882 have the following equipment and supplies:

3883
3884 (A) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure
3885 that proper storage requirements are met, if sterile preparations are stored in the refrigerator;
3886

3887 (B) a calibrated system or device to monitor the temperature where bulk chemicals are
3888 stored;
3889

3890 (C) a temperature-sensing mechanism suitably placed in the controlled temperature storage
3891 space to reflect accurately the true temperature;
3892

3893 (D) if applicable, a Class A prescription balance, or analytical balance and weights. Such
3894 balance shall be properly maintained and subject to periodic inspection by the Texas State
3895 Board of Pharmacy;
3896

3897 (E) equipment and utensils necessary for the proper compounding of sterile preparations.
3898 Such equipment and utensils used in the compounding process shall be:
3899

3900 (i) of appropriate design, appropriate capacity, and be operated within designed operational
3901 limits;
3902

3903 (ii) of suitable composition so that surfaces that contact components, in-process material, or
3904 drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity,
3905 strength, quality, or purity of the drug preparation beyond the desired result;
3906

3907 (iii) cleaned and sanitized immediately prior to and after each use; and
3908

3909 (iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;
3910

3911 (F) appropriate disposal containers for used needles, syringes, etc., and if applicable,
3912 hazardous waste from the preparation of hazardous drugs and/or biohazardous waste;
3913

3914 (G) appropriate packaging or delivery containers to maintain proper storage conditions for
3915 sterile preparations;
3916

3917 (H) infusion devices, if applicable; and
3918

3919 (I) all necessary supplies, including:
3920

3921 (i) disposable needles, syringes, and other supplies for aseptic mixing;
3922

3923 (ii) disinfectant cleaning solutions;
3924

- 3925 (iii) sterile 70% isopropyl alcohol;
- 3926
- 3927 (iv) sterile gloves, both for hazardous and non-hazardous drug compounding;
- 3928
- 3929 (v) sterile alcohol-based or water-less alcohol based surgical scrub;
- 3930
- 3931 (vi) hand washing agents with bactericidal action;
- 3932
- 3933 (vii) disposable, lint free towels or wipes;
- 3934
- 3935 (viii) appropriate filters and filtration equipment;
- 3936
- 3937 (ix) hazardous spill kits, if applicable; and
- 3938
- 3939 (x) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.
- 3940

3941 (9) Labeling.

3942

3943 (A) Prescription drug or medication orders. In addition to the labeling requirements for the

3944 pharmacy's specific license classification, the label dispensed or distributed pursuant to a

3945 prescription drug or medication order shall contain the following:

3946

3947 (i) the generic name(s) or the official name(s) of the principal active ingredient(s) of the

3948 compounded sterile preparation;

3949

3950 (ii) for outpatient prescription orders other than sterile radiopharmaceuticals, a statement

3951 that the compounded sterile preparation has been compounded by the pharmacy. (An auxiliary

3952 label may be used on the container to meet this requirement);

3953

3954 (iii) a beyond-use date. The beyond-use date shall be determined as outlined in Chapter

3955 797, Pharmacy Compounding--Sterile Preparations of the USP/NF, and paragraph (7)(G) of this

3956 subsection;

3957

3958 (B) Batch. If the sterile preparation is compounded in a batch, the following shall also be

3959 included on the batch label:

3960

3961 (i) unique lot number assigned to the batch;

3962

3963 (ii) quantity;

3964

3965 (iii) appropriate ancillary instructions, such as storage instructions or cautionary statements,

3966 including hazardous drug warning labels where appropriate; and

3967

3968 (iv) device-specific instructions, where appropriate.

3969

3970 (C) Pharmacy bulk package. The label of a pharmacy bulk package shall:

3971

3972 (i) state prominently "Pharmacy Bulk Package--Not for Direct Infusion;"

3973

3974 (ii) contain or refer to information on proper techniques to help ensure safe use of the
3975 preparation; and
3976

3977 (iii) bear a statement limiting the time frame in which the container may be used once it has
3978 been entered, provided it is held under the labeled storage conditions.
3979

3980 (10) Written drug information for prescription drug orders only. Written information about the
3981 compounded preparation or its major active ingredient(s) shall be given to the patient at the time
3982 of dispensing a prescription drug order. A statement which indicates that the preparation was
3983 compounded by the pharmacy must be included in this written information. If there is no written
3984 information available, the patient shall be advised that the drug has been compounded and how
3985 to contact a pharmacist, and if appropriate, the prescriber, concerning the drug. This paragraph
3986 does not apply to the preparation of radiopharmaceuticals.
3987

3988 (11) Pharmaceutical Care Services. In addition to the pharmaceutical care requirements for the
3989 pharmacy's specific license classification, the following requirements for sterile preparations
3990 compounded pursuant to prescription drug orders must be met. This paragraph does not apply
3991 to the preparation of radiopharmaceuticals.
3992

3993 (A) Primary provider. There shall be a designated physician primarily responsible for the
3994 patient's medical care. There shall be a clear understanding between the physician, the patient,
3995 and the pharmacy of the responsibilities of each in the areas of the delivery of care, and the
3996 monitoring of the patient. This shall be documented in the patient medication record (PMR).
3997

3998 (B) Patient training. The pharmacist-in-charge shall develop policies to ensure that the patient
3999 and/or patient's caregiver receives information regarding drugs and their safe and appropriate
4000 use, including instruction when applicable, regarding:

4001 (i) appropriate disposition of hazardous solutions and ancillary supplies;

4002 (ii) proper disposition of controlled substances in the home;

4003 (iii) self-administration of drugs, where appropriate;

4004 (iv) emergency procedures, including how to contact an appropriate individual in the event of
4005 problems or emergencies related to drug therapy; and
4006

4007 (v) if the patient or patient's caregiver prepares sterile preparations in the home, the
4008 following additional information shall be provided:
4009

4010 (I) safeguards against microbial contamination, including aseptic techniques for
4011 compounding intravenous admixtures and aseptic techniques for injecting additives to premixed
4012 intravenous solutions;
4013

4014 (II) appropriate storage methods, including storage durations for sterile pharmaceuticals
4015 and expirations of self-mixed solutions;
4016

4017 (III) handling and disposition of premixed and self-mixed intravenous admixtures; and
4018
4019
4020
4021
4022

4023 (IV) proper disposition of intravenous admixture compounding supplies such as syringes,
4024 vials, ampules, and intravenous solution containers.

4025
4026 (C) Pharmacist-patient relationship. It is imperative that a pharmacist-patient relationship be
4027 established and maintained throughout the patient's course of therapy. This shall be
4028 documented in the patient's medication record (PMR).

4029
4030 (D) Patient monitoring. The pharmacist-in-charge shall develop policies to ensure that:

4031
4032 (i) the patient's response to drug therapy is monitored and conveyed to the appropriate
4033 health care provider;

4034
4035 (ii) the first dose of any new drug therapy is administered in the presence of an individual
4036 qualified to monitor for and respond to adverse drug reactions; and

4037
4038 (iii) reports of adverse events with a compounded sterile preparation are reviewed promptly
4039 and thoroughly to correct and prevent future occurrences.

4040
4041 (12) Drugs, components, and materials used in sterile compounding.

4042
4043 (A) Drugs used in sterile compounding shall be a USP/NF grade substances manufactured in
4044 an FDA-registered facility.

4045
4046 (B) If USP/NF grade substances are not available shall be of a chemical grade in one of the
4047 following categories:

4048
4049 (i) Chemically Pure (CP);

4050
4051 (ii) Analytical Reagent (AR);

4052
4053 (iii) American Chemical Society (ACS); or

4054
4055 (iv) Food Chemical Codex.

4056
4057 (C) If a drug, component or material is not purchased from a FDA-registered facility, the
4058 pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the
4059 supplier and the pharmacist shall compare the monograph of drugs in a similar class to the
4060 Certificate of Analysis.

4061
4062 (D) All components shall:

4063
4064 (i) be manufactured in an FDA-registered facility; or

4065
4066 (ii) in the professional judgment of the pharmacist, be of high quality and obtained from
4067 acceptable and reliable alternative sources; and

4068
4069 (iii) stored in properly labeled containers in a clean, dry area, under proper temperatures.

4070

4071 (E) Drug preparation containers and closures shall not be reactive, additive, or absorptive so
4072 as to alter the safety, identity, strength, quality, or purity of the compounded drug preparation
4073 beyond the desired result.

4074
4075 (F) Components, drug preparation containers, and closures shall be rotated so that the oldest
4076 stock is used first.

4077
4078 (G) Container closure systems shall provide adequate protection against foreseeable external
4079 factors in storage and use that can cause deterioration or contamination of the compounded
4080 drug preparation.

4081
4082 (H) A pharmacy may not compound a preparation that contains ingredients appearing on a
4083 federal Food and Drug Administration list of drug products withdrawn or removed from the
4084 market for safety reasons.

4085
4086 (13) Compounding process.

4087
4088 (A) Standard operating procedures (SOPs). All significant procedures performed in the
4089 compounding area shall be covered by written SOPs designed to ensure accountability,
4090 accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall
4091 be developed and implemented for:

- 4092 (i) the facility;
4093
4094 (ii) equipment;
4095
4096 (iii) personnel;
4097
4098 (iv) preparation evaluation;
4099
4100 (v) quality assurance;
4101
4102 (vi) preparation recall;
4103
4104 (vii) packaging; and
4105
4106 (viii) storage of compounded sterile preparations.

4107
4108
4109 (B) USP/NF. Any compounded formulation with an official monograph in the USP/NF shall be
4110 compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

4111
4112 (C) Personnel Cleansing and Garbing.

4113
4114 (i) Any person with an apparent illness or open lesion, including rashes, sunburn, weeping
4115 sores, conjunctivitis, and active respiratory infection, that may adversely affect the safety or
4116 quality of a drug preparation being compounded shall be excluded from working in ISO Class 5,
4117 ISO Class 7, and ISO Class 8 compounding areas until the condition is remedied.

4118
4119 (ii) Before entering the buffer area, compounding personnel must remove the following:
4120

4121 (I) personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters,
4122 vests);
4123
4124 (II) all cosmetics, because they shed flakes and particles; and
4125
4126 (III) all hand, wrist, and other body jewelry or piercings (e.g., earrings, lip or eyebrow
4127 piercings) that can interfere with the effectiveness of personal protective equipment (e.g., fit of
4128 gloves and cuffs of sleeves).
4129
4130 (iii) The wearing of artificial nails or extenders is prohibited while working in the sterile
4131 compounding environment. Natural nails shall be kept neat and trimmed.
4132
4133 (iv) Personnel shall don personal protective equipment and perform hand hygiene in an
4134 order that proceeds from the dirtiest to the cleanest activities as follows:
4135
4136 (I) Activities considered the dirtiest include donning of dedicated shoes or shoe covers,
4137 head and facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye
4138 shield. Eye shields are optional unless working with irritants like germicidal disinfecting agents
4139 or when preparing hazardous drugs.
4140
4141 (II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face
4142 masks, personnel shall perform a hand hygiene procedure by removing debris from underneath
4143 fingernails using a nail cleaner under running warm water followed by vigorous hand washing.
4144 Personnel shall begin washing arms at the hands and continue washing to elbows for at least
4145 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in
4146 the ante-area. Hands and forearms to the elbows shall be completely dried using lint-free
4147 disposable towels, an electronic hands-free hand dryer, or a HEPA filtered hand dryer.
4148
4149 (III) After completion of hand washing, personnel shall don clean non-shedding gowns with
4150 sleeves that fit snugly around the wrists and enclosed at the neck.
4151
4152 (IV) Once inside the buffer area or segregated compounding area, and prior to donning
4153 sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless
4154 alcohol-based surgical hand scrub with persistent activity following manufacturers'
4155 recommendations. Hands shall be allowed to dry thoroughly before donning sterile gloves.
4156
4157 (V) Sterile gloves that form a continuous barrier with the gown shall be the last item
4158 donned before compounding begins. Sterile gloves shall be donned using proper technique to
4159 ensure the sterility of the glove is not compromised while donning. The cuff of the sterile glove
4160 shall cover the cuff of the gown at the wrist. When preparing hazardous preparations, the
4161 compounder shall double glove or shall use single gloves ensuring that the gloves are sterile
4162 powder-free chemotherapy-rated gloves. Routine application of sterile 70% IPA shall occur
4163 throughout the compounding day and whenever non-sterile surfaces are touched.
4164
4165 (v) When compounding personnel shall temporarily exit the buffer area during a work shift,
4166 the exterior gown, if not visibly soiled, may be removed and retained in the ante-area, to be re-
4167 donned during that same work shift only. However, shoe covers, hair and facial hair covers, face
4168 mask/eye shield, and gloves shall be replaced with new ones before re-entering the buffer area
4169 along with performing proper hand hygiene.
4170

4171 (vi) During high-risk compounding activities that precede terminal sterilization, such as
4172 weighing and mixing of non-sterile ingredients, compounding personnel shall be garbed and
4173 gloved the same as when performing compounding in an ISO Class 5 environment. Properly
4174 garbed and gloved compounding personnel who are exposed to air quality that is either known
4175 or suspected to be worse than ISO Class 7 shall re-garb personal protective equipment along
4176 with washing their hands properly, performing antiseptic hand cleansing with a sterile 70% IPA-
4177 based or another suitable sterile alcohol-based surgical hand scrub, and donning sterile gloves
4178 upon re-entering the ISO Class 7 buffer area.

4179
4180 (vii) When compounding aseptic isolators or compounding aseptic containment isolators are
4181 the source of the ISO Class 5 environment, at the start of each new compounding procedure, a
4182 new pair of sterile gloves shall be donned within the CAI or CACI. In addition, the compounding
4183 personnel should follow the requirements as specified in this subparagraph, unless the isolator
4184 manufacturer can provide written documentation based on validated environmental testing that
4185 any components of personal protective equipment or cleansing are not required.

4186
4187 (14) Quality Assurance.

4188
4189 (A) Initial Formula Validation. Prior to routine compounding of a sterile preparation, a
4190 pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding
4191 a preparation that is sterile and that contains the stated amount of active ingredient(s).

4192 (i) Low risk preparations.

4193 (I) Quality assurance practices include, but are not limited to the following:

4194
4195 (-a-) Routine disinfection and air quality testing of the direct compounding environment to
4196 minimize microbial surface contamination and maintain ISO Class 5 air quality.

4197 (-b-) Visual confirmation that compounding personnel are properly donning and wearing
4198 appropriate items and types of protective garments and goggles.

4199 (-c-) Review of all orders and packages of ingredients to ensure that the correct identity
4200 and amounts of ingredients were compounded.

4201 (-d-) Visual inspection of compounded sterile preparations, except for sterile
4202 radiopharmaceuticals, to ensure the absence of particulate matter in solutions, the absence of
4203 leakage from vials and bags, and the accuracy and thoroughness of labeling.

4204 (II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at
4205 least annually by each person authorized to compound in a low-risk level under conditions that
4206 closely simulate the most challenging or stressful conditions encountered during compounding
4207 of low-risk level sterile preparations. Once begun, this test is completed without interruption
4208 within an ISO Class 5 air quality environment. Three sets of four 5-milliliter aliquots of sterile
4209 Soybean-Casein Digest Medium are transferred with the same sterile 10-milliliter syringe and
4210 vented needle combination into separate sealed, empty, sterile 30-milliliter clear vials (i.e., four
4211 5-milliliter aliquots into each of three 30-milliliter vials). Sterile adhesive seals are aseptically
4212 affixed to the rubber closures on the three filled vials. The vials are incubated within a range of
4213 20 - 35 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the
4214 medium on or before 14 days. The media-fill test must include a positive-control sample.

4221
4222 (ii) Medium risk preparations.

4223
4224 (I) Quality assurance procedures for medium-risk level compounded sterile preparations
4225 include all those for low-risk level compounded sterile preparations, as well as a more
4226 challenging media-fill test passed annually, or more frequently.

4227
4228 (II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at
4229 least annually under conditions that closely simulate the most challenging or stressful conditions
4230 encountered during compounding. This test is completed without interruption within an ISO
4231 Class 5 air quality environment. Six 100-milliliter aliquots of sterile Soybean-Casein Digest
4232 Medium are aseptically transferred by gravity through separate tubing sets into separate
4233 evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile
4234 10-milliliter syringe and 18-gauge needle combination is used to exchange two 5-milliliter
4235 aliquots of medium from one container to the other container in the pair. For example, after a 5-
4236 milliliter aliquot from the first container is added to the second container in the pair, the second
4237 container is agitated for 10 seconds, then a 5-milliliter aliquot is removed and returned to the
4238 first container in the pair. The first container is then agitated for 10 seconds, and the next 5-
4239 milliliter aliquot is transferred from it back to the second container in the pair. Following the two
4240 5-milliliter aliquot exchanges in each pair of containers, a 5-milliliter aliquot of medium from each
4241 container is aseptically injected into a sealed, empty, sterile 10-milliliter clear vial, using a sterile
4242 10-milliliter syringe and vented needle. Sterile adhesive seals are aseptically affixed to the
4243 rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35
4244 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the medium
4245 on or before 14 days. The media-fill test must include a positive-control sample.

4246
4247 (iii) High risk preparations.

4248
4249 (I) Procedures for high-risk level compounded sterile preparations include all those for low-
4250 risk level compounded sterile preparations. In addition, a media-fill test that represents high-risk
4251 level compounding is performed twice a year by each person authorized to compound high-risk
4252 level compounded sterile preparations.

4253
4254 (II) Example of a Media-Fill Test Procedure Compounded Sterile Preparations Sterilized by
4255 Filtration. This test, or an equivalent test, is performed under conditions that closely simulate the
4256 most challenging or stressful conditions encountered when compounding high-risk level
4257 compounded sterile preparations. Note: Sterility tests for autoclaved compounded sterile
4258 preparations are not required unless they are prepared in batches of more than 25 units. This
4259 test is completed without interruption in the following sequence:

4260
4261 (-a-) Dissolve 3 grams of non-sterile commercially available Soybean-Casein Digest
4262 Medium in 100 milliliters of non-bacteriostatic water to make a 3% non-sterile solution.

4263
4264 (-b-) Draw 25 milliliters of the medium into each of three 30-milliliter sterile syringes.
4265 Transfer 5 milliliters from each syringe into separate sterile 10-milliliter vials. These vials are the
4266 positive controls to generate exponential microbial growth, which is indicated by visible turbidity
4267 upon incubation.

4268
4269 (-c-) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron
4270 porosity filter unit and a 20-gauge needle to each syringe. Inject the next 10 milliliters from each

4271 syringe into three separate 10-milliliter sterile vials. Repeat the process for three more vials.
4272 Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at
4273 20 to 35 degrees Celsius for a minimum of 14 days. Inspect for microbial growth over 14 days
4274 as described in Chapter 797 Pharmaceutical Compounding--Sterile Preparations, of the
4275 USP/NF.

4276
4277 (III) Filter Integrity Testing. Filters need to undergo testing to evaluate the integrity of filters
4278 used to sterilize high-risk preparations, such as Bubble Point Testing or comparable filter
4279 integrity testing. Such testing is not a replacement for sterility testing and shall not be interpreted
4280 as such. Such test shall be performed after a sterilization procedure on all filters used to sterilize
4281 each high-risk preparation or batch preparation and the results documented. The results should
4282 be compared with the filter manufacturer's specification for the specific filter used. If a filter fails
4283 the integrity test, the preparation or batch must be sterilized again using new unused filters.

4284
4285 (B) Finished preparation release checks and tests.

4286
4287 (i) All high-risk level compounded sterile preparations that are prepared in groups of more
4288 than 25 identical individual single-dose packages (such as ampuls, bags, syringes, and vials), or
4289 in multiple dose vials for administration to multiple patients, or are exposed longer than 12 hours
4290 at 2 - 8 degrees Celsius and longer than six hours at warmer than 8 degrees Celsius before
4291 they are sterilized shall be tested to ensure they are sterile and do not contain excessive
4292 bacterial endotoxins as specified in Chapter 71, Sterility Tests of the USP/NF before being
4293 dispensed or administered.

4294
4295 (ii) All compounded sterile preparations, except for sterile radiopharmaceuticals, that are
4296 intended to be solutions must be visually examined for the presence of particulate matter and
4297 not administered or dispensed when such matter is observed.

4298
4299 (iii) The prescription drug and medication orders, written compounding procedure,
4300 preparation records, and expended materials used to make compounded sterile preparations at
4301 all contamination risk levels shall be inspected for accuracy of correct identities and amounts of
4302 ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical
4303 appearance before they are dispensed or administered.

4304
4305 (iv) Written procedures for checking compounding accuracy shall be followed for every
4306 compounded sterile preparation during preparation, in accordance with pharmacy's policies and
4307 procedures, and immediately prior to release, including label accuracy and the accuracy of the
4308 addition of all drug products or ingredients used to prepare the finished preparation and their
4309 volumes or quantities. A pharmacist shall ensure that components used in compounding are
4310 accurately weighed, measured, or subdivided as appropriate to conform to the formula being
4311 prepared.

4312
4313 (C) Environmental Testing.

4314
4315 (i) Viable and nonviable environmental sampling testing. Environmental sampling shall
4316 occur, at a minimum, every six months as part of a comprehensive quality management
4317 program and under any of the following conditions:

4318
4319 (l) as part of the commissioning and certification of new facilities and equipment;

4320

4321 (II) following any servicing of facilities and equipment;
4322
4323 (III) as part of the re-certification of facilities and equipment;
4324
4325 (IV) in response to identified problems with end products or staff technique; or
4326
4327 (V) in response to issues with compounded sterile preparations, observed compounding
4328 personnel work practices, or patient-related infections (where the compounded sterile
4329 preparation is being considered as a potential source of the infection).
4330
4331 (ii) Total particle counts. Certification that each ISO classified area (e.g., ISO Class 5, 7, and
4332 8), is within established guidelines shall be performed no less than every six months and
4333 whenever the equipment is relocated or the physical structure of the buffer area or ante-area
4334 has been altered. All certification records shall be maintained and reviewed to ensure that the
4335 controlled environments comply with the proper air cleanliness, room pressures, and air
4336 changes per hour. Testing shall be performed by qualified operators using current, state-of-the-
4337 art equipment, with results of the following:
4338
4339 (I) ISO Class 5 - not more than 3520 particles 0.5 micrometer and larger size per cubic
4340 meter of air;
4341
4342 (II) ISO Class 7 - not more than 352,000 particles of 0.5 micrometer and larger size per
4343 cubic meter of air for any buffer area; and
4344
4345 (III) ISO Class 8 - not more than 3,520,000 particles of 0.5 micrometer and larger size per
4346 cubic meter of air for any ante-area.
4347
4348 (iii) Pressure differential monitoring. A pressure gauge or velocity meter shall be installed to
4349 monitor the pressure differential or airflow between the buffer area and the ante-area and
4350 between the ante-area and the general environment outside the compounding area. The results
4351 shall be reviewed and documented on a log at least every work shift (minimum frequency shall
4352 be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 or
4353 ISO Class 8 and the general pharmacy area shall not be less than 0.02 inch water column.
4354
4355 (iv) Sampling plan. An appropriate environmental sampling plan shall be developed for
4356 airborne viable particles based on a risk assessment of compounding activities performed.
4357 Selected sampling sites shall include locations within each ISO Class 5 environment and in the
4358 ISO Class 7 and 8 areas and in the segregated compounding areas at greatest risk of
4359 contamination. The plan shall include sample location, method of collection, frequency of
4360 sampling, volume of air sampled, and time of day as related to activity in the compounding area
4361 and action levels.
4362
4363 (v) Viable air sampling. Evaluation of airborne microorganisms using volumetric collection
4364 methods in the controlled air environments shall be performed by properly trained individuals for
4365 all compounding risk levels. For low-, medium-, and high-risk level compounding, air sampling
4366 shall be performed at locations that are prone to contamination during compounding activities
4367 and during other activities such as staging, labeling, gowning, and cleaning. Locations shall
4368 include zones of air backwash turbulence within the laminar airflow workbench and other areas
4369 where air backwash turbulence may enter the compounding area. For low-risk level
4370 compounded sterile preparations within 12-hour or less beyond-use-date prepared in a primary

4371 engineering control that maintains an ISO Class 5, air sampling shall be performed at locations
4372 inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class
4373 5 environment during the certification of the primary engineering control.
4374

4375 (vi) Air sampling frequency and process. Air sampling shall be performed at least every 6
4376 months as a part of the re-certification of facilities and equipment. A sufficient volume of air shall
4377 be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment
4378 followed. At the end of the designated sampling or exposure period for air sampling activities,
4379 the microbial growth media plates are recovered and their covers secured and they are inverted
4380 and incubated at a temperature and for a time period conducive to multiplication of
4381 microorganisms. Sampling data shall be collected and reviewed on a periodic basis as a means
4382 of evaluating the overall control of the compounding environment. If an activity consistently
4383 shows elevated levels of microbial growth, competent microbiology or infection control
4384 personnel shall be consulted. A colony forming unit (cfu) count greater than 1 cfu per cubic
4385 meter of air for ISO Class 5, greater than 10 cfu per cubic meter of air for ISO Class 7, and
4386 greater than 100 cfu per cubic meter of air for ISO Class 8 or worse should prompt a re-
4387 evaluation of the adequacy of personnel work practices, cleaning procedures, operational
4388 procedures, and air filtration efficiency within the aseptic compounding location. An investigation
4389 into the source of the contamination shall be conducted. The source of the problem shall be
4390 eliminated, the affected area cleaned, and resampling performed. Counts of cfu are to be used
4391 as an approximate measure of the environmental microbial bioburden. Action levels are
4392 determined on the basis of cfu data gathered at each sampling location and trended over time.
4393 Regardless of the number of cfu identified in the pharmacy, further corrective actions will be
4394 dictated by the identification of microorganisms recovered by an appropriate credentialed
4395 laboratory of any microbial bioburden captured as a cfu using an impactation air sampler. Highly
4396 pathogenic microorganisms (e.g., gram-negative rods, coagulase positive staphylococcus,
4397 molds and yeasts) can be potentially fatal to patient receiving compounded sterile preparations
4398 and must be immediately remedied, regardless of colony forming unit count, with the
4399 assistance, if needed, of a competent microbiologist, infection control professional, or industrial
4400 hygienist.
4401

4402 (vii) Compounding accuracy checks. Written procedures for checking compounding
4403 accuracy shall be followed for every compounded sterile preparation during preparation and
4404 immediately prior to release, including label accuracy and the accuracy of the addition of all
4405 drug products or ingredients used to prepare the finished preparation and their volumes or
4406 quantities. At each step of the compounding process, the pharmacist shall ensure that
4407 components used in compounding are accurately weighed, measured, or subdivided as
4408 appropriate to conform to the formula being prepared.
4409

4410 (15) Quality control.
4411

4412 (A) Quality control procedures. The pharmacy shall follow established quality control
4413 procedures to monitor the compounding environment and quality of compounded drug
4414 preparations for conformity with the quality indicators established for the preparation. When
4415 developing these procedures, pharmacy personnel shall consider the provisions of USP
4416 Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical
4417 Compounding-Non-sterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical
4418 Compounding--Sterile Preparations, USP Chapter 800, Hazardous Drugs--Handling in
4419 Healthcare Settings, USP Chapter 823, Positron Emission Tomography Drugs for
4420 Compounding, Investigational, and Research Uses, USP Chapter 1160, Pharmaceutical

4421 Calculations in Prescription Compounding, and USP Chapter 1163, Quality Assurance in
4422 Pharmaceutical Compounding of the current USP/NF. Such procedures shall be documented
4423 and be available for inspection.

4424
4425 (B) Verification of compounding accuracy and sterility.

4426
4427 (i) The accuracy of identities, concentrations, amounts, and purities of ingredients in
4428 compounded sterile preparations shall be confirmed by reviewing labels on packages, observing
4429 and documenting correct measurements with approved and correctly standardized devices, and
4430 reviewing information in labeling and certificates of analysis provided by suppliers.

4431
4432 (ii) If the correct identity, purity, strength, and sterility of ingredients and components of
4433 compounded sterile preparations cannot be confirmed such ingredients and components shall
4434 be discarded immediately. Any compounded sterile preparation that fails sterility testing
4435 following sterilization by one method (e.g., filtration) is to be discarded and not subjected to a
4436 second method of sterilization.

4437
4438 (iii) If individual ingredients, such as bulk drug substances, are not labeled with expiration
4439 dates, when the drug substances are stable indefinitely in their commercial packages under
4440 labeled storage conditions, such ingredients may gain or lose moisture during storage and use
4441 and shall require testing to determine the correct amount to weigh for accurate content of active
4442 chemical moieties in compounded sterile preparations.

4443
4444 (e) Records. Any testing, cleaning, procedures, or other activities required in this subsection
4445 shall be documented and such documentation shall be maintained by the pharmacy.

4446
4447 (1) Maintenance of records. Every record required under this section must be:

4448
4449 (A) kept by the pharmacy and be available, for at least two years for inspecting and copying
4450 by the board or its representative and to other authorized local, state, or federal law
4451 enforcement agencies; and

4452
4453 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
4454 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,
4455 the requested records must be provided in an electronic format. Failure to provide the records
4456 set out in this section, either on site or within 72 hours, constitutes prima facie evidence of
4457 failure to keep and maintain records in violation of the Act.

4458
4459 (2) Compounding records.

4460
4461 (A) Compounding pursuant to patient specific prescription drug orders or medication orders.
4462 Compounding records for all compounded preparations shall be maintained by the pharmacy
4463 and shall include:

4464
4465 (i) the date and time of preparation;

4466
4467 (ii) a complete formula, including methodology and necessary equipment which includes the
4468 brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name
4469 and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of

4470 each; however, if the sterile preparation is compounded according to the manufacturer's
4471 labeling instructions, then documentation of the formula is not required;

4472
4473 (iii) written or electronic signature or initials of the pharmacist or pharmacy technician or
4474 pharmacy technician trainee performing the compounding;

4475
4476 (iv) written or electronic signature or initials of the pharmacist responsible for supervising
4477 pharmacy technicians or pharmacy technician trainees and conducting final checks of
4478 compounded pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform
4479 the compounding function;

4480
4481 (v) the container used and the number of units of finished preparation prepared; and

4482
4483 (vi) a reference to the location of the following documentation which may be maintained with
4484 other records, such as quality control records:

4485
4486 (I) the criteria used to determine the beyond-use date; and

4487
4488 (II) documentation of performance of quality control procedures.

4489
4490 (B) Compounding records when batch compounding or compounding in anticipation of future
4491 prescription drug or medication orders.

4492
4493 (i) Master work sheet. A master work sheet shall be developed and approved by a
4494 pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work
4495 sheet shall be used as the preparation work sheet from which each batch is prepared and on
4496 which all documentation for that batch occurs. The master work sheet shall contain at a
4497 minimum:

4498
4499 (I) the formula;

4500
4501 (II) the components;

4502
4503 (III) the compounding directions;

4504
4505 (IV) a sample label;

4506
4507 (V) evaluation and testing requirements;

4508
4509 (VI) specific equipment used during preparation; and

4510
4511 (VII) storage requirements.

4512
4513 (ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall
4514 document the following:

4515
4516 (I) identity of all solutions and ingredients and their corresponding amounts,
4517 concentrations, or volumes;

4518
4519 (II) lot number for each component;

- 4520
4521 (III) component manufacturer/distributor or suitable identifying number;
4522
4523 (IV) container specifications (e.g., syringe, pump cassette);
4524
4525 (V) unique lot or control number assigned to batch;
4526
4527 (VI) expiration date of batch-prepared preparations;
4528
4529 (VII) date of preparation;
4530
4531 (VIII) name, initials, or electronic signature of the person(s) involved in the preparation;
4532
4533 (IX) name, initials, or electronic signature of the responsible pharmacist;
4534
4535 (X) finished preparation evaluation and testing specifications, if applicable; and
4536
4537 (XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.
4538
4539 (f) Office Use Compounding and Distribution of Sterile Compounded Preparations
4540
4541 (1) General.
4542
4543 (A) A pharmacy may compound, dispense, deliver, and distribute a compounded sterile
4544 preparation as specified in Subchapter D, Texas Pharmacy Act Chapter 562.
4545
4546 (B) A Class A-S pharmacy is not required to register or be licensed under Chapter 431,
4547 Health and Safety Code, to distribute sterile compounded preparations to a Class C or Class C-
4548 S pharmacy.
4549
4550 (C) A Class C-S pharmacy is not required to register or be licensed under Chapter 431,
4551 Health and Safety Code, to distribute sterile compounded preparations that the Class C-S
4552 pharmacy has compounded for other Class C or Class C-S pharmacies under common
4553 ownership.
4554
4555 (D) To compound and deliver a compounded preparation under this subsection, a pharmacy
4556 must:
4557
4558 (i) verify the source of the raw materials to be used in a compounded drug;
4559
4560 (ii) comply with applicable United States Pharmacopoeia guidelines, including the testing
4561 requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No.
4562 104-191);
4563
4564 (iii) enter into a written agreement with a practitioner for the practitioner's office use of a
4565 compounded preparation;
4566
4567 (iv) comply with all applicable competency and accrediting standards as determined by the
4568 board; and
4569

4570 (v) comply with the provisions of this subsection.

4571

4572 (E) This subsection does not apply to Class B pharmacies compounding sterile
4573 radiopharmaceuticals that are furnished for departmental or physicians' use if such authorized
4574 users maintain a Texas radioactive materials license.

4575

4576 (2) Written Agreement. A pharmacy that provides sterile compounded preparations to
4577 practitioners for office use or to another pharmacy shall enter into a written agreement with the
4578 practitioner or pharmacy. The written agreement shall:

4579

4580 (A) address acceptable standards of practice for a compounding pharmacy and a practitioner
4581 and receiving pharmacy that enter into the agreement including a statement that the
4582 compounded drugs may only be administered to the patient and may not be dispensed to the
4583 patient or sold to any other person or entity except to a veterinarian as authorized by §563.054
4584 of the Act;

4585

4586 (B) require the practitioner or receiving pharmacy to include on a patient's chart, medication
4587 order or medication administration record the lot number and beyond-use date of a
4588 compounded preparation administered to a patient;

4589

4590 (C) describe the scope of services to be performed by the pharmacy and practitioner or
4591 receiving pharmacy, including a statement of the process for:

4592

4593 (i) a patient to report an adverse reaction or submit a complaint; and

4594

4595 (ii) the pharmacy to recall batches of compounded preparations.

4596

4597 (3) Recordkeeping.

4598

4599 (A) Maintenance of Records.

4600

4601 (i) Records of orders and distribution of sterile compounded preparations to a practitioner for
4602 office use or to an institutional pharmacy for administration to a patient shall:

4603

4604 (I) be kept by the pharmacy and be available, for at least two years from the date of the
4605 record, for inspecting and copying by the board or its representative and to other authorized
4606 local, state, or federal law enforcement agencies;

4607

4608 (II) maintained separately from the records of preparations dispensed pursuant to a
4609 prescription or medication order; and

4610

4611 (III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
4612 Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in
4613 an electronic format, the requested records must be provided in an electronic format. Failure to
4614 provide the records set out in this subsection, either on site or within 72 hours for whatever
4615 reason, constitutes prima facie evidence of failure to keep and maintain records.

4616

4617 (ii) Records may be maintained in an alternative data retention system, such as a data
4618 processing system or direct imaging system provided the data processing system is capable of

4619 producing a hard copy of the record upon the request of the board, its representative, or other
4620 authorized local, state, or federal law enforcement or regulatory agencies.

4621

4622 (B) Orders. The pharmacy shall maintain a record of all sterile compounded preparations
4623 ordered by a practitioner for office use or by an institutional pharmacy for administration to a
4624 patient. The record shall include the following information:

4625

4626 (i) date of the order;

4627

4628 (ii) name, address, and phone number of the practitioner who ordered the preparation and if
4629 applicable, the name, address and phone number of the institutional pharmacy ordering the
4630 preparation; and

4631

4632 (iii) name, strength, and quantity of the preparation ordered.

4633

4634 (C) Distributions. The pharmacy shall maintain a record of all sterile compounded
4635 preparations distributed pursuant to an order to a practitioner for office use or by an institutional
4636 pharmacy for administration to a patient. The record shall include the following information:

4637

4638 (i) date the preparation was compounded;

4639

4640 (ii) date the preparation was distributed;

4641

4642 (iii) name, strength and quantity in each container of the preparation;

4643

4644 (iv) pharmacy's lot number;

4645

4646 (v) quantity of containers shipped; and

4647

4648 (vi) name, address, and phone number of the practitioner or institutional pharmacy to whom
4649 the preparation is distributed.

4650

4651 (D) Audit Trail.

4652

4653 (i) The pharmacy shall store the order and distribution records of preparations for all sterile
4654 compounded preparations ordered by and or distributed to a practitioner for office use or by a
4655 pharmacy licensed to compound sterile preparations for administration to a patient in such a
4656 manner as to be able to provide an audit trail for all orders and distributions of any of the
4657 following during a specified time period:

4658

4659 (I) any strength and dosage form of a preparation (by either brand or generic name or
4660 both);

4661

4662 (II) any ingredient;

4663

4664 (III) any lot number;

4665

4666 (IV) any practitioner;

4667

4668 (V) any facility; and

4669
4670 (VI) any pharmacy, if applicable.
4671
4672 (ii) The audit trail shall contain the following information:
4673
4674 (I) date of order and date of the distribution;
4675
4676 (II) practitioner's name, address, and name of the institutional pharmacy, if applicable;
4677
4678 (III) name, strength and quantity of the preparation in each container of the preparation;
4679
4680 (IV) name and quantity of each active ingredient;
4681
4682 (V) quantity of containers distributed; and
4683
4684 (VI) pharmacy's lot number.
4685
4686 (4) Labeling. The pharmacy shall affix a label to the preparation containing the following
4687 information:
4688
4689 (A) name, address, and phone number of the compounding pharmacy;
4690
4691 (B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation
4692 is distributed to a veterinarian the statement: "Compounded Preparation";
4693
4694 (C) name and strength of the preparation or list of the active ingredients and strengths;
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4696 (D) pharmacy's lot number;
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4698 (E) beyond-use date as determined by the pharmacist using appropriate documented criteria;
4699
4700 (F) quantity or amount in the container;
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4702 (G) appropriate ancillary instructions, such as storage instructions or cautionary statements,
4703 including hazardous drug warning labels where appropriate; and
4704
4705 (H) device-specific instructions, where appropriate.
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4707 (g) Recall Procedures.
4708
4709 (1) The pharmacy shall have written procedures for the recall of any compounded sterile
4710 preparation provided to a patient, to a practitioner for office use, or a pharmacy for
4711 administration. Written procedures shall include, but not be limited to the requirements as
4712 specified in paragraph (3) of this subsection.
4713
4714 (2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by
4715 the pharmacy upon identification of a potential or confirmed harm to a patient.
4716
4717 (3) In the event of a recall, the pharmacist-in-charge shall ensure that:
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- 4719 (A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is
4720 notified, in writing, of the recall;
4721
- 4722 (B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;
4723
- 4724 (C) the board is notified of the recall, in writing, not later than 24 hours after the recall is
4725 issued;
4726
- 4727 (D) if the preparation is distributed for office use, the Texas Department of State Health
4728 Services, Drugs and Medical Devices Group, is notified of the recall, in writing;
4729
- 4730 (E) the preparation is quarantined; and
4731
- 4732 (F) the pharmacy keeps a written record of the recall including all actions taken to notify all
4733 parties and steps taken to ensure corrective measures.
4734
- 4735 (4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if
4736 there is potential for or confirmed harm to a patient.
4737
- 4738 (5) A pharmacy that compounds sterile preparations shall notify the board immediately of any
4739 adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially
4740 attributable to a sterile preparation compounded by the pharmacy.
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4742