

## RULE ANALYSIS

**Introduction:** THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS A ADOPTED RULE

**Short Title:** Personnel

**Rule Numbers:** §§291.32, 291.53, 291.73

**Statutory Authority:** Texas Pharmacy Act, Chapter 551-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

**Purpose:** The amendments, if adopted, clarify that pharmacists may not serve as the pharmacist-in-charge of other pharmacies if the pharmacist is required to be a full time pharmacist; eliminate references to sterile compounding; add transferring or receiving a prescription to the list of pharmacist duties; and correct grammar.

**The Board reviewed and voted to propose the amendments during the August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register* at 40 TexReg 6510, 6516, and 6517.**

1 **SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)**

2 **22 TAC §§291.32 - 291.34**

3 The Texas State Board of Pharmacy proposes amendments to §291.32 concerning Personnel,  
4 §291.33 concerning Operational Standards, and §291.34 concerning Records. The amendments,  
5 if adopted, clarify that pharmacists may not serve as the pharmacist-in-charge of other  
6 pharmacies if the pharmacist is required to be a full time pharmacist; correct grammar; clarify  
7 the duties of a pharmacist to include transferring or receiving a transfer of original prescription  
8 information on behalf of a patient; clarify that prescriptions must be transferred within four  
9 business hours; update the requirements with regard to interchangeable biological products; and  
10 update the rules regarding distributions to include dangerous drugs.

11 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year  
12 period the rules are in effect, there will be no fiscal implications for state or local government as  
13 a result of enforcing or administering the rules.

14 Ms. Dodson has determined that, for each year of the first five-year period the rules will be in  
15 effect, the public benefit anticipated as a result of enforcing the amendments will ensure the  
16 pharmacies are adequately supervised by the pharmacist-in-charge; ensure only pharmacists are  
17 performing duties of a pharmacist; ensure patients receive transferred prescriptions in a timely  
18 manner; and ensure biologicals are handled appropriately. There is no fiscal impact for  
19 individuals, small or large businesses, or to other entities which are required to comply with  
20 these sections.

21 Comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of  
22 Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,  
23 Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., October  
24 30, 2015.

25 The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act  
26 (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as  
27 authorizing the agency to protect the public through the effective control and regulation of the  
28 practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules  
29 for the proper administration and enforcement of the Act.

30 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 -  
31 569, Texas Occupations Code.

32 **§291.32. Personnel.**

33 (a) Pharmacist-in-charge.

34 (1) General.

35 (A) Each Class A pharmacy shall have one pharmacist-in-charge who is employed on a full-time  
36 basis, who may be the pharmacist-in-charge for only one such pharmacy; provided, however,  
37 such pharmacist-in-charge may be the pharmacist-in-charge of:

38 (i) more than one Class A pharmacy, if the additional Class A pharmacies are not open to  
39 provide pharmacy services simultaneously; or

40 (ii) during an emergency, up to two Class A pharmacies open simultaneously if the pharmacist-  
41 in-charge works at least 10 hours per week in each pharmacy for no more than a period of 30  
42 consecutive days.

43 (B) The pharmacist-in-charge shall comply with the provisions of §291.17 of this title (relating  
44 to Inventory Requirements).

45 (C) The pharmacist-in-charge of a Class A pharmacy may not serve as the pharmacist-in-charge  
46 of a Class B pharmacy or a Class C pharmacy with 101 beds or more.

47 (2) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of  
48 pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-  
49 charge may advise the owner on administrative or operational concerns. The pharmacist-in-  
50 charge shall have responsibility for, at a minimum, the following:

51 (A) educating and training of pharmacy technicians and pharmacy technician trainees;

52 (B) supervising a system to assure appropriate procurement of prescription drugs and devices  
53 and other products dispensed from the Class A pharmacy;

54 (C) disposing of and distributing drugs from the Class A pharmacy;

55 (D) storing all materials, including drugs, chemicals, and biologicals;

56 (E) maintaining records of all transactions of the Class A pharmacy necessary to maintain  
57 accurate control over and accountability for all pharmaceutical materials required by applicable  
58 state and federal laws and sections;

59 (F) supervising a system to assure maintenance of effective controls against the theft or diversion  
60 of prescription drugs, and records for such drugs;

61 (G) adhering to policies and procedures regarding the maintenance of records in a data  
62 processing system such that the data processing system is in compliance with Class A  
63 (community) pharmacy requirements;

64 (H) legally operating the pharmacy, including meeting all inspection and other requirements of  
65 all state and federal laws or sections governing the practice of pharmacy; and

66 (I) if the pharmacy uses an automated pharmacy dispensing system, shall be responsible for the  
67 following:

68 (i) consulting with the owner concerning and adherence to the policies and procedures for system  
69 operation, safety, security, accuracy and access, patient confidentiality, prevention of  
70 unauthorized access, and malfunction;

71 (ii) inspecting medications in the automated pharmacy dispensing system, at least monthly, for  
72 expiration date, misbranding, physical integrity, security, and accountability;

73 (iii) assigning, discontinuing, or changing personnel access to the automated pharmacy  
74 dispensing system;

75 (iv) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed healthcare  
76 professionals performing any services in connection with an automated pharmacy dispensing  
77 system have been properly trained on the use of the system and can demonstrate comprehensive  
78 knowledge of the written policies and procedures for operation of the system; and

79 (v) ensuring that the automated pharmacy dispensing system is stocked accurately and an  
80 accountability record is maintained in accordance with the written policies and procedures of  
81 operation.

82 (b) Owner. The owner of a Class A pharmacy shall have responsibility for all administrative and  
83 operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on  
84 administrative and operational concerns. The owner shall have responsibility for, at a minimum,  
85 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with  
86 the pharmacist-in-charge or another Texas licensed pharmacist:

87 (1) establishing [~~establishment of~~] policies for procurement of prescription drugs and devices and  
88 other products dispensed from the Class A pharmacy;

89 (2) establishing [~~establishment of~~] policies and procedures for the security of the prescription  
90 department including the maintenance of effective controls against the theft or diversion of  
91 prescription drugs;

92 (3) if the pharmacy uses an automated pharmacy dispensing system, reviewing and approving all  
93 policies and procedures for system operation, safety, security, accuracy and access, patient  
94 confidentiality, prevention of unauthorized access, and malfunction;

95 (4) providing the pharmacy with the necessary equipment and resources commensurate with its  
96 level and type of practice; and

97 (5) establishing [~~establishment of~~] policies and procedures regarding maintenance, storage, and  
98 retrieval of records in a data processing system such that the system is in compliance with state  
99 and federal requirements.

100 (c) Pharmacists.

101 (1) General.

102 (A) The pharmacist-in-charge shall be assisted by sufficient number of additional licensed  
103 pharmacists as may be required to operate the Class A pharmacy competently, safely, and  
104 adequately to meet the needs of the patients of the pharmacy.

105 (B) All pharmacists shall assist the pharmacist-in-charge in meeting his or her responsibilities in  
106 ordering, dispensing, and accounting for prescription drugs.

107 (C) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and  
108 pharmacy technician trainees and for designating and delegating duties, other than those listed in  
109 paragraph (2) of this subsection, to pharmacy technicians and pharmacy technician trainees. Each  
110 pharmacist shall be responsible for any delegated act performed by pharmacy technicians and  
111 pharmacy technician trainees under his or her supervision.

112 (D) Pharmacists shall directly supervise pharmacy technicians and pharmacy technician trainees  
113 who are entering prescription data into the pharmacy's data processing system by one of the  
114 following methods.

115 (i) Physically present supervision. A pharmacist shall be physically present to directly supervise  
116 a pharmacy technician or pharmacy technician trainee who is entering prescription data into the  
117 data processing system. Each prescription entered into the data processing system shall be  
118 verified at the time of data entry. If the pharmacist is not physically present due to a temporary  
119 absence as specified in §291.33(b)(3) of this title (relating to Operational Standards), on return  
120 the pharmacist must:

121 (I) conduct a drug regimen review for the prescriptions data entered during this time period as  
122 specified in §291.33(c)(2) of this title; and

123 (II) verify that prescription data entered during this time period was entered accurately.

124 (ii) Electronic supervision. A pharmacist may electronically supervise a pharmacy technician or  
125 pharmacy technician trainee who is entering prescription data into the data processing system  
126 provided the pharmacist:

127 (I) is on-site, in the pharmacy where the technician/trainee is located;

128 (II) has immediate access to any original document containing prescription information or other  
129 information related to the dispensing of the prescription. Such access may be through imaging  
130 technology provided the pharmacist has the ability to review the original, hardcopy documents if  
131 needed for clarification; and

132 (III) verifies the accuracy of the data entered information prior to the release of the information  
133 to the system for storage and/or generation of the prescription label.

134 (iii) Electronic verification of data entry by pharmacy technicians or pharmacy technician  
135 trainees. A pharmacist may electronically verify the data entry of prescription information into a  
136 data processing system provided:

137 (I) a pharmacist is on-site in the pharmacy where the pharmacy technicians/trainees are located;

138 (II) the pharmacist electronically conducting the verification is either a:

139 (-a-) Texas licensed pharmacist; or

140 (-b-) pharmacist employed by a Class E pharmacy that:

141 (-1-) has the same owner as the Class A pharmacy where the pharmacy technicians/trainees are  
142 located; or

143 (-2-) has entered into a written contract or agreement with the Class A pharmacy, which outlines  
144 the services to be provided and the responsibilities and accountabilities of each pharmacy in  
145 compliance with federal and state laws and regulations;

146 (III) the pharmacy establishes controls to protect the privacy and security of confidential records;  
147 and

148 (IV) the pharmacy keeps permanent records of prescriptions electronically verified for a period  
149 of two years.

150 (E) All pharmacists, while on duty, shall be responsible for the legal operation of the pharmacy  
151 and for complying with all state and federal laws or rules governing the practice of pharmacy.

152 (F) A dispensing pharmacist shall be responsible for and ensure that the drug is dispensed and  
153 delivered safely, and accurately as prescribed, unless the pharmacy's data processing system can  
154 record the identity of each pharmacist involved in a specific portion of the dispensing processing.  
155 If the system can track the identity of each pharmacist involved in the dispensing process, each  
156 pharmacist involved in the dispensing process shall be responsible for and ensure that the portion  
157 of the process the pharmacist is performing results in the safe and accurate dispensing and  
158 delivery of the drug as prescribed. The dispensing process shall include, but not be limited to,  
159 drug regimen review and verification of accurate prescription data entry, including data entry of  
160 prescriptions placed on hold, packaging, preparation, compounding, transferring, [and] labeling,  
161 and performance of the final check of the dispensed prescription. An intern has the same  
162 responsibilities described in this subparagraph as a pharmacist but must perform his or her duties  
163 under the supervision of a pharmacist.

164 (2) Duties. Duties which may only be performed by a pharmacist are as follows:

165 (A) receiving oral prescription drug orders and reducing these orders to writing, either manually  
166 or electronically;

- 167 (B) interpreting prescription drug orders;
- 168 (C) selecting drug products;
- 169 (D) performing the final check of the dispensed prescription before delivery to the patient to  
170 ensure that the prescription has been dispensed accurately as prescribed;
- 171 (E) communicating to the patient or patient's agent information about the prescription drug or  
172 device which in the exercise of the pharmacist's professional judgment, the pharmacist deems  
173 significant, as specified in §291.33(c) of this title;
- 174 (F) communicating to the patient or the patient's agent on his or her request information  
175 concerning any prescription drugs dispensed to the patient by the pharmacy;
- 176 (G) assuring that a reasonable effort is made to obtain, record, and maintain patient medication  
177 records;
- 178 (H) interpreting patient medication records and performing drug regimen reviews;
- 179 (I) performing a specific act of drug therapy management for a patient delegated to a pharmacist  
180 by a written protocol from a physician licensed in this state in compliance with the Medical  
181 Practice Act; [~~and~~]
- 182 (J) verifying that controlled substances listed on invoices are received by clearly recording  
183 his/her initials and date of receipt of the controlled substances; and[~~-~~]
- 184 (K) transferring or receiving a transfer of original prescription information on behalf of a patient.
- 185 (d) - (e) (No change.)
- 186 *§291.33.Operational Standards.*
- 187 (a) - (b) (No change.)
- 188 (c) Prescription dispensing and delivery.
- 189 (1) - (2) (No change.)
- 190 (3) [~~Generic~~] Substitution of generically equivalent drugs or interchangeable biological products.  
191 A pharmacist may dispense a generically equivalent drug or interchangeable biological product  
192 and shall comply with the provisions of §309.3 of this title (relating to [~~Generic~~] Substitution  
193 Requirements).
- 194 (4) - (6) (No change.)
- 195 (7) Labeling.

- 196 (A) At the time of delivery of the drug, the dispensing container shall bear a label in plain  
197 language and printed in an easily readable font size, unless otherwise specified, with at least the  
198 following information:
- 199 (i) name, address and phone number of the pharmacy;
  - 200 (ii) unique identification number of the prescription that is printed in an easily readable font size  
201 comparable to but no smaller than ten-point Times Roman;
  - 202 (iii) date the prescription is dispensed;
  - 203 (iv) initials or an identification code of the dispensing pharmacist;
  - 204 (v) name of the prescribing practitioner;
  - 205 (vi) if the prescription was signed by a pharmacist, the name of the pharmacist who signed the  
206 prescription for a dangerous drug under delegated authority of a physician as specified in Subtitle  
207 B, Chapter 157, Occupations Code;
  - 208 (vii) name of the patient or if such drug was prescribed for an animal, the species of the animal  
209 and the name of the owner that is printed in an easily readable font size comparable to but no  
210 smaller than ten-point Times Roman. The name of the patient's partner or family member is not  
211 required to be on the label of a drug prescribed for a partner for a sexually transmitted disease or  
212 for a patient's family members if the patient has an illness determined by the Centers for Disease  
213 Control and Prevention, the World Health Organization, or the Governor's office to be pandemic;
  - 214 (viii) instructions for use that is printed in an easily readable font [size] comparable to but no  
215 smaller than ten-point Times Roman;
  - 216 (ix) quantity dispensed;
  - 217 (x) appropriate ancillary instructions such as storage instructions or cautionary statements such  
218 as warnings of potential harmful effects of combining the drug product with any product  
219 containing alcohol;
  - 220 (xi) if the prescription is for a Schedules II - IV controlled substance, the statement "Caution:  
221 Federal law prohibits the transfer of this drug to any person other than the patient for whom it  
222 was prescribed";
  - 223 (xii) if the pharmacist has selected a generically equivalent drug or interchangeable biological  
224 product pursuant to the provisions of the Act, Chapter 562, the statement "Substituted for Brand  
225 Prescribed" or "Substituted for 'Brand Name'" where "Brand Name" is the actual name of the  
226 brand name product prescribed;

227 (xiii) the name and strength of the actual drug or biological product dispensed that is printed in  
228 an easily readable font size comparable to but no smaller than ten-point Times Roman, unless  
229 otherwise directed by the prescribing practitioner;

230 (I) The name shall be either:

231 (-a-) the brand name; or

232 (-b-) if no brand name, then the generic drug or interchangeable biological product name and  
233 name of the manufacturer or distributor of such generic drug or interchangeable biological  
234 product. (The name of the manufacturer or distributor may be reduced to an abbreviation or  
235 initials, provided the abbreviation or initials are sufficient to identify the manufacturer or  
236 distributor. For combination drug products or non-sterile compounded drug preparations having  
237 no brand name, the principal active ingredients shall be indicated on the label.)

238 (II) Except as provided in clause (xii) of this subparagraph, the brand name of the prescribed  
239 drug or biological product shall not appear on the prescription container label unless it is the drug  
240 product actually dispensed.

241 (xiv) if the drug is dispensed in a container other than the manufacturer's original container, the  
242 date after which the prescription should not be used or beyond-use-date. Unless otherwise  
243 specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is  
244 dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may  
245 be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is  
246 not required on the label of a prescription dispensed to a person at the time of release from prison  
247 or jail if the prescription is for not more than a 10-day supply of medication; and

248 (xv) either on the prescription label or the written information accompanying the prescription,  
249 the statement "Do not flush unused medications or pour down a sink or drain." A drug product  
250 on a list developed by the Federal Food and Drug Administration of medicines recommended for  
251 disposal by flushing is not required to bear this statement.

252 (B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type  
253 size smaller than ten-point Times Roman, the pharmacy shall provide the patient written  
254 information containing the information as specified in subparagraph (A) of this paragraph in an  
255 easily readable font [size] comparable to but no smaller than ten-point Times Roman.

256 (C) The label is not required to include the initials or identification code of the dispensing  
257 pharmacist as specified in subparagraph (A) of this paragraph if the identity of the dispensing  
258 pharmacist is recorded in the pharmacy's data processing system. The record of the identity of  
259 the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

260 (D) The dispensing container is not required to bear the label as specified in subparagraph (A) of  
261 this paragraph if:

262 (i) the drug is prescribed for administration to an ultimate user who is institutionalized in a  
263 licensed health care institution (e.g., nursing home, hospice, hospital);

264 (ii) no more than a 90-day supply is dispensed at one time;

265 (iii) the drug is not in the possession of the ultimate user prior to administration;

266 (iv) the pharmacist-in-charge has determined that the institution:

267 (I) maintains medication administration records which include adequate directions for use for the  
268 drug(s) prescribed;

269 (II) maintains records of ordering, receipt, and administration of the drug(s); and

270 (III) provides for appropriate safeguards for the control and storage of the drug(s); and

271 (v) the dispensing container bears a label that adequately:

272 (I) identifies the:

273 (-a-) pharmacy by name and address;

274 (-b-) unique identification number of the prescription;

275 (-c-) name and strength of the drug dispensed;

276 (-d-) name of the patient; and

277 (-e-) name of the prescribing practitioner or, if applicable, the name of the advanced practice  
278 nurse, physician assistant, or pharmacist who signed the prescription drug order;

279 (II) if the drug is dispensed in a container other than the manufacturer's original container,  
280 specifies the date after which the prescription should not be used or beyond-use-date. Unless  
281 otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the  
282 drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-  
283 date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-  
284 use-date is not required on the label of a prescription dispensed to a person at the time of release  
285 from prison or jail if the prescription is for not more than a 10-day supply of medication; and

286 (III) sets forth the directions for use and cautionary statements, if any, contained on the  
287 prescription drug order or required by law.

288 (8) (No change.)

289 (d) - (i) (No change.)

290 §291.34.Records.

291 (a) (No change.)

292 (b) Prescriptions.

293 (1) - (6) (No change.)

294 (7) Prescription drug order information.

295 (A) (No change.)

296 (B) At the time of dispensing, a pharmacist is responsible for documenting the following  
297 information on either the original hard copy prescription or in the pharmacy's data processing  
298 system:

299 (i) unique identification number of the prescription drug order;

300 (ii) initials or identification code of the dispensing pharmacist;

301 (iii) initials or identification code of the pharmacy technician or pharmacy technician trainee  
302 performing data entry of the prescription, if applicable;

303 (iv) quantity dispensed, if different from the quantity prescribed;

304 (v) date of dispensing, if different from the date of issuance; and

305 (vi) brand name or manufacturer of the drug or biological product actually dispensed, if the drug  
306 was prescribed by generic name or interchangeable biological name or if a drug or  
307 interchangeable biological product other than the one prescribed was dispensed pursuant to the  
308 provisions of the Act, Chapters 562 and 563.

309 (8) - (10) (No change.)

310 (c) - (f) (No change.)

311 (g) Transfer of prescription drug order information. For the purpose of initial or refill dispensing,  
312 the transfer of original prescription drug order information is permissible between pharmacies,  
313 subject to the following requirements.

314 (1) The transfer of original prescription drug order information for controlled substances listed in  
315 Schedule III, IV, or V is permissible between pharmacies on a one-time basis only. However,  
316 pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum  
317 refills permitted by law and the prescriber's authorization.

- 318 (2) The transfer of original prescription drug order information for dangerous drugs is  
319 permissible between pharmacies without limitation up to the number of originally authorized  
320 refills.
- 321 (3) The transfer is communicated orally by telephone or via facsimile directly by a pharmacist to  
322 another pharmacist; by a pharmacist to a student-intern, extended-intern, or resident-intern; or by  
323 a student-intern, extended-intern, or resident-intern to another pharmacist.
- 324 (4) Both the original and the transferred prescription drug orders are maintained for a period of  
325 two years from the date of last refill.
- 326 (5) The individual transferring the prescription drug order information shall ensure the following  
327 occurs:
- 328 (A) write the word "void" on the face of the invalidated prescription or the prescription is voided  
329 in the data processing system;
- 330 (B) record the name, address, if for a controlled substance, the DEA registration number of the  
331 pharmacy to which it was transferred, and the name of the receiving individual on the reverse of  
332 the invalidated prescription or stored with the invalidated prescription drug order in the data  
333 processing system;
- 334 (C) record the date of the transfer and the name of the individual transferring the information;  
335 and
- 336 (D) if the prescription is transferred electronically, provide the following information:
- 337 (i) date of original dispensing and prescription number;
- 338 (ii) number of refills remaining and if a controlled substance, the date(s) and location(s) of  
339 previous refills;
- 340 (iii) name, address, and if a controlled substance, the DEA registration number of the transferring  
341 pharmacy;
- 342 (iv) name of the individual transferring the prescription; and
- 343 (v) if a controlled substance, name, address and DEA registration number, and prescription  
344 number from the pharmacy that originally dispensed the prescription, if different.
- 345 (6) The individual receiving the transferred prescription drug order information shall:
- 346 (A) write the word "transfer" on the face of the prescription or the prescription record indicates  
347 the prescription was a transfer; and

348 (B) reduce to writing all of the information required to be on a prescription as specified in  
349 subsection (b)(7) of this section (relating to Prescriptions) and including the following  
350 information:

351 (i) date of issuance and prescription number;

352 (ii) original number of refills authorized on the original prescription drug order;

353 (iii) date of original dispensing;

354 (iv) number of valid refills remaining and if a controlled substance, date(s) and location(s) of  
355 previous refills;

356 (v) name, address, and if for a controlled substance, the DEA registration number of the  
357 transferring pharmacy;

358 (vi) name of the individual transferring the prescription; and

359 (vii) name, address, and if for a controlled substance, the DEA registration number, of the  
360 pharmacy that originally dispensed the prescription, if different; or

361 (C) if the prescription is transferred electronically, create an electronic record for the prescription  
362 that includes the receiving pharmacist's name and all of the information transferred with the  
363 prescription including all of the information required to be on a prescription as specified in  
364 subsection (b)(7) of this section (relating to Prescriptions) and the following:

365 (i) date of original dispensing;

366 (ii) number of refills remaining and if a controlled substance, the prescription number(s), date(s)  
367 and location(s) of previous refills;

368 (iii) name, address, and if for a controlled substance, the DEA registration number;

369 (iv) name of the individual transferring the prescription; and

370 (v) name, address, and if for a controlled substance, the DEA registration number, of the  
371 pharmacy that originally filled the prescription.

372 (7) Both the individual transferring the prescription and the individual receiving the prescription  
373 must engage in confirmation of the prescription information by such means as:

374 (A) the transferring individual faxes the hard copy prescription to the receiving individual; or

375 (B) the receiving individual repeats the verbal information from the transferring individual and  
376 the transferring individual verbally confirms that the repeated information is correct.

377 (8) Pharmacies transferring prescriptions electronically shall comply with the following:

378 (A) Prescription drug orders may not be transferred by non-electronic means during periods of  
379 downtime except on consultation with and authorization by a prescribing practitioner; provided  
380 however, during downtime, a hard copy of a prescription drug order may be made available for  
381 informational purposes only, to the patient or a pharmacist, and the prescription may be read to a  
382 pharmacist by telephone.

383 (B) The original prescription drug order shall be invalidated in the data processing system for  
384 purposes of filling or refilling, but shall be maintained in the data processing system for refill  
385 history purposes.

386 (C) If the data processing system does not have the capacity to store all the information as  
387 specified in paragraphs (5) and (6) of this subsection, the pharmacist is required to record this  
388 information on the original or transferred prescription drug order.

389 (D) The data processing system shall have a mechanism to prohibit the transfer or refilling of  
390 controlled substance prescription drug orders that have been previously transferred.

391 (E) Pharmacies electronically accessing the same prescription drug order records may  
392 electronically transfer prescription information if the following requirements are met.

393 (i) The original prescription is voided and the pharmacies' data processing systems shall store all  
394 the information as specified in paragraphs (5) and (6) of this subsection.

395 (ii) Pharmacies not owned by the same entity ~~[person]~~ may electronically access the same  
396 prescription drug order records, provided the owner, chief executive officer, or designee of each  
397 pharmacy signs an agreement allowing access to such prescription drug order records.

398 (iii) An electronic transfer between pharmacies may be initiated by a pharmacist intern,  
399 pharmacy technician, or pharmacy technician trainee acting under the direct supervision of a  
400 pharmacist.

401 (9) An individual may not refuse to transfer original prescription information to another  
402 individual who is acting on behalf of a patient and who is making a request for this information  
403 as specified in this subsection. The transfer of original prescription information must be  
404 completed within four business hours of the request. ~~[done in a timely manner.]~~

405 (10) When transferring a compounded prescription, a pharmacy is required to provide all of the  
406 information regarding the compounded preparation including the formula unless the formula is  
407 patented or otherwise protected, in which case, the transferring pharmacy shall, at a minimum,  
408 provide the quantity or strength of all of the active ingredients of the compounded preparation.

409 (11) ~~(10)~~ The electronic transfer of multiple or bulk prescription records between two  
410 pharmacies is permitted provided:

411 (A) a record of the transfer as specified in paragraph (5) of this section is maintained by the  
412 transferring pharmacy;

413 (B) the information specified in paragraph (6) of this subsection is maintained by the receiving  
414 pharmacy; and

415 (C) in the event that the patient or patient's agent is unaware of the transfer of the prescription  
416 drug order record, the transferring pharmacy must notify the patient or patient's agent of the  
417 transfer and must provide the patient or patient's agent with the telephone number of the  
418 pharmacy receiving the multiple or bulk prescription drug order records.

419 (h) Distribution of prescription drugs [~~controlled substances~~] to another registrant. A pharmacy  
420 may distribute prescription drugs [~~controlled substances~~] to a practitioner, another pharmacy, or  
421 other registrant, without being registered to distribute, under the following conditions.

422 (1) If the distribution is for a controlled substance, the [The] registrant to whom the controlled  
423 substance is to be distributed is registered under the Controlled Substances Act to possess  
424 [~~dispense~~] that controlled substance.

425 (2) The total number of dosage units of prescription drugs [~~controlled substances~~] distributed by  
426 a pharmacy may not exceed 5.0% of all prescription drugs [~~controlled substances~~] dispensed and  
427 distributed by the pharmacy during the 12-month period in which the pharmacy is registered; if  
428 at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to  
429 distribute prescription drugs [~~controlled substances~~].

430 (3) If the distribution is for a dangerous drug, a record shall be maintained that indicates the:

431 (A) date of distribution;

432 (B) name, strength, and quantity of dangerous drug distributed;

433 (C) name and address of the distributing pharmacy; and

434 (D) name and address of the pharmacy, practitioner, or other registrant to whom the dangerous  
435 drugs are distributed.

436 (4) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be  
437 maintained that indicates the:

438 (A) [~~the actual~~] date of distribution;

439 (B) [~~the~~] name, strength, and quantity of controlled substances distributed;

440 (C) [~~the~~] name, address, and DEA registration number of the distributing pharmacy; and

441 (D) ~~the~~ name, address, and DEA registration number of the pharmacy, practitioner, or other  
442 registrant to whom the controlled substances are distributed.

443 (5) ~~(4)~~ If the distribution is for a Schedule II controlled substance, the following is applicable.

444 (A) The pharmacy, practitioner, or other registrant who is receiving the controlled substances  
445 shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222) to the distributing pharmacy.

446 (B) The distributing pharmacy shall:

447 (i) complete the area on the DEA order form (DEA 222) titled "To Be Filled in by Supplier";

448 (ii) maintain Copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and

449 (iii) forward Copy 2 of the DEA order form (DEA 222) to the Divisional Office of the Drug  
450 Enforcement Administration.

451 (i) - (l) (No change.)

452 The agency certifies that legal counsel has reviewed the proposal and found it to be within the  
453 state agency's legal authority to adopt.

454 Filed with the Office of the Secretary of State on September 14, 2015.

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456 Gay Dodson, R.Ph.

457 Executive Director

458 Texas State Board of Pharmacy

459 Earliest possible date of adoption: October 25, 2015

460 For further information, please call: (512) 305-8028

461

1 **SUBCHAPTER C. NUCLEAR PHARMACY (CLASS B)**

2 **22 TAC §291.53**

3 The Texas State Board of Pharmacy proposes amendments to §291.53 concerning Personnel.  
4 The amendments, if adopted, clarify that pharmacists may not serve as the pharmacist-in-charge  
5 of other pharmacies if the pharmacist is required to be a full time pharmacist.

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

9 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in  
10 effect, the public benefit anticipated as a result of enforcing the amendments will ensure the  
11 health, safety, and welfare of the citizens of Texas when receiving prescriptions from nuclear  
12 pharmacies. There is no fiscal impact for individuals, small or large businesses, or to other  
13 entities which are required to comply with this section.

14 Comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of  
15 Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,  
16 Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., October  
17 30, 2015.

18 The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act  
19 (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as  
20 authorizing the agency to protect the public through the effective control and regulation of the  
21 practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules  
22 for the proper administration and enforcement of the Act.

23 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 -  
24 569, Texas Occupations Code.

25 **§291.53. Personnel.**

26 (a) Pharmacists-in-Charge.

27 (1) General.

28 (A) Every nuclear pharmacy shall have an authorized nuclear pharmacist designated on the  
29 nuclear pharmacy license as the pharmacist-in-charge who shall be responsible for a nuclear  
30 pharmacy's compliance with laws and regulations, both state and federal, pertaining to the  
31 practice of nuclear pharmacy.

32 (B) The nuclear pharmacy pharmacist-in-charge shall see that directives from the board are  
33 communicated to the owner(s), management, other pharmacists, and interns of the nuclear  
34 pharmacy.

35 (C) Each Class B pharmacy shall have one pharmacist-in-charge who is employed on a full-time  
36 basis, who may be the pharmacist-in-charge for only one such pharmacy; provided, however,  
37 such pharmacist-in-charge may be the pharmacist-in-charge of:

38 (i) more than one Class B pharmacy, if the additional Class B pharmacies are not open to provide  
39 pharmacy services simultaneously; or

40 (ii) during an emergency, up to two Class B pharmacies open simultaneously if the pharmacist-  
41 in-charge works at least 10 hours per week in each pharmacy for no more than a period of 30  
42 consecutive days.

43 (D) The pharmacist-in-charge of a Class B pharmacy may not serve as the pharmacist-in-charge  
44 of a Class A pharmacy or a Class C pharmacy with 101 beds or more.

45 (2) (No change.)

46 (b) - (d) (No change.)

47 The agency certifies that legal counsel has reviewed the proposal and found it to be within the  
48 state agency's legal authority to adopt.

49 Filed with the Office of the Secretary of State on September 14, 2015.

50 TRD-201503750

51 Gay Dodson, R.Ph.

52 Executive Director

53 Texas State Board of Pharmacy

54 Earliest possible date of adoption: October 25, 2015

55 For further information, please call: (512) 305-8028

56

1    **SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)**

2    **22 TAC §291.73, §291.76**

3    The Texas State Board of Pharmacy proposes amendments to §291.73 concerning Personnel and  
4    §291.76 concerning Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center.  
5    The amendments to §291.73, if adopted, clarify that pharmacists may not serve as the  
6    pharmacist-in-charge of other pharmacies if the pharmacist is required to be a full time  
7    pharmacist; eliminate references to sterile compounding; and correct grammar. The amendments  
8    to §291.76, if adopted, update the rules for pharmacies in Freestanding Ambulatory Surgical  
9    Centers to be consistent with other sections; eliminate language that is no longer necessary; and  
10   correct grammar.

11   Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year  
12   period the rules are in effect, there will be no fiscal implications for state or local government as  
13   a result of enforcing or administering the rules.

14   Ms. Dodson has determined that, for each year of the first five-year period the rules will be in  
15   effect, the public benefit anticipated as a result of enforcing the amendments will ensure the  
16   pharmacies are adequately supervised by the pharmacist-in-charge; and ensure the public health  
17   and safety of pharmacies located in freestanding ambulatory surgical centers. There is no fiscal  
18   impact for individuals, small or large businesses, or to other entities which are required to  
19   comply with these sections.

20   Comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of  
21   Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,  
22   Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., October  
23   30, 2015.

24   The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act  
25   (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as  
26   authorizing the agency to protect the public through the effective control and regulation of the  
27   practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules  
28   for the proper administration and enforcement of the Act.

29   The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 -  
30   569, Texas Occupations Code.

31    **§291.73. Personnel.**

32    (a) Requirements for pharmacist services.

33    (1) A Class C pharmacy in a facility with 101 beds or more shall be under the continuous on-site  
34    supervision of a pharmacist during the time it is open for pharmacy services; provided, however,  
35    that pharmacy technicians and pharmacy technician trainees may distribute prepackaged and

36 prelabeled drugs from a drug storage area of the facility (e.g., a surgery suite), in the absence of  
37 physical supervision of a pharmacist, under the following conditions:

38 (A) the distribution is under the control of a pharmacist; and

39 (B) a pharmacist is on duty in the facility.

40 (2) A Class C pharmacy in a facility with 100 beds or less shall have the services of a pharmacist  
41 at least on a part-time or consulting basis according to the needs of the facility except that a  
42 pharmacist shall be on-site at least once every seven days.

43 (3) A pharmacist shall be accessible at all times to respond to other health professional's  
44 questions and needs. Such access may be through a telephone which is answered 24 hours a day,  
45 e.g., answering or paging service, a list of phone numbers where the pharmacist may be reached,  
46 or any other system which accomplishes this purpose.

47 (b) Pharmacist-in-charge.

48 (1) General.

49 (A) Each institutional pharmacy in a facility with 101 beds or more shall have one full-time  
50 pharmacist-in-charge, who may be pharmacist-in-charge for only one such pharmacy except as  
51 specified in subparagraph (C) of this paragraph.

52 (B) Each institutional pharmacy in a facility with 100 beds or less shall have one pharmacist-in-  
53 charge who is employed or under contract, at least on a consulting or part-time basis, but may be  
54 employed on a full-time basis, if desired, and who may be pharmacist-in-charge for no more than  
55 three facilities or 150 beds.

56 (C) A pharmacist-in-charge may be in charge of one facility with 101 beds or more and one  
57 facility with 100 beds or less, including a rural hospital, provided the total number of beds does  
58 not exceed 150 beds.

59 (D) The pharmacist-in-charge shall be assisted by additional pharmacists, pharmacy technicians  
60 and pharmacy technician trainees commensurate with the scope of services provided.

61 (E) If the pharmacist-in-charge is employed on a part-time or consulting basis, a written  
62 agreement shall exist between the facility and the pharmacist, and a copy of the written  
63 agreement shall be made available to the board upon request.

64 (F) The pharmacist-in-charge of a Class C pharmacy with 101 beds or more, may not serve as the  
65 pharmacist-in-charge of a Class A pharmacy or a Class B pharmacy.

66 (2) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum,  
67 the following:

- 68 (A) providing the appropriate level of pharmaceutical care services to patients of the facility;
- 69 (B) ensuring that drugs and/or devices are prepared for distribution safely, and accurately as  
70 prescribed;
- 71 (C) supervising a system to assure maintenance of effective controls against the theft or diversion  
72 of prescription drugs, and records for such drugs;
- 73 (D) providing written guidelines and approval of the procedure to assure that all pharmaceutical  
74 requirements are met when any part of preparing, sterilizing, and labeling of sterile preparations  
75 is not performed under direct pharmacy supervision;
- 76 (E) participating in the development of a formulary for the facility, subject to approval of the  
77 appropriate committee of the facility;
- 78 (F) developing a system to assure that drugs to be administered to patients are distributed  
79 pursuant to an original or direct copy of the practitioner's medication order;
- 80 (G) developing a system for the filling and labeling of all containers from which drugs are to be  
81 distributed or dispensed;
- 82 (H) assuring that the pharmacy maintains and makes available a sufficient inventory of antidotes  
83 and other emergency drugs as well as current antidote information, telephone numbers of  
84 regional poison control center and other emergency assistance organizations, and such other  
85 materials and information as may be deemed necessary by the appropriate committee of the  
86 facility;
- 87 (I) maintaining records of all transactions of the institutional pharmacy as may be required by  
88 applicable law, state and federal, and as may be necessary to maintain accurate control over and  
89 accountability for all pharmaceutical materials including pharmaceuticals, components used in  
90 the compounding of preparations, and participate in policy decisions regarding prescription drug  
91 delivery devices;
- 92 (J) participating in those aspects of the facility's patient care evaluation program which relate to  
93 pharmaceutical utilization and effectiveness;
- 94 (K) participating in teaching and/or research programs in the facility;
- 95 (L) implementing the policies and decisions of the appropriate committee(s) relating to  
96 pharmaceutical services of the facility;
- 97 (M) providing effective and efficient messenger or delivery service to connect the institutional  
98 pharmacy with appropriate areas of the facility on a regular basis throughout the normal workday  
99 of the facility;

100 (N) developing a system for the labeling, storage, and distribution of investigational new drugs,  
101 including access to related drug information for healthcare personnel in the pharmacy and  
102 nursing station where such drugs are being administered, concerning the dosage form, route of  
103 administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of  
104 toxicity of investigational new drugs;

105 (O) assuring that records in a data processing system are maintained such that the data  
106 processing system is in compliance with Class C (Institutional) pharmacy requirements;

107 (P) assuring that a reasonable effort is made to obtain, record, and maintain patient medication  
108 records;

109 (Q) assuring the legal operation of the pharmacy, including meeting all inspection and other  
110 requirements of all state and federal laws or rules governing the practice of pharmacy; and

111 (R) if the pharmacy uses an automated medication supply system, shall be responsible for the  
112 following:

113 (i) reviewing and approving all policies and procedures for system operation, safety, security,  
114 accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

115 (ii) inspecting medications in the automated medication supply system, at least monthly, for  
116 expiration date, misbranding, physical integrity, security, and accountability; except that  
117 inspection of medications in the automated medication supply system may be performed  
118 quarterly if:

119 (I) the facility uses automated medication supply systems that monitors expiration dates of  
120 prescription drugs; and

121 (II) security of the system is checked at regularly defined intervals (e.g., daily or weekly);

122 (iii) assigning, discontinuing, or changing personnel access to the automated medication supply  
123 system;

124 (iv) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed healthcare  
125 professionals performing any services in connection with an automated medication supply  
126 system have been properly trained on the use of the system and can demonstrate comprehensive  
127 knowledge of the written policies and procedures for operation of the system; and

128 (v) ensuring that the automated medication supply system is stocked accurately and an  
129 accountability record is maintained in accordance with the written policies and procedures of  
130 operation.

131 (c) (No change.)

132 (d) Pharmacists.

133 (1) - (2) (No change.)

134 (3) Special requirements for compounding.

135 ~~[(A) [Non-Sterile Preparations.] All pharmacists engaged in compounding non-sterile~~  
136 ~~preparations shall meet the training requirements specified in §291.131 of this title (relating to~~  
137 ~~Pharmacies Compounding Non-sterile Preparations).~~

138 ~~[(B) Sterile Preparations. All pharmacists engaged in compounding sterile preparations shall~~  
139 ~~meet the training requirements specified in §291.133 of this title (relating to Pharmacies~~  
140 ~~Compounding Sterile Preparations).]~~

141 (e) Pharmacy technicians and pharmacy technician trainees.

142 (1) General.

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

146 (B) A pharmacy technician performing the duties specified in paragraph (2)(C) of this subsection  
147 shall complete training regarding:

148 (i) procedures for one pharmacy technician to verify the accuracy of actions performed by  
149 another pharmacy technician including required documentation; and

150 (ii) the duties that may be performed by one pharmacy technician and checked by another  
151 pharmacy technician.

152 (C) In addition to the training requirements specified in subparagraph (A) of this paragraph,  
153 pharmacy technicians working in a rural hospital and performing the duties specified in  
154 paragraph (2)(D)(ii) of this subsection shall complete the following. Training on the:

155 (i) procedures for verification of the accuracy of actions performed by pharmacy technicians  
156 including required documentation;

157 (ii) duties which may and may not be performed by pharmacy technicians in the absence of a  
158 pharmacist; and

159 (iii) the pharmacy technician's role in preventing dispensing and distribution errors.

160 (2) Duties. Duties may include, but need not be limited to, the following functions under the  
161 supervision of and responsible to a pharmacist:

162 (A) Facilities with 101 beds or more. The following functions must be performed under the  
163 physically present supervision of a pharmacist:

- 164 (i) pre-packing and labeling unit and multiple dose packages, provided a pharmacist supervises  
165 and conducts a final check and affixes his or her name, initials or electronic signature to the  
166 appropriate quality control records prior to distribution;
- 167 (iii) bulk compounding or batch preparation provided a pharmacist supervises and conducts in-  
168 process and final checks and affixes his or her name, initials, or electronic signature to the  
169 appropriate quality control records prior to distribution;
- 170 (iv) distributing routine orders for stock supplies to patient care areas;
- 171 (v) entering medication order and drug distribution information into a data processing system,  
172 provided judgmental decisions are not required and a pharmacist checks the accuracy of the  
173 information entered into the system prior to releasing the order;
- 174 (vi) loading unlabeled drugs into an automated compounding or counting device provided a  
175 pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his  
176 or her name, initials or electronic signature to the appropriate quality control records;
- 177 (vii) accessing automated medication supply systems after proper training on the use of the  
178 automated medication supply system and demonstration of comprehensive knowledge of the  
179 written policies and procedures for its operation; and
- 180 (viii) compounding non-sterile preparations pursuant to medication orders provided the  
181 pharmacy technicians or pharmacy technician trainees have completed the training specified in  
182 §291.131 of this title.~~;~~and
- 183 ~~{(ix) compounding sterile preparations pursuant to medication orders provided the pharmacy~~  
184 ~~technicians or pharmacy technician trainees:}~~
- 185 ~~{(I) have completed the training specified in §291.133 of this title; and}~~
- 186 ~~{(II) are supervised by a pharmacist who has completed the training specified in §291.133 of this~~  
187 ~~title, and who conducts in-process and final checks, and affixes his or her name, initials, or~~  
188 ~~electronic signature to the label or if batch prepared, to the appropriate quality control records.~~  
189 ~~(The name, initials, or electronic signature are not required on the label if it is maintained in a~~  
190 ~~permanent record of the pharmacy.)}~~
- 191 (B) - (D) (No change.)
- 192 (3) Procedures.
- 193 (A) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in  
194 accordance with standard, written procedures and guidelines.
- 195 (B) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders  
196 in the same manner as those working in a Class A pharmacy.

197 (f) Owner. The owner of a Class C pharmacy shall have responsibility for all administrative and  
198 operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on  
199 administrative and operational concerns. The owner shall have responsibility for, at a minimum,  
200 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with  
201 the pharmacist-in-charge or another Texas licensed pharmacist:

202 (1) ~~establishing [establishment of]~~ policies for procurement of prescription drugs and devices and  
203 other products dispensed from the Class C pharmacy;

204 (2) ~~establishing and maintaining [establishment and maintenance of]~~ effective controls against  
205 the theft or diversion of prescription drugs;

206 (3) if the pharmacy uses an automated pharmacy dispensing system, reviewing and approving all  
207 policies and procedures for system operation, safety, security, accuracy and access, patient  
208 confidentiality, prevention of unauthorized access, and malfunction;

209 (4) providing the pharmacy with the necessary equipment and resources commensurate with its  
210 level and type of practice; and

211 (5) ~~establishing [establishment of]~~ policies and procedures regarding maintenance, storage, and  
212 retrieval of records in a data processing system such that the system is in compliance with state  
213 and federal requirements.

214 (g) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows.

215 (1) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that  
216 bears the person's name and identifies him or her as a pharmacy technician~~[, or a certified~~  
217 ~~pharmacy technician, if the technician maintains current certification with the Pharmacy~~  
218 ~~Technician Certification Board or any other entity providing an examination approved by the~~  
219 ~~board].~~

220 (2) - (4) (No change.)

221 *§291.76. Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center.*

222 (a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities,  
223 and operation of a pharmacy located in a freestanding ambulatory surgical center that is licensed  
224 by the Texas Department of State Health Services. Class C pharmacies located in a freestanding  
225 ambulatory surgical center shall comply with this section, in lieu of §§291.71 - 291.75 of this  
226 title (relating to Purpose; Definitions; Personnel; Operational Standards; and Records).

227 (b) Definitions. The following words and terms, when used in these sections, shall have the  
228 following meanings, unless the context clearly indicates otherwise.

229 (1) Act--The Texas Pharmacy Act, [~~Chapters 551—566 and 568—569,~~] Occupations Code,  
230 Subtitle J, as amended.

- 231 (2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion,  
232 or any other means to the body of a patient by:
- 233 (A) a practitioner, an authorized agent under his supervision, or other person authorized by law;  
234 or
- 235 (B) the patient at the direction of a practitioner.
- 236 (3) [(2)] Ambulatory surgical center (ASC)--A freestanding facility that is licensed by the Texas  
237 Department of State Health Services that primarily provides surgical services to patients who do  
238 not require overnight hospitalization or extensive recovery, convalescent time or observation.  
239 The planned total length of stay for an ASC patient shall not exceed 23 hours. Patient stays of  
240 greater than 23 hours shall be the result of an unanticipated medical condition and shall occur  
241 infrequently. The 23-hour period begins with the induction of anesthesia. [to provide surgical  
242 services to patients who do not require overnight hospital care.]
- 243 (4) Automated medication supply system--A mechanical system that performs operations or  
244 activities relative to the storage and distribution of medications for administration and which  
245 collects, controls, and maintains all transaction information.
- 246 ~~[(3) Automated drug dispensing system--An automated device that measures, counts, and/or~~  
247 ~~packages a specified quantity of dosage units for a designated drug product.]~~
- 248 (5) [(4)] Board--The Texas State Board of Pharmacy.
- 249 (6) [(5)] Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult  
250 with the ASC in areas that pertain to the practice of pharmacy.
- 251 (7) [(6)] Controlled substance--A drug, immediate precursor, or other substance listed in  
252 Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or  
253 a drug immediate precursor, or other substance included in Schedule I - V of the Federal  
254 Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-  
255 513).
- 256 ~~[(7) Direct copy--Electronic copy or carbonized copy of a medication order including a facsimile~~  
257 ~~(FAX) or digital image.]~~
- 258 (8) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or  
259 device in the course of professional practice to an ultimate user or his agent by or pursuant to the  
260 lawful order of a practitioner.
- 261 (9) Distribute--The delivery of a prescription drug or device other than by administering or  
262 dispensing.
- 263 (10) Downtime--Period of time during which a data processing system is not operable.

264 (11) Electronic signature--A unique security code or other identifier which specifically identifies  
265 the person entering information into a data processing system. A facility which utilizes electronic  
266 signatures must:

267 (A) maintain a permanent list of the unique security codes assigned to persons authorized to use  
268 the data processing system; and

269 (B) have an ongoing security program which is capable of identifying misuse and/or  
270 unauthorized use of electronic signatures.

271 (12) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained  
272 at a nursing station or other ASC department (excluding the pharmacy) for the purpose of  
273 administration to a patient of the ASC.

274 (13) Formulary--List of drugs approved for use in the ASC by an appropriate committee of the  
275 ambulatory surgical center.

276 (14) Hard copy--A physical document that is readable without the use of a special device (i.e.,  
277 data processing system, computer, etc.).

278 (15) Investigational new drug--New drug intended for investigational use by experts qualified to  
279 evaluate the safety and effectiveness of the drug as authorized by the federal Food and Drug  
280 Administration.

281 (16) Medication order--~~An [A written order from a practitioner or a verbal]~~ order from a  
282 practitioner or his authorized agent for administration of a drug or device.

283 (17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who  
284 has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to  
285 the practice of pharmacy.

286 (18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are  
287 stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other areas or  
288 departments of the ASC, or dispensed to an ultimate user or his or her agent.

289 (19) Prescription drug--

290 (A) A substance for which federal or state law requires a prescription before it may be legally  
291 dispensed to the public;

292 (B) A drug or device that under federal law is required, prior to being dispensed or delivered, to  
293 be labeled with either of the following statements:

294 (i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend  
295 that complies with federal law; or

- 296 (ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or
- 297 (C) A drug or device that is required by any applicable federal or state law or regulation to be  
298 dispensed on prescription only or is restricted to use by a practitioner only.
- 299 (20) Prescription drug order--
- 300 (A) An [~~A written order from a practitioner or verbal~~] order from a practitioner or his authorized  
301 agent to a pharmacist for a drug or device to be dispensed; or
- 302 (B) An [~~A written order or a verbal~~] order pursuant to Subtitle B, Chapter 157, Occupations  
303 Code.
- 304 (21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week  
305 or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is  
306 open.
- 307 (22) Part-time pharmacist--A pharmacist who works less than full-time.
- 308 (23) Pharmacy technician--An individual who is registered with the board as a pharmacy  
309 technician and whose responsibility in a pharmacy is to provide technical services that do not  
310 require professional judgment regarding preparing and distributing drugs and who works under  
311 the direct supervision of and is responsible to a pharmacist.
- 312 (24) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy  
313 technician trainee and is authorized to participate in a pharmacy's technician training program.
- 314 (25) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and  
315 Safety Code, Chapter 481, as amended.
- 316 (c) Personnel.
- 317 (1) Pharmacist-in-charge.
- 318 (A) General. Each ambulatory surgical center shall have one pharmacist-in-charge who is  
319 employed or under contract, at least on a consulting or part-time basis, but may be employed on  
320 a full-time basis.
- 321 (B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum,  
322 the following:
- 323 (i) establishing [~~establishment of~~] specifications for procurement and storage of all materials,  
324 including drugs, chemicals, and biologicals;
- 325 (ii) participating [~~participation~~] in the development of a formulary for the ASC, subject to  
326 approval of the appropriate committee of the ASC;

- 327 (iii) distributing [~~distribution of~~] drugs to be administered to patients pursuant to [~~an original or~~  
328 ~~direct copy of~~] the practitioner's medication order;
- 329 (iv) filling and labeling all containers from which drugs are to be distributed or dispensed;
- 330 (v) maintaining and making available a sufficient inventory of antidotes and other emergency  
331 drugs, both in the pharmacy and patient care areas, as well as current antidote information,  
332 telephone numbers of regional poison control center and other emergency assistance  
333 organizations, and such other materials and information as may be deemed necessary by the  
334 appropriate committee of the ASC;
- 335 (vi) maintaining records of all transactions of the ASC pharmacy as may be required by  
336 applicable state and federal law, and as may be necessary to maintain accurate control over and  
337 accountability for all pharmaceutical materials;
- 338 (vii) participating [~~participation~~] in those aspects of the ASC's patient care evaluation program  
339 which relate to pharmaceutical material utilization and effectiveness;
- 340 (viii) participating [~~participation~~] in teaching and/or research programs in the ASC;
- 341 (ix) implementing [~~implementation of~~] the policies and decisions of the appropriate committee(s)  
342 relating to pharmaceutical services of the ASC;
- 343 (x) providing effective and efficient messenger and delivery service to connect the ASC  
344 pharmacy with appropriate areas of the ASC on a regular basis throughout the normal workday  
345 of the ASC;
- 346 (xi) labeling, storing, and distributing [~~storage, and distribution of~~] investigational new drugs,  
347 including maintaining [~~maintenance of~~] information in the pharmacy and nursing station where  
348 such drugs are being administered, concerning the dosage form, route of administration, strength,  
349 actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of  
350 investigational new drugs;
- 351 (xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this  
352 subsection; and
- 353 (xiii) maintaining [~~maintenance of~~] records in a data processing system such that the data  
354 processing system is in compliance with the requirements for a Class C (institutional) pharmacy  
355 located in a freestanding ASC.
- 356 (2) Consultant pharmacist.
- 357 (A) The consultant pharmacist may be the pharmacist-in-charge.
- 358 (B) A written contract shall exist between the ASC and any consultant pharmacist, and a copy of  
359 the written contract shall be made available to the board upon request.

360 (3) Pharmacists.

361 (A) General.

362 (i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed  
363 pharmacists as may be required to operate the ASC pharmacy competently, safely, and  
364 adequately to meet the needs of the patients of the facility.

365 (ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as  
366 outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for  
367 pharmaceutical materials.

368 (iii) All pharmacists shall be responsible for any delegated act performed by pharmacy  
369 technicians or pharmacy technician trainees under his or her supervision.

370 (iv) All pharmacists while on duty shall be responsible for complying with all state and federal  
371 laws or rules governing the practice of pharmacy.

372 (B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need  
373 not be limited to, the following:

374 (i) receiving and interpreting prescription drug orders and oral medication orders and reducing  
375 these orders to writing either manually or electronically;

376 (ii) selecting [~~selection of~~] prescription drugs and/or devices and/or suppliers; and

377 (iii) interpreting patient profiles.

378 (C) Special requirements for compounding non-sterile preparations. All pharmacists engaged in  
379 compounding non-sterile preparations shall meet the training requirements specified in §291.131  
380 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

381 (4) Pharmacy technicians and pharmacy technician trainees.

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

385 (B) Duties. Pharmacy technicians and pharmacy technician trainees may not perform any of the  
386 duties listed in paragraph (3)(B) of this subsection. Duties may include, but need not be limited  
387 to, the following functions, under the direct supervision of a pharmacist:

388 (i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises  
389 and conducts a final check and affixes his or her name, initials, electronic signature to the  
390 appropriate quality control records prior to distribution;

- 391 (ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication  
392 orders, provided a pharmacist supervises and checks the preparation;
- 393 (iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy  
394 technicians or pharmacy technician trainees have completed the training specified in §291.131 of  
395 this title;
- 396 (iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final  
397 checks and affixes his or her name, initials, or electronic signature to the appropriate quality  
398 control records prior to distribution;
- 399 (v) distributing routine orders for stock supplies to patient care areas;
- 400 (vi) entering medication order and drug distribution information into a data processing system,  
401 provided judgmental decisions are not required and a pharmacist checks the accuracy of the  
402 information entered into the system prior to releasing the order or in compliance with the  
403 absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section;
- 404 (vii) maintaining inventories of drug supplies;
- 405 (viii) maintaining pharmacy records; and
- 406 (ix) loading ~~bulk unlabeled~~ drugs into an automated medication supply system. For the purpose  
407 of this clause, direct supervision may be accomplished by physically present supervision or  
408 electronic monitoring by a pharmacist. [drug dispensing system provided a pharmacist  
409 supervises, verifies that the system was properly loaded prior to use, and affixes his or her name,  
410 initials or electronic signature to the appropriate quality control records.]
- 411 (C) Procedures.
- 412 (i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in  
413 accordance with standard written procedures and guidelines.
- 414 (ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders  
415 in the same manner as pharmacy technicians or pharmacy technician trainees working in a Class  
416 A pharmacy.
- 417 (D) Special requirements for compounding non-sterile preparations. All pharmacy technicians  
418 and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet  
419 the training requirements specified in §291.131 of this title.
- 420 (5) Owner. The owner of an ASC pharmacy shall have responsibility for all administrative and  
421 operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on  
422 administrative and operational concerns. The owner shall have responsibility for, at a minimum,  
423 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with  
424 the pharmacist-in-charge or another Texas licensed pharmacist:

425 (A) ~~establishing~~ [establishment of] policies for procurement of prescription drugs and devices  
426 and other products dispensed from the ASC pharmacy;

427 (B) ~~establishing and maintaining~~ [establishment and maintenance of] effective controls against  
428 the theft or diversion of prescription drugs;

429 (C) if the pharmacy uses an automated medication supply [~~pharmacy dispensing~~] system,  
430 reviewing and approving all policies and procedures for system operation, safety, security,  
431 accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

432 (D) providing the pharmacy with the necessary equipment and resources commensurate with its  
433 level and type of practice; and

434 (E) ~~establishing~~ [establishment of] policies and procedures regarding maintenance, storage, and  
435 retrieval of records in a data processing system such that the system is in compliance with state  
436 and federal requirements.

437 (6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows:

438 (A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge  
439 that bears the person's name and identifies him or her as a pharmacy technician [~~trainee-a~~  
440 ~~registered pharmacy technician, or a certified pharmacy technician if the technician maintains~~  
441 ~~current certification with the Pharmacy Technician Certification Board or any other entity~~  
442 ~~providing an examination approved by the board~~].

443 (B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification  
444 tag or badge that bears the person's name and identifies him or her as a pharmacy technician  
445 trainee.

446 (C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears  
447 the person's name and identifies him or her as a pharmacist intern.

448 (D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's  
449 name and identifies him or her as a pharmacist.

450 (d) Operational standards.

451 (1) Licensing requirements.

452 (A) An ASC pharmacy shall register annually or biennially with the board on a pharmacy license  
453 application provided by the board, following the procedures specified in §291.1 of this title  
454 (relating to Pharmacy License Application).

455 [~~(B) If the ASC pharmacy is owned or operated by a pharmacy management or consulting firm,~~  
456 ~~the following conditions apply.~~]

457 ~~[(i) The pharmacy license application shall list the pharmacy management or consulting firm as~~  
458 ~~the owner or operator.]~~

459 ~~[(ii) The pharmacy management or consulting firm shall obtain DEA and DPS controlled~~  
460 ~~substances registrations that are issued in the name of the firm, unless the following occur:]~~

461 ~~[(I) the pharmacy management or consulting firm and the facility cosign a contractual pharmacy~~  
462 ~~service agreement which assigns overall responsibility for controlled substances to the facility;~~  
463 ~~and]~~

464 ~~[(H) such pharmacy management or consulting firm maintains dual responsibility for the~~  
465 ~~controlled substances.]~~

466 (B) ~~[(C)]~~ An ASC pharmacy which changes ownership shall notify the board within 10 days of  
467 the change of ownership and apply for a new and separate license as specified in §291.3 of this  
468 title (relating to Required Notifications).

469 (C) ~~[(D)]~~ An ASC pharmacy which changes location and/or name shall notify the board of the  
470 change within 10 days and file for an amended license as specified in §291.3 of this title.

471 (D) ~~[(E)]~~ An ASC pharmacy owned by a partnership or corporation which changes managing  
472 officers shall notify the board in writing of the names of the new managing officers within 10  
473 days of the change, following the procedures in §291.3 of this title.

474 (E) ~~[(F)]~~ An ASC pharmacy shall notify the board in writing within 10 days of closing, following  
475 the procedures in §291.5 of this title (relating to Closing a Pharmacy).

476 (F) ~~[(G)]~~ A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be  
477 charged for issuance and renewal of a license and the issuance of an amended license.

478 (G) ~~[(H)]~~ A separate license is required for each principal place of business and only one  
479 pharmacy license may be issued to a specific location.

480 (H) ~~[(I)]~~ An ASC pharmacy, licensed under the Act, §560.051(a)(3), concerning institutional  
481 pharmacy (Class C), which also operates another type of pharmacy which would otherwise be  
482 required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class  
483 A), or the Act, §560.051(a)(2), concerning nuclear pharmacy (Class B), is not required to secure  
484 a license for the other type of pharmacy; provided, however, such license is required to comply  
485 with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating  
486 to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title  
487 (relating to Records), and §291.35 of this title (relating to Official Prescription Records), or  
488 §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53  
489 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and  
490 §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent  
491 such sections are applicable to the operation of the pharmacy.

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

494 (J) [~~(K)~~] [~~Effective August 31, 2014, an~~] ASC pharmacy personnel shall not compound sterile  
495 preparations unless the pharmacy has applied for and obtained a Class C-S pharmacy license.

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

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

503 (2) Environment.

504 (A) General requirements.

505 (i) Each ambulatory surgical center shall have a designated work area separate from patient  
506 areas, and which shall have space adequate for the size and scope of pharmaceutical services and  
507 shall have adequate space and security for the storage of drugs.

508 (ii) The ASC pharmacy shall be arranged in an orderly fashion and shall be kept clean. All  
509 required equipment shall be clean and in good operating condition.

510 (B) Special requirements.

511 (i) The ASC pharmacy shall have locked storage for Schedule II controlled substances and other  
512 controlled drugs requiring additional security.

513 (ii) The ASC pharmacy shall have a designated area for the storage of poisons and externals  
514 separate from drug storage areas.

515 (C) Security.

516 (i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed and  
517 capable of being locked by key, combination, or other mechanical or electronic means, so as to  
518 prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-  
519 charge may enter the pharmacy or [authorized personnel may] have access to storage areas for  
520 prescription drugs and/or devices.

521 ~~[(ii) All storage areas for prescription drugs and/or devices shall be locked by key or~~  
522 ~~combination, so as to prevent access by unauthorized personnel.]~~

523 ~~(iii)~~ (ii) The pharmacist-in-charge shall consult with ASC personnel with respect to security of  
524 the drug storage areas, including provisions for adequate safeguards against theft or diversion of  
525 dangerous drugs and controlled substances, and to security of records for such drugs.

526 ~~[prescription drugs and/or devices.]~~

527 (iii) The pharmacy shall have locked storage for Schedule II controlled substances and other  
528 drugs requiring additional security.

529 (3) Equipment and supplies. Ambulatory surgical centers supplying drugs for postoperative use  
530 shall have the following equipment and supplies:

531 (A) data processing system including a printer or comparable equipment;

532 (B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and

533 (C) adequate supply of prescription labels and other applicable identification labels.~~;~~

534 (4) Library. A reference library shall be maintained that includes the following in hard-copy or  
535 electronic format and that pharmacy personnel shall be capable of accessing at all times:

536 (A) current copies of the following:

537 (i) Texas Pharmacy Act and rules;

538 (ii) Texas Dangerous Drug Act and rules;

539 (iii) Texas Controlled Substances Act and rules;

540 (iv) Federal Controlled Substances Act and rules or official publication describing the  
541 requirements of the Federal Controlled Substances Act and rules;

542 (B) at least one current or updated general drug information reference which is required to ~~[from~~  
543 ~~each of the following categories:]~~

544 ~~[(i) Drug interactions. A reference text on drug interactions, such as Drug Interaction Facts. A~~  
545 ~~separate reference is not required if other references maintained by the pharmacy] contain drug~~  
546 ~~interaction information including information needed to determine severity or significance of the~~  
547 ~~interaction and appropriate recommendations or actions to be taken; and~~

548 ~~[(ii) General information. A general information reference text, such as:]~~

549 ~~[(I) Facts and Comparisons with current supplements;]~~

550 ~~[(H) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the~~  
551 ~~Healthcare Provider);]~~

552 ~~{(III) AHFS Drug Information with current supplements;}~~

553 ~~{(IV) Remington's Pharmaceutical Sciences; or}~~

554 ~~{(V) Clinical Pharmacology;}~~

555 ~~{(C) a current or updated reference on injectable drug products, such as Handbook of Injectable~~  
556 ~~Drugs;}~~

557 (C) ~~[(D)]~~ basic antidote information and the telephone number of the nearest regional poison  
558 control center.<sup>[;]</sup>

559 ~~{(E) if the pharmacy compounds sterile preparations, specialty references appropriate for the~~  
560 ~~scope of services provided by the pharmacy, e.g., if the pharmacy prepares cytotoxic drugs, a~~  
561 ~~reference text on the preparation of cytotoxic drugs, such as Procedures for Handling Cytotoxic~~  
562 ~~Drugs; and}~~

563 ~~{(F) metric apothecary weight and measure conversion charts.}~~

564 (5) Drugs.

565 (A) Procurement, preparation, and storage.

566 (i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of  
567 drugs, but may receive input from other appropriate staff of the facility, relative to such  
568 responsibility.

569 (ii) The pharmacist-in-charge shall have the responsibility for determining specifications of all  
570 drugs procured by the facility.

571 (iii) ASC pharmacies may not sell, purchase, trade, or possess prescription drug samples, unless  
572 the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).

573 (iv) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in  
574 §291.15 of this title (relating to Storage of Drugs).

575 (v) Any drug bearing an expiration date may not be dispensed or distributed beyond the  
576 expiration date of the drug.

577 (vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined together  
578 until such drugs are disposed of.

579 (B) Formulary.

580 (i) A formulary may be developed by an appropriate committee of the ASC ~~[ambulatory surgical~~  
581 ~~center]~~.

582 (ii) The pharmacist-in-charge or consultant pharmacist shall be a full voting member of any  
583 committee which involves pharmaceutical services.

584 (iii) A practitioner may grant approval for pharmacists at the ASC to interchange, in accordance  
585 with the facility's formulary, for the drugs on the practitioner's medication orders provided:

586 (I) a formulary has been developed;

587 (II) the formulary has been approved by the medical staff of the ASC;

588 (III) there is a reasonable method for the practitioner to override any interchange; and

589 (IV) the practitioner authorizes pharmacist in the ACS to interchange on his/her medication  
590 orders in accordance with the facility's formulary through his/her written agreement to abide by  
591 the policies and procedures of the medical staff and facility.

592 (C) Prepackaging [~~of drugs~~] and loading [~~of bulk unlabeled~~] drugs into automated medication  
593 supply [~~drug dispensing~~] system.

594 (i) Prepackaging of drugs.

595 (I) Drugs may be prepackaged in quantities suitable for distribution to other Class C pharmacies  
596 under common ownership or for internal distribution only by a pharmacist or by pharmacy  
597 technicians or pharmacy technician trainees under the direction and direct supervision of a  
598 pharmacist.

599 (II) The label of a prepackaged unit shall indicate:

600 (-a-) brand name and strength of the drug; or if no brand name, then the generic name, strength,  
601 and name of the manufacturer or distributor;

602 (-b-) facility's lot number;

603 (-c-) expiration date; [~~and~~]

604 (-d-) quantity of the drug, if quantity is greater than one; and[-]

605 (-e-) if the drug is distributed to another Class C pharmacy, name of the facility responsible for  
606 prepackaging the drug.

607 (III) Records of prepackaging shall be maintained to show:

608 (-a-) the name of the drug, strength, and dosage form;

609 (-b-) facility's lot number;

- 610 (-c-) manufacturer or distributor;
- 611 (-d-) manufacturer's lot number;
- 612 (-e-) expiration date;
- 613 (-f-) quantity per prepackaged unit;
- 614 (-g-) number of prepackaged units;
- 615 (-h-) date packaged;
- 616 (-i-) name, initials, or electronic signature of the prepacker; ~~and~~
- 617 (-j-) signature or electronic signature of the responsible pharmacist; and[-]
- 618 (-k-) if the drug is distributed to another Class C pharmacy, name of the facility receiving the  
619 prepackaged drug.
- 620 (IV) Stock packages, repackaged units, and control records shall be quarantined together until  
621 checked/released by the pharmacist.
- 622 (ii) Loading bulk unit of use ~~[unlabeled]~~ drugs into automated medication supply ~~[drug~~  
623 ~~dispensing]~~ systems.
- 624 ~~[(4)]~~ Automated medication supply ~~[drug dispensing]~~ systems may be loaded with bulk unit of  
625 use ~~[unlabeled]~~ drugs only by a pharmacist or by pharmacy technicians or pharmacy technician  
626 trainees under the direction and direct supervision of a pharmacist. For the purpose of this clause,  
627 direct supervision may be accomplished by physically present supervision or electronic  
628 monitoring by a pharmacist. In order for the pharmacist to electronically monitor, the medication  
629 supply system must allow for bar code scanning to verify the loading of drugs, and a record of  
630 the loading must be maintained by the system and accessible for electronic review by the  
631 pharmacist.
- 632 ~~[(II) The label of an automated drug dispensing system container shall indicate the brand name~~  
633 ~~and strength of the drug; or if no brand name, then the generic name, strength, and name of the~~  
634 ~~manufacturer or distributor.]~~
- 635 ~~[(III) Records of loading bulk unlabeled drugs into an automated drug dispensing system shall be~~  
636 ~~maintained to show:]~~
- 637 ~~[(a) name of the drug, strength, and dosage form;]~~
- 638 ~~[(b) manufacturer or distributor;]~~
- 639 ~~[(c) manufacturer's lot number;]~~

640 ~~[(d) expiration date;]~~

641 ~~[(e) date of loading;]~~

642 ~~[(f) name, initials, or electronic signature of the person loading the automated drug dispensing~~  
643 ~~system; and]~~

644 ~~[(g) signature or electronic signature of the responsible pharmacist.]~~

645 ~~[(IV) The automated drug dispensing system shall not be used until a pharmacist verifies that the~~  
646 ~~system is properly loaded and affixes his or her signature or electronic signature to the record~~  
647 ~~specified in subclause (III) of this clause.]~~

648 (6) Medication orders.

649 (A) Drugs may be administered to patients in ASCs only on the order of a practitioner. No  
650 change in the order for drugs may be made without the approval of a practitioner except as  
651 authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.

652 (B) Drugs may be distributed only pursuant to the ~~[original or a direct copy of the]~~ practitioner's  
653 medication order.

654 ~~[(C) Pharmacy technicians and pharmacy technician trainees may not receive oral medication~~  
655 ~~orders.]~~

656 (C) ~~[(D)]~~ ASC pharmacies shall be exempt from the labeling provisions and patient notification  
657 requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to  
658 medication orders.

659 (D) ~~[(E)]~~ In ASCs with a full-time pharmacist, if a practitioner orders a drug for administration  
660 to a bona fide patient of the facility when the pharmacy is closed, the following is applicable.

661 (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of  
662 a patient may be removed from the ASC pharmacy.

663 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

664 (iii) A record shall be made at the time of withdrawal by the authorized person removing the  
665 drugs and devices. The record shall contain the following information:

666 (I) name of the patient;

667 (II) name of device or drug, strength, and dosage form;

668 (III) dose prescribed;

- 669 (IV) quantity taken;
- 670 (V) time and date; and
- 671 (VI) signature or electronic signature of person making withdrawal.
- 672 (iv) The ~~[original or direct copy of the]~~ medication order in the patient's chart may substitute for  
673 such record, provided the medication order meets all the requirements of clause (iii) of this  
674 subparagraph.
- 675 (v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more than 72  
676 hours from the time of such withdrawal.
- 677 (E) ~~[(F)]~~ In ASCs with a part-time or consultant pharmacist, if a practitioner orders a drug for  
678 administration to a bona fide patient of the ASC when the pharmacist is not on duty, or when the  
679 pharmacy is closed, the following is applicable.
- 680 (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be  
681 removed from the ASC pharmacy.
- 682 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.
- 683 (iii) A record shall be made at the time of withdrawal by the authorized person removing the  
684 drugs and devices; the record shall meet the same requirements as specified in subparagraph (D)  
685 ~~[(E)]~~ of this paragraph.
- 686 (iv) The pharmacist shall conduct an audit of patient's medical record according to the schedule  
687 set out in the policy and procedures at [verify each distribution after] a reasonable interval, but  
688 ~~[in no event may]~~ such interval must occur at least once in every calendar week that the  
689 pharmacy is open [exceed seven days].
- 690 (7) Floor stock. In facilities using a floor stock method of drug distribution, the following is  
691 applicable for removing drugs or devices in the absence of a pharmacist.
- 692 (A) Prescription drugs and devices may be removed from the pharmacy only in the original  
693 manufacturer's container or prepackaged container.
- 694 (B) Only a designated licensed nurse or practitioner may remove such drugs and devices.
- 695 (C) A record shall be made at the time of withdrawal by the authorized person removing the drug  
696 or device; the record shall contain the following information:
- 697 (i) name of the drug, strength, and dosage form;
- 698 (ii) quantity removed;

- 699 (iii) location of floor stock;
- 700 (iv) date and time; and
- 701 (v) signature or electronic signature of person making the withdrawal.
- 702 (D) A pharmacist shall verify the withdrawal according to the following schedule.
- 703 (i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as practical,  
704 but in no event more than 72 hours from the time of such withdrawal.
- 705 (ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after a  
706 reasonable interval, but ~~[in no event may]~~ such interval must occur at least once in every  
707 calendar week that the pharmacy is open ~~[exceed seven days]~~.
- 708 (8) Policies and procedures. Written policies and procedures for a drug distribution system,  
709 appropriate for the ambulatory surgical center, shall be developed and implemented by the  
710 pharmacist-in-charge with the advice of the appropriate committee. The written policies and  
711 procedures for the drug distribution system shall include, but not be limited to, procedures  
712 regarding the following:
- 713 (A) controlled substances;
- 714 (B) investigational drugs;
- 715 (C) prepackaging and manufacturing;
- 716 (D) medication errors;
- 717 (E) orders of physician or other practitioner;
- 718 (F) floor stocks;
- 719 (G) adverse drug reactions;
- 720 (H) drugs brought into the facility by the patient;
- 721 (I) self-administration;
- 722 (J) emergency drug tray;
- 723 (K) formulary, if applicable;
- 724 (L) drug storage areas;
- 725 (M) drug samples;

- 726 (N) drug product defect reports;
- 727 (O) drug recalls;
- 728 (P) outdated drugs;
- 729 (Q) preparation and distribution of IV admixtures;
- 730 (R) procedures for supplying drugs for postoperative use, if applicable;
- 731 (S) use of automated medication supply [~~drug dispensing~~] systems; [~~and~~]
- 732 (T) use of data processing systems; and [-]
- 733 (U) drug regimen review.
- 734 (9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall  
735 be supplied according to the following procedures.
- 736 (A) Drugs may only be supplied to patients who have been admitted to the ASC [~~ambulatory~~  
737 ~~surgical center~~].
- 738 (B) Drugs may only be supplied in accordance with the system of control and accountability  
739 established for drugs supplied from the ambulatory surgical center; such system shall be  
740 developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the  
741 pharmacist-in-charge.
- 742 (C) Only drugs listed on the approved postoperative drug list may be supplied; such list shall be  
743 developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the  
744 nature and type to meet the immediate postoperative needs of the ambulatory surgical center  
745 patient.
- 746 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in  
747 suitable containers and appropriately prelabeled (including name, address, and phone number of  
748 the facility, and necessary auxiliary labels) by the pharmacy, provided, however that topicals and  
749 ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-  
750 hour supply.
- 751 (E) At the time of delivery of the drug, the practitioner or licensed nurse under the practitioner's  
752 supervision shall complete the label, such that the prescription container bears a label with at  
753 least the following information:
- 754 (i) date supplied;
- 755 (ii) name of practitioner;

- 756 (iii) name of patient;
- 757 (iv) directions for use;
- 758 (v) brand name and strength of the drug; or if no brand name, then the generic name of the drug  
759 dispensed, strength, and the name of the manufacturer or distributor of the drug; and
- 760 (vi) unique identification number.
- 761 (F) After the drug has been labeled [~~by the practitioner~~], the practitioner or a licensed nurse  
762 under the supervision of the practitioner shall give the appropriately labeled, prepackaged  
763 medication to the patient.
- 764 (G) A perpetual record of drugs which are supplied from the ASC shall be maintained which  
765 includes:
- 766 (i) name, address, and phone number of the facility;
- 767 (ii) date supplied;
- 768 (iii) name of practitioner;
- 769 (iv) name of patient;
- 770 (v) directions for use;
- 771 (vi) brand name and strength of the drug; or if no brand name, then the generic name of the drug  
772 dispensed, strength, and the name of the manufacturer or distributor of the drug; and
- 773 (vii) unique identification number.
- 774 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall  
775 review the records at least once in every calendar week that the pharmacy is open [~~every seven~~  
776 ~~days~~].
- 777 (10) Drug regimen review.
- 778 (A) A pharmacist shall evaluate medication orders and patient medication records for:
- 779 (i) known allergies;
- 780 (ii) rational therapy--contraindications;
- 781 (iii) reasonable dose and route of administration;
- 782 (iv) reasonable directions for use;

- 783 (v) duplication of therapy;
- 784 (vi) drug-drug interactions;
- 785 (vii) drug-food interactions;
- 786 (viii) drug-disease interactions;
- 787 (ix) adverse drug reactions;
- 788 (x) proper utilization, including overutilization or underutilization; and
- 789 (xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug  
 790 effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of  
 791 the drug in its current regimen.
- 792 (B) A retrospective, random drug regimen review as specified in the pharmacy's policies and  
 793 procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed  
 794 31 days between such reviews.
- 795 (C) Any questions regarding the order must be resolved with the prescriber and a written  
 796 notation of these discussions made and maintained.
- 797 (e) Records.
- 798 (1) Maintenance of records.
- 799 (A) Every inventory or other record required to be kept under the provisions of this section  
 800 (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center  
 801 [~~Institutional Pharmacy (Class C)~~]) shall be:
- 802 (i) kept by the pharmacy and be available, for at least two years from the date of such inventory  
 803 or record, for inspecting and copying by the board or its representative, and other authorized  
 804 local, state, or federal law enforcement agencies; and
- 805 (ii) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas  
 806 State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the  
 807 requested records must be provided in a mutually agreeable electronic format if specifically  
 808 requested by the board or its representative. Failure to provide the records set out in this  
 809 subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep  
 810 and maintain records in violation of the Act.
- 811 (B) Records of controlled substances listed in Schedule [Schedules I and] II shall be maintained  
 812 separately and readily retrievable from all other records of the pharmacy.

813 (C) Records of controlled substances listed in Schedules III - V shall be maintained separately or  
814 readily retrievable from all other records of the pharmacy. For purposes of this subparagraph  
815 ~~[subsection]~~, readily retrievable means that the controlled substances shall be asterisked, red-  
816 lined, or in some other manner readily identifiable apart from all other items appearing on the  
817 record.

818 (D) Records, except when specifically required to be maintained in original or hard-copy form,  
819 may be maintained in an alternative data retention system, such as a data processing or direct  
820 imaging system~~[-e.g., microfilm or microfiche,]~~ provided:

821 (i) the records in the alternative data retention system contain all of the information required on  
822 the manual record; and

823 (ii) the alternative data retention system is capable of producing a hard copy of the record upon  
824 the request of the board, its representative, or other authorized local, state, or federal law  
825 enforcement or regulatory agencies.

826 (E) Controlled substance records shall be maintained in a manner to establish receipt and  
827 distribution of all controlled substances.

828 (F) An ASC pharmacy shall maintain a perpetual inventory of controlled substances listed in  
829 Schedule II - V which shall be verified for completeness and reconciled at least once in every  
830 calendar week that the pharmacy is open.

831 (G) Distribution records for controlled substances, listed in Schedule II - V, shall include the  
832 following information:

833 (i) patient's name;

834 (ii) practitioner's name who order the drug;

835 (iii) name of drug, dosage form, and strength;

836 (iv) time and date of administration to patient and quantity administered;

837 (v) signature or electronic signature of individual administering the controlled substance;

838 (vi) returns to the pharmacy; and

839 (vii) waste (waste is required to be witnessed and cosigned, manually or electronically, by  
840 another individual).

841 (H) The record required by subparagraph (G) of this paragraph shall be maintained separately  
842 from patient records.

843 (I) A pharmacist shall conduct an audit by randomly comparing the distribution records required  
844 by subparagraph (G) with the medication orders in the patient record on a periodic basis to verify  
845 proper administration of drugs not to exceed 30 days between such reviews.

846 ~~[(2) Outpatient records.]~~

847 ~~[(A) Only a registered pharmacist may receive, certify, and receive prescription drug orders.]~~

848 ~~[(B) Outpatient records shall be maintained as provided in §291.34 and §291.35 of this title~~  
849 ~~contained in Community Pharmacy (Class A).]~~

850 ~~[(C) Outpatient prescriptions, including, but not limited to, discharge prescriptions, that are~~  
851 ~~written by the practitioner, must be written on a form which meets the requirements of the Act,~~  
852 ~~§562.006. Medication order forms or copies thereof do not meet the requirements for outpatient~~  
853 ~~forms.]~~

854 ~~[(D) Controlled substances listed in Schedule II must be written on an electronic prescription~~  
855 ~~form in accordance with the Texas Controlled Substances Act, §481.075, and rules promulgated~~  
856 ~~pursuant to the Texas Controlled Substances Act, unless exempted by the Texas Controlled~~  
857 ~~Substances Rules, 37 TAC §13.74. Outpatient prescriptions for Schedule II controlled substances~~  
858 ~~that are exempted from the official prescription requirement must be manually signed by the~~  
859 ~~practitioner.]~~

860 (2) [(3)] Patient records.

861 (A) Each ~~[original]~~ medication order or set of orders issued together shall bear the following  
862 information:

863 (i) patient name;

864 (ii) drug name, strength, and dosage form;

865 (iii) directions for use;

866 (iv) date; and

867 (v) signature or electronic signature of the practitioner or that of his or her authorized agent,  
868 defined as a licensed nurse employee or consultant/full or part-time pharmacist of the ASC.

869 (B) Medication ~~[Original medication]~~ orders shall be maintained with the medication  
870 administration record in the medical records of the patient.

871 ~~[(C) Controlled substances records shall be maintained as follows.]~~

872 ~~[(i) All records for controlled substances shall be maintained in a readily retrievable manner.]~~

873 ~~[(ii) Controlled substances records shall be maintained in a manner to establish receipt and~~  
874 ~~distribution of all controlled substances.]~~

875 ~~[(D) Records of controlled substances listed in Schedule II shall be maintained as follows.]~~

876 ~~[(i) Records of controlled substances listed in Schedule II shall be maintained separately from~~  
877 ~~records of controlled substances in Schedules III, IV, and V, and all other records.]~~

878 ~~[(ii) An ASC pharmacy shall maintain a perpetual inventory of any controlled substance listed in~~  
879 ~~Schedule II.]~~

880 ~~[(iii) Distribution records for Schedule II—V controlled substances floor stock shall include the~~  
881 ~~following information:]~~

882 ~~[(I) patient's name;]~~

883 ~~[(II) practitioner who ordered drug;]~~

884 ~~[(III) name of drug, dosage form, and strength;]~~

885 ~~[(IV) time and date of administration to patient and quantity administered;]~~

886 ~~[(V) signature or electronic signature of individual administering controlled substance;]~~

887 ~~[(VI) returns to the pharmacy; and]~~

888 ~~[(VII) waste (waste is required to be witnessed and cosigned, manually or electronically, by~~  
889 ~~another individual).]~~

890 ~~[(E) Floor stock records shall be maintained as follows.]~~

891 ~~[(i) Distribution records for Schedules III—V controlled substances floor stock shall include the~~  
892 ~~following information:]~~

893 ~~[(I) patient's name;]~~

894 ~~[(II) practitioner who ordered controlled substance;]~~

895 ~~[(III) name of controlled substance, dosage form, and strength;]~~

896 ~~[(IV) time and date of administration to patient;]~~

897 ~~[(V) quantity administered;]~~

898 ~~[(VI) signature or electronic signature of individual administering drug;]~~

899 ~~{(VII) returns to the pharmacy; and}~~

900 ~~{(VIII) waste (waste is required to be witnessed and cosigned, manually or electronically, by~~  
901 ~~another individual).}~~

902 ~~{(ii) The record required by clause (i) of this subparagraph shall be maintained separately from~~  
903 ~~patient records.}~~

904 ~~{(iii) A pharmacist shall review distribution records with medication orders on a periodic basis to~~  
905 ~~verify proper usage of drugs, not to exceed 30 days between such reviews.}~~

906 (3) [(F)] General requirements for records maintained in a data processing system [~~are as~~  
907 ~~follows~~].

908 (A) [(†)] If an ASC pharmacy's data processing system is not in compliance with the board's  
909 requirements, the pharmacy must maintain a manual recordkeeping system.

910 (B) [(ii)] [~~Requirements for backup systems.~~] The facility shall maintain a backup copy of  
911 information stored in the data processing system using disk, tape, or other electronic backup  
912 system and update this backup copy on a regular basis to assure that data is not lost due to  
913 system failure.

914 ~~{(iii) Change or discontinuance of a data processing system.}~~

915 (C) [(†)] [~~Records of distribution and return for all controlled substances, nalbuphine (Nubain),~~  
916 ~~and carisoprodol (Soma).~~] A pharmacy that changes or discontinues use of a data processing  
917 system must:

918 (i) [(a)] transfer the records to the new data processing system; or

919 (ii) [(b)] purge the records to a printout which contains: [~~the same information as required on~~  
920 ~~the audit trail printout as specified in subparagraph (G)(ii) of this paragraph. The information on~~  
921 ~~this printout shall be sorted and printed by drug name and list all distributions/returns~~  
922 ~~chronologically.~~]

923 (I) all of the information required on the original document; or

924 (II) for records of distribution and return for all controlled substances, the same information as  
925 required on the audit trail printout as specified in subparagraph (F) of this paragraph. The  
926 information on the printout shall be sorted and printed by drug name and list all distributions and  
927 returns chronologically.

928 ~~{(H) Other records. A pharmacy that change or discontinues use of a data processing system~~  
929 ~~must:}~~

930 ~~{(a) transfer the records to the new data processing system; or}~~

931 ~~[(b) purge the records to a printout which contains all of the information required on the~~  
932 ~~original document.]~~

933 ~~(D) [(H)] [Maintenance of purged records.]~~ Information purged from a data processing system  
934 must be maintained by the pharmacy for two years from the date of initial entry into the data  
935 processing system.

936 ~~(E) [(iv)] [Loss of data.]~~ The pharmacist-in-charge shall report to the board in writing any  
937 significant loss of information from the data processing system within 10 days of discovery of  
938 the loss.

939 ~~[(G) Data processing system maintenance of records for the distribution and return of all~~  
940 ~~controlled substances, nalbuphine (Nubain), or tramadol (Ultram) to the pharmacy.]~~

941 ~~[(i) Each time a controlled substance, nalbuphine (Nubain), or tramadol (Ultram) is distributed~~  
942 ~~from or returned to the pharmacy, a record of such distribution or return shall be entered into the~~  
943 ~~data processing system.]~~

944 ~~(F) [(ii)]~~ The data processing system shall have the capacity to produce a hard-copy printout of  
945 an audit trail of drug distribution and return for any strength and dosage form of a drug (by either  
946 brand or generic name or both) during a specified time period. This printout shall contain the  
947 following information:

948 ~~(i) [(I)]~~ patient's name and room number or patient's facility identification number;

949 ~~(ii) [(H)]~~ prescribing or attending practitioner's name;

950 ~~(iii) [(HH)]~~ name, strength, and dosage form of the drug product actually distributed;

951 ~~(iv) [(IV)]~~ total quantity distributed from and returned to the pharmacy;

952 ~~(v) [(V)]~~ if not immediately retrievable via electronic image, the following shall also be included  
953 on the printout:

954 ~~(I) [(a)]~~ prescribing or attending practitioner's address; and

955 ~~(II) [(b)]~~ practitioner's DEA registration number, if the medication order is for a controlled  
956 substance.

957 ~~(G) [(iii)]~~ An audit trail printout for each strength and dosage form of these drugs distributed  
958 during the preceding month shall be produced at least monthly and shall be maintained in a  
959 separate file at the facility. The information on this printout shall be sorted by drug name and list  
960 all distributions/returns for that drug chronologically.

961 ~~(H) [(iv)]~~ The pharmacy may elect not to produce the monthly audit trail printout if the data  
962 processing system has a workable (electronic) data retention system which can produce an audit

963 trail of drug distribution and returns for the preceding two years. The audit trail required in this  
964 clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of  
965 the Texas State Board of Pharmacy, or other authorized local, state, or federal law enforcement  
966 or regulatory agencies.

967 ~~[(H) Failure to maintain records. Failure to provide records set out in this subsection, either on  
968 site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep  
969 and maintain records.]~~

970 (I) ~~[Data processing system downtime.]~~ In the event that an ASC pharmacy which uses a data  
971 processing system experiences system downtime, the pharmacy must have an auxiliary  
972 procedure which will ensure that all data is retained for on-line data entry as soon as the system  
973 is available for use again.

974 (4) Distribution of controlled substances to another registrant. A pharmacy may distribute  
975 controlled substances to a practitioner, another pharmacy, or other registrant, without being  
976 registered to distribute, under the following conditions.

977 (A) The registrant to whom the controlled substance is to be distributed is registered under the  
978 Controlled Substances Act to possess ~~[dispense]~~ that controlled substance.

979 (B) The total number of dosage units of controlled substances distributed by a pharmacy may not  
980 exceed 5.0% of all controlled substances dispensed by the pharmacy during the 12-month period  
981 in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required  
982 to obtain an additional registration to distribute controlled substances.

983 (C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be  
984 maintained which indicates:

985 (i) the actual date of distribution;

986 (ii) the name, strength, and quantity of controlled substances distributed;

987 (iii) the name, address, and DEA registration number of the distributing pharmacy; and

988 (iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other  
989 registrant to whom the controlled substances are distributed.

990 (D) If the distribution is for a Schedule II controlled substance, the following is applicable.

991 (i) The pharmacy, practitioner, or other registrant who is receiving the controlled substances  
992 shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222[€]) to the distributing pharmacy.

993 (ii) The distributing pharmacy shall:

994 (I) complete the area on the DEA order form (DEA 222[€]) titled "To Be Filled in by Supplier";

- 995 (II) maintain Copy 1 of the DEA order form (DEA 222[~~€~~]) at the pharmacy for two years; and
- 996 (III) forward Copy 2 of the DEA order form (DEA 222[~~€~~]) to the divisional office of the Drug  
997 Enforcement Administration.
- 998 (5) Other records. Other records to be maintained by the pharmacy include:
- 999 (A) a permanent log of the initials or identification codes which will identify each pharmacist by  
1000 name. The initials or identification code shall be unique to ensure that each pharmacist can be  
1001 identified, i.e., identical initials or identification codes cannot be used;
- 1002 (B) Copy 3 of DEA order form (DEA 222[~~€~~]), which has been properly dated, initialed, and  
1003 filed, and all copies of each unaccepted or defective order form and any attached statements or  
1004 other documents and/or for each order filled using the DEA Controlled Substance Ordering  
1005 System (CSOS), the original signed order and all linked records for that order;
- 1006 (C) a [~~hard~~] copy of the power of attorney to sign DEA 222[~~€~~] order forms (if applicable);
- 1007 (D) suppliers' invoices of dangerous drugs and controlled substances dated and initialed or  
1008 signed by the person receiving the drugs; a pharmacist shall verify that the controlled drugs listed  
1009 on the invoices were added to the pharmacy's perpetual inventory [actually received] by clearly  
1010 recording his/her initials and the [~~actual~~] date of review [receipt] of the perpetual inventory  
1011 [~~controlled substances~~];
- 1012 (E) supplier's credit memos for controlled substances and dangerous drugs;
- 1013 (F) a [~~hard~~] copy of inventories required by §291.17 of this title (relating to Inventory  
1014 Requirements) except that a perpetual inventory of controlled substances listed in Schedule II  
1015 may be kept in a data processing system if the data processing system is capable of producing a  
1016 [~~hard~~] copy of the perpetual inventory on-site;
- 1017 (G) [~~hard-copy~~] reports of surrender or destruction of controlled substances and/or dangerous  
1018 drugs to an appropriate state or federal agency;
- 1019 [~~(H) a hard-copy Schedule V nonprescription register book;~~]
- 1020 (H) [(H)] records of distribution of controlled substances and/or dangerous drugs to other  
1021 pharmacies, practitioners, or registrants; and
- 1022 (I) [(I)] a [~~hard~~] copy of any notification required by the Texas Pharmacy Act or these rules,  
1023 including, but not limited to, the following:
- 1024 (i) reports of theft or significant loss of controlled substances to DEA, DPS, and the board;
- 1025 (ii) notification of a change in pharmacist-in-charge of a pharmacy; and

1026 (iii) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs,  
1027 medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and  
1028 disease.

1029 (6) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping  
1030 system for invoices and financial data shall comply with the following procedures.

1031 (A) Controlled substance records. Invoices and financial data for controlled substances may be  
1032 maintained at a central location provided the following conditions are met.

1033 (i) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by  
1034 registered or certified mail to the divisional director of the Drug Enforcement Administration as  
1035 required by the Code of Federal Regulations, Title 21, §1304(a), and submits a copy of this  
1036 written notification to the Texas State Board of Pharmacy. Unless the registrant is informed by  
1037 the divisional director of the Drug Enforcement Administration that permission to keep central  
1038 records is denied, the pharmacy may maintain central records commencing 14 days after receipt  
1039 of notification by the divisional director.

1040 (ii) The pharmacy maintains a copy of the notification required in this subparagraph.

1041 (iii) The records to be maintained at the central record location shall not include executed DEA  
1042 order forms, prescription drug orders, or controlled substance inventories, which shall be  
1043 maintained at the pharmacy.

1044 (B) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained  
1045 at a central location.

1046 (C) Access to records. If the records are kept [~~on microfilm, computer media, or~~] in any form  
1047 requiring special equipment to render the records easily readable, the pharmacy shall provide  
1048 access to such equipment with the records.

1049 (D) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the  
1050 pharmacy location within two business days of written request of a board agent or any other  
1051 authorized official.

1052 The agency certifies that legal counsel has reviewed the proposal and found it to be within the  
1053 state agency's legal authority to adopt.

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1060 For further information, please call: (512) 305-8028

1061