

RULE ANALYSIS

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

Short Title: Operational Standards

Rule Numbers: §291.74

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, eliminate references to pharmacies operated by management companies which are no longer authorized by DEA; implement provisions of SB 460 regarding notification for a change of location; and remove references to Class C-S pharmacy which are no longer necessary.

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

5
6 **§291.74. Operational Standards.**
7

8 (a) Licensing requirements.

9 (1) A Class C pharmacy shall register annually or biennially with the board on a pharmacy
10 license application provided by the board, following the procedures specified in §291.1 of this
11 title (relating to Pharmacy License Application).

12 (2) ~~If the institutional pharmacy is owned or operated by a hospital management or consulting~~
13 ~~firm, the following conditions apply.~~

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

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

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

21 ~~—(ii) such hospital pharmacy management or consulting firm maintains dual responsibility for~~
22 ~~the controlled substances.]~~

23 ~~[(3)]~~ A Class C pharmacy which changes ownership shall notify the board within 10 days of
24 the change of ownership and apply for a new and separate license as specified in §291.3 of this
25 title (relating to Required Notifications).

26 **(3)** ~~[(4)]~~ A Class C pharmacy which changes location and/or name shall notify the board
27 ~~[within 10 days]~~ of the change ~~[and file for an amended license]~~ as specified in §291.3 of this
28 title.

29 **(4)** ~~[(5)]~~ A Class C pharmacy owned by a partnership or corporation which changes managing
30 officers shall notify the board in writing of the names of the new managing officers within 10
31 days of the change following the procedures in §291.3 of this title.

32 **(5)** ~~[(6)]~~ A Class C pharmacy shall notify the board in writing within 10 days of closing, following
33 the procedures in §291.5 of this title (relating to Closing a Pharmacy).

34 **(6)** ~~[(7)]~~ A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
35 charged for the issuance and renewal of a license and the issuance of an amended license.

36 **(7)** ~~[(8)]~~ A separate license is required for each principal place of business and only one
37 pharmacy license may be issued to a specific location.

38 **(8)** ~~[(9)]~~ A Class C pharmacy, licensed under the Act, §560.051(a)(3), which also operates
39 another type of pharmacy which would otherwise be required to be licensed under the Act,
40 §560.051(a)(1) (Community Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear Pharmacy
41 (Class B)), is not required to secure a license for the such other type of pharmacy; provided,
42 however, such licensee is required to comply with the provisions of §291.31 of this title (relating
43 to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to
44 Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title
45 (relating to Official Prescription Records), contained in Community Pharmacy (Class A), or
46 §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of
47 this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and
48 §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the
49 extent such sections are applicable to the operation of the pharmacy.

50 **(9)** ~~[(10)]~~ A Class C pharmacy engaged in the compounding of non-sterile preparations shall
51 comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-
52 sterile Preparations).

53 ~~[(11) Prior to August 31, 2014, a Class C pharmacy engaged in the compounding of sterile
54 preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies
55 Compounding Sterile Preparations).]~~

56 **(10)** ~~[(12) Effective August 31, 2014, a]~~ Class C pharmacy **personnel** shall not compound
57 sterile preparations unless the pharmacy has applied for and obtained a Class C-S pharmacy.

58 **(11)** ~~[(13)]~~ A Class C pharmacy engaged in the provision of remote pharmacy services,
59 including storage and dispensing of prescription drugs, shall comply with the provisions of
60 §291.121 of this title (relating to Remote Pharmacy Services).

61 **(12)** ~~[(14)]~~ A Class C pharmacy engaged in centralized prescription dispensing and/or
62 prescription drug or medication order processing shall comply with the provisions of §291.123 of
63 this title (relating to Central Prescription Drug or Medication Order Processing) and/or §291.125
64 of this title (relating to Centralized Prescription Dispensing).

65 **(13)** ~~[(15)]~~ A Class C pharmacy with an ongoing clinical pharmacy program that proposes to
66 allow a pharmacy technician to verify the accuracy of work performed by another pharmacy
67 technician relating to the filling of floor stock and unit dose distribution systems for a patient
68 admitted to the hospital if the patient's orders have previously been reviewed and approved by a
69 pharmacist shall make application to the board as follows.

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

- 72 (i) name, address, and pharmacy license number;
- 73 (ii) name and license number of the pharmacist-in-charge;
- 74 (iii) name and registration numbers of the pharmacy technicians;
- 75 (iv) anticipated date the pharmacy plans to begin allowing a pharmacy technician to verify
76 the accuracy of work performed by another pharmacy technician;
- 77 (v) documentation that the pharmacy has an ongoing clinical pharmacy program; and
- 78 (vi) any other information specified on the application.

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

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

85 **(14)** ~~[(16)]~~ A rural hospital that wishes to allow a pharmacy technician to perform the duties
86 specified in §291.73(e)(2)(D) of this title (relating to Personnel), shall make application to the
87 board as follows.

88 (A) Prior to allowing a pharmacy technician to perform the duties specified in
89 §291.73(e)(2)(D) of this title, the pharmacist-in-charge must submit an application on a form
90 provided by the board, containing the following information:

- 91 (i) name, address, and pharmacy license number;
- 92 (ii) name and license number of the pharmacist-in-charge;
- 93 (iii) name and registration number of the pharmacy technicians;
- 94 (iv) proposed date the pharmacy wishes to start allowing pharmacy technicians to perform
95 the duties specified in §291.73(e)(2)(D) of this title;
- 96 (v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the
97 rural hospital is either:

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

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

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

103 (B) A rural hospital may not allow a pharmacy technician to perform the duties specified in
104 §291.73(e)(2)(D) of this title until the board has reviewed and approved the application and
105 issued an amended license to the pharmacy.

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

109 (b) Environment.

110 (1) General requirements.

111 (A) The institutional pharmacy shall have adequate space necessary for the storage,
112 compounding, labeling, dispensing, and sterile preparation of drugs prepared in the pharmacy,
113 and additional space, depending on the size and scope of pharmaceutical services.

114 (B) The institutional pharmacy shall be arranged in an orderly fashion and shall be kept
115 clean. All required equipment shall be clean and in good operating condition.

116 (C) A sink with hot and cold running water exclusive of restroom facilities shall be available to
117 all pharmacy personnel and shall be maintained in a sanitary condition at all times.

118 (D) The institutional pharmacy shall be properly lighted and ventilated.

119 (E) The temperature of the institutional pharmacy shall be maintained within a range
120 compatible with the proper storage of drugs. The temperature of the refrigerator and/or freezer
121 shall be maintained within a range compatible with the proper storage of drugs.

122 (F) If the institutional pharmacy has flammable materials, the pharmacy shall have a
123 designated area for the storage of flammable materials. Such area shall meet the requirements
124 set by local and state fire laws.

125 (G) The institutional pharmacy shall store antiseptics, other drugs for external use, and
126 disinfectants separately from internal and injectable medications.

127 (2) Security requirements.

128 (A) The institutional pharmacy shall be enclosed and capable of being locked by key,
129 combination or other mechanical or electronic means, so as to prohibit access by unauthorized
130 individuals. Only individuals authorized by the pharmacist-in-charge shall enter the pharmacy.

131 (B) Each pharmacist on duty shall be responsible for the security of the institutional
132 pharmacy, including provisions for adequate safeguards against theft or diversion of dangerous
133 drugs, controlled substances, and records for such drugs.

134 (C) The institutional pharmacy shall have locked storage for Schedule II controlled
135 substances and other drugs requiring additional security.

136 (c) Equipment and supplies. Institutional pharmacies distributing medication orders shall have
137 the following equipment:

138 (1) data processing system including a printer or comparable equipment; and

139 (2) refrigerator and/or freezer and a system or device (e.g., thermometer) to monitor the
140 temperature to ensure that proper storage requirements are met.

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

143 (1) current copies of the following:

144 (A) Texas Pharmacy Act and rules;

145 (B) Texas Dangerous Drug Act and rules;

146 (C) Texas Controlled Substances Act and regulations; and

147 (D) Federal Controlled Substances Act and regulations (or official publication describing the
148 requirements of the Federal Controlled Substances Act and regulations);

149 (2) at least one current or updated reference from each of the following categories:

150 (A) drug interactions. A reference text on drug interactions, such as Drug Interaction Facts. A
151 separate reference is not required if other references maintained by the pharmacy contain drug
152 interaction information including information needed to determine severity or significance of the
153 interaction and appropriate recommendations or actions to be taken;

154 (B) a general information reference text, such as:
155 (i) Facts and Comparisons with current supplements;
156 (ii) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the
157 Healthcare Provider);
158 (iii) AHFS Drug Information with current supplements;
159 (iv) Remington's Pharmaceutical Sciences; or
160 (v) Clinical Pharmacology;

161 (3) a current or updated reference on injectable drug products, such as Handbook of
162 Injectable Drugs;

163 (4) basic antidote information and the telephone number of the nearest regional poison control
164 center;

165 (5) metric-apothecary weight and measure conversion charts.

166 (e) Absence of a pharmacist.

167 (1) Medication orders.

168 (A) In facilities with a full-time pharmacist, if a practitioner orders a drug for administration to a
169 bona fide patient of the facility when the pharmacy is closed, the following is applicable.

170 (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic
171 needs may be removed from the institutional pharmacy.

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

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

175 (I) name of patient;
176 (II) name of device or drug, strength, and dosage form;
177 (III) dose prescribed;
178 (IV) quantity taken;
179 (V) time and date; and
180 (VI) signature (first initial and last name or full signature) or electronic signature of person
181 making withdrawal.

182 (iv) The original or direct copy of the medication order may substitute for such record,
183 providing the medication order meets all the requirements of clause (iii) of this subparagraph.

184 (v) The pharmacist shall verify the withdrawal of drugs from the pharmacy and perform a
185 drug regimen review as specified in subsection (g)(1)(B) of this section as soon as practical, but
186 in no event more than 72 hours from the time of such withdrawal.

187 (B) In facilities with a part-time or consultant pharmacist, if a practitioner orders a drug for
188 administration to a bona fide patient of the facility when the pharmacist is not on duty, or when
189 the pharmacy is closed, the following is applicable.

190 (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be
191 removed from the institutional pharmacy.

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

193 (iii) A record shall be made at the time of withdrawal by the authorized person removing the
194 drugs and devices; the record shall meet the same requirements as specified in subparagraph
195 (A)(iii) and (iv) of this paragraph.

196 (iv) The pharmacist shall verify the withdrawal of drugs from the pharmacy and perform a
197 drug regimen review as specified in subsection (g)(1)(B) of this section after a reasonable
198 interval, but in no event may such interval exceed seven days.

199 (2) Floor stock. In facilities using a floor stock method of drug distribution, the following is
200 applicable.

201 (A) Prescription drugs and devices may be removed from the pharmacy only in the original
202 manufacturer's container or prepackaged container.

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

204 (C) A record shall be made at the time of withdrawal by the authorized person removing the
205 drug or device; the record shall contain the following information:

206 (i) name of the drug, strength, and dosage form;

207 (ii) quantity removed;

208 (iii) location of floor stock;

209 (iv) date and time; and

210 (v) signature (first initial and last name or full signature) or electronic signature of person
211 making the withdrawal.

212 (D) The pharmacist shall verify the withdrawal of drugs from the pharmacy after a reasonable
213 interval, but in no event may such interval exceed seven days.

214 (3) Rural hospitals. In rural hospitals when a pharmacy technician performs the duties listed in
215 §291.73(e)(2)(D) of this title, the following is applicable:

216 (A) the pharmacy technician shall make a record of all drugs distributed from the pharmacy.
217 The record shall be maintained in the pharmacy for two years and contain the following
218 information:

219 (i) name of patient or location where floor stock is distributed;

220 (ii) name of device or drug, strength, and dosage form;

221 (iii) dose prescribed or ordered;

222 (iv) quantity distributed;

223 (v) time and date of the distribution; and

224 (vi) signature (first initial and last name or full signature) or electronic signature of nurse or
225 practitioner that verified the actions of the pharmacy technician.

226 (B) The original or direct copy of the medication order may substitute for the record specified
227 in subparagraph (A) of this paragraph, provided the medication order meets all the requirements
228 of subparagraph (A) of this paragraph.

229 (C) The pharmacist shall:

230 (i) verify and document the verification of all distributions made from the pharmacy in the
231 absence of a pharmacist as soon as practical, but in no event more than seven (7) days from
232 the time of such distribution;

233 (ii) perform a drug regimen review for all medication orders as specified in subsection
234 (g)(1)(B) of this section as soon as practical, but in no event more than seven (7) days from the
235 time of such distribution and document such verification including any discrepancies noted by
236 the pharmacist;

237 (iii) review any discrepancy noted by the pharmacist with the pharmacy technician(s) and
238 make any change in procedures or processes necessary to prevent future problems; and

239 (iv) report any adverse events that have a potential for harm to a patient to the appropriate
240 committee of the hospital that reviews adverse events.

241 (f) Drugs.

242 (1) Procurement, preparation and storage.

243 (A) The pharmacist-in-charge shall have the responsibility for the procurement and storage of
244 drugs, but may receive input from other appropriate staff of the facility, relative to such
245 responsibility.

246 (B) The pharmacist-in-charge shall have the responsibility for determining specifications of all
247 drugs procured by the facility.

248 (C) Institutional pharmacies may not sell, purchase, trade or possess prescription drug
249 samples, unless the pharmacy meets the requirements as specified in §291.16 of this title
250 (relating to Samples).

251 (D) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in
252 §291.15 of this title (relating to Storage of Drugs).

253 (E) Any drug bearing an expiration date may not be distributed beyond the expiration date of
254 the drug.

255 (F) Outdated and other unusable drugs shall be removed from stock and shall be
256 quarantined together until such drugs are disposed of properly.

257 (2) Formulary.

258 (A) A formulary shall be developed by the facility committee performing the pharmacy and
259 therapeutics function for the facility. For the purpose of this section, a formulary is a compilation
260 of pharmaceuticals that reflects the current clinical judgment of a facility's medical staff.

261 (B) The pharmacist-in-charge or pharmacist designated by the pharmacist-in-charge shall be
262 a full voting member of the committee performing the pharmacy and therapeutics function for
263 the facility, when such committee is performing the pharmacy and therapeutics function.

264 (C) A practitioner may grant approval for pharmacists at the facility to interchange, in
265 accordance with the facility's formulary, for the prescribed drugs on the practitioner's medication
266 orders provided:

267 (i) the pharmacy and therapeutics committee has developed a formulary;

268 (ii) the formulary has been approved by the medical staff committee of the facility;

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

270 (iv) the practitioner authorizes pharmacists in the facility to interchange on his/her
271 medication orders in accordance with the facility's formulary through his/her written agreement
272 to abide by the policies and procedures of the medical staff and facility.

273 (3) Prepackaging of drugs.

274 (A) Distribution within a facility.

275 (i) Drugs may be prepackaged in quantities suitable for internal distribution by a pharmacist
276 or by pharmacy technicians or pharmacy technician trainees under the direction and direct
277 supervision of a pharmacist.

278 (ii) The label of a prepackaged unit shall indicate:

279 (I) brand name and strength of the drug; or if no brand name, then the generic name,
280 strength, and name of the manufacturer or distributor;

281 (II) facility's unique lot number;

282 (III) expiration date based on currently available literature; and

283 (IV) quantity of the drug, if the quantity is greater than one.

284 (iii) Records of prepackaging shall be maintained to show:

285 (I) name of the drug, strength, and dosage form;

286 (II) facility's unique lot number;

287 (III) manufacturer or distributor;

288 (IV) manufacturer's lot number;

289 (V) expiration date;

290 (VI) quantity per prepackaged unit;

291 (VII) number of prepackaged units;

292 (VIII) date packaged;

293 (IX) name, initials, or electronic signature of the packer; and

294 (X) name, initials, or electronic signature of the responsible pharmacist.

295 (iv) Stock packages, prepackaged units, and control records shall be quarantined together
296 until checked/released by the pharmacist.

297 (B) Distribution to other Class C (Institutional) pharmacies under common ownership.

298 (i) Drugs may be prepackaged in quantities suitable for distribution to other Class C

299 (Institutional) pharmacies under common ownership by a pharmacist or by pharmacy
300 technicians or pharmacy technician trainees under the direction and direct supervision of a
301 pharmacist.

302 (ii) The label of a prepackaged unit shall indicate:
303 (I) brand name and strength of the drug; or if no brand name, then the generic name,
304 strength, and name of the manufacturer or distributor;
305 (II) facility's unique lot number;
306 (III) expiration date based on currently available literature;
307 (IV) quantity of the drug, if the quantity is greater than one; and
308 (V) name of the facility responsible for prepackaging the drug.
309 (iii) Records of prepackaging shall be maintained to show:
310 (I) name of the drug, strength, and dosage form;
311 (II) facility's unique lot number;
312 (III) manufacturer or distributor;
313 (IV) manufacturer's lot number;
314 (V) expiration date;
315 (VI) quantity per prepackaged unit;
316 (VII) number of prepackaged units;
317 (VIII) date packaged;
318 (IX) name, initials, or electronic signature of the prepacker;
319 (X) name, initials, or electronic signature of the responsible pharmacist; and
320 (XI) name of the facility receiving the prepackaged drug.
321 (iv) Stock packages, prepackaged units, and control records shall be quarantined together
322 until checked/released by the pharmacist.
323 (v) The pharmacy shall have written procedure for the recall of any drug prepackaged for
324 another Class C Pharmacy under common ownership. The recall procedures shall require:
325 (I) notification to the pharmacy to which the prepackaged drug was distributed;
326 (II) quarantine of the product if there is a suspicion of harm to a patient;
327 (III) a mandatory recall if there is confirmed or probable harm to a patient; and
328 (IV) notification to the board if a mandatory recall is instituted.
329 (4) Sterile preparations prepared in a location other than the pharmacy. A distinctive
330 supplementary label shall be affixed to the container of any admixture. The label shall bear at a
331 minimum:
332 (A) patient's name and location, if not immediately administered;
333 (B) name and amount of drug(s) added;
334 (C) name of the basic solution;
335 (D) name or identifying code of person who prepared admixture; and
336 (E) expiration date of solution.
337 (5) Distribution.
338 (A) Medication orders.
339 (i) Drugs may be given to patients in facilities only on the order of a practitioner. No change
340 in the order for drugs may be made without the approval of a practitioner except as authorized
341 by the practitioner in compliance with paragraph (2)(C) of this subsection.
342 (ii) Drugs may be distributed only from the original or a direct copy of the practitioner's
343 medication order.
344 (iii) Pharmacy technicians and pharmacy technician trainees may not receive verbal
345 medication orders.
346 (iv) Institutional pharmacies shall be exempt from the labeling provisions and patient
347 notification requirements of §562.006 and §562.009 of the Act, as respects drugs distributed
348 pursuant to medication orders.
349 (B) Procedures.
350 (i) Written policies and procedures for a drug distribution system (best suited for the
351 particular institutional pharmacy) shall be developed and implemented by the pharmacist-in-

352 charge, with the advice of the committee performing the pharmacy and therapeutics function for
353 the facility.

354 (ii) The written policies and procedures for the drug distribution system shall include, but not
355 be limited to, procedures regarding the following:

356 (I) pharmaceutical care services;

357 (II) handling, storage and disposal of cytotoxic drugs and waste;

358 (III) disposal of unusable drugs and supplies;

359 (IV) security;

360 (V) equipment;

361 (VI) sanitation;

362 (VII) reference materials;

363 (VIII) drug selection and procurement;

364 (IX) drug storage;

365 (X) controlled substances;

366 (XI) investigational drugs, including the obtaining of protocols from the principal investigator;

367 (XII) prepackaging and manufacturing;

368 (XIII) stop orders;

369 (XIV) reporting of medication errors, adverse drug reactions/events, and drug product
370 defects;

371 (XV) physician orders;

372 (XVI) floor stocks;

373 (XVII) drugs brought into the facility;

374 (XVIII) furlough medications;

375 (XIX) self-administration;

376 (XX) emergency drug supply;

377 (XXI) formulary;

378 (XXII) monthly inspections of nursing stations and other areas where drugs are stored,
379 distributed, administered or dispensed;

380 (XXIII) control of drug samples;

381 (XXIV) outdated and other unusable drugs;

382 (XXV) routine distribution of patient medication;

383 (XXVI) preparation and distribution of sterile preparations;

384 (XXVII) handling of medication orders when a pharmacist

385 is not on duty;

386 (XXVIII) use of automated compounding or counting devices;

387 (XXIX) use of data processing and direct imaging systems;

388 (XXX) drug administration to include infusion devices and drug delivery systems;

389 (XXXI) drug labeling;

390 (XXXII) recordkeeping;

391 (XXXIII) quality assurance/quality control;

392 (XXXIV) duties and education and training of professional and nonprofessional staff;

393 (XXXV) procedures for a pharmacy technician to verify the accuracy of work performed by
394 another pharmacy technician, if applicable;

395 (XXXVI) operation of the pharmacy when a pharmacist

396 in not on-site; and

397 (XXXVII) emergency preparedness plan, to include continuity of patient therapy and public
398 safety.

399 (6) Discharge Prescriptions. Discharge prescriptions must be dispensed and labeled in
400 accordance with §291.33 of this title (relating to Operational Standards) except that certain
401 medications packaged in unit-of-use containers, such as metered-dose inhalers, insulin pens,
402 topical creams or ointments, or ophthalmic or otic preparation that are administered to the

403 patient during the time the patient was a patient in the hospital, may be provided to the patient
404 upon discharge provided the pharmacy receives a discharge order and the product bears a
405 label containing the following information:

- 406 (A) name of the patient;
- 407 (B) name and strength of the medication;
- 408 (C) name of the prescribing or attending practitioner;
- 409 (D) directions for use;
- 410 (E) duration of therapy (if applicable); and
- 411 (F) name and telephone number of the pharmacy.

412 (g) Pharmaceutical care services.

413 (1) The pharmacist-in-charge shall assure that at least the following pharmaceutical care
414 services are provided to patients of the facility.

415 (A) Drug utilization review. A systematic ongoing process of drug utilization review shall be
416 developed in conjunction with the medical staff to increase the probability of desired patient
417 outcomes and decrease the probability of undesired outcomes from drug therapy.

418 (B) Drug regimen review.

419 (i) For the purpose of promoting therapeutic appropriateness, a pharmacist shall evaluate
420 medication orders and patient medication records for:

- 421 (I) known allergies;
- 422 (II) rational therapy--contraindications;
- 423 (III) reasonable dose and route of administration;
- 424 (IV) reasonable directions for use;
- 425 (V) duplication of therapy;
- 426 (VI) drug-drug interactions;
- 427 (VII) drug-food interactions;
- 428 (VIII) drug-disease interactions;
- 429 (IX) adverse drug reactions;
- 430 (X) proper utilization, including overutilization or underutilization; and
- 431 (XI) clinical laboratory or clinical monitoring methods to monitor and evaluate drug
432 effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of
433 the drug in its current regimen.

434 (ii) The drug regimen review shall be conducted on a prospective basis when a pharmacist
435 is on duty, except for an emergency order, and on a retrospective basis as specified in
436 subsection (e)(1) of this section when a pharmacist is not on duty.

437 (iii) Any questions regarding the order must be resolved with the prescriber and a written
438 notation of these discussions made and maintained.

439 (iv) The drug regimen review may be conducted by remotely accessing the pharmacy's
440 electronic data base from outside the pharmacy by an individual Texas licensed pharmacist
441 employee of the pharmacy, provided the pharmacy establishes controls to protect the privacy of
442 the patient and the security of confidential records.

443 (C) Education. The pharmacist-in-charge in cooperation with appropriate multi-disciplinary
444 staff of the facility shall develop policies that assure that:

- 445 (i) the patient and/or patient's caregiver receives information regarding drugs and their safe
446 and appropriate use; and
- 447 (ii) health care providers are provided with patient specific drug information.

448 (D) Patient monitoring. The pharmacist-in-charge in cooperation with appropriate multi-
449 disciplinary staff of the facility shall develop policies to ensure that the patient's response to drug
450 therapy is monitored and conveyed to the appropriate health care provider.

451 (2) Other pharmaceutical care services which may be provided by pharmacists in the facility
452 include, but are not limited to, the following:

453 (A) managing drug therapy as delegated by a practitioner as allowed under the provisions of
454 the Medical Practice Act;

455 (B) administering immunizations and vaccinations under written protocol of a physician;

456 (C) managing patient compliance programs;

457 (D) providing preventative health care services; and

458 (E) providing case management of patients who are being treated with high-risk or high-cost
459 drugs, or who are considered "high risk" due to their age, medical condition, family history, or
460 related concern.

461 (h) Emergency rooms.

462 (1) During the times a pharmacist is on duty in the facility any prescription drugs supplied to an
463 outpatient, including emergency department patients, may only be dispensed by a pharmacist.

464 (2) When a pharmacist is not on duty in the facility, the following is applicable for supplying
465 prescription drugs to be taken home by the patient for self-administration from the emergency
466 room. If the patient has been admitted to the emergency room and assessed by a practitioner at
467 the hospital, the following procedures shall be observed in supplying prescription drugs from the
468 emergency room.

469 (A) Dangerous drugs and/or controlled substances may only be supplied in accordance with
470 the system of control and accountability for dangerous drugs and/or controlled substances
471 administered or supplied from the emergency room; such system shall be developed and
472 supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-
473 charge.

474 (B) Only dangerous drugs and/or controlled substances listed on the emergency room drug
475 list may be supplied; such list shall be developed by the pharmacist-in-charge and the facility's
476 emergency department committee (or like group or person responsible for policy in that
477 department) and shall consist of dangerous drugs and/or controlled substances of the nature
478 and type to meet the immediate needs of emergency room patients.

479 (C) Dangerous drugs and/or controlled substances may only be supplied in prepackaged
480 quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled
481 (including necessary auxiliary labels) by the institutional pharmacy.

482 (D) At the time of delivery of the dangerous drugs and/or controlled substances, the
483 practitioner or licensed nurse under the supervision of a practitioner shall appropriately
484 complete the label with at least the following information:

485 (i) name, address, and phone number of the facility;

486 (ii) date supplied;

487 (iii) name of practitioner;

488 (iv) name of patient;

489 (v) directions for use;

490 (vi) brand name and strength of the dangerous drug or controlled substance; or if no brand
491 name, then the generic name, strength, and the name of the manufacturer or distributor of the
492 dangerous drug or controlled substance;

493 (vii) quantity supplied; and

494 (viii) unique identification number.

495 (E) The practitioner, or a licensed nurse under the supervision of the practitioner, shall give
496 the appropriately labeled, prepackaged drug to the patient and explain the correct use of the
497 drug.

498 (F) A perpetual record of dangerous drugs and/or controlled substances supplied from the
499 emergency room shall be maintained in the emergency room. Such record shall include the
500 following:

501 (i) date supplied;

502 (ii) practitioner's name;

503 (iii) patient's name;

504 (iv) brand name and strength of the dangerous drug or controlled substance; or if no brand
505 name, then the generic name, strength, and the name of the manufacturer or distributor of the
506 dangerous drug or controlled substance;

507 (v) quantity supplied; and

508 (vi) unique identification number.

509 (G) The pharmacist-in-charge, or staff pharmacist designated by the pharmacist-in-charge,
510 shall verify the correctness of this record at least once every seven days.

511 (i) Radiology departments.

512 (1) During the times a pharmacist is on duty, any prescription drugs dispensed to an
513 outpatient, including radiology department patients, may only be dispensed by a pharmacist.

514 (2) When a pharmacist is not on duty, the following procedures shall be observed in supplying
515 prescription drugs from the radiology department.

516 (A) Prescription drugs may only be supplied to patients who have been scheduled for an x-
517 ray examination at the facility.

518 (B) Prescription drugs may only be supplied in accordance with the system of control and
519 accountability for prescription drugs administered or supplied from the radiology department and
520 supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-
521 charge.

522 (C) Only prescription drugs listed on the radiology drug list may be supplied; such list shall
523 be developed by the pharmacist-in-charge and the facility's radiology committee (or like group
524 or persons responsible for policy in that department) and shall consist of drugs for the
525 preparation of a patient for a radiological procedure.

526 (D) Prescription drugs may only be supplied in prepackaged quantities in suitable containers
527 and prelabeled by the institutional pharmacy with the following information:

528 (i) name and address of the facility;

529 (ii) directions for use;

530 (iii) name and strength of the prescription drug--if generic name, the name of the
531 manufacturer or distributor of the prescription drug;

532 (iv) quantity;

533 (v) facility's lot number and expiration date; and

534 (vi) appropriate ancillary label(s).

535 (E) At the time of delivery of the prescription drug, the practitioner or practitioner's agent shall
536 complete the label with the following information:

537 (i) date supplied;

538 (ii) name of physician;

539 (iii) name of patient; and

540 (iv) unique identification number.

541 (F) The practitioner or practitioner's agent shall give the appropriately labeled, prepackaged
542 prescription drug to the patient.

543 (G) A perpetual record of prescription drugs supplied from the radiology department shall be
544 maintained in the radiology department. Such records shall include the following:

545 (i) date supplied;

546 (ii) practitioner's name;

547 (iii) patient's name;

548 (iv) brand name and strength of the prescription drug; or if no brand name, then the generic
549 name, strength, dosage form, and the name of the manufacturer or distributor of the prescription
550 drug;

551 (v) quantity supplied; and

552 (vi) unique identification number.

553 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall
554 verify the correctness of this record at least once every seven days.

555 (j) Automated devices and systems.
556 (1) Automated compounding or counting devices. If a pharmacy uses automated compounding
557 or counting devices:
558 (A) the pharmacy shall have a method to calibrate and verify the accuracy of the automated
559 compounding or counting device and document the calibration and verification on a routine
560 basis;
561 (B) the devices may be loaded with unlabeled drugs only by a pharmacist or by pharmacy
562 technicians or pharmacy technician trainees under the direction and direct supervision of a
563 pharmacist;
564 (C) the label of an automated compounding or counting device container shall indicate the
565 brand name and strength of the drug; or if no brand name, then the generic name, strength, and
566 name of the manufacturer or distributor;
567 (D) records of loading unlabeled drugs into an automated compounding or counting device
568 shall be maintained to show:
569 (i) name of the drug, strength, and dosage form;
570 (ii) manufacturer or distributor;
571 (iii) manufacturer's lot number;
572 (iv) expiration date;
573 (v) date of loading;
574 (vi) name, initials, or electronic signature of the person loading the automated compounding
575 or counting device; and
576 (vii) signature or electronic signature of the responsible pharmacist; and
577 (E) the automated compounding or counting device shall not be used until a pharmacist
578 verifies that the system is properly loaded and affixes his or her signature to the record specified
579 in subparagraph (D) of this paragraph.
580 (2) Automated medication supply systems.
581 (A) Authority to use automated medication supply systems. A pharmacy may use an
582 automated medication supply system to fill medication orders provided that:
583 (i) the pharmacist-in-charge is responsible for the supervision of the operation of the system;
584 (ii) the automated medication supply system has been tested by the pharmacy and found to
585 dispense accurately. The pharmacy shall make the results of such testing available to the Board
586 upon request; and
587 (iii) the pharmacy will make the automated medication supply system available for
588 inspection by the board for the purpose of validating the accuracy of the system.
589 (B) Quality assurance program. A pharmacy which uses an automated medication supply
590 system to fill medication orders shall operate according to a written program for quality
591 assurance of the automated medication supply system which:
592 (i) requires continuous monitoring of the automated medication supply system; and
593 (ii) establishes mechanisms and procedures to test the accuracy of the automated
594 medication supply system at least every six months and whenever any upgrade or change is
595 made to the system and documents each such activity.
596 (C) Policies and procedures of operation.
597 (i) When an automated medication supply system is used to store or distribute medications
598 for administration pursuant to medication orders, it shall be operated according to written
599 policies and procedures of operation. The policies and procedures of operation shall establish
600 requirements for operation of the automated medication supply system and shall describe
601 policies and procedures that:
602 (I) include a description of the policies and procedures of operation;
603 (II) provide for a pharmacist's review and approval of each original or new medication
604 order prior to withdrawal from the automated medication supply system;

605 (-a-) before the order is filled when a pharmacist is on duty except for an emergency
606 order;

607 (-b-) retrospectively within 72 hours in a facility with a full-time pharmacist when a
608 pharmacist is not on duty at the time the order is made; or

609 (-c-) retrospectively within 7 days in a facility with a part-time or consultant pharmacist
610 when a pharmacist is not on duty at the time the order is made;

611 (III) provide for access to the automated medication supply system for stocking and
612 retrieval of medications which is limited to licensed healthcare professionals, pharmacy
613 technicians, or pharmacy technician trainees acting under the supervision of a pharmacist;

614 (IV) provide that a pharmacist is responsible for the accuracy of the restocking of the
615 system. The actual restocking may be performed by a pharmacy technician or pharmacy
616 technician trainee;

617 (V) provide for an accountability record to be maintained which documents all transactions
618 relative to stocking and removing medications from the automated medication supply system;

619 (VI) require a prospective or retrospective drug regimen review is conducted as specified
620 in subsection (g) of this section; and

621 (VII) establish and make provisions for documentation of a preventative maintenance
622 program for the automated medication supply system.

623 (ii) A pharmacy which uses an automated medication supply system to fill medication
624 orders shall, at least annually, review its written policies and procedures, revise them if
625 necessary, and document the review.

626 (D) Automated medication supply systems used for storage and recordkeeping of
627 medications located outside of the pharmacy department (e.g., Pyxis). A pharmacy technician or
628 pharmacy technician trainee may restock an automated medication supply system located
629 outside of the pharmacy department with prescription drugs provided:

630 (i) prior to distribution of the prescription drugs a pharmacist verifies that the prescription
631 drugs pulled to stock the automated supply system match the list of prescription drugs
632 generated by the automated medication supply system except as specified in
633 §291.73(e)(2)(C)(ii) of this title; or

634 (ii) all of the following occur:

635 (I) the prescription drugs to restock the system are labeled and verified with a machine
636 readable product identifier, such as a barcode;

637 (II) either:

638 (-a-) the drugs are in tamper evident product packaging, packaged by an FDA registered
639 repackager or manufacture, that is shipped to the pharmacy; or

640 (-b-) if any manipulation of the product occurs in the pharmacy prior to restocking, such
641 as repackaging or extemporaneous compounding, the product must be checked by a
642 pharmacist; and

643 (III) quality assurance audits are conducted according to established policies and
644 procedures to ensure accuracy of the process.

645 (E) Recovery Plan. A pharmacy which uses an automated medication supply system to store
646 or distribute medications for administration pursuant to medication orders shall maintain a
647 written plan for recovery from a disaster or any other situation which interrupts the ability of the
648 automated medication supply system to provide services necessary for the operation of the
649 pharmacy. The written plan for recovery shall include:

650 (i) planning and preparation for maintaining pharmacy services when an automated
651 medication supply system is experiencing downtime;

652 (ii) procedures for response when an automated medication supply system is experiencing
653 downtime;

654 (iii) procedures for the maintenance and testing of the written plan for recovery; and

655 (iv) procedures for notification of the Board and other appropriate agencies whenever an
656 automated medication supply system experiences downtime for more than two days of
657 operation or a period of time which significantly limits the pharmacy's ability to provide pharmacy
658 services.

659 (3) Verification of medication orders prepared by the pharmacy department through the use of
660 an automated medication supply system. A pharmacist must check drugs prepared pursuant to
661 medication orders to ensure that the drug is prepared for distribution accurately as prescribed.
662 This paragraph does not apply to automated medication supply systems used for storage and
663 recordkeeping of medications located outside of the pharmacy department.

664 (A) This check shall be considered accomplished if:

665 (i) a check of the final product is conducted by a pharmacist after the automated system has
666 completed preparation of the medication order and prior to delivery to the patient; or

667 (ii) the following checks are conducted by a pharmacist:

668 (I) if the automated medication supply system contains unlabeled stock drugs, a
669 pharmacist verifies that those drugs have been accurately stocked; and

670 (II) a pharmacist checks the accuracy of the data entry of each original or new medication
671 order entered into the automated medication supply system before the order is filled.

672 (B) If the final check is accomplished as specified in subparagraph (A)(ii) of this paragraph,
673 the following additional requirements must be met.

674 (i) The medication order preparation process must be fully automated from the time the
675 pharmacist releases the medication order to the automated system until a completed medication
676 order, ready for delivery to the patient, is produced.

677 (ii) The pharmacy has conducted initial testing and has a continuous quality assurance
678 program which documents that the automated medication supply system dispenses accurately
679 as specified in paragraph (2)(A) and (B) of this subsection.

680 (iii) The automated medication supply system documents and maintains:

681 (I) the name(s), initials, or identification code(s) of each pharmacist responsible for the
682 checks outlined in subparagraph (A)(ii) of this paragraph; and

683 (II) the name(s), initials, or identification code(s) and specific activity(ies) of each
684 pharmacist or pharmacy technician or pharmacy technician trainee who performs any other
685 portion of the medication order preparation process.

686 (iv) The pharmacy establishes mechanisms and procedures to test the accuracy of the
687 automated medication supply system at least every month rather than every six months as
688 specified in paragraph (2)(B) of this subsection.

689 (4) Automated checking device.

690 (A) For the purpose of this subsection, an automated checking device is a fully automated
691 device which confirms, after a drug is prepared for distribution but prior to delivery to the patient,
692 that the correct drug and strength has been labeled with the correct label for the correct patient.

693 (B) The final check of a drug prepared pursuant to a medication order shall be considered
694 accomplished using an automated checking device provided:

695 (i) a check of the final product is conducted by a pharmacist prior to delivery to the patient or
696 the following checks are performed by a pharmacist:

697 (I) the prepackaged drug used to fill the order is checked by a pharmacist who verifies that
698 the drug is labeled and packaged accurately; and

699 (II) a pharmacist checks the accuracy of each original or new medication order.

700 (ii) the medication order is prepared, labeled, and made ready for delivery to the patient in
701 compliance with Class C (Institutional) Pharmacy rules; and

702 (iii) prior to delivery to the patient:

703 (I) the automated checking device confirms that the correct drug and strength has been
704 labeled with the correct label for the correct patient; and

705 (II) a pharmacist performs all other duties required to ensure that the medication order has
706 been prepared safely and accurately as prescribed.

707 (C) If the final check is accomplished as specified in subparagraph (B) of this paragraph, the
708 following additional requirements must be met.

709 (i) The pharmacy has conducted initial testing of the automated checking device and has a
710 continuous quality assurance program which documents that the automated checking device
711 accurately confirms that the correct drug and strength has been labeled with the correct label for
712 the correct patient.

713 (ii) The pharmacy documents and maintains:

714 (I) the name(s), initials, or identification code(s) of each pharmacist responsible for the
715 checks outlined in subparagraph (B)(i) of this paragraph; and

716 (II) the name(s), initials, or identification code(s) and specific activity(ies) of each
717 pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other
718 portion of the medication order preparation process.

719 (iii) The pharmacy establishes mechanisms and procedures to test the accuracy of the
720 automated checking device at least monthly.