

## RULE ANALYSIS

**Introduction:** THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED 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 **SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)**

2 **22 TAC §291.74**

3 The Texas State Board of Pharmacy proposes amendments to §291.74, concerning Operational  
4 Standards.

5 The proposed amendments, if adopted, eliminate references to pharmacies operated by  
6 management companies; implement provisions of SB 460 regarding notification for a change of  
7 location; and remove references to Class C-S pharmacy which are no longer necessary.

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

11 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in  
12 effect, the public benefit anticipated as a result of enforcing the amendments will ensure  
13 pharmacies are properly licensed.

14 Written comments on the amendments may be submitted to Allison Vordenbaumen Benz, R.Ph.,  
15 M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street,  
16 Suite 3-600, Austin, Texas 78701, FAX (512) 305-6778. Comments must be received by 5 p.m.,  
17 October 25, 2016.

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

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

25 ***§291.74.Operational Standards.***

26 (a) Licensing requirements.

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

30 ~~[(2) If the institutional pharmacy is owned or operated by a hospital management or consulting  
31 firm, the following conditions apply.]~~

32 ~~[(A) The pharmacy license application shall list the hospital management or consulting firm as  
33 the owner or operator.]~~

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

36 ~~[(i) the hospital management or consulting firm and the facility co-sign a contractual pharmacy~~  
37 ~~service agreement which assigns overall responsibility for controlled substances to the facility;~~  
38 ~~and]~~

39 ~~[(ii) such hospital pharmacy management or consulting firm maintains dual responsibility for the~~  
40 ~~controlled substances.]~~

41 (2) ~~[(3)]~~ A Class C pharmacy which changes ownership shall notify the board within 10 days of  
42 the change of ownership and apply for a new and separate license as specified in §291.3 of this  
43 title (relating to Required Notifications).

44 (3) ~~[(4)]~~ A Class C pharmacy which changes location and/or name shall notify the board [~~within~~  
45 ~~10 days]~~ of the change [~~and file for an amended license]~~ as specified in §291.3 of this title.

46 (4) ~~[(5)]~~ A Class C pharmacy owned by a partnership or corporation which changes managing  
47 officers shall notify the board in writing of the names of the new managing officers within 10  
48 days of the change following the procedures in §291.3 of this title.

49 (5) ~~[(6)]~~ A Class C pharmacy shall notify the board in writing within 10 days of closing,  
50 following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

51 (6) ~~[(7)]~~ A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be  
52 charged for the issuance and renewal of a license and the issuance of an amended license.

53 (7) ~~[(8)]~~ A separate license is required for each principal place of business and only one  
54 pharmacy license may be issued to a specific location.

55 (8) ~~[(9)]~~ A Class C pharmacy, licensed under the Act, §560.051(a)(3), which also operates  
56 another type of pharmacy which would otherwise be required to be licensed under the Act,  
57 §560.051(a)(1) (Community Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear Pharmacy  
58 (Class B)), is not required to secure a license for the such other type of pharmacy; provided,  
59 however, such licensee is required to comply with the provisions of §291.31 of this title (relating  
60 to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to  
61 Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title  
62 (relating to Official Prescription Records), contained in Community Pharmacy (Class A), or  
63 §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53  
64 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and  
65 §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent  
66 such sections are applicable to the operation of the pharmacy.

67 (9) ~~[(10)]~~ A Class C pharmacy engaged in the compounding of non-sterile preparations shall  
68 comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-  
69 sterile Preparations).

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

73 (10) ~~[(12)]~~ ~~[Effective August 31, 2014, a]~~ Class C pharmacy personnel shall not compound  
74 sterile preparations unless the pharmacy has applied for and obtained a Class C-S pharmacy.

75 (11) ~~[(13)]~~ A Class C pharmacy engaged in the provision of remote pharmacy services, including  
76 storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of  
77 this title (relating to Remote Pharmacy Services).

78 (12) ~~[(14)]~~ A Class C pharmacy engaged in centralized prescription dispensing and/or  
79 prescription drug or medication order processing shall comply with the provisions of §291.123 of  
80 this title (relating to Central Prescription Drug or Medication Order Processing) and/or §291.125  
81 of this title (relating to Centralized Prescription Dispensing).

82 (13) ~~[(15)]~~ A Class C pharmacy with an ongoing clinical pharmacy program that proposes to  
83 allow a pharmacy technician to verify the accuracy of work performed by another pharmacy  
84 technician relating to the filling of floor stock and unit dose distribution systems for a patient  
85 admitted to the hospital if the patient's orders have previously been reviewed and approved by a  
86 pharmacist shall make application to the board as follows.

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

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

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

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

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

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

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

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

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

102 ~~(14)~~ [(16)] A rural hospital that wishes to allow a pharmacy technician to perform the duties  
103 specified in §291.73(e)(2)(D) of this title (relating to Personnel), shall make application to the  
104 board as follows.

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

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

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

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

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

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

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

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

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

120 (B) A rural hospital may not allow a pharmacy technician to perform the duties specified in  
121 §291.73(e)(2)(D) of this title until the board has reviewed and approved the application and  
122 issued an amended license to the pharmacy.

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

126 (b) Environment.

127 (1) General requirements.

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

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

- 133 (C) A sink with hot and cold running water exclusive of restroom facilities shall be available to  
134 all pharmacy personnel and shall be maintained in a sanitary condition at all times.
- 135 (D) The institutional pharmacy shall be properly lighted and ventilated.
- 136 (E) The temperature of the institutional pharmacy shall be maintained within a range compatible  
137 with the proper storage of drugs. The temperature of the refrigerator and/or freezer shall be  
138 maintained within a range compatible with the proper storage of drugs.
- 139 (F) If the institutional pharmacy has flammable materials, the pharmacy shall have a designated  
140 area for the storage of flammable materials. Such area shall meet the requirements set by local  
141 and state fire laws.
- 142 (G) The institutional pharmacy shall store antiseptics, other drugs for external use, and  
143 disinfectants separately from internal and injectable medications.
- 144 (2) Security requirements.
- 145 (A) The institutional pharmacy shall be enclosed and capable of being locked by key,  
146 combination or other mechanical or electronic means, so as to prohibit access by unauthorized  
147 individuals. Only individuals authorized by the pharmacist-in-charge shall enter the pharmacy.
- 148 (B) Each pharmacist on duty shall be responsible for the security of the institutional pharmacy,  
149 including provisions for adequate safeguards against theft or diversion of dangerous drugs,  
150 controlled substances, and records for such drugs.
- 151 (C) The institutional pharmacy shall have locked storage for Schedule II controlled substances  
152 and other drugs requiring additional security.
- 153 (c) Equipment and supplies. Institutional pharmacies distributing medication orders shall have  
154 the following equipment:
- 155 (1) data processing system including a printer or comparable equipment; and
- 156 (2) refrigerator and/or freezer and a system or device (e.g., thermometer) to monitor the  
157 temperature to ensure that proper storage requirements are met.
- 158 (d) Library. A reference library shall be maintained that includes the following in hard-copy or  
159 electronic format and that pharmacy personnel shall be capable of accessing at all times:
- 160 (1) current copies of the following:
- 161 (A) Texas Pharmacy Act and rules;
- 162 (B) Texas Dangerous Drug Act and rules;

- 163 (C) Texas Controlled Substances Act and regulations; and
- 164 (D) Federal Controlled Substances Act and regulations (or official publication describing the  
165 requirements of the Federal Controlled Substances Act and regulations);
- 166 (2) at least one current or updated reference from each of the following categories:
- 167 (A) drug interactions. A reference text on drug interactions, such as Drug Interaction Facts. A  
168 separate reference is not required if other references maintained by the pharmacy contain drug  
169 interaction information including information needed to determine severity or significance of the  
170 interaction and appropriate recommendations or actions to be taken;
- 171 (B) a general information reference text, such as:
- 172 (i) Facts and Comparisons with current supplements;
- 173 (ii) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the  
174 Healthcare Provider);
- 175 (iii) AHFS Drug Information with current supplements;
- 176 (iv) Remington's Pharmaceutical Sciences; or
- 177 (v) Clinical Pharmacology;
- 178 (3) a current or updated reference on injectable drug products, such as Handbook of Injectable  
179 Drugs;
- 180 (4) basic antidote information and the telephone number of the nearest regional poison control  
181 center;
- 182 (5) metric-apothecary weight and measure conversion charts.
- 183 (e) Absence of a pharmacist.
- 184 (1) Medication orders.
- 185 (A) In facilities with a full-time pharmacist, if a practitioner orders a drug for administration to a  
186 bona fide patient of the facility when the pharmacy is closed, the following is applicable.
- 187 (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic needs  
188 may be removed from the institutional pharmacy.
- 189 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

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

192 (I) name of patient;

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

194 (III) dose prescribed;

195 (IV) quantity taken;

196 (V) time and date; and

197 (VI) signature (first initial and last name or full signature) or electronic signature of person  
198 making withdrawal.

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

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

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

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

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

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

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

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

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

- 220 (B) Only a designated licensed nurse or practitioner may remove such drugs and devices.
- 221 (C) A record shall be made at the time of withdrawal by the authorized person removing the drug  
222 or device; the record shall contain the following information:
- 223 (i) name of the drug, strength, and dosage form;
- 224 (ii) quantity removed;
- 225 (iii) location of floor stock;
- 226 (iv) date and time; and
- 227 (v) signature (first initial and last name or full signature) or electronic signature of person  
228 making the withdrawal.
- 229 (D) The pharmacist shall verify the withdrawal of drugs from the pharmacy after a reasonable  
230 interval, but in no event may such interval exceed seven days.
- 231 (3) Rural hospitals. In rural hospitals when a pharmacy technician performs the duties listed in  
232 §291.73(e)(2)(D) of this title, the following is applicable:
- 233 (A) the pharmacy technician shall make a record of all drugs distributed from the pharmacy. The  
234 record shall be maintained in the pharmacy for two years and contain the following information:
- 235 (i) name of patient or location where floor stock is distributed;
- 236 (ii) name of device or drug, strength, and dosage form;
- 237 (iii) dose prescribed or ordered;
- 238 (iv) quantity distributed;
- 239 (v) time and date of the distribution; and
- 240 (vi) signature (first initial and last name or full signature) or electronic signature of nurse or  
241 practitioner that verified the actions of the pharmacy technician.
- 242 (B) The original or direct copy of the medication order may substitute for the record specified in  
243 subparagraph (A) of this paragraph, provided the medication order meets all the requirements of  
244 subparagraph (A) of this paragraph.
- 245 (C) The pharmacist shall:

- 246 (i) verify and document the verification of all distributions made from the pharmacy in the  
247 absence of a pharmacist as soon as practical, but in no event more than seven (7) days from the  
248 time of such distribution;
- 249 (ii) perform a drug regimen review for all medication orders as specified in subsection (g)(1)(B)  
250 of this section as soon as practical, but in no event more than seven (7) days from the time of  
251 such distribution and document such verification including any discrepancies noted by the  
252 pharmacist;
- 253 (iii) review any discrepancy noted by the pharmacist with the pharmacy technician(s) and make  
254 any change in procedures or processes necessary to prevent future problems; and
- 255 (iv) report any adverse events that have a potential for harm to a patient to the appropriate  
256 committee of the hospital that reviews adverse events.
- 257 (f) Drugs.
- 258 (1) Procurement, preparation and storage.
- 259 (A) The pharmacist-in-charge shall have the responsibility for the procurement and storage of  
260 drugs, but may receive input from other appropriate staff of the facility, relative to such  
261 responsibility.
- 262 (B) The pharmacist-in-charge shall have the responsibility for determining specifications of all  
263 drugs procured by the facility.
- 264 (C) Institutional pharmacies may not sell, purchase, trade or possess prescription drug samples,  
265 unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to  
266 Samples).
- 267 (D) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in  
268 §291.15 of this title (relating to Storage of Drugs).
- 269 (E) Any drug bearing an expiration date may not be distributed beyond the expiration date of the  
270 drug.
- 271 (F) Outdated and other unusable drugs shall be removed from stock and shall be quarantined  
272 together until such drugs are disposed of properly.
- 273 (2) Formulary.
- 274 (A) A formulary shall be developed by the facility committee performing the pharmacy and  
275 therapeutics function for the facility. For the purpose of this section, a formulary is a compilation  
276 of pharmaceuticals that reflects the current clinical judgment of a facility's medical staff.

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

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

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

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

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

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

289 (3) Prepackaging of drugs.

290 (A) Distribution within a facility.

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

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

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

297 (II) facility's unique lot number;

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

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

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

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

302 (II) facility's unique lot number;

303 (III) manufacturer or distributor;

304 (IV) manufacturer's lot number;

- 305 (V) expiration date;
- 306 (VI) quantity per prepackaged unit;
- 307 (VII) number of prepackaged units;
- 308 (VIII) date packaged;
- 309 (IX) name, initials, or electronic signature of the prepacker; and
- 310 (X) name, initials, or electronic signature of the responsible pharmacist.
- 311 (iv) Stock packages, prepackaged units, and control records shall be quarantined together until  
312 checked/released by the pharmacist.
- 313 (B) Distribution to other Class C (Institutional) pharmacies under common ownership.
- 314 (i) Drugs may be prepackaged in quantities suitable for distribution to other Class C  
315 (Institutional) pharmacies under common ownership by a pharmacist or by pharmacy technicians  
316 or pharmacy technician trainees under the direction and direct supervision of a pharmacist.
- 317 (ii) The label of a prepackaged unit shall indicate:
- 318 (I) brand name and strength of the drug; or if no brand name, then the generic name, strength,  
319 and name of the manufacturer or distributor;
- 320 (II) facility's unique lot number;
- 321 (III) expiration date based on currently available literature;
- 322 (IV) quantity of the drug, if the quantity is greater than one; and
- 323 (V) name of the facility responsible for prepackaging the drug.
- 324 (iii) Records of prepackaging shall be maintained to show:
- 325 (I) name of the drug, strength, and dosage form;
- 326 (II) facility's unique lot number;
- 327 (III) manufacturer or distributor;
- 328 (IV) manufacturer's lot number;
- 329 (V) expiration date;

- 330 (VI) quantity per prepackaged unit;
- 331 (VII) number of prepackaged units;
- 332 (VIII) date packaged;
- 333 (IX) name, initials, or electronic signature of the prepacker;
- 334 (X) name, initials, or electronic signature of the responsible pharmacist; and
- 335 (XI) name of the facility receiving the prepackaged drug.
- 336 (iv) Stock packages, prepackaged units, and control records shall be quarantined together until  
337 checked/released by the pharmacist.
- 338 (v) The pharmacy shall have written procedure for the recall of any drug prepackaged for another  
339 Class C Pharmacy under common ownership. The recall procedures shall require:
- 340 (I) notification to the pharmacy to which the prepackaged drug was distributed;
- 341 (II) quarantine of the product if there is a suspicion of harm to a patient;
- 342 (III) a mandatory recall if there is confirmed or probable harm to a patient; and
- 343 (IV) notification to the board if a mandatory recall is instituted.
- 344 (4) Sterile preparations prepared in a location other than the pharmacy. A distinctive  
345 supplementary label shall be affixed to the container of any admixture. The label shall bear at a  
346 minimum:
- 347 (A) patient's name and location, if not immediately administered;
- 348 (B) name and amount of drug(s) added;
- 349 (C) name of the basic solution;
- 350 (D) name or identifying code of person who prepared admixture; and
- 351 (E) expiration date of solution.
- 352 (5) Distribution.
- 353 (A) Medication orders.

- 354 (i) Drugs may be given to patients in facilities only on the order of a practitioner. No change in  
355 the order for drugs may be made without the approval of a practitioner except as authorized by  
356 the practitioner in compliance with paragraph (2)(C) of this subsection.
- 357 (ii) Drugs may be distributed only from the original or a direct copy of the practitioner's  
358 medication order.
- 359 (iii) Pharmacy technicians and pharmacy technician trainees may not receive verbal medication  
360 orders.
- 361 (iv) Institutional pharmacies shall be exempt from the labeling provisions and patient notification  
362 requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to  
363 medication orders.
- 364 (B) Procedures.
- 365 (i) Written policies and procedures for a drug distribution system (best suited for the particular  
366 institutional pharmacy) shall be developed and implemented by the pharmacist-in-charge, with  
367 the advice of the committee performing the pharmacy and therapeutics function for the facility.
- 368 (ii) The written policies and procedures for the drug distribution system shall include, but not be  
369 limited to, procedures regarding the following:
- 370 (I) pharmaceutical care services;
- 371 (II) handling, storage and disposal of cytotoxic drugs and waste;
- 372 (III) disposal of unusable drugs and supplies;
- 373 (IV) security;
- 374 (V) equipment;
- 375 (VI) sanitation;
- 376 (VII) reference materials;
- 377 (VIII) drug selection and procurement;
- 378 (IX) drug storage;
- 379 (X) controlled substances;
- 380 (XI) investigational drugs, including the obtaining of protocols from the principal investigator;
- 381 (XII) prepackaging and manufacturing;

- 382 (XIII) stop orders;
- 383 (XIV) reporting of medication errors, adverse drug reactions/events, and drug product defects;
- 384 (XV) physician orders;
- 385 (XVI) floor stocks;
- 386 (XVII) drugs brought into the facility;
- 387 (XVIII) furlough medications;
- 388 (XIX) self-administration;
- 389 (XX) emergency drug supply;
- 390 (XXI) formulary;
- 391 (XXII) monthly inspections of nursing stations and other areas where drugs are stored,  
392 distributed, administered or dispensed;
- 393 (XXIII) control of drug samples;
- 394 (XXIV) outdated and other unusable drugs;
- 395 (XXV) routine distribution of patient medication;
- 396 (XXVI) preparation and distribution of sterile preparations;
- 397 (XXVII) handling of medication orders when a pharmacist is not on duty;
- 398 (XXVIII) use of automated compounding or counting devices;
- 399 (XXIX) use of data processing and direct imaging systems;
- 400 (XXX) drug administration to include infusion devices and drug delivery systems;
- 401 (XXXI) drug labeling;
- 402 (XXXII) recordkeeping;
- 403 (XXXIII) quality assurance/quality control;
- 404 (XXXIV) duties and education and training of professional and nonprofessional staff;

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

407 (XXXVI) operation of the pharmacy when a pharmacist is not on-site; and

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

410 (6) Discharge Prescriptions. Discharge prescriptions must be dispensed and labeled in  
411 accordance with §291.33 of this title (relating to Operational Standards) except that certain  
412 medications packaged in unit-of-use containers, such as metered-dose inhalers, insulin pens,  
413 topical creams or ointments, or ophthalmic or otic preparation that are administered to the patient  
414 during the time the patient was a patient in the hospital, may be provided to the patient upon  
415 discharge provided the pharmacy receives a discharge order and the product bears a label  
416 containing the following information:

417 (A) name of the patient;

418 (B) name and strength of the medication;

419 (C) name of the prescribing or attending practitioner;

420 (D) directions for use;

421 (E) duration of therapy (if applicable); and

422 (F) name and telephone number of the pharmacy.

423 (g) Pharmaceutical care services.

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

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

429 (B) Drug regimen review.

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

432 (I) known allergies;

433 (II) rational therapy--contraindications;

- 434 (III) reasonable dose and route of administration;
- 435 (IV) reasonable directions for use;
- 436 (V) duplication of therapy;
- 437 (VI) drug-drug interactions;
- 438 (VII) drug-food interactions;
- 439 (VIII) drug-disease interactions;
- 440 (IX) adverse drug reactions;
- 441 (X) proper utilization, including overutilization or underutilization; and
- 442 (XI) clinical laboratory or clinical monitoring methods to monitor and evaluate drug  
443 effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of  
444 the drug in its current regimen.
- 445 (ii) The drug regimen review shall be conducted on a prospective basis when a pharmacist is on  
446 duty, except for an emergency order, and on a retrospective basis as specified in subsection  
447 (e)(1) of this section when a pharmacist is not on duty.
- 448 (iii) Any questions regarding the order must be resolved with the prescriber and a written  
449 notation of these discussions made and maintained.
- 450 (iv) The drug regimen review may be conducted by remotely accessing the pharmacy's electronic  
451 data base from outside the pharmacy by an individual Texas licensed pharmacist employee of the  
452 pharmacy, provided the pharmacy establishes controls to protect the privacy of the patient and  
453 the security of confidential records.
- 454 (C) Education. The pharmacist-in-charge in cooperation with appropriate multi-disciplinary staff  
455 of the facility shall develop policies that assure that:
- 456 (i) the patient and/or patient's caregiver receives information regarding drugs and their safe and  
457 appropriate use; and
- 458 (ii) health care providers are provided with patient specific drug information.
- 459 (D) Patient monitoring. The pharmacist-in-charge in cooperation with appropriate multi-  
460 disciplinary staff of the facility shall develop policies to ensure that the patient's response to drug  
461 therapy is monitored and conveyed to the appropriate health care provider.
- 462 (2) Other pharmaceutical care services which may be provided by pharmacists in the facility  
463 include, but are not limited to, the following:

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

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

467 (C) managing patient compliance programs;

468 (D) providing preventative health care services; and

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

472 (h) Emergency rooms.

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

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

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

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

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

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

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

- 497 (ii) date supplied;
- 498 (iii) name of practitioner;
- 499 (iv) name of patient;
- 500 (v) directions for use;
- 501 (vi) brand name and strength of the dangerous drug or controlled substance; or if no brand name,  
502 then the generic name, strength, and the name of the manufacturer or distributor of the dangerous  
503 drug or controlled substance;
- 504 (vii) quantity supplied; and
- 505 (viii) unique identification number.
- 506 (E) The practitioner, or a licensed nurse under the supervision of the practitioner, shall give the  
507 appropriately labeled, prepackaged drug to the patient and explain the correct use of the drug.
- 508 (F) A perpetual record of dangerous drugs and/or controlled substances supplied from the  
509 emergency room shall be maintained in the emergency room. Such record shall include the  
510 following:
- 511 (i) date supplied;
- 512 (ii) practitioner's name;
- 513 (iii) patient's name;
- 514 (iv) brand name and strength of the dangerous drug or controlled substance; or if no brand name,  
515 then the generic name, strength, and the name of the manufacturer or distributor of the dangerous  
516 drug or controlled substance;
- 517 (v) quantity supplied; and
- 518 (vi) unique identification number.
- 519 (G) The pharmacist-in-charge, or staff pharmacist designated by the pharmacist-in-charge, shall  
520 verify the correctness of this record at least once every seven days.
- 521 (i) Radiology departments.
- 522 (1) During the times a pharmacist is on duty, any prescription drugs dispensed to an outpatient,  
523 including radiology department patients, may only be dispensed by a pharmacist.

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

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

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

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

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

538 (i) name and address of the facility;

539 (ii) directions for use;

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

542 (iv) quantity;

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

544 (vi) appropriate ancillary label(s).

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

547 (i) date supplied;

548 (ii) name of physician;

549 (iii) name of patient; and

550 (iv) unique identification number.

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

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

555 (i) date supplied;

556 (ii) practitioner's name;

557 (iii) patient's name;

558 (iv) brand name and strength of the prescription drug; or if no brand name, then the generic  
559 name, strength, dosage form, and the name of the manufacturer or distributor of the prescription  
560 drug;

561 (v) quantity supplied; and

562 (vi) unique identification number.

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

565 (j) Automated devices and systems.

566 (1) Automated compounding or counting devices. If a pharmacy uses automated compounding or  
567 counting devices:

568 (A) the pharmacy shall have a method to calibrate and verify the accuracy of the automated  
569 compounding or counting device and document the calibration and verification on a routine  
570 basis;

571 (B) the devices may be loaded with unlabeled drugs only by a pharmacist or by pharmacy  
572 technicians or pharmacy technician trainees under the direction and direct supervision of a  
573 pharmacist;

574 (C) the label of an automated compounding or counting device container shall indicate the brand  
575 name and strength of the drug; or if no brand name, then the generic name, strength, and name of  
576 the manufacturer or distributor;

577 (D) records of loading unlabeled drugs into an automated compounding or counting device shall  
578 be maintained to show:

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

580 (ii) manufacturer or distributor;

581 (iii) manufacturer's lot number;

582 (iv) expiration date;

583 (v) date of loading;

584 (vi) name, initials, or electronic signature of the person loading the automated compounding or  
585 counting device; and

586 (vii) signature or electronic signature of the responsible pharmacist; and

587 (E) the automated compounding or counting device shall not be used until a pharmacist verifies  
588 that the system is properly loaded and affixes his or her signature to the record specified in  
589 subparagraph (D) of this paragraph.

590 (2) Automated medication supply systems.

591 (A) Authority to use automated medication supply systems. A pharmacy may use an automated  
592 medication supply system to fill medication orders provided that:

593 (i) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

594 (ii) the automated medication supply system has been tested by the pharmacy and found to  
595 dispense accurately. The pharmacy shall make the results of such testing available to the Board  
596 upon request; and

597 (iii) the pharmacy will make the automated medication supply system available for inspection by  
598 the board for the purpose of validating the accuracy of the system.

599 (B) Quality assurance program. A pharmacy which uses an automated medication supply system  
600 to fill medication orders shall operate according to a written program for quality assurance of the  
601 automated medication supply system which:

602 (i) requires continuous monitoring of the automated medication supply system; and

603 (ii) establishes mechanisms and procedures to test the accuracy of the automated medication  
604 supply system at least every six months and whenever any upgrade or change is made to the  
605 system and documents each such activity.

606 (C) Policies and procedures of operation.

607 (i) When an automated medication supply system is used to store or distribute medications for  
608 administration pursuant to medication orders, it shall be operated according to written policies  
609 and procedures of operation. The policies and procedures of operation shall establish  
610 requirements for operation of the automated medication supply system and shall describe  
611 policies and procedures that:

612 (I) include a description of the policies and procedures of operation;

613 (II) provide for a pharmacist's review and approval of each original or new medication order  
614 prior to withdrawal from the automated medication supply system:

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

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

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

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

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

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

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

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

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

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

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

642 (ii) all of the following occur:

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

645 (II) either:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

697 (4) Automated checking device.

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

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

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

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

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

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

710 (iii) prior to delivery to the patient:

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

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

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

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

721 (ii) The pharmacy documents and maintains:

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

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

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

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

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