

RULE REVIEW ANALYSIS

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

Short Title: Pharmacies (Institutional Pharmacy (Class C))

Rule Number: Chapter 291, §§291.71-291.77

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

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

1 **TITLE 22 EXAMINING BOARDS**

2 **PART 15 TEXAS STATE BOARD OF PHARMACY**

3 **CHAPTER 291 PHARMACIES**

4 **SUBCHAPTER D INSTITUTIONAL PHARMACY (CLASS C)**

5 **§291.71 Purpose**

6 The purpose of these sections is to provide standards in the conduct, practice activities, and operation of a
7 pharmacy located in a hospital or other inpatient facility that is licensed under the Texas Hospital
8 Licensing Law, the Health and Safety Code, Chapter 241, or the Texas Mental Health Code, Chapter 6,
9 Texas Civil Statutes, Article 5547-1 et seq., or a pharmacy located in a hospital maintained or operated by
10 the state. The intent of these standards is to establish a minimum acceptable level of pharmaceutical care
11 to the patient so that the patient's health is protected while contributing to positive patient outcomes.

12 **§291.72 Definitions**

13 The following words and terms, when used in this subchapter, shall have the following meanings, unless
14 the context clearly indicates otherwise.

15 (1) Accurately as prescribed--Distributing and/or delivering a medication drug order:

16 (A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed;

17 (B) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner;
18 and

19 (C) with correct labeling as ordered by the practitioner and required by rule.

20 (2) Act--The Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Occupations Code, as amended.

21 (3) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any
22 other means to the body of a patient by:

23 (A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

24 (B) the patient at the direction of a practitioner.

25 (4) Automated compounding or counting device--An automated device that compounds, measures, counts
26 and/or packages a specified quantity of dosage units of a designated drug product.

27 (5) Automated medication supply system--A mechanical system that performs operations or activities
28 relative to the storage and distribution of medications for administration and which collects, controls, and
29 maintains all transaction information.

30 (6) Board--The State Board of Pharmacy.

31 (7) Clinical Pharmacy Program--An ongoing program in which pharmacists are on duty during the time
32 the pharmacy is open for pharmacy services and pharmacists provide direct focused, medication-related
33 care for the purpose of optimizing patients' medication therapy and achieving definite outcomes, which
34 includes the following activities:

- 35 (A) prospective medication therapy consultation, selection, and adjustment;
- 36 (B) monitoring laboratory values and therapeutic drug monitoring;
- 37 (C) identifying and resolving medication-related problems; and
- 38 (D) disease state management.
- 39 (8) Confidential record--Any health-related record that contains information that identifies an individual
40 and that is maintained by a pharmacy or pharmacist, such as a patient medication record, prescription
41 drug order, or medication drug order.
- 42 (9) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the
43 facility in areas that pertain to the practice of pharmacy.
- 44 (10) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or
45 Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug, immediate
46 precursor, or other substance included in Schedules I - V of the Federal Comprehensive Drug Abuse
47 Prevention and Control Act of 1970, as amended (Public Law 91-513).
- 48 (11) Dangerous drug--A drug or device that:
- 49 (A) is not included in Penalty Group 1, 2, 3, or 4, Chapter 481, Health and Safety Code, and is unsafe for
50 self-medication; or
- 51 (B) bears or is required to bear the legend:
- 52 (i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that
53 complies with federal law; or
- 54 (ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."
- 55 (12) Device--An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or
56 other similar or related article, including any component part or accessory, that is required under federal
57 or state law to be ordered or prescribed by a practitioner.
- 58 (13) Direct copy--Electronic copy or carbonized copy of a medication order, including a facsimile (FAX)
59 or digital image.
- 60 (14) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device
61 in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of
62 a practitioner.
- 63 (15) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.
- 64 (16) Distributing pharmacist--The pharmacist who checks the medication order prior to distribution.
- 65 (17) Downtime--Period of time during which a data processing system is not operable.
- 66 (18) Drug regimen review--
- 67 (A) An evaluation of medication orders and patient medication records for:

- 68 (i) known allergies;
- 69 (ii) rational therapy--contraindications;
- 70 (iii) reasonable dose and route of administration;
- 71 (iv) reasonable directions for use;
- 72 (v) duplication of therapy;
- 73 (vi) drug-drug interactions;
- 74 (vii) drug-food interactions;
- 75 (viii) drug-disease interactions;
- 76 (ix) adverse drug reactions; and
- 77 (x) proper utilization, including overutilization or underutilization.
- 78 (B) The drug regimen review may be conducted prior to administration of the first dose (prospective) or
79 after administration of the first dose (retrospective).
- 80 (19) Electronic signature--A unique security code or other identifier which specifically identifies the
81 person entering information into a data processing system. A facility which utilizes electronic signatures
82 must:
- 83 (A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data
84 processing system; and
- 85 (B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of
86 electronic signatures.
- 87 (20) Expiration date--The date (and time, when applicable) beyond which a product should not be used.
- 88 (21) Facility--
- 89 (A) a hospital or other patient facility that is licensed under Chapter 241 or 577, Health and Safety Code;
- 90 (B) a hospice patient facility that is licensed under Chapter 142, Health and Safety Code;
- 91 (C) an ambulatory surgical center licensed under Chapter 243, Health and Safety Code; or
- 92 (D) a hospital maintained or operated by the state.
- 93 (22) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a
94 nursing station or other hospital department (excluding the pharmacy) for the purpose of administration to
95 a patient of the facility.
- 96 (23) Formulary--List of drugs approved for use in the facility by the committee which performs the
97 pharmacy and therapeutics function for the facility.
- 98 (24) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the

- 99 pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.
- 100 (25) Hard copy--A physical document that is readable without the use of a special device (i.e., data
101 processing system, computer, etc).
- 102 (26) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105
103 degrees F (41 degrees C).
- 104 (27) Institutional pharmacy--Area or areas in a facility where drugs are stored, bulk compounded,
105 delivered, compounded, dispensed, and distributed to other areas or departments of the facility, or
106 dispensed to an ultimate user or his or her agent.
- 107 (28) Investigational new drug--New drug intended for investigational use by experts qualified to evaluate
108 the safety and effectiveness of the drug as authorized by the Food and Drug Administration.
- 109 (29) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.
- 110 (30) Medication order--A written order from a practitioner or a verbal order from a practitioner or his
111 authorized agent for administration of a drug or device.
- 112 (31) Number of beds--The total number of beds is determined by the:
- 113 (A) number of beds for which the hospital is licensed by the Texas Department of State Health Services;
114 or
- 115 (B) average daily census as calculated by dividing the total number of inpatients admitted during the
116 previous calendar year by 365 (or 366 if the previous calendar year is a leap year).
- 117 (32) Part-time pharmacist--A pharmacist either employed or under contract, who routinely works less
118 than full-time.
- 119 (33) Patient--A person who is receiving services at the facility (including patients receiving ambulatory
120 procedures and patients conditionally admitted as observation patients), or who is receiving long term
121 care services or Medicare extended care services in a swing bed on the hospital premise or an adjacent,
122 readily accessible facility that is under the authority of the hospital's governing body. For the purposes of
123 this definition, the term "long term care services" means those services received in a skilled nursing
124 facility which is a distinct part of the hospital and the distinct part is not licensed separately or formally
125 approved as a nursing home by the state, even though it is designated or certified as a skilled nursing
126 facility. A patient includes a person confined in any correctional institution operated by the state of Texas.
- 127 (34) Perpetual inventory--An inventory which documents all receipts and distributions of a drug product,
128 such that an accurate, current balance of the amount of the drug product present in the pharmacy is
129 indicated.
- 130 (35) Pharmaceutical care--The provision of drug therapy and other pharmaceutical services intended to
131 assist in the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting
132 or slowing of a disease process.
- 133 (36) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the
134 authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of
135 pharmacy.
- 136 (37) Pharmacy and therapeutics function--Committee of the medical staff in the facility which assists in

- 137 the formulation of broad professional policies regarding the evaluation, selection, distribution, handling,
138 use, and administration, and all other matters relating to the use of drugs and devices in the facility.
- 139 (38) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and
140 whose responsibility in a pharmacy is to provide technical services that do not require professional
141 judgment regarding preparing and distributing drugs and who works under the direct supervision of and is
142 responsible to a pharmacist.
- 143 (39) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy
144 technician trainee and is authorized to participate in a pharmacy's technician training program.
- 145 (40) Pre-packaging--The act of re-packaging and re-labeling quantities of drug products from a
146 manufacturer's original container into unit-dose packaging or a multiple dose container for distribution
147 within the facility except as specified in §291.74(f)(3)(B) of this title (relating to Operational Standards).
- 148 (41) Prescription drug--
- 149 (A) A substance for which federal or state law requires a prescription before it may be legally dispensed
150 to the public;
- 151 (B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be
152 labeled with either of the following statements:
- 153 (i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend that
154 complies with federal law; or
- 155 (ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or
- 156 (C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed
157 on prescription only or is restricted to use by a practitioner only.
- 158 (42) Prescription drug order--
- 159 (A) a written order from a practitioner or a verbal order from a practitioner or his authorized agent to a
160 pharmacist for a drug or device to be dispensed; or
- 161 (B) a written order or a verbal order pursuant to Subtitle B, Chapter 157, Occupations Code.
- 162 (43) Rural hospital--A licensed hospital with 75 beds or fewer that:
- 163 (A) is located in a county with a population of 50,000 or less as defined by the United States Census
164 Bureau in the most recent U.S. census; or
- 165 (B) has been designated by the Centers for Medicare and Medicaid Services as a critical access hospital,
166 rural referral center, or sole community hospital.
- 167 (44) Sample--A prescription drug which is not intended to be sold and is intended to promote the sale of
168 the drug.
- 169 (45) Supervision--
- 170 (A) Physically present supervision--In a Class C pharmacy, a pharmacist shall be physically present to
171 directly supervise pharmacy technicians or pharmacy technician trainees.

172 (B) Electronic supervision--In a Class C pharmacy in a facility with 100 beds or less, a pharmacist
173 licensed in Texas may electronically supervise pharmacy technicians or pharmacy technician trainees to
174 perform the duties specified in §291.73(e)(2) of this title (relating to Personnel) provided:

175 (i) the pharmacy uses a system that monitors the data entry of medication orders and the filling of such
176 orders by an electronic method that shall include the use of one or more the following types of
177 technology:

178 (I) digital interactive video, audio, or data transmission;

179 (II) data transmission using computer imaging by way of still-image capture and store and forward; and

180 (III) other technology that facilitates access to pharmacy services;

181 (ii) the pharmacy establishes controls to protect the privacy and security of confidential records;

182 (iii) the pharmacist responsible for the duties performed by a pharmacy technician or pharmacy technician
183 trainee verifies:

184 (I) the data entry; and

185 (II) the accuracy of the filled orders prior to release of the order; and

186 (iv) the pharmacy keeps permanent digital records of duties electronically supervised and data
187 transmissions associated with electronically supervised duties for a period of two years.

188 (C) If the conditions of subparagraph (B) of this paragraph are met, electronic supervision shall be
189 considered the equivalent of direct supervision for the purposes of the Act.

190 (46) Tech-Check-Tech--Allowing a pharmacy technician to verify the accuracy of work performed by
191 another pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a
192 patient admitted to the hospital if the patient's orders have previously been reviewed and approved by a
193 pharmacist.

194 (47) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and Safety
195 Code, Chapter 481, as amended.

196 (48) Unit-dose packaging--The ordered amount of drug in a dosage form ready for administration to a
197 particular patient, by the prescribed route at the prescribed time, and properly labeled with name, strength,
198 and expiration date of the drug.

199 (49) Unusable drugs--Drugs or devices that are unusable for reasons, such as they are adulterated,
200 misbranded, expired, defective, or recalled.

201 (50) Written protocol--A physician's order, standing medical order, standing delegation order, or other
202 order or protocol as defined by rule of the Texas Medical Board under the Texas Medical Practice Act
203 Subtitle B, Chapter 157, Occupations Code.

204 **§291.73 Personnel**

205 (a) Requirements for pharmacist services.

206 (1) A Class C pharmacy in a facility with 101 beds or more shall be under the continuous on-site

207 supervision of a pharmacist during the time it is open for pharmacy services; provided, however, that
208 pharmacy technicians and pharmacy technician trainees may distribute prepackaged and pre-labeled drugs
209 from a drug storage area of the facility (e.g., a surgery suite), in the absence of physical supervision of a
210 pharmacist, under the following conditions:

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

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

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

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

220 (b) Pharmacist-in-charge.

221 (1) General.

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

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

229 (C) A pharmacist-in-charge may be in charge of one facility with 101 beds or more and one facility with
230 100 beds or less, including a rural hospital, provided the total number of beds does not exceed 150 beds.

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

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

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

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

240 (A) providing the appropriate level of pharmaceutical care services to patients of the facility;

241 (B) ensuring that drugs and/or devices are prepared for distribution safely, and accurately as prescribed;

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

- 244 (D) providing written guidelines and approval of the procedure to assure that all pharmaceutical
245 requirements are met when any part of preparing, sterilizing, and labeling of sterile preparations is not
246 performed under direct pharmacy supervision;
- 247 (E) participating in the development of a formulary for the facility, subject to approval of the appropriate
248 committee of the facility;
- 249 (F) developing a system to assure that drugs to be administered to patients are distributed pursuant to an
250 original or direct copy of the practitioner's medication order;
- 251 (G) developing a system for the filling and labeling of all containers from which drugs are to be
252 distributed or dispensed;
- 253 (H) assuring that the pharmacy maintains and makes available a sufficient inventory of antidotes and
254 other emergency drugs as well as current antidote information, telephone numbers of regional poison
255 control center and other emergency assistance organizations, and such other materials and information as
256 may be deemed necessary by the appropriate committee of the facility;
- 257 (I) maintaining records of all transactions of the institutional pharmacy as may be required by applicable
258 law, state and federal, and as may be necessary to maintain accurate control over and accountability for
259 all pharmaceutical materials including pharmaceuticals, components used in the compounding of
260 preparations, and participate in policy decisions regarding prescription drug delivery devices;
- 261 (J) participating in those aspects of the facility's patient care evaluation program which relate to
262 pharmaceutical utilization and effectiveness;
- 263 (K) participating in teaching and/or research programs in the facility;
- 264 (L) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical
265 services of the facility;
- 266 (M) providing effective and efficient messenger or delivery service to connect the institutional pharmacy
267 with appropriate areas of the facility on a regular basis throughout the normal workday of the facility;
- 268 (N) developing a system for the labeling, storage, and distribution of investigational new drugs, including
269 access to related drug information for healthcare personnel in the pharmacy and nursing station where
270 such drugs are being administered, concerning the dosage form, route of administration, strength, actions,
271 uses, side effects, adverse effects, interactions and symptoms of toxicity of investigational new drugs;
- 272 (O) assuring that records in a data processing system are maintained such that the data processing system
273 is in compliance with Class C (Institutional) pharmacy requirements;
- 274 (P) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;
- 275 (Q) assuring the legal operation of the pharmacy, including meeting all inspection and other requirements
276 of all state and federal laws or rules governing the practice of pharmacy; and
- 277 (R) if the pharmacy uses an automated medication supply system, shall be responsible for the following:
- 278 (i) reviewing and approving all policies and procedures for system operation, safety, security, accuracy
279 and access, patient confidentiality, prevention of unauthorized access, and malfunction;
- 280 (ii) inspecting medications in the automated medication supply system, at least monthly, for expiration

281 date, misbranding, physical integrity, security, and accountability; except that inspection of medications
282 in the automated medication supply system may be performed quarterly if:

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

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

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

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

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

293 (c) Consultant pharmacist.

294 (1) The consultant pharmacist may be the pharmacist-in-charge.

295 (2) A written agreement shall exist between the facility and any consultant pharmacist, and a copy of the
296 written agreement shall be made available to the board upon request.

297 (d) Pharmacists.

298 (1) General.

299 (A) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists
300 as may be required to operate the institutional pharmacy competently, safely, and adequately to meet the
301 needs of the patients of the facility.

302 (B) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in
303 subsection (b)(2) of this section and in ordering, administering, and accounting for pharmaceutical
304 materials.

305 (C) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or
306 pharmacy technician trainees under his or her supervision.

307 (D) All pharmacists while on duty, shall be responsible for complying with all state and federal laws or
308 rules governing the practice of pharmacy.

309 (E) A distributing pharmacist shall be responsible for and ensure that the drug is prepared for distribution
310 safely, and accurately as prescribed unless the pharmacy's data processing system can record the identity
311 of each pharmacist involved in a specific portion of the preparation of medication orders for distribution,
312 in which case each pharmacist involved in the preparation of medication orders shall be responsible for
313 and ensure that the portion of the process the pharmacist is performing results in the safe and accurate
314 distribution and delivery of the drug as ordered. The preparation and distribution process for medication
315 orders shall include, but not be limited to, drug regimen review, and verification of accurate medication
316 order data entry, preparation, and distribution, and performance of the final check of the prepared
317 medication.

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

320 (A) providing those acts or services necessary to provide pharmaceutical care;

321 (B) receiving, interpreting, and evaluating prescription drug orders, and reducing verbal medication
322 orders to writing either manually or electronically;

323 (C) participating in drug and/or device selection as authorized by law, drug and/or device supplier
324 selection, drug administration, drug regimen review, or drug or drug-related research;

325 (D) performing a specific act of drug therapy management for a patient delegated to a pharmacist by a
326 written protocol from a physician licensed in this state in compliance with the Medical Practice Act
327 Subtitle B, Chapter 157, Occupations Code;

328 (E) accepting the responsibility for:

329 (i) distributing prescription drugs and devices with drug components pursuant to medication orders;

330 (ii) compounding and labeling of prescription drugs and devices with drug components;

331 (iii) proper and safe storage of prescription drugs and devices with drug components; and

332 (iv) maintaining proper records for prescription drugs and devices with drug components.

333 (3) Special requirements for compounding. All pharmacists engaged in compounding non-sterile
334 preparations shall meet the training requirements specified in §291.131 of this title (relating to
335 Pharmacies Compounding Non-sterile Preparations).

336 (e) Pharmacy technicians and pharmacy technician trainees.

337 (1) General.

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

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

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

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

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

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

- 352 (ii) duties which may and may not be performed by pharmacy technicians in the absence of a pharmacist;
353 and
- 354 (iii) the pharmacy technician's role in preventing dispensing and distribution errors.
- 355 (2) Duties. Duties may include, but need not be limited to, the following functions under the supervision
356 of and responsible to a pharmacist:
- 357 (A) Facilities with 101 beds or more. The following functions must be performed under the physically
358 present supervision of a pharmacist:
- 359 (i) pre-packing and labeling unit and multiple dose packages, provided a pharmacist supervises and
360 conducts a final check and affixes his or her name, initials or electronic signature to the appropriate
361 quality control records prior to distribution;
- 362 (ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders,
363 provided a pharmacist supervises and checks the preparation prior to distribution;
- 364 (iii) bulk compounding or batch preparation provided a pharmacist supervises and conducts in-process
365 and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality
366 control records prior to distribution;
- 367 (iv) distributing routine orders for stock supplies to patient care areas;
- 368 (v) entering medication order and drug distribution information into a data processing system, provided
369 judgmental decisions are not required and a pharmacist checks the accuracy of the information entered
370 into the system prior to releasing the order;
- 371 (vi) loading unlabeled drugs into an automated compounding or counting device provided a pharmacist
372 supervises, verifies that the system was properly loaded prior to use, and affixes his or her name, initials
373 or electronic signature to the appropriate quality control records;
- 374 (vii) accessing automated medication supply systems after proper training on the use of the automated
375 medication supply system and demonstration of comprehensive knowledge of the written policies and
376 procedures for its operation; and
- 377 (viii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy
378 technicians or pharmacy technician trainees have completed the training specified in §291.131 of this
379 title.
- 380 (B) Facilities with 100 beds or less.
- 381 (i) Physically present supervision. The following functions must be performed under the physically
382 present supervision of a pharmacist unless the pharmacy meets the requirements for a rural hospital and
383 has been approved by the board to allow pharmacy technicians to perform the duties specified in
384 §552.1011 of the Texas Pharmacy Act (Act) and subparagraph (D)(ii) of this paragraph:
- 385 (I) pre-packing and labeling unit and multiple dose packages, provided a pharmacist supervises and
386 conducts a final check and affixes his or her name, initials or electronic signature to the appropriate
387 quality control records prior to distribution;
- 388 (II) bulk compounding or batch preparation provided a pharmacist supervises and conducts in-process and
389 final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control

390 records prior to distribution;

391 (III) loading unlabeled drugs into an automated compounding or counting device provided a pharmacist
392 supervises, verifies that the system was properly loaded prior to use, and affixes his or her name, initials,
393 or electronic signature to the appropriate quality control records; and

394 (IV) compounding medium-risk and high-risk sterile preparations pursuant to medication orders provided
395 the pharmacy technicians or pharmacy technician trainees:

396 (-a-) have completed the training specified in §291.133 of this title; and

397 (-b-) are supervised by a pharmacist who has completed the training specified in §291.133 of this title and
398 who conducts in-process and final checks, and affixes his or her name, initials, or electronic signature to
399 the label or if batch prepared, to the appropriate quality control records. (The name, initials, initials or
400 electronic signature are not required on the label if it is maintained in a permanent record of the
401 pharmacy.)

402 (ii) Electronic supervision or physically present supervision. The following functions may be performed
403 under the electronic supervision or physically present supervision of a pharmacist:

404 (I) preparing, packaging, or labeling prescription drugs pursuant to medication orders, provided a
405 pharmacist checks the preparation prior to distribution;

406 (II) distributing routine orders for stock supplies to patient care areas;

407 (III) entering medication order and drug distribution information into a data processing system, provided
408 judgmental decisions are not required and a pharmacist checks the accuracy of the information entered
409 into the system prior to releasing the order;

410 (IV) accessing automated medication supply systems after proper training on the use of the automated
411 medication supply system and demonstration of comprehensive knowledge of the written policies and
412 procedures for its operation;

413 (V) compounding non-sterile preparations pursuant to medication orders provided the pharmacy
414 technicians or pharmacy technician trainees have completed the training specified in §291.131 of this
415 title; and

416 (VI) compounding low-risk sterile preparations pursuant to medication orders provided the pharmacy
417 technicians or pharmacy technician trainees:

418 (-a-) have completed the training specified in §291.133 of this title; and

419 (-b-) are supervised by a pharmacist who has completed the training specified in §291.133 of this title,
420 and who conducts in-process and final checks, and affixes his or her name, initials, or electronic signature
421 to the label or if batch prepared, to the appropriate quality control records. (The name, initials, or
422 electronic signature are not required on the label if it is maintained in a permanent record of the
423 pharmacy.)

424 (C) Facilities with an ongoing clinical pharmacy program. A Class C pharmacy with an ongoing clinical
425 pharmacy program may allow a pharmacy technician to verify the accuracy of the duties specified in
426 clause (ii) of this subparagraph when performed by another pharmacy technician, under the following
427 conditions:

- 428 (i) The pharmacy technician:
- 429 (I) is a registered pharmacy technician and not a pharmacy technician trainee; and
- 430 (II) meets the training requirements specified in §297.6 of this title and the training requirements
431 specified in paragraph (1) of this subsection.
- 432 (ii) If the requirements of clause (i) of this subparagraph are met, a pharmacy technician may verify the
433 accuracy of the following duties performed by another pharmacy technician:
- 434 (I) filling medication carts;
- 435 (II) distributing routine orders for stock supplies to patient care areas; and
- 436 (III) accessing and restocking automated medication supply systems after proper training on the use of the
437 automated medication supply system and demonstration of comprehensive knowledge of the written
438 policies and procedures for its operation; and
- 439 (iii) The patient's orders have previously been reviewed and approved by a pharmacist.
- 440 (iv) A pharmacist is on duty in the facility at all times that the pharmacy is open for pharmacy services.
- 441 (D) Rural Hospitals.
- 442 (i) A rural hospital may allow a pharmacy technician to perform the duties specified in clause (ii) of this
443 subparagraph when a pharmacist is not on duty, if:
- 444 (I) the pharmacy technician:
- 445 (-a-) is a registered pharmacy technician and not a pharmacy technician trainee; and
- 446 (-b-) meets the training requirements specified in §297.6 of this title and those specified in paragraph (1)
447 of this subsection;
- 448 (II) a pharmacist is accessible at all times to respond to any questions and needs of the pharmacy
449 technician or other hospital employees, by telephone, answering or paging service, e-mail, or any other
450 system that makes a pharmacist immediately accessible;
- 451 (III) the pharmacy is appropriately staffed to meet the needs of the pharmacy; and
- 452 (IV) a nurse or practitioner at the rural hospital or a pharmacist through electronic supervision as
453 specified in paragraph (2)(B)(ii) of this subsection, verifies the accuracy of the actions of the pharmacy
454 technician.
- 455 (ii) If the requirements of clause (i) of this subparagraph are met, the pharmacy technician may, during
456 the hours that the institutional pharmacy in the hospital is open, perform the following duties in the
457 pharmacy without the direct supervision of a pharmacist:
- 458 (I) enter medication order and drug distribution information into a data processing system;
- 459 (II) prepare, package, or label a prescription drug according to a medication order if a licensed nurse or
460 practitioner verifies the accuracy of the order before administration of the drug to the patient;

- 461 (III) fill a medication cart used in the rural hospital;
- 462 (IV) distribute routine orders for stock supplies to patient care areas; and
- 463 (V) access and restock automated medication supply cabinets.
- 464 (3) Procedures.
- 465 (A) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance
466 with standard, written procedures and guidelines.
- 467 (B) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the
468 same manner as those working in a Class A pharmacy.
- 469 (f) Owner. The owner of a Class C pharmacy shall have responsibility for all administrative and
470 operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative
471 and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the
472 owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or
473 another Texas licensed pharmacist:
- 474 (1) establishing policies for procurement of prescription drugs and devices and other products dispensed
475 from the Class C pharmacy;
- 476 (2) establishing and maintaining effective controls against the theft or diversion of prescription drugs;
- 477 (3) if the pharmacy uses an automated pharmacy dispensing system, reviewing and approving all policies
478 and procedures for system operation, safety, security, accuracy and access, patient confidentiality,
479 prevention of unauthorized access, and malfunction;
- 480 (4) providing the pharmacy with the necessary equipment and resources commensurate with its level and
481 type of practice; and
- 482 (5) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data
483 processing system such that the system is in compliance with state and federal requirements.
- 484 (g) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows.
- 485 (1) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears
486 the person's name and identifies him or her as a pharmacy technician.
- 487 (2) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or
488 badge that bears the person's name and identifies him or her as a pharmacy technician trainee.
- 489 (3) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the
490 person's name and identifies him or her as a pharmacist intern.
- 491 (4) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name
492 and identifies him or her as a pharmacist.

493 **§291.74 Operational Standards**

- 494 (a) Licensing requirements.

- 495 (1) A Class C pharmacy shall register annually or biennially with the board on a pharmacy license
496 application provided by the board, following the procedures specified in §291.1 of this title (relating to
497 Pharmacy License Application).
- 498 (2) If the institutional pharmacy is owned or operated by a hospital management or consulting firm, the
499 following conditions apply.
- 500 (A) The pharmacy license application shall list the hospital management or consulting firm as the owner
501 or operator.
- 502 (B) The hospital management or consulting firm shall obtain DEA and DPS controlled substance
503 registrations that are issued in their name, unless the following occurs:
- 504 (i) the hospital management or consulting firm and the facility cosign a contractual pharmacy service
505 agreement which assigns overall responsibility for controlled substances to the facility; and
- 506 (ii) such hospital pharmacy management or consulting firm maintains dual responsibility for the
507 controlled substances.
- 508 (3) A Class C pharmacy which changes ownership shall notify the board within 10 days of the change of
509 ownership and apply for a new and separate license as specified in §291.3 of this title (relating to
510 Required Notifications).
- 511 (4) A Class C pharmacy which changes location and/or name shall notify the board within 10 days of the
512 change and file for an amended license as specified in §291.3 of this title.
- 513 (5) A Class C pharmacy owned by a partnership or corporation which changes managing officers shall
514 notify the board in writing of the names of the new managing officers within 10 days of the change
515 following the procedures in §291.3 of this title.
- 516 (6) A Class C pharmacy shall notify the board in writing within 10 days of closing, following the
517 procedures in §291.5 of this title (relating to Closing a Pharmacy).
- 518 (7) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the
519 issuance and renewal of a license and the issuance of an amended license.
- 520 (8) A separate license is required for each principal place of business and only one pharmacy license may
521 be issued to a specific location.
- 522 (9) A Class C pharmacy, licensed under the Act, §560.051(a)(3), which also operates another type of
523 pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) (Community
524 Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear Pharmacy (Class B)), is not required to secure a
525 license for the such other type of pharmacy; provided, however, such licensee is required to comply with
526 the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel),
527 §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and
528 §291.35 of this title (relating to Official Prescription Records), contained in Community Pharmacy (Class
529 A), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of
530 this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of
531 this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are
532 applicable to the operation of the pharmacy.
- 533 (10) A Class C pharmacy engaged in the compounding of non-sterile preparations shall comply with the
534 provisions of §291.131 of this title (relating to Pharmacies Compounding Non-sterile Preparations).

535 (11) Prior to August 31, 2014, a Class C pharmacy engaged in the compounding of sterile preparations
536 shall comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding Sterile
537 Preparations).

538 (12) Effective August 31, 2014, a Class C pharmacy shall not compound sterile preparations unless the
539 pharmacy has applied for and obtained a Class C-S pharmacy.

540 (13) A Class C pharmacy engaged in the provision of remote pharmacy services, including storage and
541 dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to
542 Remote Pharmacy Services).

543 (14) A Class C pharmacy engaged in centralized prescription dispensing and/or prescription drug or
544 medication order processing shall comply with the provisions of §291.123 of this title (relating to Central
545 Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized
546 Prescription Dispensing).

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

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

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

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

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

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

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

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

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

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

567 (16) A rural hospital that wishes to allow a pharmacy technician to perform the duties specified in
568 §291.73(e)(2)(D) of this title (relating to Personnel), shall make application to the board as follows.

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

- 572 (i) name, address, and pharmacy license number;
- 573 (ii) name and license number of the pharmacist-in-charge;
- 574 (iii) name and registration number of the pharmacy technicians;
- 575 (iv) proposed date the pharmacy wishes to start allowing pharmacy technicians to perform the duties
576 specified in §291.73(e)(2)(D) of this title;
- 577 (v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural hospital is
578 either:
- 579 (I) located in a county with a population of 50,000 or less as defined by the United States Census Bureau
580 in the most recent U.S. census; or
- 581 (II) designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural
582 referral center, or sole community hospital; and
- 583 (vi) any other information specified on the application.
- 584 (B) A rural hospital may not allow a pharmacy technician to perform the duties specified in
585 §291.73(e)(2)(D) of this title until the board has reviewed and approved the application and issued an
586 amended license to the pharmacy.
- 587 (C) Every two years in conjunction with the application for renewal of the pharmacy license, the
588 pharmacist-in-charge shall update the application for pharmacy technicians to perform the duties
589 specified in §291.73(e)(2)(D) of this title.
- 590 (b) Environment.
- 591 (1) General requirements.
- 592 (A) The institutional pharmacy shall have adequate space necessary for the storage, compounding,
593 labeling, dispensing, and sterile preparation of drugs prepared in the pharmacy, and additional space,
594 depending on the size and scope of pharmaceutical services.
- 595 (B) The institutional pharmacy shall be arranged in an orderly fashion and shall be kept clean. All
596 required equipment shall be clean and in good operating condition.
- 597 (C) A sink with hot and cold running water exclusive of restroom facilities shall be available to all
598 pharmacy personnel and shall be maintained in a sanitary condition at all times.
- 599 (D) The institutional pharmacy shall be properly lighted and ventilated.
- 600 (E) The temperature of the institutional pharmacy shall be maintained within a range compatible with the
601 proper storage of drugs. The temperature of the refrigerator and/or freezer shall be maintained within a
602 range compatible with the proper storage of drugs.
- 603 (F) If the institutional pharmacy has flammable materials, the pharmacy shall have a designated area for
604 the storage of flammable materials. Such area shall meet the requirements set by local and state fire laws.
- 605 (G) The institutional pharmacy shall store antiseptics, other drugs for external use, and disinfectants
606 separately from internal and injectable medications.

607 (2) Security requirements.

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

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

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

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

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

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

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

623 (1) current copies of the following:

624 (A) Texas Pharmacy Act and rules;

625 (B) Texas Dangerous Drug Act and rules;

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

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

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

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

634 (B) a general information reference text, such as:

635 (i) Facts and Comparisons with current supplements;

636 (ii) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the Healthcare
637 Provider);

638 (iii) AHFS Drug Information with current supplements;

639 (iv) Remington's Pharmaceutical Sciences; or

- 640 (v) Clinical Pharmacology;
- 641 (3) a current or updated reference on injectable drug products, such as Handbook of Injectable Drugs;
- 642 (4) basic antidote information and the telephone number of the nearest regional poison control center;
- 643 (5) metric-apothecary weight and measure conversion charts.
- 644 (e) Absence of a pharmacist.
- 645 (1) Medication orders.
- 646 (A) In facilities with a full-time pharmacist, if a practitioner orders a drug for administration to a bona
647 fide patient of the facility when the pharmacy is closed, the following is applicable.
- 648 (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic needs may be
649 removed from the institutional pharmacy.
- 650 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.
- 651 (iii) A record shall be made at the time of withdrawal by the authorized person removing the drugs and
652 devices. The record shall contain the following information:
- 653 (I) name of patient;
- 654 (II) name of device or drug, strength, and dosage form;
- 655 (III) dose prescribed;
- 656 (IV) quantity taken;
- 657 (V) time and date; and
- 658 (VI) signature (first initial and last name or full signature) or electronic signature of person making
659 withdrawal.
- 660 (iv) The original or direct copy of the medication order may substitute for such record, providing the
661 medication order meets all the requirements of clause (iii) of this subparagraph.
- 662 (v) The pharmacist shall verify the withdrawal of drugs from the pharmacy and perform a drug regimen
663 review as specified in subsection (g)(1)(B) of this section as soon as practical, but in no event more than
664 72 hours from the time of such withdrawal.
- 665 (B) In facilities with a part-time or consultant pharmacist, if a practitioner orders a drug for administration
666 to a bona fide patient of the facility when the pharmacist is not on duty, or when the pharmacy is closed,
667 the following is applicable.
- 668 (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be removed from
669 the institutional pharmacy.
- 670 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.
- 671 (iii) A record shall be made at the time of withdrawal by the authorized person removing the drugs and

672 devices; the record shall meet the same requirements as specified in subparagraph (A)(iii) and (iv) of this
673 paragraph.

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

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

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

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

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

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

684 (ii) quantity removed;

685 (iii) location of floor stock;

686 (iv) date and time; and

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

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

691 (3) Rural hospitals. In rural hospitals when a pharmacy technician performs the duties listed in
692 §291.73(e)(2)(D) of this title, the following is applicable:

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

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

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

697 (iii) dose prescribed or ordered;

698 (iv) quantity distributed;

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

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

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

- 705 (C) The pharmacist shall:
- 706 (i) verify and document the verification of all distributions made from the pharmacy in the absence of a
707 pharmacist as soon as practical, but in no event more than seven (7) days from the time of such
708 distribution;
- 709 (ii) perform a drug regimen review for all medication orders as specified in subsection (g)(1)(B) of this
710 section as soon as practical, but in no event more than seven (7) days from the time of such distribution
711 and document such verification including any discrepancies noted by the pharmacist;
- 712 (iii) review any discrepancy noted by the pharmacist with the pharmacy technician(s) and make any
713 change in procedures or processes necessary to prevent future problems; and
- 714 (iv) report any adverse events that have a potential for harm to a patient to the appropriate committee of
715 the hospital that reviews adverse events.
- 716 (f) Drugs.
- 717 (1) Procurement, preparation and storage.
- 718 (A) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but
719 may receive input from other appropriate staff of the facility, relative to such responsibility.
- 720 (B) The pharmacist-in-charge shall have the responsibility for determining specifications of all drugs
721 procured by the facility.
- 722 (C) Institutional pharmacies may not sell, purchase, trade or possess prescription drug samples, unless the
723 pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).
- 724 (D) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in §291.15 of this
725 title (relating to Storage of Drugs).
- 726 (E) Any drug bearing an expiration date may not be distributed beyond the expiration date of the drug.
- 727 (F) Outdated and other unusable drugs shall be removed from stock and shall be quarantined together
728 until such drugs are disposed of properly.
- 729 (2) Formulary.
- 730 (A) A formulary shall be developed by the facility committee performing the pharmacy and therapeutics
731 function for the facility. For the purpose of this section, a formulary is a compilation of pharmaceuticals
732 that reflects the current clinical judgment of a facility's medical staff.
- 733 (B) The pharmacist-in-charge or pharmacist designated by the pharmacist-in-charge shall be a full voting
734 member of the committee performing the pharmacy and therapeutics function for the facility, when such
735 committee is performing the pharmacy and therapeutics function.
- 736 (C) A practitioner may grant approval for pharmacists at the facility to interchange, in accordance with
737 the facility's formulary, for the prescribed drugs on the practitioner's medication orders provided:
- 738 (i) the pharmacy and therapeutics committee has developed a formulary;
- 739 (ii) the formulary has been approved by the medical staff committee of the facility;

- 740 (iii) there is a reasonable method for the practitioner to override any interchange; and
- 741 (iv) the practitioner authorizes pharmacists in the facility to interchange on his/her medication orders in
742 accordance with the facility's formulary through his/her written agreement to abide by the policies and
743 procedures of the medical staff and facility.
- 744 (3) Prepackaging of drugs.
- 745 (A) Distribution within a facility.
- 746 (i) Drugs may be prepackaged in quantities suitable for internal distribution by a pharmacist or by
747 pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a
748 pharmacist.
- 749 (ii) The label of a prepackaged unit shall indicate:
- 750 (I) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name
751 of the manufacturer or distributor;
- 752 (II) facility's unique lot number;
- 753 (III) expiration date based on currently available literature; and
- 754 (IV) quantity of the drug, if the quantity is greater than one.
- 755 (iii) Records of prepackaging shall be maintained to show:
- 756 (I) name of the drug, strength, and dosage form;
- 757 (II) facility's unique lot number;
- 758 (III) manufacturer or distributor;
- 759 (IV) manufacturer's lot number;
- 760 (V) expiration date;
- 761 (VI) quantity per prepackaged unit;
- 762 (VII) number of prepackaged units;
- 763 (VIII) date packaged;
- 764 (IX) name, initials, or electronic signature of the prepacker; and
- 765 (X) name, initials, or electronic signature of the responsible pharmacist.
- 766 (iv) Stock packages, prepackaged units, and control records shall be quarantined together until
767 checked/released by the pharmacist.
- 768 (B) Distribution to other Class C (Institutional) pharmacies under common ownership.
- 769 (i) Drugs may be prepackaged in quantities suitable for distribution to other Class C (Institutional)

770 pharmacies under common ownership by a pharmacist or by pharmacy technicians or pharmacy
771 technician trainees under the direction and direct supervision of a pharmacist.

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

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

775 (II) facility's unique lot number;

776 (III) expiration date based on currently available literature;

777 (IV) quantity of the drug, if the quantity is greater than one; and

778 (V) name of the facility responsible for prepackaging the drug.

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

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

781 (II) facility's unique lot number;

782 (III) manufacturer or distributor;

783 (IV) manufacturer's lot number;

784 (V) expiration date;

785 (VI) quantity per prepackaged unit;

786 (VII) number of prepackaged units;

787 (VIII) date packaged;

788 (IX) name, initials, or electronic signature of the prepacker;

789 (X) name, initials, or electronic signature of the responsible pharmacist; and

790 (XI) name of the facility receiving the prepackaged drug.

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

793 (v) The pharmacy shall have written procedure for the recall of any drug prepackaged for another Class C
794 Pharmacy under common ownership. The recall procedures shall require:

795 (I) notification to the pharmacy to which the prepackaged drug was distributed;

796 (II) quarantine of the product if there is a suspicion of harm to a patient;

797 (III) a mandatory recall if there is confirmed or probable harm to a patient; and

798 (IV) notification to the board if a mandatory recall is instituted.

- 799 (4) Sterile preparations prepared in a location other than the pharmacy. A distinctive supplementary label
800 shall be affixed to the container of any admixture. The label shall bear at a minimum:
- 801 (A) patient's name and location, if not immediately administered;
- 802 (B) name and amount of drug(s) added;
- 803 (C) name of the basic solution;
- 804 (D) name or identifying code of person who prepared admixture; and
- 805 (E) expiration date of solution.
- 806 (5) Distribution.
- 807 (A) Medication orders.
- 808 (i) Drugs may be given to patients in facilities only on the order of a practitioner. No change in the order
809 for drugs may be made without the approval of a practitioner except as authorized by the practitioner in
810 compliance with paragraph (2)(C) of this subsection.
- 811 (ii) Drugs may be distributed only from the original or a direct copy of the practitioner's medication order.
- 812 (iii) Pharmacy technicians and pharmacy technician trainees may not receive verbal medication orders.
- 813 (iv) Institutional pharmacies shall be exempt from the labeling provisions and patient notification
814 requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication
815 orders.
- 816 (B) Procedures.
- 817 (i) Written policies and procedures for a drug distribution system (best suited for the particular
818 institutional pharmacy) shall be developed and implemented by the pharmacist-in-charge, with the advice
819 of the committee performing the pharmacy and therapeutics function for the facility.
- 820 (ii) The written policies and procedures for the drug distribution system shall include, but not be limited
821 to, procedures regarding the following:
- 822 (I) pharmaceutical care services;
- 823 (II) handling, storage and disposal of cytotoxic drugs and waste;
- 824 (III) disposal of unusable drugs and supplies;
- 825 (IV) security;
- 826 (V) equipment;
- 827 (VI) sanitation;
- 828 (VII) reference materials;
- 829 (VIII) drug selection and procurement;

- 830 (IX) drug storage;
- 831 (X) controlled substances;
- 832 (XI) investigational drugs, including the obtaining of protocols from the principal investigator;
- 833 (XII) prepackaging and manufacturing;
- 834 (XIII) stop orders;
- 835 (XIV) reporting of medication errors, adverse drug reactions/events, and drug product defects;
- 836 (XV) physician orders;
- 837 (XVI) floor stocks;
- 838 (XVII) drugs brought into the facility;
- 839 (XVIII) furlough medications;
- 840 (XIX) self-administration;
- 841 (XX) emergency drug supply;
- 842 (XXI) formulary;
- 843 (XXII) monthly inspections of nursing stations and other areas where drugs are stored, distributed,
844 administered or dispensed;
- 845 (XXIII) control of drug samples;
- 846 (XXIV) outdated and other unusable drugs;
- 847 (XXV) routine distribution of patient medication;
- 848 (XXVI) preparation and distribution of sterile preparations;
- 849 (XXVII) handling of medication orders when a pharmacist is not on duty;
- 850 (XXVIII) use of automated compounding or counting devices;
- 851 (XXIX) use of data processing and direct imaging systems;
- 852 (XXX) drug administration to include infusion devices and drug delivery systems;
- 853 (XXXI) drug labeling;
- 854 (XXXII) recordkeeping;
- 855 (XXXIII) quality assurance/quality control;
- 856 (XXXIV) duties and education and training of professional and nonprofessional staff;

- 857 (XXXV) procedures for a pharmacy technician to verify the accuracy of work performed by another
858 pharmacy technician, if applicable;
- 859 (XXXVI) operation of the pharmacy when a pharmacist is not on-site; and
- 860 (XXXVII) emergency preparedness plan, to include continuity of patient therapy and public safety.
- 861 (6) Discharge Prescriptions. Discharge prescriptions must be dispensed and labeled in accordance with
862 §291.33 of this title (relating to Operational Standards) except that certain medications packaged in unit-
863 of-use containers, such as metered-dose inhalers, insulin pens, topical creams or ointments, or ophthalmic
864 or otic preparation that are administered to the patient during the time the patient was a patient in the
865 hospital, may be provided to the patient upon discharge provided the pharmacy receives a discharge order
866 and the product bears a label containing the following information:
- 867 (A) name of the patient;
- 868 (B) name and strength of the medication;
- 869 (C) name of the prescribing or attending practitioner;
- 870 (D) directions for use;
- 871 (E) duration of therapy (if applicable); and
- 872 (F) name and telephone number of the pharmacy.
- 873 (g) Pharmaceutical care services.
- 874 (1) The pharmacist-in-charge shall assure that at least the following pharmaceutical care services are
875 provided to patients of the facility.
- 876 (A) Drug utilization review. A systematic ongoing process of drug utilization review shall be developed
877 in conjunction with the medical staff to increase the probability of desired patient outcomes and decrease
878 the probability of undesired outcomes from drug therapy.
- 879 (B) Drug regimen review.
- 880 (i) For the purpose of promoting therapeutic appropriateness, a pharmacist shall evaluate medication
881 orders and patient medication records for:
- 882 (I) known allergies;
- 883 (II) rational therapy--contraindications;
- 884 (III) reasonable dose and route of administration;
- 885 (IV) reasonable directions for use;
- 886 (V) duplication of therapy;
- 887 (VI) drug-drug interactions;
- 888 (VII) drug-food interactions;

- 889 (VIII) drug-disease interactions;
- 890 (IX) adverse drug reactions;
- 891 (X) proper utilization, including overutilization or underutilization; and
- 892 (XI) clinical laboratory or clinical monitoring methods to monitor and evaluate drug effectiveness, side
893 effects, toxicity, or adverse effects, and appropriateness to continued use of the drug in its current
894 regimen.
- 895 (ii) The drug regimen review shall be conducted on a prospective basis when a pharmacist is on duty,
896 except for an emergency order, and on a retrospective basis as specified in subsection (e)(1) of this
897 section when a pharmacist is not on duty.
- 898 (iii) Any questions regarding the order must be resolved with the prescriber and a written notation of
899 these discussions made and maintained.
- 900 (iv) The drug regimen review may be conducted by remotely accessing the pharmacy's electronic data
901 base from outside the pharmacy by an individual Texas licensed pharmacist employee of the pharmacy,
902 provided the pharmacy establishes controls to protect the privacy of the patient and the security of
903 confidential records.
- 904 (C) Education. The pharmacist-in-charge in cooperation with appropriate multi-disciplinary staff of the
905 facility shall develop policies that assure that:
- 906 (i) the patient and/or patient's caregiver receives information regarding drugs and their safe and
907 appropriate use; and
- 908 (ii) health care providers are provided with patient specific drug information.
- 909 (D) Patient monitoring. The pharmacist-in-charge in cooperation with appropriate multi-disciplinary staff
910 of the facility shall develop policies to ensure that the patient's response to drug therapy is monitored and
911 conveyed to the appropriate health care provider.
- 912 (2) Other pharmaceutical care services which may be provided by pharmacists in the facility include, but
913 are not limited to, the following:
- 914 (A) managing drug therapy as delegated by a practitioner as allowed under the provisions of the Medical
915 Practice Act;
- 916 (B) administering immunizations and vaccinations under written protocol of a physician;
- 917 (C) managing patient compliance programs;
- 918 (D) providing preventative health care services; and
- 919 (E) providing case management of patients who are being treated with high-risk or high-cost drugs, or
920 who are considered "high risk" due to their age, medical condition, family history, or related concern.
- 921 (h) Emergency rooms.
- 922 (1) During the times a pharmacist is on duty in the facility any prescription drugs supplied to an
923 outpatient, including emergency department patients, may only be dispensed by a pharmacist.

- 924 (2) When a pharmacist is not on duty in the facility, the following is applicable for supplying prescription
925 drugs to be taken home by the patient for self-administration from the emergency room. If the patient has
926 been admitted to the emergency room and assessed by a practitioner at the hospital, the following
927 procedures shall be observed in supplying prescription drugs from the emergency room.
- 928 (A) Dangerous drugs and/or controlled substances may only be supplied in accordance with the system of
929 control and accountability for dangerous drugs and/or controlled substances administered or supplied
930 from the emergency room; such system shall be developed and supervised by the pharmacist-in-charge or
931 staff pharmacist designated by the pharmacist-in-charge.
- 932 (B) Only dangerous drugs and/or controlled substances listed on the emergency room drug list may be
933 supplied; such list shall be developed by the pharmacist-in-charge and the facility's emergency
934 department committee (or like group or person responsible for policy in that department) and shall consist
935 of dangerous drugs and/or controlled substances of the nature and type to meet the immediate needs of
936 emergency room patients.
- 937 (C) Dangerous drugs and/or controlled substances may only be supplied in prepackaged quantities not to
938 exceed a 72-hour supply in suitable containers and appropriately pre-labeled (including necessary
939 auxiliary labels) by the institutional pharmacy.
- 940 (D) At the time of delivery of the dangerous drugs and/or controlled substances, the practitioner or
941 licensed nurse under the supervision of a practitioner shall appropriately complete the label with at least
942 the following information:
- 943 (i) name, address, and phone number of the facility;
- 944 (ii) date supplied;
- 945 (iii) name of practitioner;
- 946 (iv) name of patient;
- 947 (v) directions for use;
- 948 (vi) brand name and strength of the dangerous drug or controlled substance; or if no brand name, then the
949 generic name, strength, and the name of the manufacturer or distributor of the dangerous drug or
950 controlled substance;
- 951 (vii) quantity supplied; and
- 952 (viii) unique identification number.
- 953 (E) The practitioner, or a licensed nurse under the supervision of the practitioner, shall give the
954 appropriately labeled, prepackaged drug to the patient and explain the correct use of the drug.
- 955 (F) A perpetual record of dangerous drugs and/or controlled substances supplied from the emergency
956 room shall be maintained in the emergency room. Such record shall include the following:
- 957 (i) date supplied;
- 958 (ii) practitioner's name;
- 959 (iii) patient's name;

- 960 (iv) brand name and strength of the dangerous drug or controlled substance; or if no brand name, then the
961 generic name, strength, and the name of the manufacturer or distributor of the dangerous drug or
962 controlled substance;
- 963 (v) quantity supplied; and
- 964 (vi) unique identification number.
- 965 (G) The pharmacist-in-charge, or staff pharmacist designated by the pharmacist-in-charge, shall verify the
966 correctness of this record at least once every seven days.
- 967 (i) Radiology departments.
- 968 (1) During the times a pharmacist is on duty, any prescription drugs dispensed to an outpatient, including
969 radiology department patients, may only be dispensed by a pharmacist.
- 970 (2) When a pharmacist is not on duty, the following procedures shall be observed in supplying
971 prescription drugs from the radiology department.
- 972 (A) Prescription drugs may only be supplied to patients who have been scheduled for an x-ray
973 examination at the facility.
- 974 (B) Prescription drugs may only be supplied in accordance with the system of control and accountability
975 for prescription drugs administered or supplied from the radiology department and supervised by the
976 pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.
- 977 (C) Only prescription drugs listed on the radiology drug list may be supplied; such list shall be developed
978 by the pharmacist-in-charge and the facility's radiology committee (or like group or persons responsible
979 for policy in that department) and shall consist of drugs for the preparation of a patient for a radiological
980 procedure.
- 981 (D) Prescription drugs may only be supplied in prepackaged quantities in suitable containers and
982 prelabeled by the institutional pharmacy with the following information:
- 983 (i) name and address of the facility;
- 984 (ii) directions for use;
- 985 (iii) name and strength of the prescription drug--if generic name, the name of the manufacturer or
986 distributor of the prescription drug;
- 987 (iv) quantity;
- 988 (v) facility's lot number and expiration date; and
- 989 (vi) appropriate ancillary label(s).
- 990 (E) At the time of delivery of the prescription drug, the practitioner or practitioner's agent shall complete
991 the label with the following information:
- 992 (i) date supplied;
- 993 (ii) name of physician;

- 994 (iii) name of patient; and
- 995 (iv) unique identification number.
- 996 (F) The practitioner or practitioner's agent shall give the appropriately labeled, prepackaged prescription
997 drug to the patient.
- 998 (G) A perpetual record of prescription drugs supplied from the radiology department shall be maintained
999 in the radiology department. Such records shall include the following:
- 1000 (i) date supplied;
- 1001 (ii) practitioner's name;
- 1002 (iii) patient's name;
- 1003 (iv) brand name and strength of the prescription drug; or if no brand name, then the generic name,
1004 strength, dosage form, and the name of the manufacturer or distributor of the prescription drug;
- 1005 (v) quantity supplied; and
- 1006 (vi) unique identification number.
- 1007 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall verify the
1008 correctness of this record at least once every seven days.
- 1009 (j) Automated devices and systems.
- 1010 (1) Automated compounding or counting devices. If a pharmacy uses automated compounding or
1011 counting devices:
- 1012 (A) the pharmacy shall have a method to calibrate and verify the accuracy of the automated compounding
1013 or counting device and document the calibration and verification on a routine basis;
- 1014 (B) the devices may be loaded with unlabeled drugs only by a pharmacist or by pharmacy technicians or
1015 pharmacy technician trainees under the direction and direct supervision of a pharmacist;
- 1016 (C) the label of an automated compounding or counting device container shall indicate the brand name
1017 and strength of the drug; or if no brand name, then the generic name, strength, and name of the
1018 manufacturer or distributor;
- 1019 (D) records of loading unlabeled drugs into an automated compounding or counting device shall be
1020 maintained to show:
- 1021 (i) name of the drug, strength, and dosage form;
- 1022 (ii) manufacturer or distributor;
- 1023 (iii) manufacturer's lot number;
- 1024 (iv) expiration date;
- 1025 (v) date of loading;

- 1026 (vi) name, initials, or electronic signature of the person loading the automated compounding or counting
1027 device; and
- 1028 (vii) signature or electronic signature of the responsible pharmacist; and
- 1029 (E) the automated compounding or counting device shall not be used until a pharmacist verifies that the
1030 system is properly loaded and affixes his or her signature to the record specified in subparagraph (D) of
1031 this paragraph.
- 1032 (2) Automated medication supply systems.
- 1033 (A) Authority to use automated medication supply systems. A pharmacy may use an automated
1034 medication supply system to fill medication orders provided that:
- 1035 (i) the pharmacist-in-charge is responsible for the supervision of the operation of the system;
- 1036 (ii) the automated medication supply system has been tested by the pharmacy and found to dispense
1037 accurately. The pharmacy shall make the results of such testing available to the Board upon request; and
- 1038 (iii) the pharmacy will make the automated medication supply system available for inspection by the
1039 board for the purpose of validating the accuracy of the system.
- 1040 (B) Quality assurance program. A pharmacy which uses an automated medication supply system to fill
1041 medication orders shall operate according to a written program for quality assurance of the automated
1042 medication supply system which:
- 1043 (i) requires continuous monitoring of the automated medication supply system; and
- 1044 (ii) establishes mechanisms and procedures to test the accuracy of the automated medication supply
1045 system at least every six months and whenever any upgrade or change is made to the system and
1046 documents each such activity.
- 1047 (C) Policies and procedures of operation.
- 1048 (i) When an automated medication supply system is used to store or distribute medications for
1049 administration pursuant to medication orders, it shall be operated according to written policies and
1050 procedures of operation. The policies and procedures of operation shall establish requirements for
1051 operation of the automated medication supply system and shall describe policies and procedures that:
- 1052 (I) include a description of the policies and procedures of operation;
- 1053 (II) provide for a pharmacist's review and approval of each original or new medication order prior to
1054 withdrawal from the automated medication supply system:
- 1055 (-a-) before the order is filled when a pharmacist is on duty except for an emergency order;
- 1056 (-b-) retrospectively within 72 hours in a facility with a full-time pharmacist when a pharmacist is not on
1057 duty at the time the order is made; or
- 1058 (-c-) retrospectively within 7 days in a facility with a part-time or consultant pharmacist when a
1059 pharmacist is not on duty at the time the order is made;
- 1060 (III) provide for access to the automated medication supply system for stocking and retrieval of

1061 medications which is limited to licensed healthcare professionals, pharmacy technicians, or pharmacy
1062 technician trainees acting under the supervision of a pharmacist;

1063 (IV) provide that a pharmacist is responsible for the accuracy of the restocking of the system. The actual
1064 restocking may be performed by a pharmacy technician or pharmacy technician trainee;

1065 (V) provide for an accountability record to be maintained which documents all transactions relative to
1066 stocking and removing medications from the automated medication supply system;

1067 (VI) require a prospective or retrospective drug regimen review is conducted as specified in subsection
1068 (g) of this section; and

1069 (VII) establish and make provisions for documentation of a preventative maintenance program for the
1070 automated medication supply system.

1071 (ii) A pharmacy which uses an automated medication supply system to fill medication orders shall, at
1072 least annually, review its written policies and procedures, revise them if necessary, and document the
1073 review.

1074 (D) Automated medication supply systems used for storage and recordkeeping of medications located
1075 outside of the pharmacy department (e.g., Pyxis). A pharmacy technician or pharmacy technician trainee
1076 may restock an automated medication supply system located outside of the pharmacy department with
1077 prescription drugs provided:

1078 (i) prior to distribution of the prescription drugs a pharmacist verifies that the prescription drugs pulled to
1079 stock the automated supply system match the list of prescription drugs generated by the automated
1080 medication supply system except as specified in §291.73(e)(2)(C)(ii) of this title; or

1081 (ii) all of the following occur:

1082 (I) the prescription drugs to restock the system are labeled and verified with a machine readable product
1083 identifier, such as a barcode;

1084 (II) either:

1085 (-a-) the drugs are in tamper evident product packaging, packaged by an FDA registered repackager or
1086 manufacture, that is shipped to the pharmacy; or

1087 (-b-) if any manipulation of the product occurs in the pharmacy prior to restocking, such as repackaging
1088 or extemporaneous compounding, the product must be checked by a pharmacist; and

1089 (III) quality assurance audits are conducted according to established policies and procedures to ensure
1090 accuracy of the process.

1091 (E) Recovery Plan. A pharmacy which uses an automated medication supply system to store or distribute
1092 medications for administration pursuant to medication orders shall maintain a written plan for recovery
1093 from a disaster or any other situation which interrupts the ability of the automated medication supply
1094 system to provide services necessary for the operation of the pharmacy. The written plan for recovery
1095 shall include:

1096 (i) planning and preparation for maintaining pharmacy services when an automated medication supply
1097 system is experiencing downtime;

- 1098 (ii) procedures for response when an automated medication supply system is experiencing downtime;
- 1099 (iii) procedures for the maintenance and testing of the written plan for recovery; and
- 1100 (iv) procedures for notification of the Board and other appropriate agencies whenever an automated
1101 medication supply system experiences downtime for more than two days of operation or a period of time
1102 which significantly limits the pharmacy's ability to provide pharmacy services.
- 1103 (3) Verification of medication orders prepared by the pharmacy department through the use of an
1104 automated medication supply system. A pharmacist must check drugs prepared pursuant to medication
1105 orders to ensure that the drug is prepared for distribution accurately as prescribed. This paragraph does
1106 not apply to automated medication supply systems used for storage and recordkeeping of medications
1107 located outside of the pharmacy department.
- 1108 (A) This check shall be considered accomplished if:
- 1109 (i) a check of the final product is conducted by a pharmacist after the automated system has completed
1110 preparation of the medication order and prior to delivery to the patient; or
- 1111 (ii) the following checks are conducted by a pharmacist:
- 1112 (I) if the automated medication supply system contains unlabeled stock drugs, a pharmacist verifies that
1113 those drugs have been accurately stocked; and
- 1114 (II) a pharmacist checks the accuracy of the data entry of each original or new medication order entered
1115 into the automated medication supply system before the order is filled.
- 1116 (B) If the final check is accomplished as specified in subparagraph (A)(ii) of this paragraph, the following
1117 additional requirements must be met.
- 1118 (i) The medication order preparation process must be fully automated from the time the pharmacist
1119 releases the medication order to the automated system until a completed medication order, ready for
1120 delivery to the patient, is produced.
- 1121 (ii) The pharmacy has conducted initial testing and has a continuous quality assurance program which
1122 documents that the automated medication supply system dispenses accurately as specified in paragraph
1123 (2)(A) and (B) of this subsection.
- 1124 (iii) The automated medication supply system documents and maintains:
- 1125 (I) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in
1126 subparagraph (A)(ii) of this paragraph; and
- 1127 (II) the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or
1128 pharmacy technician or pharmacy technician trainee who performs any other portion of the medication
1129 order preparation process.
- 1130 (iv) The pharmacy establishes mechanisms and procedures to test the accuracy of the automated
1131 medication supply system at least every month rather than every six months as specified in paragraph
1132 (2)(B) of this subsection.
- 1133 (4) Automated checking device.

- 1134 (A) For the purpose of this subsection, an automated checking device is a fully automated device which
1135 confirms, after a drug is prepared for distribution but prior to delivery to the patient, that the correct drug
1136 and strength has been labeled with the correct label for the correct patient.
- 1137 (B) The final check of a drug prepared pursuant to a medication order shall be considered accomplished
1138 using an automated checking device provided:
- 1139 (i) a check of the final product is conducted by a pharmacist prior to delivery to the patient or the
1140 following checks are performed by a pharmacist:
- 1141 (I) the prepackaged drug used to fill the order is checked by a pharmacist who verifies that the drug is
1142 labeled and packaged accurately; and
- 1143 (II) a pharmacist checks the accuracy of each original or new medication order.
- 1144 (ii) the medication order is prepared, labeled, and made ready for delivery to the patient in compliance
1145 with Class C (Institutional) Pharmacy rules; and
- 1146 (iii) prior to delivery to the patient:
- 1147 (I) the automated checking device confirms that the correct drug and strength has been labeled with the
1148 correct label for the correct patient; and
- 1149 (II) a pharmacist performs all other duties required to ensure that the medication order has been prepared
1150 safely and accurately as prescribed.
- 1151 (C) If the final check is accomplished as specified in subparagraph (B) of this paragraph, the following
1152 additional requirements must be met.
- 1153 (i) The pharmacy has conducted initial testing of the automated checking device and has a continuous
1154 quality assurance program which documents that the automated checking device accurately confirms that
1155 the correct drug and strength has been labeled with the correct label for the correct patient.
- 1156 (ii) The pharmacy documents and maintains:
- 1157 (I) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in
1158 subparagraph (B)(i) of this paragraph; and
- 1159 (II) the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy
1160 technician, or pharmacy technician trainee who performs any other portion of the medication order
1161 preparation process.
- 1162 (iii) The pharmacy establishes mechanisms and procedures to test the accuracy of the automated checking
1163 device at least monthly.
- 1164 **§291.75 Records**
- 1165 (a) Maintenance of records.
- 1166 (1) Every inventory or other record required to be kept under the provisions of §291.71 of this title
1167 (relating to Purpose), §291.72 of this title (relating to Definitions), §291.73 of this title (relating to
1168 Personnel), §291.74 of this title (relating to Operational Standards), and this section contained in
1169 Institutional Pharmacy (Class C) shall be:

- 1170 (A) kept by the institutional pharmacy and be available, for at least two years from the date of such
1171 inventory or record, for inspecting and copying by the board or its representative, and to other authorized
1172 local, state, or federal law enforcement agencies; and
- 1173 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State
1174 Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records
1175 must be provided in a mutually agreeable electronic format if specifically requested by the board or its
1176 representative. Failure to provide the records set out in this subsection, either on site or within 72 hours,
1177 constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.
- 1178 (2) Records of controlled substances listed in Schedule I and II shall be maintained separately from all
1179 other records of the pharmacy.
- 1180 (3) Records of controlled substances listed in Schedules III - V shall be maintained separately or readily
1181 retrievable from all other records of the pharmacy. For purposes of this subsection, readily retrievable
1182 means that the controlled substances shall be asterisked, redlined, or in some other manner readily
1183 identifiable apart from all other items appearing on the record.
- 1184 (4) Records, except when specifically required to be maintained in original or hard-copy form, may be
1185 maintained in an alternative data retention system, such as a data processing or direct imaging system,
1186 e.g., microfilm or microfiche, provided:
- 1187 (A) the records in the alternative data retention system contain all of the information required on the
1188 manual record; and
- 1189 (B) the alternative data retention system is capable of producing a hard copy of the record upon the
1190 request of the board, its representative, or other authorized local, state, or federal law enforcement or
1191 regulatory agencies.
- 1192 (b) Outpatient records.
- 1193 (1) Outpatient records shall be maintained as provided in §291.34 of this title (relating to Records), and
1194 §291.35 of this title (relating to Official Prescription Records), contained in Community Pharmacy (Class
1195 A).
- 1196 (2) Outpatient prescriptions, including, but not limited to, furlough and discharge prescriptions, that are
1197 written by the practitioner must be written on a form which meets the requirements of the Act, §562.006.
1198 Medication order forms or copies thereof do not meet the requirements for outpatient forms.
- 1199 (3) Controlled substances listed in Schedule II must be written on an official prescription form in
1200 accordance with the Texas Controlled Substances Act, §481.075, and rules promulgated pursuant to the
1201 Texas Controlled Substances Act, unless exempted by the Texas controlled substances regulations, 37
1202 TAC §13.74 (relating to Exceptions to Use of Forms). Outpatient prescriptions for Schedule II controlled
1203 substances that are exempted from the official prescription requirement must be manually signed by the
1204 practitioner.
- 1205 (c) Patient records.
- 1206 (1) Original medication orders.
- 1207 (A) Each original medication order shall bear the following information:
- 1208 (i) patient name and room number or identification number;

- 1209 (ii) drug name, strength, and dosage form;
- 1210 (iii) directions for use;
- 1211 (iv) date; and
- 1212 (v) signature or electronic signature of the practitioner or that of his or her authorized agent.
- 1213 (B) Original medication order shall be maintained with the medication administration records of the
1214 patients.
- 1215 (2) Patient medication records (PMR). A patient medication record shall be maintained for each patient of
1216 the facility. The PMR shall contain at a minimum the following information.
- 1217 (A) Patient information:
- 1218 (i) patient name and room number or identification number;
- 1219 (ii) gender, and date of birth or age;
- 1220 (iii) weight and height;
- 1221 (iv) known drug sensitivities and allergies to drugs and/or food;
- 1222 (v) primary diagnoses and chronic conditions;
- 1223 (vi) primary physician; and
- 1224 (vii) other drugs the patient is receiving.
- 1225 (B) Medication order information:
- 1226 (i) date of distribution;
- 1227 (ii) drug name, strength, and dosage form; and
- 1228 (iii) directions for use.
- 1229 (3) Controlled substances records. Controlled substances records shall be maintained as follows.
- 1230 (A) All records for controlled substances shall be maintained in a readily retrievable manner.
- 1231 (B) Controlled substances records shall be maintained in a manner to establish receipt and distribution of
1232 all controlled substances.
- 1233 (4) Schedule II controlled substances records. Records of controlled substances listed in Schedule II shall
1234 be maintained as follows.
- 1235 (A) Records of controlled substances listed in Schedule II shall be maintained separately from records of
1236 controlled substances in Schedules III, IV, and V, and all other records.
- 1237 (B) An institutional pharmacy shall maintain a perpetual inventory of any controlled substance listed in
1238 Schedule II.

- 1239 (C) Distribution records for controlled substances listed in Schedule II shall bear the following
1240 information:
- 1241 (i) patient's name;
- 1242 (ii) prescribing or attending practitioner;
- 1243 (iii) name of drug, dosage form, and strength;
- 1244 (iv) time and date of administration to patient and quantity administered;
- 1245 (v) name, initials, or electronic signature of the individual administering the controlled substance;
- 1246 (vi) returns to the pharmacy; and
- 1247 (vii) waste (waste is required to be witnessed and cosigned, electronically or manually, by another
1248 individual).
- 1249 (5) Floor stock records.
- 1250 (A) Distribution records for Schedule II - V controlled substances floor stock shall include the following
1251 information:
- 1252 (i) patient's name;
- 1253 (ii) prescribing or attending practitioner;
- 1254 (iii) name of controlled substance, dosage form, and strength;
- 1255 (iv) time and date of administration to patient;
- 1256 (v) quantity administered;
- 1257 (vi) name, initials, or electronic signature of the individual administering drug;
- 1258 (vii) returns to the pharmacy; and
- 1259 (viii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another
1260 individual).
- 1261 (B) The record required by subparagraph (A) of this paragraph shall be maintained separately from
1262 patient records.
- 1263 (C) A pharmacist shall review distribution records with medication orders on a periodic basis to verify
1264 proper usage of drugs, not to exceed 30 days between such reviews.
- 1265 (6) General requirements for records maintained in a data processing system.
- 1266 (A) Noncompliance with data processing requirements. If a hospital pharmacy's data processing system is
1267 not in compliance with the Board's requirements, the pharmacy must maintain a manual recordkeeping
1268 system.
- 1269 (B) Requirements for back-up systems. The facility shall maintain a back-up copy of information stored

- 1270 in the data processing system using disk, tape, or other electronic back-up system and update this back-up
1271 copy on a regular basis, at least monthly, to assure that data is not lost due to system failure.
- 1272 (C) Change or discontinuance of a data processing system.
- 1273 (i) Records of distribution and return for all controlled substances and nalbuphine (e.g., Nubain). A
1274 pharmacy that changes or discontinues use of a data processing system must:
- 1275 (I) transfer the records to the new data processing system; or
- 1276 (II) purge the records to a printout which contains the same information as required on the audit trail
1277 printout as specified in paragraph (7)(B) of this subsection. The information on this printout shall be
1278 sorted and printed by drug name and list all distributions/returns chronologically.
- 1279 (ii) Other records. A pharmacy that changes or discontinues use of a data processing system must:
- 1280 (I) transfer the records to the new data processing system; or
- 1281 (II) purge the records to a printout which contains all of the information required on the original
1282 document.
- 1283 (iii) Maintenance of purged records. Information purged from a data processing system must be
1284 maintained by the pharmacy for two years from the date of initial entry into the data processing system.
- 1285 (D) Loss of data. The pharmacist-in-charge shall report to the board in writing any significant loss of
1286 information from the data processing system within 10 days of discovery of the loss.
- 1287 (7) Data processing system maintenance of records for the distribution and return of all controlled
1288 substances and nalbuphine (e.g., Nubain) to the pharmacy.
- 1289 (A) Each time a controlled substance or nalbuphine (e.g., Nubain) is distributed from or returned to the
1290 pharmacy, a record of such distribution or return shall be entered into the data processing system.
- 1291 (B) The data processing system shall have the capacity to produce a hard copy printout of an audit trail of
1292 drug distribution and return for any strength and dosage form of a drug (by either brand or generic name
1293 or both) during a specified time period. This printout shall contain the following information:
- 1294 (i) patient's name and room number or patient's facility identification number;
- 1295 (ii) prescribing or attending practitioner's name;
- 1296 (iii) name, strength, and dosage form of the drug product actually distributed;
- 1297 (iv) total quantity distributed from and returned to the pharmacy;
- 1298 (v) if not immediately retrievable via electronic image, the following shall also be included on the
1299 printout:
- 1300 (I) prescribing or attending practitioner's address; and
- 1301 (II) practitioner's DEA registration number, if the medication order is for a controlled substance.
- 1302 (C) An audit trail printout for each strength and dosage form of these drugs distributed during the

1303 preceding month shall be produced at least monthly and shall be maintained in a separate file at the
1304 facility unless the pharmacy complies with subparagraph (D) of this paragraph. The information on this
1305 printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

1306 (D) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system
1307 has a workable (electronic) data retention system which can produce an audit trail of drug distribution and
1308 returns for the preceding two years. The audit trail required in this paragraph shall be supplied by the
1309 pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy, or
1310 other authorized local, state, or federal law enforcement or regulatory agencies.

1311 (8) Failure to maintain records. Failure to provide records set out in this subsection, either on site or
1312 within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain
1313 records.

1314 (9) Data processing system downtime. In the event that a hospital pharmacy which uses a data processing
1315 system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure
1316 that all data is retained for on-line data entry as soon as the system is available for use again.

1317 (10) Ongoing clinical pharmacy program records. If a pharmacy has an ongoing clinical pharmacy
1318 program and allows pharmacy technicians to verify the accuracy of work performed by other pharmacy
1319 technicians, the pharmacy must have a record of the pharmacy technicians and the duties performed.

1320 (d) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled
1321 substances to a practitioner, another pharmacy or other registrant, without being registered to distribute,
1322 under the following conditions.

1323 (1) The registrant to whom the controlled substance is to be distributed is registered under the Controlled
1324 Substances Act to dispense that controlled substance.

1325 (2) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed
1326 5.0% of all controlled substances dispensed or distributed by the pharmacy during the 12-month period in
1327 which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain
1328 an additional registration to distribute controlled substances.

1329 (3) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained
1330 which indicates:

1331 (A) the actual date of distribution;

1332 (B) the name, strength, and quantity of controlled substances distributed;

1333 (C) the name, address, and DEA registration number of the distributing pharmacy; and

1334 (D) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to
1335 whom the controlled substances are distributed.

1336 (4) If the distribution is for a Schedule I or II controlled substance, the following is applicable.

1337 (A) The pharmacy, practitioner or other registrant who is receiving the controlled substances shall issue
1338 copy 1 and copy 2 of a DEA order form (DEA 222) to the distributing pharmacy.

1339 (B) The distributing pharmacy shall:

- 1340 (i) complete the area on the DEA order form (DEA 222) titled TO BE FILLED IN BY SUPPLIER;
- 1341 (ii) maintain copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and
- 1342 (iii) forward copy 2 of the DEA order form (DEA 222) to the divisional office of the Drug Enforcement
1343 Administration.
- 1344 (e) Other records. Other records to be maintained by a pharmacy:
- 1345 (1) a permanent log of the initials or identification codes which will identify pharmacy personnel by name
1346 (the initials or identification code shall be unique to ensure that each person can be identified, i.e.,
1347 identical initials or identification codes cannot be used);
- 1348 (2) copy 3 of DEA order form (DEA 222) which has been properly dated, initialed, and filed, and all
1349 copies of each unaccepted or defective order form and any attached statements or other documents;
- 1350 (3) a hard copy of the power of attorney to sign DEA 222 order forms (if applicable);
- 1351 (4) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify that the
1352 controlled drugs listed on the invoices were actually received by clearly recording his/her initials and the
1353 actual date of receipt of the controlled substances;
- 1354 (5) suppliers' credit memos for controlled substances and dangerous drugs;
- 1355 (6) a hard copy of inventories required by §291.17 of this title (relating to Inventory Requirements)
1356 except that a perpetual inventory of controlled substances listed in Schedule II may be kept in a data
1357 processing system if the data processing system is capable of producing a hard copy of the perpetual
1358 inventory on-site;
- 1359 (7) hard copy reports of surrender or destruction of controlled substances and/or dangerous drugs to an
1360 appropriate state or federal agency;
- 1361 (8) a hard copy Schedule V nonprescription register book;
- 1362 (9) records of distribution of controlled substances and/or dangerous drugs to other pharmacies,
1363 practitioners, or registrants; and
- 1364 (10) a hard copy of any notification required by the Texas Pharmacy Act or these sections including, but
1365 not limited to, the following:
- 1366 (A) reports of theft or significant loss of controlled substances to DEA, DPS, and the board;
- 1367 (B) notifications of a change in pharmacist-in-charge of a pharmacy; and
- 1368 (C) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs,
1369 medication, devices, or other materials used in diagnosis or treatment of injury, illness, and disease.
- 1370 (f) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for
1371 invoices and financial data shall comply with the following procedures.
- 1372 (1) Controlled substance records. Invoices and financial data for controlled substances may be maintained
1373 at a central location provided the following conditions are met.

1374 (A) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by
1375 registered or certified mail to the divisional director of the Drug Enforcement Administration as required
1376 by Title 21, Code of Federal Regulations, §1304.04(a), and submits a copy of this written notification to
1377 the Texas State Board of Pharmacy. Unless the registrant is informed by the divisional director of the
1378 Drug Enforcement Administration that permission to keep central records is denied, the pharmacy may
1379 maintain central records commencing 14 days after receipt of notification by the divisional director.

1380 (B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this paragraph.

1381 (C) The records to be maintained at the central record location shall not include executed DEA order
1382 forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the
1383 pharmacy.

1384 (2) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a
1385 central location.

1386 (3) Access to records. If the records are kept on microfilm, computer media, or in any form requiring
1387 special equipment to render the records easily readable, the pharmacy shall provide access to such
1388 equipment with the records.

1389 (4) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy
1390 location within two business days of written request of a board agent or any other authorized official.

1391 **§291.76 Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center**

1392 (a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities, and
1393 operation of a pharmacy located in a freestanding ambulatory surgical center that is licensed by the Texas
1394 Department of State Health Services. Class C pharmacies located in a freestanding ambulatory surgical
1395 center shall comply with this section, in lieu of §§291.71 - 291.75 of this title (relating to Purpose;
1396 Definitions; Personnel; Operational Standards; and Records).

1397 (b) Definitions. The following words and terms, when used in these sections, shall have the following
1398 meanings, unless the context clearly indicates otherwise.

1399 (1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.

1400 (2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any
1401 other means to the body of a patient by:

1402 (A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

1403 (B) the patient at the direction of a practitioner.

1404 (3) Ambulatory surgical center (ASC)--A freestanding facility that is licensed by the Texas Department of
1405 State Health Services that primarily provides surgical services to patients who do not require overnight
1406 hospitalization or extensive recovery, convalescent time or observation. The planned total length of stay
1407 for an ASC patient shall not exceed 23 hours. Patient stays of greater than 23 hours shall be the result of
1408 an unanticipated medical condition and shall occur infrequently. The 23-hour period begins with the
1409 induction of anesthesia.

1410 (4) Automated medication supply system--A mechanical system that performs operations or activities
1411 relative to the storage and distribution of medications for administration and which collects, controls, and
1412 maintains all transaction information.

- 1413 (5) Board--The Texas State Board of Pharmacy.
- 1414 (6) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the ASC
1415 in areas that pertain to the practice of pharmacy.
- 1416 (7) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or
1417 Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug immediate precursor,
1418 or other substance included in Schedule I - V of the Federal Comprehensive Drug Abuse Prevention and
1419 Control Act of 1970, as amended (Public Law 91-513).
- 1420 (8) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device
1421 in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of
1422 a practitioner.
- 1423 (9) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.
- 1424 (10) Downtime--Period of time during which a data processing system is not operable.
- 1425 (11) Electronic signature--A unique security code or other identifier which specifically identifies the
1426 person entering information into a data processing system. A facility which utilizes electronic signatures
1427 must:
- 1428 (A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data
1429 processing system; and
- 1430 (B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of
1431 electronic signatures.
- 1432 (12) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a
1433 nursing station or other ASC department (excluding the pharmacy) for the purpose of administration to a
1434 patient of the ASC.
- 1435 (13) Formulary--List of drugs approved for use in the ASC by an appropriate committee of the
1436 ambulatory surgical center.
- 1437 (14) Hard copy--A physical document that is readable without the use of a special device (i.e., data
1438 processing system, computer, etc.).
- 1439 (15) Investigational new drug--New drug intended for investigational use by experts qualified to evaluate
1440 the safety and effectiveness of the drug as authorized by the federal Food and Drug Administration.
- 1441 (16) Medication order--An order from a practitioner or his authorized agent for administration of a drug
1442 or device.
- 1443 (17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the
1444 authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of
1445 pharmacy.
- 1446 (18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are stored, bulk
1447 compounded, delivered, compounded, dispensed, and/or distributed to other areas or departments of the
1448 ASC, or dispensed to an ultimate user or his or her agent.
- 1449 (19) Prescription drug--

- 1450 (A) A substance for which federal or state law requires a prescription before it may be legally dispensed
1451 to the public;
- 1452 (B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be
1453 labeled with either of the following statements:
- 1454 (i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend that
1455 complies with federal law; or
- 1456 (ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or
- 1457 (C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed
1458 on prescription only or is restricted to use by a practitioner only.
- 1459 (20) Prescription drug order--
- 1460 (A) An order from a practitioner or his authorized agent to a pharmacist for a drug or device to be
1461 dispensed; or
- 1462 (B) An order pursuant to Subtitle B, Chapter 157, Occupations Code.
- 1463 (21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the
1464 pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.
- 1465 (22) Part-time pharmacist--A pharmacist who works less than full-time.
- 1466 (23) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and
1467 whose responsibility in a pharmacy is to provide technical services that do not require professional
1468 judgment regarding preparing and distributing drugs and who works under the direct supervision of and is
1469 responsible to a pharmacist.
- 1470 (24) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy
1471 technician trainee and is authorized to participate in a pharmacy's technician training program.
- 1472 (25) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and Safety
1473 Code, Chapter 481, as amended.
- 1474 (c) Personnel.
- 1475 (1) Pharmacist-in-charge.
- 1476 (A) General. Each ambulatory surgical center shall have one pharmacist-in-charge who is employed or
1477 under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis.
- 1478 (B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the
1479 following:
- 1480 (i) establishing specifications for procurement and storage of all materials, including drugs, chemicals,
1481 and biologicals;
- 1482 (ii) participating in the development of a formulary for the ASC, subject to approval of the appropriate
1483 committee of the ASC;

- 1484 (iii) distributing drugs to be administered to patients pursuant to the practitioner's medication order;
- 1485 (iv) filling and labeling all containers from which drugs are to be distributed or dispensed;
- 1486 (v) maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both
1487 in the pharmacy and patient care areas, as well as current antidote information, telephone numbers of
1488 regional poison control center and other emergency assistance organizations, and such other materials and
1489 information as may be deemed necessary by the appropriate committee of the ASC;
- 1490 (vi) maintaining records of all transactions of the ASC pharmacy as may be required by applicable state
1491 and federal law, and as may be necessary to maintain accurate control over and accountability for all
1492 pharmaceutical materials;
- 1493 (vii) participating in those aspects of the ASC's patient care evaluation program which relate to
1494 pharmaceutical material utilization and effectiveness;
- 1495 (viii) participating in teaching and/or research programs in the ASC;
- 1496 (ix) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical
1497 services of the ASC;
- 1498 (x) providing effective and efficient messenger and delivery service to connect the ASC pharmacy with
1499 appropriate areas of the ASC on a regular basis throughout the normal workday of the ASC;
- 1500 (xi) labeling, storing, and distributing investigational new drugs, including maintaining information in the
1501 pharmacy and nursing station where such drugs are being administered, concerning the dosage form,
1502 route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of
1503 toxicity of investigational new drugs;
- 1504 (xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this subsection; and
- 1505 (xiii) maintaining records in a data processing system such that the data processing system is in
1506 compliance with the requirements for a Class C (institutional) pharmacy located in a freestanding ASC.
- 1507 (2) Consultant pharmacist.
- 1508 (A) The consultant pharmacist may be the pharmacist-in-charge.
- 1509 (B) A written contract shall exist between the ASC and any consultant pharmacist, and a copy of the
1510 written contract shall be made available to the board upon request.
- 1511 (3) Pharmacists.
- 1512 (A) General.
- 1513 (i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as
1514 may be required to operate the ASC pharmacy competently, safely, and adequately to meet the needs of
1515 the patients of the facility.
- 1516 (ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in
1517 paragraph (1)(B) of this subsection and in ordering, administering, and accounting for pharmaceutical
1518 materials.

- 1519 (iii) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or
1520 pharmacy technician trainees under his or her supervision.
- 1521 (iv) All pharmacists while on duty shall be responsible for complying with all state and federal laws or
1522 rules governing the practice of pharmacy.
- 1523 (B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be
1524 limited to, the following:
- 1525 (i) receiving and interpreting prescription drug orders and oral medication orders and reducing these
1526 orders to writing either manually or electronically;
- 1527 (ii) selecting prescription drugs and/or devices and/or suppliers; and
- 1528 (iii) interpreting patient profiles.
- 1529 (C) Special requirements for compounding non-sterile preparations. All pharmacists engaged in
1530 compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this
1531 title (relating to Pharmacies Compounding Non-Sterile Preparations).
- 1532 (4) Pharmacy technicians and pharmacy technician trainees.
- 1533 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training
1534 requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician
1535 Trainee Training).
- 1536 (B) Duties. Pharmacy technicians and pharmacy technician trainees may not perform any of the duties
1537 listed in paragraph (3)(B) of this subsection. Duties may include, but need not be limited to, the following
1538 functions, under the direct supervision of a pharmacist:
- 1539 (i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and
1540 conducts a final check and affixes his or her name, initials, electronic signature to the appropriate quality
1541 control records prior to distribution;
- 1542 (ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders,
1543 provided a pharmacist supervises and checks the preparation;
- 1544 (iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy
1545 technicians or pharmacy technician trainees have completed the training specified in §291.131 of this
1546 title;
- 1547 (iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and
1548 affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to
1549 distribution;
- 1550 (v) distributing routine orders for stock supplies to patient care areas;
- 1551 (vi) entering medication order and drug distribution information into a data processing system, provided
1552 judgmental decisions are not required and a pharmacist checks the accuracy of the information entered
1553 into the system prior to releasing the order or in compliance with the absence of pharmacist requirements
1554 contained in subsection (d)(6)(E) and (F) of this section;
- 1555 (vii) maintaining inventories of drug supplies;

- 1556 (viii) maintaining pharmacy records; and
- 1557 (ix) loading drugs into an automated medication supply system. For the purpose of this clause, direct
1558 supervision may be accomplished by physically present supervision or electronic monitoring by a
1559 pharmacist.
- 1560 (C) Procedures.
- 1561 (i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance
1562 with standard written procedures and guidelines.
- 1563 (ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the
1564 same manner as pharmacy technicians or pharmacy technician trainees working in a Class A pharmacy.
- 1565 (D) Special requirements for compounding non-sterile preparations. All pharmacy technicians and
1566 pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training
1567 requirements specified in §291.131 of this title.
- 1568 (5) Owner. The owner of an ASC pharmacy shall have responsibility for all administrative and
1569 operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative
1570 and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the
1571 owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or
1572 another Texas licensed pharmacist:
- 1573 (A) establishing policies for procurement of prescription drugs and devices and other products dispensed
1574 from the ASC pharmacy;
- 1575 (B) establishing and maintaining effective controls against the theft or diversion of prescription drugs;
- 1576 (C) if the pharmacy uses an automated medication supply system, reviewing and approving all policies
1577 and procedures for system operation, safety, security, accuracy and access, patient confidentiality,
1578 prevention of unauthorized access, and malfunction;
- 1579 (D) providing the pharmacy with the necessary equipment and resources commensurate with its level and
1580 type of practice; and
- 1581 (E) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data
1582 processing system such that the system is in compliance with state and federal requirements.
- 1583 (6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows:
- 1584 (A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears
1585 the person's name and identifies him or her as a pharmacy technician.
- 1586 (B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or
1587 badge that bears the person's name and identifies him or her as a pharmacy technician trainee.
- 1588 (C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the
1589 person's name and identifies him or her as a pharmacist intern.
- 1590 (D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name
1591 and identifies him or her as a pharmacist.

- 1592 (d) Operational standards.
- 1593 (1) Licensing requirements.
- 1594 (A) An ASC pharmacy shall register annually or biennially with the board on a pharmacy license
1595 application provided by the board, following the procedures specified in §291.1 of this title (relating to
1596 Pharmacy License Application).
- 1597 (B) An ASC pharmacy which changes ownership shall notify the board within 10 days of the change of
1598 ownership and apply for a new and separate license as specified in §291.3 of this title (relating to
1599 Required Notifications).
- 1600 (C) An ASC pharmacy which changes location and/or name shall notify the board of the change within 10
1601 days and file for an amended license as specified in §291.3 of this title.
- 1602 (D) An ASC pharmacy owned by a partnership or corporation which changes managing officers shall
1603 notify the board in writing of the names of the new managing officers within 10 days of the change,
1604 following the procedures in §291.3 of this title.
- 1605 (E) An ASC pharmacy shall notify the board in writing within 10 days of closing, following the
1606 procedures in §291.5 of this title (relating to Closing a Pharmacy).
- 1607 (F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for
1608 issuance and renewal of a license and the issuance of an amended license.
- 1609 (G) A separate license is required for each principal place of business and only one pharmacy license may
1610 be issued to a specific location.
- 1611 (H) An ASC pharmacy, licensed under the Act, §560.051(a)(3), concerning institutional pharmacy (Class
1612 C), which also operates another type of pharmacy which would otherwise be required to be licensed under
1613 the Act, §560.051(a)(1), concerning community pharmacy (Class A), or the Act, §560.051(a)(2),
1614 concerning nuclear pharmacy (Class B), is not required to secure a license for the other type of pharmacy;
1615 provided, however, such license is required to comply with the provisions of §291.31 of this title (relating
1616 to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational
1617 Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official
1618 Prescription Records), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to
1619 Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational
1620 Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to
1621 the extent such sections are applicable to the operation of the pharmacy.
- 1622 (I) An ASC pharmacy engaged in the compounding of non-sterile preparations shall comply with the
1623 provisions of §291.131 of this title.
- 1624 (J) ASC pharmacy personnel shall not compound sterile preparations unless the pharmacy has applied for
1625 and obtained a Class C-S pharmacy license.
- 1626 (K) An ASC pharmacy engaged in the provision of remote pharmacy services, including storage and
1627 dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to
1628 Remote Pharmacy Services).
- 1629 (L) An ASC pharmacy engaged in centralized prescription dispensing and/or prescription drug or
1630 medication order processing shall comply with the provisions of §291.123 of this title (relating to
1631 Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to

- 1632 Centralized Prescription Dispensing).
- 1633 (2) Environment.
- 1634 (A) General requirements.
- 1635 (i) Each ambulatory surgical center shall have a designated work area separate from patient areas, and
1636 which shall have space adequate for the size and scope of pharmaceutical services and shall have
1637 adequate space and security for the storage of drugs.
- 1638 (ii) The ASC pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required
1639 equipment shall be clean and in good operating condition.
- 1640 (B) Special requirements.
- 1641 (i) The ASC pharmacy shall have locked storage for Schedule II controlled substances and other
1642 controlled drugs requiring additional security.
- 1643 (ii) The ASC pharmacy shall have a designated area for the storage of poisons and externals separate from
1644 drug storage areas.
- 1645 (C) Security.
- 1646 (i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed and capable of
1647 being locked by key, combination, or other mechanical or electronic means, so as to prohibit access by
1648 unauthorized individuals. Only individuals authorized by the pharmacist-in-charge may enter the
1649 pharmacy or have access to storage areas for prescription drugs and/or devices.
- 1650 (ii) The pharmacist-in-charge shall consult with ASC personnel with respect to security of the drug
1651 storage areas, including provisions for adequate safeguards against theft or diversion of dangerous drugs
1652 and controlled substances, and to security of records for such drugs.
- 1653 (iii) The pharmacy shall have locked storage for Schedule II controlled substances and other drugs
1654 requiring additional security.
- 1655 (3) Equipment and supplies. Ambulatory surgical centers supplying drugs for postoperative use shall have
1656 the following equipment and supplies:
- 1657 (A) data processing system including a printer or comparable equipment;
- 1658 (B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and
- 1659 (C) adequate supply of prescription labels and other applicable identification labels.
- 1660 (4) Library. A reference library shall be maintained that includes the following in hard-copy or electronic
1661 format and that pharmacy personnel shall be capable of accessing at all times:
- 1662 (A) current copies of the following:
- 1663 (i) Texas Pharmacy Act and rules;
- 1664 (ii) Texas Dangerous Drug Act and rules;

- 1665 (iii) Texas Controlled Substances Act and rules;
- 1666 (iv) Federal Controlled Substances Act and rules or official publication describing the requirements of the
1667 Federal Controlled Substances Act and rules;
- 1668 (B) at least one current or updated general drug information reference which is required to contain drug
1669 interaction information including information needed to determine severity or significance of the
1670 interaction and appropriate recommendations or actions to be taken; and
- 1671 (C) basic antidote information and the telephone number of the nearest regional poison control center.
- 1672 (5) Drugs.
- 1673 (A) Procurement, preparation, and storage.
- 1674 (i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but
1675 may receive input from other appropriate staff of the facility, relative to such responsibility.
- 1676 (ii) The pharmacist-in-charge shall have the responsibility for determining specifications of all drugs
1677 procured by the facility.
- 1678 (iii) ASC pharmacies may not sell, purchase, trade, or possess prescription drug samples, unless the
1679 pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).
- 1680 (iv) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in §291.15 of this
1681 title (relating to Storage of Drugs).
- 1682 (v) Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of
1683 the drug.
- 1684 (vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined together until such
1685 drugs are disposed of.
- 1686 (B) Formulary.
- 1687 (i) A formulary may be developed by an appropriate committee of the ASC.
- 1688 (ii) The pharmacist-in-charge or consultant pharmacist shall be a full voting member of any committee
1689 which involves pharmaceutical services.
- 1690 (iii) A practitioner may grant approval for pharmacists at the ASC to interchange, in accordance with the
1691 facility's formulary, for the drugs on the practitioner's medication orders provided:
- 1692 (I) a formulary has been developed;
- 1693 (II) the formulary has been approved by the medical staff of the ASC;
- 1694 (III) there is a reasonable method for the practitioner to override any interchange; and
- 1695 (IV) the practitioner authorizes pharmacist in the ASC to interchange on his/her medication orders in
1696 accordance with the facility's formulary through his/her written agreement to abide by the policies and
1697 procedures of the medical staff and facility.

- 1698 (C) Prepackaging and loading drugs into automated medication supply system.
- 1699 (i) Prepackaging of drugs.
- 1700 (I) Drugs may be prepackaged in quantities suitable for distribution to other Class C pharmacies under
1701 common ownership or for internal distribution only by a pharmacist or by pharmacy technicians or
1702 pharmacy technician trainees under the direction and direct supervision of a pharmacist.
- 1703 (II) The label of a prepackaged unit shall indicate:
- 1704 (-a-) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name
1705 of the manufacturer or distributor;
- 1706 (-b-) facility's lot number;
- 1707 (-c-) expiration date;
- 1708 (-d-) quantity of the drug, if quantity is greater than one; and
- 1709 (-e-) if the drug is distributed to another Class C pharmacy, name of the facility responsible for
1710 prepackaging the drug.
- 1711 (III) Records of prepackaging shall be maintained to show:
- 1712 (-a-) the name of the drug, strength, and dosage form;
- 1713 (-b-) facility's lot number;
- 1714 (-c-) manufacturer or distributor;
- 1715 (-d-) manufacturer's lot number;
- 1716 (-e-) expiration date;
- 1717 (-f-) quantity per prepackaged unit;
- 1718 (-g-) number of prepackaged units;
- 1719 (-h-) date packaged;
- 1720 (-i-) name, initials, or electronic signature of the packer;
- 1721 (-j-) signature or electronic signature of the responsible pharmacist; and
- 1722 (-k-) if the drug is distributed to another Class C pharmacy, name of the facility receiving the
1723 prepackaged drug.
- 1724 (IV) Stock packages, repackaged units, and control records shall be quarantined together until
1725 checked/released by the pharmacist.
- 1726 (ii) Loading bulk unit of use drugs into automated medication supply systems. Automated medication
1727 supply systems may be loaded with bulk unit of use drugs only by a pharmacist or by pharmacy
1728 technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

1729 For the purpose of this clause, direct supervision may be accomplished by physically present supervision
1730 or electronic monitoring by a pharmacist. In order for the pharmacist to electronically monitor, the
1731 medication supply system must allow for bar code scanning to verify the loading of drugs, and a record of
1732 the loading must be maintained by the system and accessible for electronic review by the pharmacist.

1733 (6) Medication orders.

1734 (A) Drugs may be administered to patients in ASCs only on the order of a practitioner. No change in the
1735 order for drugs may be made without the approval of a practitioner except as authorized by the
1736 practitioner in compliance with paragraph (5)(B) of this subsection.

1737 (B) Drugs may be distributed only pursuant to the practitioner's medication order.

1738 (C) ASC pharmacies shall be exempt from the labeling provisions and patient notification requirements of
1739 §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication orders.

1740 (D) In ASCs with a full-time pharmacist, if a practitioner orders a drug for administration to a bona fide
1741 patient of the facility when the pharmacy is closed, the following is applicable.

1742 (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of a patient
1743 may be removed from the ASC pharmacy.

1744 (ii) Only a designated or practitioner may remove such drugs and devices.

1745 (iii) A record shall be made at the time of withdrawal by the authorized person removing the drugs and
1746 devices. The record shall contain the following information:

1747 (I) name of the patient;

1748 (II) name of device or drug, strength, and dosage form;

1749 (III) dose prescribed;

1750 (IV) quantity taken;

1751 (V) time and date; and

1752 (VI) signature or electronic signature of person making withdrawal.

1753 (iv) The medication order in the patient's chart may substitute for such record, provided the medication
1754 order meets all the requirements of clause (iii) of this subparagraph.

1755 (v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more than 72 hours
1756 from the time of such withdrawal.

1757 (E) In ASCs with a part-time or consultant pharmacist, if a practitioner orders a drug for administration to
1758 a bona fide patient of the ASC when the pharmacist is not on duty, or when the pharmacy is closed, the
1759 following is applicable.

1760 (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be removed from
1761 the ASC pharmacy.

1762 (ii) Only a designated or practitioner may remove such drugs and devices.

- 1763 (iii) A record shall be made at the time of withdrawal by the authorized person removing the drugs and
1764 devices; the record shall meet the same requirements as specified in subparagraph (D) of this paragraph.
- 1765 (iv) The pharmacist shall conduct an audit of patient's medical record according to the schedule set out in
1766 the policy and procedures at a reasonable interval, but such interval must occur at least once in every
1767 calendar week that the pharmacy is open.
- 1768 (7) Floor stock. In facilities using a floor stock method of drug distribution, the following is applicable for
1769 removing drugs or devices in the absence of a pharmacist.
- 1770 (A) Prescription drugs and devices may be removed from the pharmacy only in the original
1771 manufacturer's container or prepackaged container.
- 1772 (B) Only a designated or practitioner may remove such drugs and devices.
- 1773 (C) A record shall be made at the time of withdrawal by the authorized person removing the drug or
1774 device; the record shall contain the following information:
- 1775 (i) name of the drug, strength, and dosage form;
- 1776 (ii) quantity removed;
- 1777 (iii) location of floor stock;
- 1778 (iv) date and time; and
- 1779 (v) signature or electronic signature of person making the withdrawal.
- 1780 (D) A pharmacist shall verify the withdrawal according to the following schedule.
- 1781 (i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as practical, but in no
1782 event more than 72 hours from the time of such withdrawal.
- 1783 (ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after a
1784 reasonable interval, but such interval must occur at least once in every calendar week that the pharmacy is
1785 open.
- 1786 (8) Policies and procedures. Written policies and procedures for a drug distribution system, appropriate
1787 for the ambulatory surgical center, shall be developed and implemented by the pharmacist-in-charge with
1788 the advice of the appropriate committee. The written policies and procedures for the drug distribution
1789 system shall include, but not be limited to, procedures regarding the following:
- 1790 (A) controlled substances;
- 1791 (B) investigational drugs;
- 1792 (C) prepackaging and manufacturing;
- 1793 (D) medication errors;
- 1794 (E) orders of physician or other practitioner;
- 1795 (F) floor stocks;

- 1796 (G) adverse drug reactions;
- 1797 (H) drugs brought into the facility by the patient;
- 1798 (I) self-administration;
- 1799 (J) emergency drug tray;
- 1800 (K) formulary, if applicable;
- 1801 (L) drug storage areas;
- 1802 (M) drug samples;
- 1803 (N) drug product defect reports;
- 1804 (O) drug recalls;
- 1805 (P) outdated drugs;
- 1806 (Q) preparation and distribution of IV admixtures;
- 1807 (R) procedures for supplying drugs for postoperative use, if applicable;
- 1808 (S) use of automated medication supply systems;
- 1809 (T) use of data processing systems; and
- 1810 (U) drug regimen review.
- 1811 (9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall be
1812 supplied according to the following procedures.
- 1813 (A) Drugs may only be supplied to patients who have been admitted to the ASC.
- 1814 (B) Drugs may only be supplied in accordance with the system of control and accountability established
1815 for drugs supplied from the ambulatory surgical center; such system shall be developed and supervised by
1816 the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.
- 1817 (C) Only drugs listed on the approved postoperative drug list may be supplied; such list shall be
1818 developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the nature and
1819 type to meet the immediate postoperative needs of the ambulatory surgical center patient.
- 1820 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable
1821 containers and appropriately pre-labeled (including name, address, and phone number of the facility, and
1822 necessary auxiliary labels) by the pharmacy, provided, however that topicals and ophthalmics in original
1823 manufacturer's containers may be supplied in a quantity exceeding a 72-hour supply.
- 1824 (E) At the time of delivery of the drug, the practitioner shall complete the label, such that the prescription
1825 container bears a label with at least the following information:
- 1826 (i) date supplied;

- 1827 (ii) name of practitioner;
- 1828 (iii) name of patient;
- 1829 (iv) directions for use;
- 1830 (v) brand name and strength of the drug; or if no brand name, then the generic name of the drug
1831 dispensed, strength, and the name of the manufacturer or distributor of the drug; and
- 1832 (vi) unique identification number.
- 1833 (F) After the drug has been labeled, the practitioner or a licensed nurse under the supervision of the
1834 practitioner shall give the appropriately labeled, prepackaged medication to the patient.
- 1835 (G) A perpetual record of drugs which are supplied from the ASC shall be maintained which includes:
- 1836 (i) name, address, and phone number of the facility;
- 1837 (ii) date supplied;
- 1838 (iii) name of practitioner;
- 1839 (iv) name of patient;
- 1840 (v) directions for use;
- 1841 (vi) brand name and strength of the drug; or if no brand name, then the generic name of the drug
1842 dispensed, strength, and the name of the manufacturer or distributor of the drug; and
- 1843 (vii) unique identification number.
- 1844 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall review the
1845 records at least once in every calendar week that the pharmacy is open.
- 1846 (10) Drug regimen review.
- 1847 (A) A pharmacist shall evaluate medication orders and patient medication records for:
- 1848 (i) known allergies;
- 1849 (ii) rational therapy--contraindications;
- 1850 (iii) reasonable dose and route of administration;
- 1851 (iv) reasonable directions for use;
- 1852 (v) duplication of therapy;
- 1853 (vi) drug-drug interactions;
- 1854 (vii) drug-food interactions;
- 1855 (viii) drug-disease interactions;

1856 (ix) adverse drug reactions;

1857 (x) proper utilization, including overutilization or underutilization; and

1858 (xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug effectiveness, side
1859 effects, toxicity, or adverse effects, and appropriateness to continued use of the drug in its current
1860 regimen.

1861 (B) A retrospective, random drug regimen review as specified in the pharmacy's policies and procedures
1862 shall be conducted on a periodic basis to verify proper usage of drugs not to exceed 31 days between such
1863 reviews.

1864 (C) Any questions regarding the order must be resolved with the prescriber and a written notation of these
1865 discussions made and maintained.

1866 (e) Records.

1867 (1) Maintenance of records.

1868 (A) Every inventory or other record required to be kept under the provisions of this section (relating to
1869 Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center) shall be:

1870 (i) kept by the pharmacy and be available, for at least two years from the date of such inventory or record,
1871 for inspecting and copying by the board or its representative, and other authorized local, state, or federal
1872 law enforcement agencies; and

1873 (ii) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State
1874 Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records
1875 must be provided in a mutually agreeable electronic format if specifically requested by the board or its
1876 representative. Failure to provide the records set out in this subsection, either on site or within 72 hours,
1877 constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

1878 (B) Records of controlled substances listed in Schedule II shall be maintained separately and readily
1879 retrievable from all other records of the pharmacy.

1880 (C) Records of controlled substances listed in Schedules III - V shall be maintained separately or readily
1881 retrievable from all other records of the pharmacy. For purposes of this subparagraph, readily retrievable
1882 means that the controlled substances shall be asterisked, red-lined, or in some other manner readily
1883 identifiable apart from all other items appearing on the record.

1884 (D) Records, except when specifically required to be maintained in original or hard-copy form, may be
1885 maintained in an alternative data retention system, such as a data processing or direct imaging system
1886 provided:

1887 (i) the records in the alternative data retention system contain all of the information required on the
1888 manual record; and

1889 (ii) the alternative data retention system is capable of producing a hard copy of the record upon the
1890 request of the board, its representative, or other authorized local, state, or federal law enforcement or
1891 regulatory agencies.

1892 (E) Controlled substance records shall be maintained in a manner to establish receipt and distribution of
1893 all controlled substances.

- 1894 (F) An ASC pharmacy shall maintain a perpetual inventory of controlled substances listed in Schedule II -
1895 V which shall be verified for completeness and reconciled at least once in every calendar week that the
1896 pharmacy is open.
- 1897 (G) Distribution records for controlled substances, listed in Schedule II - V, shall include the following
1898 information:
- 1899 (i) patient's name;
- 1900 (ii) practitioner's name who order the drug;
- 1901 (iii) name of drug, dosage form, and strength;
- 1902 (iv) time and date of administration to patient and quantity administered;
- 1903 (v) signature or electronic signature of individual administering the controlled substance;
- 1904 (vi) returns to the pharmacy; and
- 1905 (vii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another
1906 individual).
- 1907 (H) The record required by subparagraph (G) of this paragraph shall be maintained separately from
1908 patient records.
- 1909 (I) A pharmacist shall conduct an audit by randomly comparing the distribution records required by
1910 subparagraph (G) with the medication orders in the patient record on a periodic basis to verify proper
1911 administration of drugs not to exceed 30 days between such reviews.
- 1912 (2) Patient records.
- 1913 (A) Each medication order or set of orders issued together shall bear the following information:
- 1914 (i) patient name;
- 1915 (ii) drug name, strength, and dosage form;
- 1916 (iii) directions for use;
- 1917 (iv) date; and
- 1918 (v) signature or electronic signature of the practitioner or that of his or her authorized agent, defined as a
1919 employee or consultant/full or part-time pharmacist of the ASC.
- 1920 (B) Medication orders shall be maintained with the medication administration record in the medical
1921 records of the patient.
- 1922 (3) General requirements for records maintained in a data processing system.
- 1923 (A) If an ASC pharmacy's data processing system is not in compliance with the board's requirements, the
1924 pharmacy must maintain a manual recordkeeping system.
- 1925 (B) The facility shall maintain a backup copy of information stored in the data processing system using

1926 disk, tape, or other electronic backup system and update this backup copy on a regular basis to assure that
1927 data is not lost due to system failure.

1928 (C) A pharmacy that changes or discontinues use of a data processing system must:

1929 (i) transfer the records to the new data processing system; or

1930 (ii) purge the records to a printout which contains:

1931 (I) all of the information required on the original document; or

1932 (II) for records of distribution and return for all controlled substances, the same information as required
1933 on the audit trail printout as specified in subparagraph (F) of this paragraph. The information on the
1934 printout shall be sorted and printed by drug name and list all distributions and returns chronologically.

1935 (D) Information purged from a data processing system must be maintained by the pharmacy for two years
1936 from the date of initial entry into the data processing system.

1937 (E) The pharmacist-in-charge shall report to the board in writing any significant loss of information from
1938 the data processing system within 10 days of discovery of the loss.

1939 (F) The data processing system shall have the capacity to produce a hard-copy printout of an audit trail of
1940 drug distribution and return for any strength and dosage form of a drug (by either brand or generic name
1941 or both) during a specified time period. This printout shall contain the following information:

1942 (i) patient's name and room number or patient's facility identification number;

1943 (ii) prescribing or attending practitioner's name;

1944 (iii) name, strength, and dosage form of the drug product actually distributed;

1945 (iv) total quantity distributed from and returned to the pharmacy;

1946 (v) if not immediately retrievable via electronic image, the following shall also be included on the
1947 printout:

1948 (I) prescribing or attending practitioner's address; and

1949 (II) practitioner's DEA registration number, if the medication order is for a controlled substance.

1950 (G) An audit trail printout for each strength and dosage form of these drugs distributed during the
1951 preceding month shall be produced at least monthly and shall be maintained in a separate file at the
1952 facility. The information on this printout shall be sorted by drug name and list all distributions/returns for
1953 that drug chronologically.

1954 (H) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system
1955 has a workable (electronic) data retention system which can produce an audit trail of drug distribution and
1956 returns for the preceding two years. The audit trail required in this clause shall be supplied by the
1957 pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy, or
1958 other authorized local, state, or federal law enforcement or regulatory agencies.

1959 (I) In the event that an ASC pharmacy which uses a data processing system experiences system
1960 downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for

- 1961 on-line data entry as soon as the system is available for use again.
- 1962 (4) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled
1963 substances to a practitioner, another pharmacy, or other registrant, without being registered to distribute,
1964 under the following conditions.
- 1965 (A) The registrant to whom the controlled substance is to be distributed is registered under the Controlled
1966 Substances Act to possess that controlled substance.
- 1967 (B) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed
1968 5.0% of all controlled substances dispensed by the pharmacy during the 12-month period in which the
1969 pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an
1970 additional registration to distribute controlled substances.
- 1971 (C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained
1972 which indicates:
- 1973 (i) the actual date of distribution;
- 1974 (ii) the name, strength, and quantity of controlled substances distributed;
- 1975 (iii) the name, address, and DEA registration number of the distributing pharmacy; and
- 1976 (iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to
1977 whom the controlled substances are distributed.
- 1978 (D) If the distribution is for a Schedule II controlled substance, the following is applicable.
- 1979 (i) The pharmacy, practitioner, or other registrant who is receiving the controlled substances shall issue
1980 Copy 1 and Copy 2 of a DEA order form (DEA 222) to the distributing pharmacy.
- 1981 (ii) The distributing pharmacy shall:
- 1982 (I) complete the area on the DEA order form (DEA 222) titled "To Be Filled in by Supplier";
- 1983 (II) maintain Copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and
- 1984 (III) forward Copy 2 of the DEA order form (DEA 222) to the divisional office of the Drug Enforcement
1985 Administration.
- 1986 (5) Other records. Other records to be maintained by the pharmacy include:
- 1987 (A) a permanent log of the initials or identification codes which will identify each pharmacist by name.
1988 The initials or identification code shall be unique to ensure that each pharmacist can be identified, i.e.,
1989 identical initials or identification codes cannot be used;
- 1990 (B) Copy 3 of DEA order form (DEA 222), which has been properly dated, initialed, and filed, and all
1991 copies of each unaccepted or defective order form and any attached statements or other documents and/or
1992 for each order filled using the DEA Controlled Substance Ordering System (CSOS), the original signed
1993 order and all linked records for that order;
- 1994 (C) a copy of the power of attorney to sign DEA 222 order forms (if applicable);

- 1995 (D) suppliers' invoices of dangerous drugs and controlled substances dated and initialed or signed by the
1996 person receiving the drugs; a pharmacist shall verify that the controlled drugs listed on the invoices were
1997 added to the pharmacy's perpetual inventory by clearly recording his/her initials and the date of review of
1998 the perpetual inventory;
- 1999 (E) supplier's credit memos for controlled substances and dangerous drugs;
- 2000 (F) a copy of inventories required by §291.17 of this title (relating to Inventory Requirements) except that
2001 a perpetual inventory of controlled substances listed in Schedule II may be kept in a data processing
2002 system if the data processing system is capable of producing a copy of the perpetual inventory on-site;
- 2003 (G) reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate
2004 state or federal agency;
- 2005 (H) records of distribution of controlled substances and/or dangerous drugs to other pharmacies,
2006 practitioners, or registrants; and
- 2007 (I) a copy of any notification required by the Texas Pharmacy Act or these rules, including, but not
2008 limited to, the following:
- 2009 (i) reports of theft or significant loss of controlled substances to DEA, DPS, and the board;
- 2010 (ii) notification of a change in pharmacist-in-charge of a pharmacy; and
- 2011 (iii) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs,
2012 medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and disease.
- 2013 (6) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system
2014 for invoices and financial data shall comply with the following procedures.
- 2015 (A) Controlled substance records. Invoices and financial data for controlled substances may be
2016 maintained at a central location provided the following conditions are met.
- 2017 (i) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered
2018 or certified mail to the divisional director of the Drug Enforcement Administration as required by the
2019 Code of Federal Regulations, Title 21, §1304(a), and submits a copy of this written notification to the
2020 Texas State Board of Pharmacy. Unless the registrant is informed by the divisional director of the Drug
2021 Enforcement Administration that permission to keep central records is denied, the pharmacy may
2022 maintain central records commencing 14 days after receipt of notification by the divisional director.
- 2023 (ii) The pharmacy maintains a copy of the notification required in this subparagraph.
- 2024 (iii) The records to be maintained at the central record location shall not include executed DEA order
2025 forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the
2026 pharmacy.
- 2027 (B) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a
2028 central location.
- 2029 (C) Access to records. If the records are kept in any form requiring special equipment to render the
2030 records easily readable, the pharmacy shall provide access to such equipment with the records.
- 2031 (D) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy

- 2032 location within two business days of written request of a board agent or any other authorized official.
- 2033 **§291.77 Pharmacies Compounding Sterile Preparations (Class C-S)**
- 2034 Licensing requirements. A institutional or ASC pharmacy engaged in the compounding of sterile
2035 preparations shall be designated as a Class C-S pharmacy.
- 2036 (1) A Class C-S pharmacy shall register annually or biennially with the board on a pharmacy license
2037 application provided by the board, following the procedures specified in §291.1 of this title (relating to
2038 Pharmacy License Application). A Class C-S license may not be issued unless the pharmacy has been
2039 inspected by the board to ensure the pharmacy meets the requirements as specified in §291.133 of this
2040 title (relating to Pharmacies Compounding Sterile Preparations).
- 2041 (2) A Class C-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by
2042 the board within the last renewal period.
- 2043 (3) If the Class C-S pharmacy is owned or operated by a hospital management or consulting firm, the
2044 following conditions apply.
- 2045 (A) The pharmacy license application shall list the hospital management or consulting firm as the owner
2046 or operator.
- 2047 (B) The hospital management or consulting firm shall obtain DEA and DPS controlled substance
2048 registrations that are issued in their name, unless the following occurs:
- 2049 (i) the hospital management or consulting firm and the facility cosign a contractual pharmacy service
2050 agreement which assigns overall responsibility for controlled substances to the facility; and
- 2051 (ii) such hospital pharmacy management or consulting firm maintains dual responsibility for the
2052 controlled substances.
- 2053 (4) A Class C-S pharmacy which changes ownership shall notify the board within 10 days of the change
2054 of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to
2055 Required Notifications).
- 2056 (5) A Class C-S pharmacy which changes location and/or name shall notify the board within 10 days of
2057 the change and file for an amended license as specified in §291.3 of this title.
- 2058 (6) A Class C-S pharmacy owned by a partnership or corporation which changes managing officers shall
2059 notify the board in writing of the names of the new managing officers within 10 days of the change
2060 following the procedures in §291.3 of this title.
- 2061 (7) A Class C-S pharmacy shall notify the board in writing within 10 days of closing, following the
2062 procedures in §291.5 of this title (relating to Closing a Pharmacy).
- 2063 (8) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the
2064 issuance and renewal of a license and the issuance of an amended license.
- 2065 (9) A separate license is required for each principal place of business and only one pharmacy license may
2066 be issued to a specific location.
- 2067 (10) A Class C-S pharmacy, licensed under the Act, §560.051(a)(3), which also operates another type of
2068 pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) (Community

2069 Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear Pharmacy (Class B)), is not required to secure a
2070 license for the such other type of pharmacy; provided, however, such licensee is required to comply with
2071 the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel),
2072 §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and
2073 §291.35 of this title (relating to Official Prescription Requirements), contained in Community Pharmacy
2074 (Class A), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions),
2075 §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and
2076 §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such
2077 sections are applicable to the operation of the pharmacy.

2078 (11) A Class C-S pharmacy engaged in the compounding of non-sterile preparations shall comply with
2079 the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

2080 (12) A Class C-S pharmacy engaged in the provision of remote pharmacy services, including storage and
2081 dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to
2082 Remote Pharmacy Services).

2083 (13) A Class C-S pharmacy engaged in centralized prescription dispensing and/or prescription drug or
2084 medication order processing shall comply with the provisions of §291.123 of this title (relating to Central
2085 Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized
2086 Prescription Dispensing).

2087 (14) A Class C-S pharmacy with an ongoing clinical pharmacy program that proposes to allow a
2088 pharmacy technician to verify the accuracy of work performed by another pharmacy technician relating to
2089 the filling of floor stock and unit dose distribution systems for a patient admitted to the hospital if the
2090 patient's orders have previously been reviewed and approved by a pharmacist shall make application to
2091 the board as follows.

2092 (A) The pharmacist-in-charge must submit an application on a form provided by the board, containing the
2093 following information:

2094 (i) name, address, and pharmacy license number;

2095 (ii) name and license number of the pharmacist-in-charge;

2096 (iii) name and registration numbers of the pharmacy technicians;

2097 (iv) anticipated date the pharmacy plans to begin allowing a pharmacy technician to verify the accuracy
2098 of work performed by another pharmacy technician;

2099 (v) documentation that the pharmacy has an ongoing clinical pharmacy program; and

2100 (vi) any other information specified on the application.

2101 (B) The pharmacy may not allow a pharmacy technician to check the work of another pharmacy
2102 technician until the board has reviewed and approved the application and issued an amended license to
2103 the pharmacy.

2104 (C) Every two years, in connection with the application for renewal of the pharmacy license, the
2105 pharmacy shall provide updated documentation that the pharmacy continues to have an ongoing clinical
2106 pharmacy program as specified in subparagraph (A)(v) of this paragraph.

2107 (15) A rural hospital that wishes to allow a pharmacy technician to perform the duties specified in

2108 §291.73(e)(2)(D) of this title (relating to Personnel) shall make application to the board as follows.

2109 (A) Prior to allowing a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this
2110 title, the pharmacist-in-charge must submit an application on a form provided by the board, containing the
2111 following information:

2112 (i) name, address, and pharmacy license number;

2113 (ii) name and license number of the pharmacist-in-charge;

2114 (iii) name and registration number of the pharmacy technicians;

2115 (iv) proposed date the pharmacy wishes to start allowing pharmacy technicians to perform the duties
2116 specified in §291.73(e)(2)(D) of this title;

2117 (v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural hospital is
2118 either:

2119 (I) located in a county with a population of 50,000 or less as defined by the United States Census Bureau
2120 in the most recent U.S. census; or

2121 (II) designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural
2122 referral center, or sole community hospital; and

2123 (vi) any other information specified on the application.

2124 (B) A rural hospital may not allow a pharmacy technician to perform the duties specified in
2125 §291.73(e)(2)(D) of this title until the board has reviewed and approved the application and issued an
2126 amended license to the pharmacy.

2127 (C) Every two years in conjunction with the application for renewal of the pharmacy license, the
2128 pharmacist-in-charge shall update the application for pharmacy technicians to perform the duties
2129 specified in §291.73(e)(2)(D) of this title.