

1 **Chapter 291. Pharmacies**

2 **Subchapter D. Institutional Pharmacies (Class C)**

3

4 **§291.72 Definitions.** The following words and terms, when used in this subchapter, shall
5 have the following meanings, unless the context clearly indicates otherwise.

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

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

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

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

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

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

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

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

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

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

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

26 (7) Confidential record--Any health-related record that contains information that identifies
27 an individual and that is maintained by a pharmacy or pharmacist, such as a patient
28 medication record, prescription drug order, or medication drug order.

29 (8) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult
30 with the facility in areas that pertain to the practice of pharmacy.

31 (9) Controlled substance--A drug, immediate precursor, or other substance listed in
32 Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended,
33 or a drug, immediate precursor, or other substance included in Schedules I - V of the Federal

34 Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law
35 91-513).

36 (10) Dangerous drug--A drug or device that:

37 (A) is not included in Penalty Group 1, 2, 3, or 4, Chapter 481, Health and Safety Code,
38 and is unsafe for self-medication; or

39 (B) bears or is required to bear the legend:

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

42 (ii) "Caution: federal law restricts this drug to use by or on the order of a licensed
43 veterinarian."

44 (11) Device--An instrument, apparatus, implement, machine, contrivance, implant, in vitro
45 reagent, or other similar or related article, including any component part or accessory, that is
46 required under federal or state law to be ordered or prescribed by a practitioner.

47 (12) Direct copy—Electronic copy or carbonized copy of a medication order, including a
48 facsimile (FAX) or **digital image** [~~tele autograph, or a copy transmitted between~~
49 ~~computers~~].

50 (13) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription
51 drug or device in the course of professional practice to an ultimate user or his agent by or
52 pursuant to the lawful order of a practitioner.

53 (14) Distribute--The delivery of a prescription drug or device other than by administering or
54 dispensing.

55 (15) Distributing pharmacist--The pharmacist who checks the medication order prior to
56 distribution.

57 (16) Downtime--Period of time during which a data processing system is not operable.

58 (17) Drug regimen review--

59 (A) An evaluation of medication orders and patient medication records for:

60 (i) known allergies;

61 (ii) rational therapy--contraindications;

62 (iii) reasonable dose and route of administration;

63 (iv) reasonable directions for use;

64 (v) duplication of therapy;

65 (vi) drug-drug interactions;

66 (vii) drug-food interactions;

67 (viii) drug-disease interactions;

68 (ix) adverse drug reactions; and
69 (x) proper utilization, including overutilization or underutilization.
70 (B) The drug regimen review may be conducted prior to administration of the first dose
71 (prospective) or after administration of the first dose (retrospective).
72 (18) Electronic signature--A unique security code or other identifier which specifically
73 identifies the person entering information into a data processing system. A facility which
74 utilizes electronic signatures must:
75 (A) maintain a permanent list of the unique security codes assigned to persons authorized
76 to use the data processing system; and
77 (B) have an ongoing security program which is capable of identifying misuse and/or
78 unauthorized use of electronic signatures.
79 (19) Expiration date--The date (and time, when applicable) beyond which a product should
80 not be used.
81 (20) Facility--
82 (A) a hospital or other **patient [in-patient]** facility that is licensed under Chapter 241 or
83 577, Health and Safety Code;
84 (B) a hospice **patient [in-patient]** facility that is licensed under Chapter 142, Health and
85 Safety Code;
86 (C) an ambulatory surgical center licensed under Chapter 243, Health and Safety Code; or
87 (D) a hospital maintained or operated by the state.
88 (21) Floor stock--Prescription drugs or devices not labeled for a specific patient and
89 maintained at a nursing station or other hospital department (excluding the pharmacy) for the
90 purpose of administration to a patient of the facility.
91 (22) Formulary--List of drugs approved for use in the facility by the committee which
92 performs the pharmacy and therapeutics function for the facility.
93 (23) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per
94 week or if the pharmacy is open less than 60 hours per week, one-half of the time the
95 pharmacy is open.
96 (24) Hard copy--A physical document that is readable without the use of a special device
97 (i.e., **data processing system, computer, etc [cathode ray tube (CRT), microfiche reader,**
98 **etc]**).
99 (25) Hot water--The temperature of water from the pharmacy's sink maintained at a
100 minimum of 105 degrees F (41 degrees C).

101 (26) **Patient** ~~[Inpatient]~~--A person who is receiving services at the facility ~~[is duly~~
102 ~~admitted to the licensed hospital]~~ **(including patients receiving ambulatory procedures**
103 **and patients conditionally admitted as observation patients)**, ~~[or other hospital or facility~~
104 ~~maintained or operated by the state,]~~ or who is receiving long term care services or Medicare
105 extended care services in a swing bed on the hospital premise or an adjacent, readily
106 accessible facility **that** ~~[which]~~ is under the authority of the hospital's governing body. For
107 the purposes of this definition, the term "long term care services" means those services
108 received in a skilled nursing facility which is a distinct part of the hospital and the distinct
109 part is not licensed separately or formally approved as a nursing home by the state, even
110 though it is designated or certified as a skilled nursing facility. An inpatient includes a person
111 confined in any correctional institution operated by the state of Texas.

112 (27) Institutional pharmacy--Area or areas in a facility where drugs are stored, bulk
113 compounded, delivered, compounded, dispensed, and distributed to other areas or
114 departments of the facility, or dispensed to an ultimate user or his or her agent.

115 (28) Investigational new drug--New drug intended for investigational use by experts
116 qualified to evaluate the safety and effectiveness of the drug as authorized by the Food and
117 Drug Administration.

118 (29) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code,
119 as amended.

120 (30) Medication order--A written order from a practitioner or a verbal order from a
121 practitioner or his authorized agent for administration of a drug or device.

122 (31) Part-time pharmacist--A pharmacist either employed or under contract, who routinely
123 works less than full-time.

124 (32) Perpetual inventory--An inventory which documents all receipts and distributions of a
125 drug product, such that an accurate, current balance of the amount of the drug product
126 present in the pharmacy is indicated.

127 (33) Pharmaceutical care--The provision of drug therapy and other pharmaceutical services
128 intended to assist in the cure or prevention of a disease, elimination or reduction of a patient's
129 symptoms, or arresting or slowing of a disease process.

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

133 (35) Pharmacy and therapeutics function--Committee of the medical staff in the facility
134 which assists in the formulation of broad professional policies regarding the evaluation,

135 selection, distribution, handling, use, and administration, and all other matters relating to the
136 use of drugs and devices in the facility.

137 (36) Pharmacy technician--An individual who is registered with the board as a pharmacy
138 technician and whose responsibility in a pharmacy is to provide technical services that do not
139 require professional judgment regarding preparing and distributing drugs and who works
140 under the direct supervision of and is responsible to a pharmacist.

141 (37) Pharmacy technician trainee--An individual who is registered with the board as a
142 pharmacy technician trainee and is authorized to participate in a pharmacy's technician
143 training program.

144 (38) Pre-packaging--The act of re-packaging and re-labeling quantities of drug products
145 from a manufacturer's original container into unit-dose packaging or a multiple dose
146 container for distribution within the facility **except as specified in §291.74(f)(3)(B) of this**
147 **title (relating to Records).**

148 (39) Prescription drug--

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

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

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

155 (ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian;
156 or

157 (C) A drug or device that is required by any applicable federal or state law or regulation to
158 be dispensed on prescription only or is restricted to use by a practitioner only.

159 (40) Prescription drug order--

160 (A) a written order from a practitioner or a verbal order from a practitioner or his
161 authorized agent to a pharmacist for a drug or device to be dispensed; or

162 (B) a written order or a verbal order pursuant to Subtitle B, Chapter 157, Occupations
163 Code.

164 (41) Quality assurance--The set of activities used to assure that the process used in the
165 preparation of sterile drug products lead to products that meet predetermined standards of
166 quality.

167 (42) Quality control--The set of testing activities used to determine that the ingredients,
168 components (e.g., containers), and final sterile **preparations** [pharmaceuticals] prepared

169 meet predetermined requirements with respect to identity, purity, non-pyrogenicity, and
170 sterility.

171 (43) Sample--A prescription drug which is not intended to be sold and is intended to
172 promote the sale of the drug.

173 (44) Supervision--

174 (A) Physically present supervision--In a Class C pharmacy, a pharmacist shall be
175 physically present to directly supervise pharmacy technicians or pharmacy technician
176 trainees.

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

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

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

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

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

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

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

192 (I) the data entry; and

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

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

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

198 (45) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health
199 and Safety Code, Chapter 481, as amended.

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

203 (47) Unusable drugs--Drugs or devices that are unusable for reasons, such as they are
204 adulterated, misbranded, expired, defective, or recalled.

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

208

209 **§291.73 Personnel.**

210 (a) Requirements for pharmacist services.

211 (1) A Class C pharmacy in a facility licensed for 101 beds or more shall be under the
212 continuous on-site supervision of a pharmacist during the time it is open for pharmacy
213 services; provided, however, that pharmacy technicians may distribute prepackaged and
214 prelabeled drugs from a **drug storage area of the facility e.g., a surgery suite, [satellite**
215 **pharmacy]** in the absence of **physical** [~~on-site~~] supervision of a pharmacist, under the
216 following conditions:

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

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

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

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

226 (b) Pharmacist-in-charge.

227 (1) General.

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

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

235 (C) A pharmacist-in-charge may be in charge of one facility with 101 beds or more and
236 one facility with 100 beds or less provided the total number of beds does not exceed 150
237 beds.

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

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

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

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

248 **(B) ensuring that a prospective drug use review is conducted on all new medication**
249 **orders unless a delay in administration of the drug would harm the patient in an urgent**
250 **situation (including sudden changes in a patient's clinical status);**

251 **(C) ~~{(B)}~~** ensuring that drugs and/or devices are prepared for distribution safely, and
252 accurately as prescribed;

253 **(D) supervising a system to assure maintenance of effective controls against the theft**
254 **or diversion of prescription drugs, and records for such drugs;**

255 **(E) ~~{(C)}~~** providing written guidelines and approval of the procedure to assure that all
256 pharmaceutical requirements are met when any part of preparing, sterilizing, and labeling of
257 sterile preparations is not performed under direct pharmacy supervision;

258 **(F) ~~{(D)}~~** participating in the development of a formulary for the facility, subject to
259 approval of the appropriate committee of the facility;

260 **(G) ~~{(E)}~~** developing a system to assure that drugs to be administered to **patients**
261 **[inpatients]** are distributed pursuant to an original or direct copy of the practitioner's
262 medication order;

263 **(H) ~~{(F)}~~** developing a system for the filling and labeling of all containers from which
264 drugs are to be distributed or dispensed;

265 **(I) ~~{(G)}~~** assuring that the pharmacy maintains and makes available a sufficient inventory
266 of antidotes and other emergency drugs as well as current antidote information, telephone
267 numbers of regional poison control center and other emergency assistance organizations, and

268 such other materials and information as may be deemed necessary by the appropriate
269 committee of the facility;

270 **(J)** ~~{(H)}~~ maintaining records of all transactions of the institutional pharmacy as may be
271 required by applicable law, state and federal, and as may be necessary to maintain accurate
272 control over and accountability for all pharmaceutical materials including pharmaceuticals,
273 components used in the compounding of **preparations** ~~[pharmaceuticals]~~, and **participate in**
274 **policy decisions regarding prescription** drug delivery devices;

275 **(K)** ~~{(I)}~~ participating in those aspects of the facility's patient care evaluation program
276 which relate to pharmaceutical utilization and effectiveness;

277 **(L)** ~~{(J)}~~ participating in teaching and/or research programs in the facility;

278 **(M)** ~~{(K)}~~ implementing the policies and decisions of the appropriate committee(s)
279 relating to pharmaceutical services of the facility;

280 **(N)** ~~{(L)}~~ providing effective and efficient messenger or delivery service to connect the
281 institutional pharmacy with appropriate areas of the facility on a regular basis throughout the
282 normal workday of the facility;

283 **(O)** ~~{(M)}~~ developing a system for the labeling, storage, and distribution of investigational
284 new drugs, including **access to related drug information for healthcare personnel**
285 ~~[maintenance of information]~~ where such drugs are being administered, concerning the
286 dosage form, route of administration, strength, actions, uses, side effects, adverse effects,
287 interactions and symptoms of toxicity of investigational new drugs;

288 **(P)** ~~{(N)}~~ assuring that records in a data processing system are maintained such that the
289 data processing system is in compliance with Class C (Institutional) pharmacy requirements;

290 **(Q)** ~~{(O)}~~ assuring that a reasonable effort is made to obtain, record, and maintain patient
291 medication records;

292 **(R)** ~~{(P)}~~ assuring the legal operation of the pharmacy, including meeting all inspection
293 and other requirements of all state and federal laws or rules governing the practice of
294 pharmacy; and

295 **(S)** ~~{(Q)}~~ if the pharmacy uses an automated medication supply system, shall be
296 responsible for the following:

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

300 (ii) inspecting medications in the automated medication supply system, at least monthly,
301 for expiration date, misbranding, physical integrity, security, and accountability; **except that**

302 **inspection of medications in the automated medication supply system may be**

303 **performed quarterly if:**

304 **(I) the facility uses automated medication supply systems that monitors expiration**
305 **dates of prescription drugs; and**

306 **(II) security of the system is checked at regularly defined intervals (e.g., daily or**
307 **weekly:**

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

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

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

318 (c) Consultant pharmacist.

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

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

322 (d) Pharmacists.

323 (1) General.

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

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

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

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

334 (E) A distributing pharmacist shall be responsible for and ensure that the drug is prepared
335 for distribution safely, and accurately as prescribed unless the pharmacy's data processing

336 system can record the identity of each pharmacist involved in a specific portion of the
337 preparation of medication orders for distribution, in which case each pharmacist involved in
338 the preparation of medication orders shall be responsible for and ensure that the portion of
339 the process the pharmacist is performing results in the safe and accurate distribution and
340 delivery of the drug as ordered. The preparation and distribution process for medication
341 orders shall include, but not be limited to, drug regimen review, and verification of accurate
342 medication order data entry, preparation, and distribution, and performance of the final check
343 of the prepared medication.

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

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

347 **(B) conducting a prospective drug use review on all new medication orders unless a**
348 **delay in administration of the drug would harm the patient in an urgent situation**
349 **(including sudden changes in a patient's clinical status);**

350 **(C) [(B)]** receiving, interpreting, and evaluating prescription drug orders, and reducing
351 verbal medication orders to writing either manually or electronically;

352 **(D) [(C)]** participating in drug and/or device selection as authorized by law, drug and/or
353 device supplier selection, drug administration, drug regimen review, or drug or drug-related
354 research;

355 **(E) [(D)]** performing a specific act of drug therapy management for a patient delegated to
356 a pharmacist by a written protocol from a physician licensed in this state in compliance with
357 the Medical Practice Act Subtitle B, Chapter 157, Occupations Code;

358 **(F) [(E)]** accepting the responsibility for:

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

361 (ii) compounding and labeling of **prescription** drugs and devices **with drug**
362 **components;**

363 (iii) proper and safe storage of **prescription** drugs and devices **with drug components;**
364 and

365 (iv) maintaining proper records for **prescription** drugs and devices **with drug**
366 **components.**

367 (3) Special requirements for compounding.

368 (A) Non-Sterile Preparations. All pharmacists engaged in compounding non-sterile
369 preparations shall meet the training requirements specified in §291.131 of this title (relating
370 to Pharmacies Compounding Non-sterile Preparations).

371 (B) Sterile Preparations. All pharmacists engaged in compounding sterile preparations
372 shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies
373 Compounding Sterile Preparations).

374 (e) Pharmacy technicians and pharmacy technician trainees.

375 (1) General. All pharmacy technicians and pharmacy technician trainees shall meet the
376 training requirements specified in §297.6 of this title (relating to Pharmacy Technician and
377 Pharmacy Technician Trainee Training).

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

380 (A) Facilities licensed for 101 beds or more. The following functions must be performed
381 under the physically present supervision of a pharmacist:

382 (i) pre-packing and labeling unit and multiple dose packages, provided a pharmacist
383 supervises and conducts **a final check** [~~in-process and final checks~~] and affixes his or her
384 **name, initials** [~~signature (first initial and last name or full signature)~~] or electronic signature
385 to the appropriate quality control records **prior to distribution**;

386 (ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to
387 medication orders, provided a pharmacist supervises and checks the preparation prior to
388 distribution;

389 (iii) bulk compounding or batch preparation provided a pharmacist supervises and
390 conducts in-process and final checks and affixes his or her **name, initials, or electronic**
391 **signature** to the appropriate quality control records **prior to distribution**;

392 (iv) distributing routine orders for stock supplies to patient care areas;

393 (v) entering medication order and drug distribution information into a data processing
394 system, provided judgmental decisions are not required and a pharmacist checks the accuracy
395 of the information entered into the system prior to releasing the order;

396 (vi) loading [~~bulk~~] unlabeled drugs into an automated compounding or counting device
397 provided a pharmacist supervises, verifies that the system was properly loaded prior to use,
398 and affixes his or her **name, initials** [~~signature (first initial and last name or full signature)~~]
399 or electronic signature to the appropriate quality control records;

400 (vii) accessing automated medication supply systems after proper training on the use of
401 the automated medication supply system and demonstration of comprehensive knowledge of
402 the written policies and procedures for its operation;

403 (viii) compounding non-sterile preparations pursuant to medication orders provided the
404 pharmacy technicians or pharmacy technician trainees have completed the training specified
405 in §291.131 of this title; and

406 (ix) compounding sterile preparations pursuant to medication orders provided the
407 pharmacy technicians or pharmacy technician trainees:

408 (I) have completed the training specified in §291.133 of this title; and

409 (II) are supervised by a pharmacist who has completed the training specified in
410 §291.133 of this title, and who conducts in-process and final checks, and affixes his or her
411 **name, initials, or electronic signature** to the label or if batch prepared, to the appropriate
412 quality control records. (The **name, initials, or electronic signature** are not required on the
413 label if it is maintained in a permanent record of the pharmacy.)

414 (B) Facilities licensed for 100 beds or less.

415 (i) Physically present supervision. The following functions must be performed under the
416 physically present supervision of a pharmacist:

417 (I) pre-packing and labeling unit and multiple dose packages, provided a pharmacist
418 supervises and conducts **a final check** [~~in-process and final checks~~] and affixes his or her
419 **name, initials** [~~signature (first initial and last name or full signature)~~] or electronic signature
420 to the appropriate quality control records **prior to distribution**;

421 (II) bulk compounding or batch preparation provided a pharmacist supervises and
422 conducts in-process and final checks and affixes his or her **name, initials, or electronic**
423 **signature** to the appropriate quality control records **prior to distribution**;

424 (III) loading [~~bulk~~] unlabeled drugs into an automated compounding or counting device
425 provided a pharmacist supervises, verifies that the system was properly loaded prior to use,
426 and affixes his or her **name, initials,** [~~signature (first initial and last name or full signature)~~]
427 or electronic signature to the appropriate quality control records; and

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

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

431 (-b-) are supervised by a pharmacist who has completed the training specified in
432 §291.133 of this title and who conducts in-process and final checks, and affixes his or her
433 **name, initials, or electronic signature** to the label or if batch prepared, to the appropriate

434 quality control records. (The **name, initials, initials or electronic signature** are not required
435 on the label if it is maintained in a permanent record of the pharmacy.)

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

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

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

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

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

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

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

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

454 (-b-) are supervised by a pharmacist who has completed the training specified in
455 §291.133 of this title, and who conducts in-process and final checks, and affixes his or her
456 **name, initials, or electronic signature** to the label or if batch prepared, to the appropriate
457 quality control records. (The **name, initials, or electronic signature** are not required on the
458 label if it is maintained in a permanent record of the pharmacy.)

459 (3) Procedures.

460 (A) Pharmacy technicians and pharmacy technician trainees shall handle medication orders
461 in accordance with standard, written procedures and guidelines.

462 (B) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug
463 orders in the same manner as those working in a Class A pharmacy.

464 (f) Owner. The owner of a Class C pharmacy shall have responsibility for all administrative
465 and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner
466 on administrative and operational concerns. The owner shall have responsibility for, at a

467 minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall
468 consult with the pharmacist-in-charge or another Texas licensed pharmacist:

469 (1) establishment of policies for procurement of prescription drugs and devices and other
470 products dispensed from the Class C pharmacy;

471 (2) establishment and maintenance of effective controls against the theft or diversion of
472 prescription drugs;

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

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

478 (5) establishment of policies and procedures regarding maintenance, storage, and retrieval
479 of records in a data processing system such that the system is in compliance with state and
480 federal requirements.

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

483 (1) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or
484 badge that bears the person's name and identifies him or her as a pharmacy technician, or a
485 certified pharmacy technician, if the technician maintains current certification with the
486 Pharmacy Technician Certification Board or any other entity providing an examination
487 approved by the board.

488 (2) Pharmacy technician trainees. All pharmacy technician trainees shall wear an
489 identification tag or badge that bears the person's name and identifies him or her as a
490 pharmacy technician trainee.

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

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

495

496 **§291.74 Operational Standards.**

497 (a) Licensing requirements.

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

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

503 (A) The pharmacy license application shall list the hospital management or consulting firm
504 as the owner or operator.

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

507 (i) the hospital management or consulting firm and the facility cosign a contractual
508 pharmacy service agreement which assigns overall responsibility for controlled substances to
509 the facility; and

510 (ii) such hospital pharmacy management or consulting firm maintains dual responsibility
511 for the controlled substances.

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

515 (4) A Class C pharmacy which changes location and/or name shall notify the board within
516 10 days of the change and file for an amended license as specified in §291.3 of this title.

517 (5) A Class C pharmacy owned by a partnership or corporation which changes managing
518 officers shall notify the board in writing of the names of the new managing officers within 10
519 days of the change following the procedures in §291.3 of this title.

520 (6) A Class C pharmacy shall notify the board in writing within 10 days of closing,
521 following the procedures in §291.5 of this title (relating to **Closing a Pharmacy [Closed**
522 **Pharmacies]**).

523 (7) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
524 charged for the issuance and renewal of a license and the issuance of an amended license.

525 (8) A separate license is required for each principal place of business and only one
526 pharmacy license may be issued to a specific location.

527 (9) A Class C pharmacy, licensed under the Act, §560.051(a)(3), which also operates
528 another type of pharmacy which would otherwise be required to be licensed under the Act,
529 §560.051(a)(1) (Community Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear
530 Pharmacy (Class B)), is not required to secure a license for the such other type of pharmacy;
531 provided, however, such licensee is required to comply with the provisions of §291.31 of this
532 title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title
533 (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of
534 this title (relating to Official Prescription Records), contained in Community Pharmacy

535 (Class A), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to
536 Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to
537 Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear
538 Pharmacy (Class B), to the extent such sections are applicable to the operation of the
539 pharmacy.

540 (10) A Class C (Institutional) pharmacy engaged in **the compounding of non-sterile**
541 **preparations** [~~non-sterile compounding of drug products for inpatients of the hospital~~] shall
542 comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding
543 Non-sterile Preparations);

544 (11) A Class C (Institutional) pharmacy engaged in the compounding of sterile
545 **preparations** ~~pharmaceuticals~~] shall comply with the provisions of §291.133 of this title
546 (relating to Pharmacies Compounding Sterile Preparations).

547 (12) A Class C (Institutional) pharmacy engaged in the provision of remote pharmacy
548 services, including storage and dispensing of prescription drugs, shall comply with the
549 provisions of §291.121 of this title (relating to Remote Pharmacy Services).

550 (13) A Class C (Institutional) pharmacy engaged in centralized prescription dispensing
551 and/or prescription drug or medication order processing shall comply with the provisions of
552 §291.123 of this title (relating to Centralized Prescription Drug or Medication Order
553 Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

554 (b) Environment.

555 (1) General requirements.

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

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

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

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

565 (E) The temperature of the institutional pharmacy shall be maintained within a range
566 compatible with the proper storage of drugs. The temperature of the refrigerator **and/or**
567 **freezer** shall be maintained within a range compatible with the proper storage of drugs
568 [~~requiring refrigeration.~~]

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

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

574 (2) Security requirements.

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

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

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

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

586 (1) **data processing system including a printer** [typewriter] or comparable equipment; and

587 (2) refrigerator **and/or freezer** and a system or device (e.g., thermometer) to monitor the
588 temperature [~~and humidity~~] to ensure that proper storage requirements are met.

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

591 (1) current copies of the following:

592 (A) Texas Pharmacy Act and rules;

593 (B) Texas Dangerous Drug Act and rules;

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

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

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

598 (A) drug interactions. A reference text on drug interactions, such as Drug Interaction Facts.

599 A separate reference is not required if other references maintained by the pharmacy contain
600 drug interaction information including information needed to determine severity or

601 significance of the interaction and appropriate recommendations or actions to be taken;

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

603 (i) Facts and Comparisons with current supplements;
604 (ii) United States Pharmacopeia Dispensing Information Volume I (Drug Information for
605 the Healthcare Provider);
606 (iii) AHFS Drug Information with current supplements;
607 (iv) Remington's Pharmaceutical Sciences; or
608 (v) Clinical Pharmacology;
609 (3) a current or updated reference on injectable drug products, such as Handbook of
610 Injectable Drugs;
611 (4) basic antidote information and the telephone number of the nearest regional poison
612 control center;
613 (5) metric-apothecary weight and measure conversion charts.
614 (e) Absence of a pharmacist.
615 (1) Medication orders.
616 (A) In facilities with a full-time pharmacist, if a practitioner orders a drug for
617 administration to a bona fide patient of the facility when the pharmacy is closed, the
618 following is applicable.
619 **(i) A pharmacist shall conduct a prospective drug use review of all new medication**
620 **orders unless a delay in administration of the drug would harm the patient in an urgent**
621 **situation (including sudden changes in a patient's clinical status). Such review may be**
622 **conducted electronically.**
623 **(ii)** ~~{(i)}~~ Prescription drugs and devices only in sufficient quantities for immediate
624 therapeutic needs may be removed from the institutional pharmacy.
625 **(iii)** ~~{(ii)}~~ Only a designated licensed nurse or practitioner may remove such drugs and
626 devices.
627 **(iv)** ~~{(iii)}~~ A record shall be made at the time of withdrawal by the authorized person
628 removing the drugs and devices. The record shall contain the following information:
629 (I) name of patient;
630 (II) name of device or drug, strength, and dosage form;
631 (III) dose prescribed;
632 (IV) quantity taken;
633 (V) time and date; and
634 (VI) signature (first initial and last name or full signature) or electronic signature of
635 person making withdrawal.

636 ~~(v)~~ ~~{(iv)}~~ The original or direct copy of the medication order may substitute for such
637 record, providing the medication order meets all the requirements of clause ~~(iv)~~ ~~{(iii)}~~ of this
638 subparagraph.

639 ~~(vi)~~ ~~{(v)}~~ (v) The pharmacist shall verify the withdrawal [~~and perform a drug regimen~~
640 ~~review as specified in subsection (g)(1)(B) of this section as soon~~] as practical, but in no
641 event more than 72 hours from the time of such withdrawal.

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

645 **(i) A pharmacist shall conduct a prospective drug use review of all new medication**
646 **orders unless a delay in administration of the drug would harm the patient in an urgent**
647 **situation (including sudden changes in a patient's clinical status). Such review may be**
648 **conducted electronically.**

649 ~~(ii)~~ ~~{(i)}~~ Prescription drugs and devices only in sufficient quantities for therapeutic needs
650 may be removed from the institutional pharmacy.

651 ~~(iii)~~ ~~{(ii)}~~ Only a designated licensed nurse or practitioner may remove such drugs and
652 devices.

653 ~~(iv)~~ ~~{(iii)}~~ A record shall be made at the time of withdrawal by the authorized person
654 removing the drugs and devices; the record shall meet the same requirements as specified in
655 subparagraph (A) ~~(iv)~~ ~~{(ii)}~~ and ~~(v)~~ ~~{(iv)}~~ of this paragraph.

656 (iv) The pharmacist shall verify the withdrawal [~~and perform a drug regimen review as~~
657 ~~specified in subsection (g)(1)(B) of this section~~] after a reasonable interval, but in no event
658 may such interval exceed seven days.

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

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

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

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

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

667 (ii) quantity removed;

668 (iii) location of floor stock;

669 (iv) date and time; and

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

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

674 (f) Drugs.

675 (1) Procurement, preparation and storage.

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

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

681 (C) Institutional pharmacies may not sell, purchase, trade or possess prescription drug
682 samples, unless the pharmacy meets all of the following conditions:

683 (i) the pharmacy is owned by a charitable organization described in the Internal Revenue
684 Code of 1986, or by a city, state or county government;

685 (ii) the pharmacy is a part of a health care entity which provides health care primarily to
686 indigent or low income patients at no or reduced cost;

687 (iii) the samples are for dispensing or provision at no charge to patients of such health
688 care entity; and

689 (iv) the samples are possessed in compliance with the federal Prescription Drug Marketing
690 Act of 1986.

691 (D) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in
692 §291.15 of this title (relating to Storage of Drugs).

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

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

697 (2) Formulary.

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

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

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

- 708 (i) the pharmacy and therapeutics committee has developed a formulary;
- 709 (ii) the formulary has been approved by the medical staff committee of the facility;
- 710 (iii) there is a reasonable method for the practitioner to override any interchange; and
- 711 (iv) the practitioner authorizes pharmacists in the facility to interchange on his/her
712 medication orders in accordance with the facility's formulary through his/her written
713 agreement to abide by the policies and procedures of the medical staff and facility.

714 (3) Prepackaging of drugs.

715 (A) Distribution within a facility.

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

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

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

722 (II) facility's unique lot number;

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

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

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

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

727 (II) facility's unique lot number;

728 (III) manufacturer or distributor;

729 (IV) manufacturer's lot number;

730 (V) expiration date;

731 (VI) quantity per prepackaged unit;

732 (VII) number of prepackaged units;

733 (VIII) date packaged;

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

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

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

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

739 (i) Drugs may be prepackaged in quantities suitable for distribution to other Class C
740 (Institutional) pharmacies under common ownership by a pharmacist or by pharmacy
741 technicians or pharmacy technician trainees under the direction and direct supervision of a
742 pharmacist.

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

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

746 (II) facility's unique lot number;

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

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

749 (V) name of the facility responsible for pre-packaging the drug.

750 (iii) Records of pre-packaging shall be maintained to show:

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

752 (II) facility's unique lot number;

753 (III) manufacturer or distributor;

754 (IV) manufacturer's lot number;

755 (V) expiration date;

756 (VI) quantity per prepackaged unit;

757 (VII) number of prepackaged units;

758 (VIII) date packaged;

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

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

761 (XI) name of the facility receiving the pre-packaged drug.

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

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

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

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

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

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

770 (4) Sterile **preparations** [pharmaceuticals] prepared in a location other than the pharmacy.

771 A distinctive supplementary label shall be affixed to the container of any admixture. The
772 label shall bear at a minimum:

773 (A) patient's name and location, **if not immediately administered**;

774 (B) name and amount of drug(s) added;

775 (C) name of the basic solution;

776 (D) name or identifying code of person who prepared admixture; and

777 (E) expiration date of solution.

778 (5) Distribution.

779 (A) Medication orders.

780 (i) Drugs may be given to patients in facilities only on the order of a practitioner. No
781 change in the order for drugs may be made without the approval of a practitioner except as
782 authorized by the practitioner in compliance with paragraph (2)(C) of this subsection.

783 (ii) Drugs may be distributed only from the original or a direct copy of the practitioner's
784 medication order.

785 (iii) **Pharmacy technicians and pharmacy technician trainees** [~~Supportive personnel~~]
786 may not receive verbal medication orders.

787 (iv) Institutional pharmacies shall be exempt from the labeling provisions and patient
788 notification requirements of §562.006 and §562.009 of the Act, as respects drugs distributed
789 pursuant to medication orders.

790 (B) Procedures.

791 (i) Written policies and procedures for a drug distribution system (best suited for the
792 particular institutional pharmacy) shall be developed and implemented by the pharmacist-in-
793 charge, with the advice of the committee performing the pharmacy and therapeutics function
794 for the facility.

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

797 (I) pharmaceutical care services;

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

799 (III) disposal of unusable drugs and supplies;

800 (IV) security;

801 (V) equipment;

802 (VI) sanitation;

803 (VII) reference materials;

804 (VIII) drug selection and procurement;
805 (IX) drug storage;
806 (X) controlled substances;
807 (XI) investigational drugs, including the obtaining of protocols from the principal
808 investigator;
809 (XII) repackaging and manufacturing;
810 (XIII) stop orders;
811 (XIV) reporting of medication errors, adverse drug reactions/events, and drug product
812 defects;
813 (XV) physician orders;
814 (XVI) floor stocks;
815 (XVII) drugs brought into the facility;
816 (XVIII) furlough medications;
817 (XIX) self-administration;
818 (XX) emergency drug supply;
819 (XXI) formulary;
820 (XXII) monthly inspections of nursing stations and other areas where drugs are stored,
821 distributed, administered or dispensed;
822 (XXIII) control of drug samples;
823 (XXIV) outdated and other unusable drugs;
824 (XXV) routine distribution of **patient [inpatient]** medication;
825 (XXVI) preparation and distribution of sterile **preparations** [pharmaceuticals];
826 (XXVII) handling of medication orders when a pharmacist is not on duty;
827 (XXVIII) use of automated compounding or counting devices;
828 (XXIX) use of data processing and direct imaging systems;
829 (XXX) drug administration to include infusion devices **and** [;] drug delivery systems[;
830 ~~and first dose monitoring~~];
831 (XXXI) drug labeling;
832 (XXXII) recordkeeping;
833 (XXXIII) quality assurance/quality control;
834 (XXXIV) duties and education and training of professional and nonprofessional staff;
835 and
836 (XXXV) emergency preparedness plan, to include continuity of patient therapy and
837 public safety.

838 **(6) Discharge Prescriptions. Discharge prescriptions must dispensed and labeled in**
839 **accordance with §291.33 of this title relating to Community Pharmacies (Class A)**
840 **except that certain medications packaged in unit-of-use containers, such as metered-**
841 **dose inhalers, insulin pens, topical creams or ointments, or ophthalmic or otic**
842 **preparation that are administered to the patient during the time the patient was a**
843 **patient in the hospital, may be provided to the patient upon discharge provided the**
844 **pharmacy receives a discharge order and the product bears a label containing the**
845 **following information:**

846 **(A) name of the patient;**

847 **(B) name and strength of the medication;**

848 **(C) name of the prescribing or attending practitioner;**

849 **(D) directions for use;**

850 **(E) duration of therapy (if applicable); and**

851 **(F) name and telephone number of the pharmacy.**

852 (g) Pharmaceutical care services.

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

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

858 (B) Drug regimen review.

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

861 (I) known allergies;

862 (II) rational therapy--contraindications;

863 (III) reasonable dose and route of administration;

864 (IV) reasonable directions for use;

865 (V) duplication of therapy;

866 (VI) drug-drug interactions;

867 (VII) drug-food interactions;

868 (VIII) drug-disease interactions;

869 (IX) adverse drug reactions;

870 (X) proper utilization, including overutilization or underutilization; and

871 (XI) clinical laboratory or clinical monitoring methods to monitor and evaluate drug
872 effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use
873 of the drug in its current regimen.

874 (ii) The drug regimen review shall be conducted on a prospective basis **on all new**
875 **medication orders unless a delay in administration of the drug would harm the patient**
876 **in an urgent situation (including sudden changes in a patient's clinical status)** [~~when a~~
877 ~~pharmacist is on duty, except for an emergency order~~], and on a retrospective basis as
878 specified in subsection (e)(1) of this section **for those medication orders administered**
879 **without a prospective review because a delay in administration of the drug would harm**
880 **the patient in an urgent situation (including sudden changes in a patient's clinical**
881 **status)** [~~when a pharmacist is not on duty~~].

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

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

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

890 (i) the patient and/or patient's caregiver receives information regarding drugs and their
891 safe and appropriate use; and

892 (ii) health care providers are provided with patient specific drug information.

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

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

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

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

901 (C) managing patient compliance programs;

902 (D) providing preventative health care services; and

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

906 (h) Emergency rooms.

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

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

915 —~~[(A) If the patient has been admitted to the emergency room and assessed by a practitioner~~
916 ~~at the hospital, the following procedures shall be observed in supplying prescription drugs~~
917 ~~from the emergency room.]~~

918 **(A)** ~~[(i)]~~ Dangerous drugs and/or controlled substances may only be supplied in
919 accordance with the system of control and accountability for dangerous drugs and/or
920 controlled substances administered or supplied from the emergency room; such system shall
921 be developed and supervised by the pharmacist-in-charge or staff pharmacist designated by
922 the pharmacist-in-charge.

923 **(B)** ~~[(ii)]~~ Only dangerous drugs and/or controlled substances listed on the emergency
924 room drug list may be supplied; such list shall be developed by the pharmacist-in-charge and
925 the facility's emergency department committee (or like group or person responsible for policy
926 in that department) and shall consist of dangerous drugs and/or controlled substances of the
927 nature and type to meet the immediate needs of emergency room patients.

928 **(C)** ~~[(iii)]~~ Dangerous drugs and/or controlled substances may only be supplied in
929 prepackaged quantities not to exceed a 72-hour supply in suitable containers and
930 appropriately prelabeled (including necessary auxiliary labels) by the institutional pharmacy.

931 **(D)** ~~[(iv)]~~ At the time of delivery of the dangerous drugs and/or controlled substances,
932 the practitioner or licensed nurse under the supervision of a practitioner shall appropriately
933 complete the label with at least the following information:

934 **(i)** ~~[(I)]~~ name, address, and phone number of the facility;

935 **(ii)** ~~[(II)]~~ date supplied;

936 **(iii)** ~~[(III)]~~ name of practitioner;

937 **(iv)** ~~{(IV)}~~ name of patient;
938 **(v)** ~~{(V)}~~ directions for use;
939 **(vi)** ~~{(VI)}~~ brand name and strength of the dangerous drug or controlled substance; or if
940 no brand name, then the generic name, strength, and the name of the manufacturer or
941 distributor of the dangerous drug or controlled substance;
942 **(vii)** ~~{(VII)}~~ quantity supplied; and
943 **(viii)** ~~{(VIII)}~~ unique identification number.

944 **(E)** ~~{(v)}~~ The practitioner, or a licensed nurse under the supervision of the practitioner,
945 shall give the appropriately labeled, prepackaged drug to the patient and explain the correct
946 use of the drug.

947 **(F)** ~~{(vi)}~~ A perpetual record of dangerous drugs and/or controlled substances supplied
948 from the emergency room shall be maintained in the emergency room. Such record shall
949 include the following:

950 **(i)** ~~{(I)}~~ date supplied;
951 **(ii)** ~~{(II)}~~ practitioner's name;
952 **(iii)** ~~{(III)}~~ patient's name;
953 **(iv)** ~~{(IV)}~~ brand name and strength of the dangerous drug or controlled substance; or if
954 no brand name, then the generic name, strength, and the name of the manufacturer or
955 distributor of the dangerous drug or controlled substance;
956 **(v)** ~~{(V)}~~ quantity supplied; and
957 **(vi)** ~~{(VI)}~~ unique identification number.

958 **(G)** ~~{(vii)}~~ The pharmacist-in-charge, or staff pharmacist designated by the pharmacist-
959 in-charge, shall verify the correctness of this record at least once every seven days.

960 ~~{(B) If the patient has been admitted to the emergency room of a hospital and a practitioner~~
961 ~~telephones an order for a dangerous drug to be supplied, the following is applicable.}~~

962 ~~{(i) Dangerous drugs may only be supplied to patients of hospitals after the normal~~
963 ~~business hours of local pharmacies and when pharmacy services are not reasonably available~~
964 ~~to the patient.}~~

965 ~~{(ii) The practitioner shall cosign any order for a dangerous drug which is telephoned to~~
966 ~~the hospital emergency room within 72 hours.}~~

967 ~~{(iii) The practitioner shall have a previous patient/physician relationship with the patient~~
968 ~~admitted to the emergency room.}~~

969 ~~{(iv) The dangerous drugs may only be supplied in accordance with the system of control~~
970 ~~and accountability for drugs administered or supplied from the emergency room; such system~~

971 shall be developed and supervised by the pharmacist in charge or staff pharmacist designated
972 by the pharmacist in charge.}]

973 ~~{(v) Only dangerous drugs listed on the emergency room drug list may be supplied; such~~
974 ~~list shall be developed by the pharmacist in charge and the facility's emergency department~~
975 ~~committee (or like group or person responsible for policy in that department) and shall~~
976 ~~consist of dangerous drugs of the nature and type to meet the immediate needs of emergency~~
977 ~~room patients.}]~~

978 ~~{(vi) The dangerous drugs may only be supplied in prepackaged quantities not to exceed a~~
979 ~~72-hour supply in suitable containers and appropriately prelabeled (including necessary~~
980 ~~auxiliary labels) by the institutional pharmacy.}]~~

981 ~~{(vii) At any time of delivery of the dangerous drugs, a licensed nurse shall complete the~~
982 ~~label with at least the following information:}]~~

983 ~~{(I) name, address, and phone number of the facility;}]~~

984 ~~{(II) date supplied;}]~~

985 ~~{(III) name of the practitioner;}]~~

986 ~~{(IV) name of the patient;}]~~

987 ~~{(V) directions for use;}]~~

988 ~~{(VI) brand name and strength of the dangerous drug; or if no brand name, then the~~
989 ~~generic name, strength, and the name of the manufacturer or distributor of the dangerous~~
990 ~~drug;}]~~

991 ~~{(VII) quantity supplied; and}]~~

992 ~~{(VIII) unique identification number.}]~~

993 ~~{(viii) A licensed nurse shall give the appropriately labeled, prepackaged dangerous drug~~
994 ~~to the patient and explain the correct use of the drug.}]~~

995 ~~{(ix) A perpetual record of dangerous drugs supplied from the emergency room shall be~~
996 ~~maintained in the emergency room. Such record shall include the following:}]~~

997 ~~{(I) date supplied;}]~~

998 ~~{(II) practitioner's name;}]~~

999 ~~{(III) patient's name;}]~~

1000 ~~{(IV) brand name and strength of the dangerous drug; or if no brand name, then the~~
1001 ~~generic name, strength, and the name of the manufacturer or distributor of the dangerous~~
1002 ~~drug;}]~~

1003 ~~{(V) quantity supplied; and}]~~

1004 ~~{(VI) unique identification number.}]~~

1005 ~~[(x) The pharmacist in charge or staff pharmacist designated by the pharmacist in charge~~
1006 ~~shall verify the correctness of this record at least once every seven days.]~~

1007 ~~[(C) Prior to implementing the procedures for supplying dangerous drugs to emergency~~
1008 ~~room patients of a hospital on the telephone order of a practitioner, as specified in~~
1009 ~~subparagraph (B) of this paragraph, the hospital shall notify the board of its intent to~~
1010 ~~implement this policy. Such notification shall be signed by the hospital administrator,~~
1011 ~~medical director, and pharmacist in charge and contain the following information:]~~

1012 ~~[(i) the hours the hospital pharmacy is open for pharmacy services; and]~~
1013 ~~[(ii) documentation of the lack of pharmacy services after normal business hours of the~~
1014 ~~hospital pharmacy.]~~

1015 (i) Radiology departments.

1016 (1) During the times a pharmacist is on duty, any prescription drugs dispensed to an
1017 outpatient, including radiology department patients, may only be dispensed by a pharmacist.

1018 (2) When a pharmacist is not on duty, the following procedures shall be observed in
1019 supplying prescription drugs from the radiology department.

1020 (A) Prescription drugs may only be supplied to patients who have been scheduled for an x-
1021 ray examination at the facility.

1022 (B) Prescription drugs may only be supplied in accordance with the system of control and
1023 accountability for prescription drugs administered or supplied from the radiology department
1024 and supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-
1025 in-charge.

1026 (C) Only prescription drugs listed on the radiology drug list may be supplied; such list
1027 shall be developed by the pharmacist-in-charge and the facility's radiology committee (or like
1028 group or persons responsible for policy in that department) and shall consist of drugs for the
1029 preparation of a patient for a radiological procedure.

1030 (D) Prescription drugs may only be supplied in prepackaged quantities in suitable
1031 containers and prelabeled by the institutional pharmacy with the following information:

1032 (i) name and address of the facility;

1033 (ii) directions for use;

1034 (iii) name and strength of the prescription drug--if generic name, the name of the
1035 manufacturer or distributor of the prescription drug;

1036 (iv) quantity;

1037 (v) facility's lot number and expiration date; and

1038 (vi) appropriate ancillary label(s).

1039 (E) At the time of delivery of the prescription drug, the practitioner or practitioner's agent
1040 shall complete the label with the following information:

- 1041 (i) date supplied;
- 1042 (ii) name of physician;
- 1043 (iii) name of patient; and
- 1044 (iv) unique identification number.

1045 (F) The practitioner or practitioner's agent shall give the appropriately labeled,
1046 prepackaged prescription drug to the patient.

1047 (G) A perpetual record of prescription drugs supplied from the radiology department shall
1048 be maintained in the radiology department. Such records shall include the following:

- 1049 (i) date supplied;
- 1050 (ii) practitioner's name;
- 1051 (iii) patient's name;
- 1052 (iv) brand name and strength of the prescription drug; or if no brand name, then the
1053 generic name, strength, dosage form, and the name of the manufacturer or distributor of the
1054 prescription drug;
- 1055 (v) quantity supplied; and
- 1056 (vi) unique identification number.

1057 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge,
1058 shall verify the correctness of this record at least once every seven days.

1059 (j) Automated devices and systems.

1060 (1) Automated compounding or counting devices. If a pharmacy uses automated
1061 compounding or counting devices:

- 1062 (A) the pharmacy shall have a method to calibrate and verify the accuracy of the
1063 automated compounding or counting device and document the calibration and verification on
1064 a routine basis;
- 1065 (B) the devices may be loaded with [~~bulk or~~] unlabeled drugs only by a pharmacist or by
1066 pharmacy technicians under the direction and direct supervision of a pharmacist;
- 1067 (C) the label of an automated compounding or counting device container shall indicate the
1068 brand name and strength of the drug; or if no brand name, then the generic name, strength,
1069 and name of the manufacturer or distributor;
- 1070 (D) records of loading [~~bulk or~~] unlabeled drugs into an automated compounding or
1071 counting device shall be maintained to show:
- 1072 (i) name of the drug, strength, and dosage form;

1073 (ii) manufacturer or distributor;
1074 (iii) manufacturer's lot number;
1075 (iv) expiration date;
1076 (v) date of loading;
1077 (vi) name, initials, or electronic signature of the person loading the automated
1078 compounding or counting device; and
1079 (vii) signature or electronic signature of the responsible pharmacist; and
1080 (E) the automated compounding or counting device shall not be used until a pharmacist
1081 verifies that the system is properly loaded and affixes his or her signature to the record
1082 specified in subparagraph (D) of this paragraph.

1083 (2) Automated medication supply systems.

1084 (A) Authority to use automated medication supply systems. A pharmacy may use an
1085 automated medication supply system to fill medication orders provided that:

1086 (i) the pharmacist-in-charge is responsible for the supervision of the operation of the
1087 system;

1088 (ii) the automated medication supply system has been tested by the pharmacy and found
1089 to dispense accurately. The pharmacy shall make the results of such testing available to the
1090 Board upon request; and

1091 (iii) the pharmacy will make the automated medication supply system available for
1092 inspection by the board for the purpose of validating the accuracy of the system.

1093 (B) Quality assurance program. A pharmacy which uses an automated medication supply
1094 system to fill medication orders shall operate according to a written program for quality
1095 assurance of the automated medication supply system which:

1096 (i) requires continuous monitoring of the automated medication supply system; and

1097 (ii) establishes mechanisms and procedures to test the accuracy of the automated
1098 medication supply system at least every six months and whenever any upgrade or change is
1099 made to the system and documents each such activity.

1100 (C) Policies and procedures of operation.

1101 (i) When an automated medication supply system is used to store or distribute medications
1102 for administration pursuant to medication orders, it shall be operated according to written
1103 policies and procedures of operation. The policies and procedures of operation shall establish
1104 requirements for operation of the automated medication supply system and shall describe
1105 policies and procedures that:

1106 (I) include a description of the policies and procedures of operation;

1107 (II) provide for a pharmacist's review and approval of each original or new medication
1108 order **prior to withdrawal from** ~~{filled through the use of}~~ the automated medication supply
1109 system **unless a delay in administration of the drug would harm the patient in an urgent**
1110 **situation (including sudden changes in a patient's clinical status);**

1111 ~~—— [(a) before the order is filled when a pharmacist is on duty except for an emergency~~
1112 ~~order;~~

1113 ~~—— (b) retrospectively within 72 hours in a facility with a full-time pharmacist when a~~
1114 ~~pharmacist is not on duty at the time the order is made; or~~

1115 ~~—— (c) retrospectively within 7 days in a facility with a part-time or consultant~~
1116 ~~pharmacist when a pharmacist is not on duty at the time the order is made;]~~

1117 (III) provide for access to the automated medication supply system for stocking and
1118 retrieval of medications which is limited to licensed healthcare professionals, pharmacy
1119 technicians, or pharmacy technician trainees acting under the supervision of a pharmacist;

1120 (IV) provide that a pharmacist is responsible for the accuracy of the restocking of the
1121 system. The actual restocking may be performed by a pharmacy technician or pharmacy
1122 technician trainee;

1123 (V) provide for an accountability record to be maintained which documents all
1124 transactions relative to stocking and removing medications from the automated medication
1125 supply system;

1126 (VI) require a prospective or retrospective drug regimen review is conducted as
1127 specified in subsection (g) of this section; and

1128 (VII) establish and make provisions for documentation of a preventative maintenance
1129 program for the automated medication supply system.

1130 (ii) A pharmacy which uses an automated medication supply system to fill medication
1131 orders shall, at least annually, review its written policies and procedures, revise them if
1132 necessary, and document the review.

1133 **(D) Automated medication supply systems used for storage and recordkeeping of**
1134 **medications located outside of the pharmacy department (e.g., Pyxis). A pharmacy**
1135 **technician or pharmacy technician trainee may re-stock an automated medication**
1136 **supply system located outside of the pharmacy department with prescription drugs**
1137 **other than IV admixtures provided:**

1138 **(i) prior to distribution of the prescription drugs a pharmacist verifies the that the**
1139 **prescription drugs pulled to stock the automated supply system match the list of**
1140 **prescription drugs generated by the automated medication supply system;**

- 1141 **(ii) the prescription drugs to re-stock the system are labeled with a machine**
1142 **readable product identifier, such as a barcode;**
1143 **(iv) any previous manipulation of the product such as repackaging or**
1144 **extemporaneous compounding has been checked by a pharmacist; and**
1145 **(v) Quality assurance audits are conducted according to established policies and**
1146 **procedures to ensure accuracy of the process.**

1147 (D) Recovery Plan. A pharmacy which uses an automated medication supply system to
1148 store or distribute medications for administration pursuant to medication orders shall
1149 maintain a written plan for recovery from a disaster or any other situation which interrupts
1150 the ability of the automated medication supply system to provide services necessary for the
1151 operation of the pharmacy. The written plan for recovery shall include:

- 1152 (i) planning and preparation for maintaining pharmacy services when an automated
1153 medication supply system is experiencing downtime;
- 1154 (ii) procedures for response when an automated medication supply system is
1155 experiencing downtime;
- 1156 (iii) procedures for the maintenance and testing of the written plan for recovery; and
- 1157 (iv) procedures for notification of the Board and other appropriate agencies whenever an
1158 automated medication supply system experiences downtime for more than two days of
1159 operation or a period of time which significantly limits the pharmacy's ability to provide
1160 pharmacy services.

1161 (3) Verification of medication orders prepared by the pharmacy department through the use
1162 of an automated medication supply system. A pharmacist must check drugs prepared
1163 pursuant to medication orders to ensure that the drug is prepared for distribution accurately as
1164 prescribed. This paragraph does not apply to automated medication supply systems used for
1165 storage and recordkeeping of medications located outside of the pharmacy department.

1166 (A) This check shall be considered accomplished if:

- 1167 (i) a check of the final product is conducted by a pharmacist after the automated system
1168 has completed preparation of the medication order and prior to delivery to the patient; or
- 1169 (ii) the following checks are conducted by a pharmacist:

1170 (I) if the automated medication supply system contains [~~bulk~~] **unlabeled** stock drugs, a
1171 pharmacist verifies that those drugs have been accurately stocked; and

1172 (II) a pharmacist checks the accuracy of the data entry of each original or new
1173 medication order entered into the automated medication supply system before the order is
1174 filled.

1175 (B) If the final check is accomplished as specified in subparagraph (A)(ii) of this
1176 paragraph, the following additional requirements must be met.

1177 (i) The medication order preparation process must be fully automated from the time the
1178 pharmacist releases the medication order to the automated system until a completed
1179 medication order, ready for delivery to the patient, is produced.

1180 (ii) The pharmacy has conducted initial testing and has a continuous quality assurance
1181 program which documents that the automated medication supply system dispenses accurately
1182 as specified in paragraph (2)(A) and (B) of this subsection.

1183 (iii) The automated medication supply system documents and maintains:

1184 (I) the name(s), initials, or identification code(s) of each pharmacist responsible for the
1185 checks outlined in subparagraph (A)(ii) of this paragraph; and

1186 (II) the name(s), initials, or identification code(s) and specific activity(ies) of each
1187 pharmacist or pharmacy technician who performs any other portion of the medication order
1188 preparation process.

1189 (iv) The pharmacy establishes mechanisms and procedures to test the accuracy of the
1190 automated medication supply system at least every month rather than every six months as
1191 specified in paragraph (2)(B) of this subsection.

1192 (4) Automated checking device.

1193 (A) For the purpose of this subsection, an automated checking device is a fully automated
1194 device which confirms, after a drug is prepared for distribution but prior to delivery to the
1195 patient, that the correct drug and strength has been labeled with the correct label for the
1196 correct patient.

1197 (B) The final check of a drug prepared pursuant to a medication order shall be considered
1198 accomplished using an automated checking device provided:

1199 (i) a check of the final product is conducted by a pharmacist prior to delivery to the
1200 patient or the following checks are performed by a pharmacist:

1201 (I) the prepackaged drug used to fill the order is checked by a pharmacist who verifies
1202 that the drug is labeled and packaged accurately; and

1203 (II) a pharmacist checks the accuracy of each original or new medication order.

1204 (ii) the medication order is prepared, labeled, and made ready for delivery to the patient
1205 in compliance with Class C (Institutional) Pharmacy rules; and

1206 (iii) prior to delivery to the patient:

1207 (I) the automated checking device confirms that the correct drug and strength has been
1208 labeled with the correct label for the correct patient; and

1209 (II) a pharmacist performs all other duties required to ensure that the medication order
1210 has been prepared safely and accurately as prescribed.

1211 (C) If the final check is accomplished as specified in subparagraph (B) of this paragraph,
1212 the following additional requirements must be met.

1213 (i) The pharmacy has conducted initial testing of the automated checking device and has
1214 a continuous quality assurance program which documents that the automated checking
1215 device accurately confirms that the correct drug and strength has been labeled with the
1216 correct label for the correct patient.

1217 (ii) The pharmacy documents and maintains:

1218 (I) the name(s), initials, or identification code(s) of each pharmacist responsible for the
1219 checks outlined in subparagraph (B)(i) of this paragraph; and

1220 (II) the name(s), initials, or identification code(s) and specific activity(ies) of each
1221 pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other
1222 portion of the medication order preparation process.

1223 (iii) The pharmacy establishes mechanisms and procedures to test the accuracy of the
1224 automated checking device at least monthly.

1225

1226 **§291.75 Records.**

1227 (a) Maintenance of records.

1228 (1) Every inventory or other record required to be kept under the provisions of §291.71 of
1229 this title (relating to Purpose), §291.72 of this title (relating to Definitions), §291.73 of this
1230 title (relating to Personnel), §291.74 of this title (relating to Operational Standards), and this
1231 section contained in Institutional Pharmacy (Class C) shall be:

1232 (A) kept by the institutional pharmacy and be available, for at least two years from the date
1233 of such inventory or record, for inspecting and copying by the board or its representative, and
1234 to other authorized local, state, or federal law enforcement agencies; and

1235 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
1236 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
1237 format, the requested records must be provided in a mutually agreeable electronic format if
1238 specifically requested by the board or its representative. Failure to provide the records set out
1239 in this subsection, either on site or within 72 hours, constitutes prima facie evidence of
1240 failure to keep and maintain records in violation of the Act.

1241 (2) Records of controlled substances listed in Schedule I and II shall be maintained
1242 separately from all other records of the pharmacy.

1243 (3) Records of controlled substances listed in Schedules III - V shall be maintained
1244 separately or readily retrievable from all other records of the pharmacy. For purposes of this
1245 subsection, readily retrievable means that the controlled substances shall be asterisked,
1246 redlined, or in some other manner readily identifiable apart from all other items appearing on
1247 the record.

1248 (4) Records, except when specifically required to be maintained in original or hard-copy
1249 form, may be maintained in an alternative data retention system, such as a data processing or
1250 direct imaging system, e.g., microfilm or microfiche, provided:

1251 (A) the records in the alternative data retention system contain all of the information
1252 required on the manual record; and

1253 (B) the alternative data retention system is capable of producing a hard copy of the record
1254 upon the request of the board, its representative, or other authorized local, state, or federal
1255 law enforcement or regulatory agencies.

1256 (b) Outpatient records.

1257 (1) Outpatient records shall be maintained as provided in §291.34 of this title (relating to
1258 Records), and §291.35 of this title (relating to Official Prescription Records), contained in
1259 Community Pharmacy (Class A).

1260 (2) Outpatient prescriptions, including, but not limited to, furlough and discharge
1261 prescriptions, that are written by the practitioner must be written on a form which meets the
1262 requirements of the Act, §562.006. Medication order forms or copies thereof do not meet the
1263 requirements for outpatient forms.

1264 (3) Controlled substances listed in Schedule II must be written on an official prescription
1265 form in accordance with the Texas Controlled Substances Act, §481.075, and rules
1266 promulgated pursuant to the Texas Controlled Substances Act, unless exempted by the Texas
1267 controlled substances regulations, 37 TAC §13.74 (relating to Exceptions to Use of Forms).
1268 Outpatient prescriptions for Schedule II controlled substances that are exempted from the
1269 official prescription requirement must be manually signed by the practitioner.

1270 (c) **Patient** ~~Inpatient~~ records.

1271 (1) Original medication orders.

1272 (A) Each original medication order shall bear the following information:

1273 (i) patient name and room number or identification number;

1274 (ii) drug name, strength, and dosage form;

1275 (iii) directions for use;

1276 (iv) date; and

1277 (v) signature or electronic signature of the practitioner or that of his or her authorized
1278 agent.

1279 (B) Original medication order shall be maintained with the medication administration
1280 records of the patients.

1281 (2) Patient medication records (PMR). A patient medication record shall be maintained for
1282 each **patient** [inpatient] of the facility. The PMR shall contain at a minimum the following
1283 information.

1284 (A) Patient information:

1285 (i) patient name and room number or identification number;

1286 (ii) gender, and date of birth or age;

1287 (iii) weight and height;

1288 (iv) known drug sensitivities and allergies to drugs and/or food;

1289 (v) primary diagnoses and chronic conditions;

1290 (vi) primary physician; and

1291 (vii) other drugs the patient is receiving.

1292 (B) Medication order information:

1293 (i) date of distribution;

1294 (ii) drug name, strength, and dosage form; and

1295 (iii) directions for use.

1296 (3) Controlled substances records. Controlled substances records shall be maintained as
1297 follows.

1298 (A) All records for controlled substances shall be maintained in a readily retrievable
1299 manner.

1300 (B) Controlled substances records shall be maintained in a manner to establish receipt and
1301 distribution of all controlled substances.

1302 (4) Schedule II controlled substances records. Records of controlled substances listed in
1303 Schedule II shall be maintained as follows.

1304 (A) Records of controlled substances listed in Schedule II shall be maintained separately
1305 from records of controlled substances in Schedules III, IV, and V, and all other records.

1306 (B) An institutional pharmacy shall maintain a perpetual inventory of any controlled
1307 substance listed in Schedule II.

1308 (C) Distribution records for controlled substances listed in Schedule II shall bear the
1309 following information:

1310 (i) patient's name;

1311 (ii) prescribing or attending practitioner;
1312 (iii) name of drug, dosage form, and strength;
1313 (iv) time and date of administration to patient and quantity administered;
1314 (v) **name, initials,** [~~signature (first initial and last name or full signature)~~] or electronic
1315 signature of the individual administering the controlled substance;
1316 (vi) returns to the pharmacy; and
1317 (vii) waste (waste is required to be witnessed and cosigned, electronically or manually,
1318 by another individual).
1319 (5) Floor stock records.
1320 (A) Distribution records for Schedule II - V controlled substances floor stock shall include
1321 the following information:
1322 (i) patient's name;
1323 (ii) prescribing or attending practitioner;
1324 (iii) name of controlled substance, dosage form, and strength;
1325 (iv) time and date of administration to patient;
1326 (v) quantity administered;
1327 (vi) **name, initials,** [~~signature (first initial and last name or full signature)~~] or electronic
1328 signature of the individual administering drug;
1329 (vii) returns to the pharmacy; and
1330 (viii) waste (waste is required to be witnessed and cosigned, manually or electronically,
1331 by another individual).
1332 (B) The record required by subparagraph (A) of this paragraph shall be maintained
1333 separately from patient records.
1334 (C) A pharmacist shall review distribution records with medication orders on a periodic
1335 basis to verify proper usage of drugs, not to exceed 30 days between such reviews.
1336 (6) General requirements for records maintained in a data processing system.
1337 (A) Noncompliance with data processing requirements. If a hospital pharmacy's data
1338 processing system is not in compliance with the Board's requirements, the pharmacy must
1339 maintain a manual recordkeeping system.
1340 (B) Requirements for back-up systems. The facility shall maintain a back-up copy of
1341 information stored in the data processing system using disk, tape, or other electronic back-up
1342 system and update this back-up copy on a regular basis, at least monthly, to assure that data
1343 is not lost due to system failure.
1344 (C) Change or discontinuance of a data processing system.

1345 (i) Records of distribution and return for all controlled substances, nalbuphine (e.g.,
1346 Nubain)[, ~~tripleennamine (e.g., PBZ)~~] and carisoprodol (e.g., Soma). A pharmacy that
1347 changes or discontinues use of a data processing system must:

1348 (I) transfer the records to the new data processing system; or

1349 (II) purge the records to a printout which contains the same information as required on
1350 the audit trail printout as specified in paragraph (7)(B) of this subsection. The information on
1351 this printout shall be sorted and printed by drug name and list all distributions/returns
1352 chronologically.

1353 (ii) Other records. A pharmacy that changes or discontinues use of a data processing
1354 system must:

1355 (I) transfer the records to the new data processing system; or

1356 (II) purge the records to a printout which contains all of the information required on the
1357 original document.

1358 (iii) Maintenance of purged records. Information purged from a data processing system
1359 must be maintained by the pharmacy for two years from the date of initial entry into the data
1360 processing system.

1361 (D) Loss of data. The pharmacist-in-charge shall report to the board in writing any
1362 significant loss of information from the data processing system within 10 days of discovery
1363 of the loss.

1364 (7) Data processing system maintenance of records for the distribution and return of all
1365 controlled substances, nalbuphine (e.g., Nubain)[, ~~tripleennamine (e.g., PBZ)~~,] and
1366 carisoprodol (e.g., Soma) to the pharmacy.

1367 (A) Each time a controlled substance, nalbuphine (e.g., Nubain)[, ~~tripleennamine (e.g.,
1368 PBZ)~~,] or carisoprodol (e.g., Soma) is distributed from or returned to the pharmacy, a record
1369 of such distribution or return shall be entered into the data processing system.

1370 (B) The data processing system shall have the capacity to produce a hard copy printout of
1371 an audit trail of drug distribution and return for any strength and dosage form of a drug (by
1372 either brand or generic name or both) during a specified time period. This printout shall
1373 contain the following information:

1374 (i) patient's name and room number or patient's facility identification number;

1375 (ii) prescribing or attending practitioner's name;

1376 (iii) name, strength, and dosage form of the drug product actually distributed;

1377 (iv) total quantity distributed from and returned to the pharmacy;

1378 (v) if not immediately retrievable via **electronic image [CRT display]**, the following
1379 shall also be included on the printout:

1380 (I) prescribing or attending practitioner's address; and

1381 (II) practitioner's DEA registration number, if the medication order is for a controlled
1382 substance.

1383 (C) An audit trail printout for each strength and dosage form of these drugs distributed
1384 during the preceding month shall be produced at least monthly and shall be maintained in a
1385 separate file at the facility **unless the pharmacy complies with subparagraph (D) of this**
1386 **section**. The information on this printout shall be sorted by drug name and list all
1387 distributions/returns for that drug chronologically.

1388 (D) The pharmacy may elect not to produce the monthly audit trail printout if the data
1389 processing system has a workable (electronic) data retention system which can produce an
1390 audit trail of drug distribution and returns for the preceding two years. The audit trail
1391 required in this paragraph shall be supplied by the pharmacy within 72 hours, if requested by
1392 an authorized agent of the Texas State Board of Pharmacy, or other authorized local, state, or
1393 federal law enforcement or regulatory agencies.

1394 (8) Failure to maintain records. Failure to provide records set out in this subsection, either
1395 on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to
1396 keep and maintain records.

1397 (9) Data processing system downtime. In the event that a hospital pharmacy which uses a
1398 data processing system experiences system downtime, the pharmacy must have an auxiliary
1399 procedure which will ensure that all data is retained for on-line data entry as soon as the
1400 system is available for use again.

1401 (d) Distribution of controlled substances to another registrant. A pharmacy may distribute
1402 controlled substances to a practitioner, another pharmacy or other registrant, without being
1403 registered to distribute, under the following conditions.

1404 (1) The registrant to whom the controlled substance is to be distributed is registered under
1405 the Controlled Substances Act to dispense that controlled substance.

1406 (2) The total number of dosage units of controlled substances distributed by a pharmacy
1407 may not exceed 5.0% of all controlled substances dispensed or distributed by the pharmacy
1408 during the 12-month period in which the pharmacy is registered; if at any time it does exceed
1409 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled
1410 substances.

1411 (3) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be
1412 maintained which indicates:

1413 (A) the actual date of distribution;

1414 (B) the name, strength, and quantity of controlled substances distributed;

1415 (C) the name, address, and DEA registration number of the distributing pharmacy;

1416 and (D) the name, address, and DEA registration number of the pharmacy, practitioner, or
1417 other registrant to whom the controlled substances are distributed.

1418 (4) If the distribution is for a Schedule I or II controlled substance, the following is
1419 applicable.

1420 (A) The pharmacy, practitioner or other registrant who is receiving the controlled
1421 substances shall issue copy 1 and copy 2 of a DEA order form (DEA 222) to the distributing
1422 pharmacy.

1423 (B) The distributing pharmacy shall:

1424 (i) complete the area on the DEA order form (DEA 222) titled TO BE FILLED IN BY
1425 SUPPLIER;

1426 (ii) maintain copy 1 of the DEA order form (DEA 222) at the pharmacy for two years;
1427 and

1428 (iii) forward copy 2 of the DEA order form (DEA 222) to the divisional office of the
1429 Drug Enforcement Administration.

1430 (e) Other records. Other records to be maintained by a pharmacy:

1431 (1) a permanent log of the initials or identification codes which will identify pharmacy
1432 personnel by name (the initials or identification code shall be unique to ensure that each
1433 person can be identified, i.e., identical initials or identification codes cannot be used);

1434 (2) copy 3 of DEA order form (DEA 222) which has been properly dated, initialed, and
1435 filed, and all copies of each unaccepted or defective order form and any attached statements
1436 or other documents;

1437 (3) a hard copy of the power of attorney to sign DEA 222 order forms (if applicable);

1438 (4) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall
1439 verify that the controlled drugs listed on the invoices were actually received by clearly
1440 recording his/her initials and the actual date of receipt of the controlled substances;

1441 (5) suppliers' credit memos for controlled substances and dangerous drugs;

1442 (6) a hard copy of inventories required by §291.17 of this title (relating to Inventory
1443 Requirements) except that a perpetual inventory of controlled substances listed in Schedule II

1444 may be kept in a data processing system if the data processing system is capable of producing
1445 a hard copy of the perpetual inventory on-site;

1446 (7) hard copy reports of surrender or destruction of controlled substances and/or dangerous
1447 drugs to an appropriate state or federal agency;

1448 (8) a hard copy Schedule V nonprescription register book;

1449 (9) records of distribution of controlled substances and/or dangerous drugs to other
1450 pharmacies, practitioners, or registrants; and

1451 (10) a hard copy of any notification required by the Texas Pharmacy Act or these sections
1452 including, but not limited to, the following:

1453 (A) reports of theft or significant loss of controlled substances to DEA, DPS, and the
1454 board;

1455 (B) notifications of a change in pharmacist-in-charge of a pharmacy; and

1456 (C) reports of a fire or other disaster which may affect the strength, purity, or labeling of
1457 drugs, medication, devices, or other materials used in diagnosis or treatment of injury, illness,
1458 and disease.

1459 (f) Permission to maintain central records. Any pharmacy that uses a centralized
1460 recordkeeping system for invoices and financial data shall comply with the following
1461 procedures.

1462 (1) Controlled substance records. Invoices and financial data for controlled substances may
1463 be maintained at a central location provided the following conditions are met.

1464 (A) Prior to the initiation of central recordkeeping, the pharmacy submits written
1465 notification by registered or certified mail to the divisional director of the Drug Enforcement
1466 Administration as required by Title 21, Code of Federal Regulations, §1304.04(a), and
1467 submits a copy of this written notification to the Texas State Board of Pharmacy. Unless the
1468 registrant is informed by the divisional director of the Drug Enforcement Administration that
1469 permission to keep central records is denied, the pharmacy may maintain central records
1470 commencing 14 days after receipt of notification by the divisional director.

1471 (B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this
1472 paragraph.

1473 (C) The records to be maintained at the central record location shall not include executed
1474 DEA order forms, prescription drug orders, or controlled substance inventories, which shall
1475 be maintained at the pharmacy.

1476 (2) Dangerous drug records. Invoices and financial data for dangerous drugs may be
1477 maintained at a central location.

1478 (3) Access to records. If the records are kept on microfilm, computer media, or in any form
1479 requiring special equipment to render the records easily readable, the pharmacy shall provide
1480 access to such equipment with the records.

1481 (4) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the
1482 pharmacy location within two business days of written request of a board agent or any other
1483 authorized official.

1484

1485 **§291.76 Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center**

1486

1487 (a) Purpose. The purpose of this section is to provide standards in the conduct, practice
1488 activities, and operation of a pharmacy located in a freestanding ambulatory surgical center
1489 that is licensed by the Texas Department of State Health Services. Class C pharmacies
1490 located in a freestanding ambulatory surgical center shall comply with this section, in lieu of
1491 §§291.71 - 291.75 of this title (relating to Purpose; Definitions; Personnel; Operational
1492 Standards; and Records).

1493 (b) Definitions. The following words and terms, when used in these sections, shall have the
1494 following meanings, unless the context clearly indicates otherwise.

1495 (1) Act--The Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Occupations Code, as
1496 amended.

1497 (2) Ambulatory surgical center (ASC)--A freestanding facility that is licensed by the Texas
1498 Department of State Health Services to provide surgical services to patients who do not
1499 require overnight hospital care.

1500 (3) Automated drug dispensing system--An automated device that measures, counts, and/or
1501 packages a specified quantity of dosage units for a designated drug product.

1502 (4) Board--The Texas State Board of Pharmacy.

1503 (5) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult
1504 with the ASC in areas that pertain to the practice of pharmacy.

1505 (6) Controlled substance--A drug, immediate precursor, or other substance listed in
1506 Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended,
1507 or a drug immediate precursor, or other substance included in Schedule I - V of the Federal
1508 Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law
1509 91-513).

- 1510 (7) Direct copy--Electronic copy or carbonized copy of a medication order including a
1511 facsimile (FAX) **or digital image.** [~~tele-autograph, or a copy transmitted between~~
1512 ~~computers.~~]
- 1513 (8) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription
1514 drug or device in the course of professional practice to an ultimate user or his agent by or
1515 pursuant to the lawful order of a practitioner.
- 1516 (9) Distribute--The delivery of a prescription drug or device other than by administering or
1517 dispensing.
- 1518 (10) Downtime--Period of time during which a data processing system is not operable.
- 1519 (11) Electronic signature--A unique security code or other identifier which specifically
1520 identifies the person entering information into a data processing system. A facility which
1521 utilizes electronic signatures must:
- 1522 (A) maintain a permanent list of the unique security codes assigned to persons authorized
1523 to use the data processing system; and
- 1524 (B) have an ongoing security program which is capable of identifying misuse and/or
1525 unauthorized use of electronic signatures.
- 1526 (12) Floor stock--Prescription drugs or devices not labeled for a specific patient and
1527 maintained at a nursing station or other ASC department (excluding the pharmacy) for the
1528 purpose of administration to a patient of the ASC.
- 1529 (13) Formulary--List of drugs approved for use in the ASC by an appropriate committee of
1530 the ambulatory surgical center.
- 1531 (14) Hard copy--A physical document that is readable without the use of a special device
1532 (i.e., **data processing system, computer, etc** [~~athode-ray tube (CRT), microfiche reader,~~
1533 ~~etc.~~]).
- 1534 (15) Investigational new drug--New drug intended for investigational use by experts
1535 qualified to evaluate the safety and effectiveness of the drug as authorized by the federal
1536 Food and Drug Administration.
- 1537 (16) Medication order--A written order from a practitioner or a verbal order from a
1538 practitioner or his authorized agent for administration of a drug or device.
- 1539 (17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist
1540 who has the authority or responsibility for a pharmacy's compliance with laws and rules
1541 pertaining to the practice of pharmacy.

1542 (18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are
1543 stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other
1544 areas or departments of the ASC, or dispensed to an ultimate user or his or her agent.

1545 (19) Prescription drug--

1546 (A) A substance for which federal or state law requires a prescription before it may be
1547 legally dispensed to the public;

1548 (B) A drug or device that under federal law is required, prior to being dispensed or
1549 delivered, to be labeled with either of the following statements:

1550 (i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another
1551 legend that complies with federal law; or

1552 (ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian;
1553 or

1554 (C) A drug or device that is required by any applicable federal or state law or regulation to
1555 be dispensed on prescription only or is restricted to use by a practitioner only.

1556 (20) Prescription drug order--

1557 (A) A written order from a practitioner or verbal order from a practitioner or his authorized
1558 agent to a pharmacist for a drug or device to be dispensed; or

1559 (B) A written order or a verbal order pursuant to Subtitle B, Chapter 157, Occupations
1560 Code.

1561 (21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per
1562 week or if the pharmacy is open less than 60 hours per week, one-half of the time the
1563 pharmacy is open.

1564 (22) Part-time pharmacist--A pharmacist who works less than full-time.

1565 (23) Pharmacy technician--An individual who is registered with the board as a pharmacy
1566 technician and whose responsibility in a pharmacy is to provide technical services that do not
1567 require professional judgment regarding preparing and distributing drugs and who works
1568 under the direct supervision of and is responsible to a pharmacist.

1569 (24) Pharmacy technician trainee--An individual who is registered with the board as a
1570 pharmacy technician trainee and is authorized to participate in a pharmacy's technician
1571 training program.

1572 (25) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health
1573 and Safety Code, Chapter 481, as amended.

1574 (c) Personnel.

1575 (1) Pharmacist-in-charge.

1576 (A) General. Each ambulatory surgical center shall have one pharmacist-in-charge who is
1577 employed or under contract, at least on a consulting or part-time basis, but may be employed
1578 on a full-time basis.

1579 (B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a
1580 minimum, the following:

1581 (i) establishment of specifications for procurement and storage of all materials, including
1582 drugs, chemicals, and biologicals;

1583 (ii) participation in the development of a formulary for the ASC, subject to approval of
1584 the appropriate committee of the ASC;

1585 (iii) distribution of drugs to be administered to **patients** [~~inpatients~~] pursuant to an
1586 original or direct copy of the practitioner's medication order;

1587 (iv) filling and labeling all containers from which drugs are to be distributed or
1588 dispensed;

1589 (v) maintaining and making available a sufficient inventory of antidotes and other
1590 emergency drugs, both in the pharmacy and **patient** [~~inpatient~~] care areas, as well as current
1591 antidote information, telephone numbers of regional poison control center and other
1592 emergency assistance organizations, and such other materials and information as may be
1593 deemed necessary by the appropriate committee of the ASC;

1594 (vi) records of all transactions of the ASC pharmacy as may be required by applicable
1595 state and federal law, and as may be necessary to maintain accurate control over and
1596 accountability for all pharmaceutical materials;

1597 (vii) participation in those aspects of the ASC's patient care evaluation program which
1598 relate to pharmaceutical material utilization and effectiveness;

1599 (viii) participation in teaching and/or research programs in the ASC;

1600 (ix) implementation of the policies and decisions of the appropriate committee(s) relating
1601 to pharmaceutical services of the ASC;

1602 (x) effective and efficient messenger and delivery service to connect the ASC pharmacy
1603 with appropriate areas of the ASC on a regular basis throughout the normal workday of the
1604 ASC;

1605 (xi) labeling, storage, and distribution of investigational new drugs, including
1606 maintenance of information in the pharmacy and nursing station where such drugs are being
1607 administered, concerning the dosage form, route of administration, strength, actions, uses,
1608 side effects, adverse effects, interactions, and symptoms of toxicity of investigational new
1609 drugs;

1610 (xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this
1611 subsection; and

1612 (xiii) maintenance of records in a data processing system such that the data processing
1613 system is in compliance with the requirements for a Class C (institutional) pharmacy located
1614 in a freestanding ASC.

1615 (2) Consultant pharmacist.

1616 (A) The consultant pharmacist may be the pharmacist-in-charge.

1617 (B) A written contract shall exist between the ASC and any consultant pharmacist, and a
1618 copy of the written contract shall be made available to the board upon request.

1619 (3) Pharmacists.

1620 (A) General.

1621 (i) The pharmacist-in-charge shall be assisted by a sufficient number of additional
1622 licensed pharmacists as may be required to operate the ASC pharmacy competently, safely,
1623 and adequately to meet the needs of the patients of the facility.

1624 (ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as
1625 outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting
1626 for pharmaceutical materials.

1627 (iii) All pharmacists shall be responsible for any delegated act performed by pharmacy
1628 technicians under his or her supervision.

1629 (iv) All pharmacists while on duty shall be responsible for complying with all state and
1630 federal laws or rules governing the practice of pharmacy.

1631 (B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but
1632 need not be limited to, the following:

1633 (i) receiving and interpreting prescription drug orders and oral medication orders and
1634 reducing these orders to writing either manually or electronically;

1635 (ii) selection of prescription drugs and/or devices and/or suppliers; and

1636 (iii) interpreting patient profiles.

1637 (C) Special requirements for compounding.

1638 (i) Non-Sterile Preparations. All pharmacists engaged in compounding non-sterile
1639 preparations shall meet the training requirements specified in §291.131 of this title (relating
1640 to Pharmacies Compounding Non-Sterile Preparations).

1641 (ii) Sterile Preparations. All pharmacists engaged in compounding sterile preparations
1642 shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies
1643 Compounding Sterile Preparations).

1644 (4) Pharmacy technicians and pharmacy technician trainees.

1645 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the
1646 training requirements specified in §297.6 of this title (relating to Pharmacy Technician and
1647 Pharmacy Technician Trainee Training).

1648 (B) Duties. Duties may include, but need not be limited to, the following functions, under
1649 the direct supervision of a pharmacist:

1650 (i) prepacking and labeling unit and multiple dose packages, provided a pharmacist
1651 supervises and conducts **a final check** [~~in-process and final checks~~] and affixes his or her
1652 **name, initials,** [~~signature or~~] electronic signature to the appropriate quality control records
1653 **prior to distribution;**

1654 (ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to
1655 medication orders, provided a pharmacist supervises and checks the preparation;

1656 **(iii) compounding non-sterile preparations pursuant to medication orders provided**
1657 **the pharmacy technicians or pharmacy technician trainees have completed the training**
1658 **specified in §291.131 of this title (relating to Pharmacies Compounding Non-sterile**
1659 **Preparations);**

1660 **(iv) compounding sterile preparations pursuant to medication orders provided the**
1661 **pharmacy technicians or pharmacy technician trainees:**

1662 (I) **have completed the training specified in §291.133 of this title (relating to**
1663 **Pharmacies Compounding Sterile Preparations); and**

1664 (II) **are supervised by a pharmacist who has completed the sterile preparations**
1665 **training specified in §291.133 of this title, conducts in-process and final**
1666 **checks, and affixes his or her name, initials, or electronic signature to the**
1667 **label or if batch prepared to the appropriate quality control records. (The**
1668 **name, initials, or electronic signature are not required on the label if it is**
1669 **maintained in a permanent record of the pharmacy.)**

1670 [~~(iii) compounding non-sterile and sterile preparations pursuant to medication orders;~~

1671 ~~—(I) have completed the training specified in §291.26 of this title (relating to Pharmacies~~
1672 ~~Compounding Sterile Pharmaceuticals); and~~

1673 ~~—(II) are supervised by a pharmacist who has completed the sterile products training~~

1674 ~~specified in §291.26 of this title, conducts in-process and final checks, and affixes his or her~~

1675 ~~initials to the label or if batch prepared, to the appropriate quality control records. (The~~

1676 ~~initials are not required on the label if it is maintained in a permanent record of the~~

1677 ~~pharmacy.)~~}]

1678 (iv) bulk compounding, provided a pharmacist supervises and conducts in-process and
1679 final checks and affixes his or her **name, initials, or electronic signature** to the appropriate
1680 quality control records **prior to distribution**;

1681 (v) distributing routine orders for stock supplies to patient care areas;

1682 (vi) entering medication order and drug distribution information into a data processing
1683 system, provided judgmental decisions are not required and a pharmacist checks the accuracy
1684 of the information entered into the system prior to releasing the order or in compliance with
1685 the absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this
1686 section;

1687 (vii) maintaining inventories of drug supplies;

1688 (viii) maintaining pharmacy records; and

1689 (ix) loading bulk unlabeled drugs into an automated drug dispensing system provided a
1690 pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes
1691 his or her **name, initials or** ~~[signature]~~ or electronic signature to the appropriate quality
1692 control records.

1693 (C) Procedures.

1694 (i) Pharmacy technicians and pharmacy technician trainees shall handle medication
1695 orders in accordance with standard written procedures and guidelines.

1696 (ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug
1697 orders in the same manner as pharmacy technicians working in a Class A pharmacy.

1698 (D) Special requirements for compounding.

1699 (i) Non-Sterile Preparations. All pharmacy technicians and pharmacy technician trainees
1700 engaged in compounding non-sterile preparations shall meet the training requirements
1701 specified in §291.131 of this title.

1702 (ii) Sterile Preparations. All pharmacy technicians and pharmacy technician trainees
1703 engaged in compounding sterile preparations shall meet the training requirements specified
1704 in **§291.133** ~~[§291.131]~~ of this title.

1705 (5) Owner. The owner of an ASC pharmacy shall have responsibility for all administrative
1706 and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner
1707 on administrative and operational concerns. The owner shall have responsibility for, at a
1708 minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall
1709 consult with the pharmacist-in-charge or another Texas licensed pharmacist:

1710 (A) establishment of policies for procurement of prescription drugs and devices and other
1711 products dispensed from the ASC pharmacy;

1712 (B) establishment and maintenance of effective controls against the theft or diversion of
1713 prescription drugs;

1714 (C) if the pharmacy uses an automated pharmacy dispensing system, reviewing and
1715 approving all policies and procedures for system operation, safety, security, accuracy and
1716 access, patient confidentiality, prevention of unauthorized access, and malfunction;

1717 (D) providing the pharmacy with the necessary equipment and resources commensurate
1718 with its level and type of practice; and

1719 (E) establishment of policies and procedures regarding maintenance, storage, and retrieval
1720 of records in a data processing system such that the system is in compliance with state and
1721 federal requirements.

1722 (6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as
1723 follows:

1724 (A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or
1725 badge that bears the person's name and identifies him or her as a pharmacy technician trainee
1726 a registered pharmacy technician, or a certified pharmacy technician, if the technician
1727 maintains current certification with the Pharmacy Technician Certification Board or any
1728 other entity providing an examination approved by the board.

1729 (B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an
1730 identification tag or badge that bears the person's name and identifies him or her as a
1731 pharmacy technician trainee.

1732 (C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that
1733 bears the person's name and identifies him or her as a pharmacist intern.

1734 (D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the
1735 person's name and identifies him or her as a pharmacist.

1736 (d) Operational standards.

1737 (1) Licensing requirements.

1738 (A) An ASC pharmacy shall register annually with the board on a pharmacy license
1739 application provided by the board, following the procedures specified in §291.1 of this title
1740 (relating to Pharmacy License Application).

1741 (B) If the ASC pharmacy is owned or operated by a pharmacy management or consulting
1742 firm, the following conditions apply.

1743 (i) The pharmacy license application shall list the pharmacy management or consulting
1744 firm as the owner or operator.

1745 (ii) The pharmacy management or consulting firm shall obtain DEA and DPS controlled
1746 substances registrations that are issued in the name of the firm, unless the following occur:

1747 (I) the pharmacy management or consulting firm and the facility cosign a contractual
1748 pharmacy service agreement which assigns overall responsibility for controlled substances to
1749 the facility; and

1750 (II) such pharmacy management or consulting firm maintains dual responsibility for the
1751 controlled substances.

1752 (C) An ASC pharmacy which changes ownership shall notify the board within 10 days of
1753 the change of ownership and apply for a new and separate license as specified in §291.3 of
1754 this title (relating to Required Notifications).

1755 (D) An ASC pharmacy which changes location and/or name shall notify the board of the
1756 change within 10 days and file for an amended license as specified in §291.3 of this title.

1757 (E) An ASC pharmacy owned by a partnership or corporation which changes managing
1758 officers shall notify the board in writing of the names of the new managing officers within 10
1759 days of the change, following the procedures in §291.3 of this title.

1760 (F) An ASC pharmacy shall notify the board in writing within 10 days of closing,
1761 following the procedures in §291.5 of this title (relating to **Closing a Pharmacy [Closed**
1762 **Pharmacies]**).

1763 (G) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
1764 charged for issuance and renewal of a license and the issuance of an amended license.

1765 (H) A separate license is required for each principal place of business and only one
1766 pharmacy license may be issued to a specific location.

1767 (I) An ASC pharmacy, licensed under the Act, §560.051(a)(3), concerning institutional
1768 pharmacy (Class C), which also operates another type of pharmacy which would otherwise
1769 be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy
1770 (Class A), or the Act, §560.051(a)(2), concerning nuclear pharmacy (Class B), is not required
1771 to secure a license for the other type of pharmacy; provided, however, such license is
1772 required to comply with the provisions of §291.31 of this title (relating to Definitions),
1773 §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational
1774 Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to
1775 Official Prescription Records), or §291.51 of this title (relating to Purpose), §291.52 of this
1776 title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title
1777 (relating to Operational Standards), and §291.55 of this title (relating to Records), contained

1778 in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of
1779 the pharmacy.

1780 (J) An ASC pharmacy engaged in **the compounding of non-sterile preparations** [~~non-~~
1781 ~~sterile compounding of drug products for inpatients of the hospital~~] shall comply with the
1782 provisions of §291.131 of this title.

1783 (K) An ASC pharmacy engaged in the compounding of sterile **preparations**
1784 [~~pharmaceuticals~~] shall comply with the provisions of §291.133 of this title.

1785 (L) An ASC pharmacy engaged in the provision of remote pharmacy services, including
1786 storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of
1787 this title (relating to Remote Pharmacy Services).

1788 (M) An ASC pharmacy engaged in centralized prescription dispensing and/or prescription
1789 drug or medication order processing shall comply with the provisions of §291.123 of this title
1790 (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125
1791 of this title (relating to Centralized Prescription Dispensing).

1792 (2) Environment.

1793 (A) General requirements.

1794 (i) Each ambulatory surgical center shall have a designated work area separate from
1795 patient areas, and which shall have space adequate for the size and scope of pharmaceutical
1796 services and shall have adequate space and security for the storage of drugs.

1797 (ii) The ASC pharmacy shall be arranged in an orderly fashion and shall be kept clean.
1798 All required equipment shall be clean and in good operating condition.

1799 (B) Special requirements.

1800 (i) The ASC pharmacy shall have locked storage for Schedule II controlled substances
1801 and other controlled drugs requiring additional security.

1802 (ii) The ASC pharmacy shall have a designated area for the storage of poisons and
1803 externals separate from drug storage areas.

1804 (C) Security.

1805 (i) Only authorized personnel may have access to storage areas for prescription drugs
1806 and/or devices.

1807 (ii) All storage areas for prescription drugs and/or devices shall be locked by key or
1808 combination, so as to prevent access by unauthorized personnel.

1809 (iii) The pharmacist-in-charge shall consult with ASC personnel with respect to security
1810 of the drug storage areas, including provisions for adequate safeguards against theft or
1811 diversion of prescription drugs and/or devices.

1812 (3) Equipment and supplies. Ambulatory surgical centers supplying drugs for postoperative
1813 use shall have the following equipment and supplies:

1814 (A) **data processing system including a printer** [~~typewriter~~] or comparable equipment;
1815 and

1816 (B) adequate supply of child-resistant, moisture-proof, and light-proof containers;

1817 (C) adequate supply of prescription labels and other applicable identification labels;

1818 (4) Library. A reference library shall be maintained **that** [~~which~~] includes the following in
1819 hard-copy or electronic format **and that pharmacy personnel shall be capable of accessing**
1820 **at all times**:

1821 (A) current copies of the following:

1822 (i) Texas Pharmacy Act and rules;

1823 (ii) Texas Dangerous Drug Act and rules;

1824 (iii) Texas Controlled Substances Act and rules;

1825 (iv) Federal Controlled Substances Act and rules or official publication describing the
1826 requirements of the Federal Controlled Substances Act and rules;

1827 (B) at least one current or updated reference from each of the following categories:

1828 (i) Drug interactions. A reference text on drug interactions, such as Drug Interaction
1829 Facts. A separate reference is not required if other references maintained by the pharmacy
1830 contain drug interaction information including information needed to determine severity or
1831 significance of the interaction and appropriate recommendations or actions to be taken;

1832 (ii) General information. A general information reference text, such as:

1833 (I) Facts and Comparisons with current supplements;

1834 (II) United States Pharmacopeia Dispensing Information Volume I (Drug Information
1835 for the Healthcare Provider);

1836 (III) AHFS Drug Information with current supplements;

1837 (IV) Remington's Pharmaceutical Sciences; or

1838 (V) Clinical Pharmacology;

1839 (C) a current or updated reference on injectable drug products, such as Handbook of
1840 Injectable Drugs;

1841 (D) basic antidote information and the telephone number of the nearest regional poison
1842 control center.

1843 (E) if the pharmacy compounds sterile preparations, specialty references appropriate for
1844 the scope of services provided by the pharmacy, e.g., if the pharmacy prepares cytotoxic

1845 drugs, a reference text on the preparation of cytotoxic drugs, such as Procedures for Handling
1846 Cytotoxic Drugs.

1847 (F) metric-apothecary weight and measure conversion charts.

1848 (5) Drugs.

1849 (A) Procurement, preparation, and storage.

1850 (i) The pharmacist-in-charge shall have the responsibility for the procurement and storage
1851 of drugs, but may receive input from other appropriate staff of the facility, relative to such
1852 responsibility.

1853 (ii) The pharmacist-in-charge shall have the responsibility for determining specifications
1854 of all drugs procured by the facility.

1855 (iii) ASC pharmacies may not sell, purchase, trade, or possess prescription drug samples,
1856 unless the pharmacy meets all of the following conditions:

1857 (I) the pharmacy is owned by a charitable organization described in the Internal
1858 Revenue Code of 1986, or by a city, state or county government;

1859 (II) the pharmacy is a part of a health care entity which provides health care primarily to
1860 indigent or low income patients at no or reduced cost;

1861 (III) the samples are for dispensing or provision at no charge to patients of such health
1862 care entity; and

1863 (IV) the samples are possessed in compliance with the federal Prescription Drug
1864 Marketing Act of 1986.

1865 (iv) All drugs shall be stored at the proper temperatures, as defined **in the USP/NF and**
1866 **in §291.15 of this title (relating to Storage of Drugs.)** [by the following terms.]

1867 ~~[(I) Room temperature—temperature maintained between 15 degrees Celsius (59 degrees~~
1868 ~~Fahrenheit) and 30 degrees Celsius (86 degrees Fahrenheit).~~

1869 ~~—(II) Cool—temperature between 8 degrees Celsius (46 degrees Fahrenheit) and 15~~
1870 ~~degrees Celsius (59 degrees Fahrenheit). An article for which storage in a cool place is~~
1871 ~~directed may, alternatively, be stored in a refrigerator unless otherwise specified on the~~
1872 ~~labeling.~~

1873 ~~—(III) Refrigerate—temperature that is thermostatically maintained between 2 degrees~~
1874 ~~Celsius (36 degrees Fahrenheit) and 8 degrees Celsius (46 degrees Fahrenheit).~~

1875 ~~—(IV) Freeze—temperature that is thermostatically maintained between minus 20 degrees~~
1876 ~~Celsius (minus 4 degrees Fahrenheit) and minus 10 degrees Celsius (14 degrees Fahrenheit).]~~

1877 (v) Any drug bearing an expiration date may not be dispensed or distributed beyond the
1878 expiration date of the drug.

1879 (vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined
1880 together until such drugs are disposed of.

1881 (B) Formulary.

1882 (i) A formulary may be developed by an appropriate committee of the ambulatory
1883 surgical center.

1884 (ii) The pharmacist-in-charge or consultant pharmacist shall be a full voting member of
1885 any committee which involves pharmaceutical services.

1886 (C) Prepackaging of drugs and loading of bulk unlabeled drugs into automated drug
1887 dispensing system.

1888 (i) Prepackaging of drugs.

1889 (I) Drugs may be prepackaged in quantities suitable for internal distribution only by a
1890 pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction
1891 and direct supervision of a pharmacist.

1892 (II) The label of a prepackaged unit shall indicate:

1893 (-a-) brand name and strength of the drug; or if no brand name, then the generic name,
1894 strength, and name of the manufacturer or distributor;

1895 (-b-) facility's lot number;

1896 (-c-) expiration date; and

1897 (-d-) quantity of the drug, if quantity is greater than one.

1898 (III) Records of prepackaging shall be maintained to show:

1899 (-a-) the name of the drug, strength, and dosage form;

1900 (-b-) facility's lot number;

1901 (-c-) manufacturer or distributor;

1902 (-d-) manufacturer's lot number;

1903 (-e-) expiration date;

1904 (-f-) quantity per prepackaged unit;

1905 (-g-) number of prepackaged units;

1906 (-h-) date packaged;

1907 (-i-) name, initials, or electronic signature of the packer; and

1908 (-j-) signature or electronic signature of the responsible pharmacist.

1909 (IV) Stock packages, repackaged units, and control records shall be quarantined together
1910 until checked/released by the pharmacist.

1911 (ii) Loading bulk unlabeled drugs into automated drug dispensing systems.

1912 (I) Automated drug dispensing systems may be loaded with bulk unlabeled drugs only
1913 by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the
1914 direction and direct supervision of a pharmacist.

1915 (II) The label of an automated drug dispensing system container shall indicate the brand
1916 name and strength of the drug; or if no brand name, then the generic name, strength, and
1917 name of the manufacturer or distributor.

1918 (III) Records of loading bulk unlabeled drugs into an automated drug dispensing system
1919 shall be maintained to show:

1920 (-a-) name of the drug, strength, and dosage form;

1921 (-b-) manufacturer or distributor;

1922 (-c-) manufacturer's lot number;

1923 (-d-) expiration date;

1924 (-e-) date of loading;

1925 (-f-) name, initials, or electronic signature of the person loading the automated drug
1926 dispensing system; and

1927 (-g-) signature or electronic signature of the responsible pharmacist.

1928 (IV) The automated drug dispensing system shall not be used until a pharmacist verifies
1929 that the system is properly loaded and affixes his or her signature or electronic signature to
1930 the record specified in subclause (III) of this clause.

1931 (6) Medication orders.

1932 (A) Drugs may be administered to patients in ASCs only on the order of a practitioner. No
1933 change in the order for drugs may be made without the approval of a practitioner.

1934 (B) Drugs may be distributed only pursuant to the original or a direct copy of the
1935 practitioner's medication order.

1936 (C) Pharmacy technicians and pharmacy technician trainees may not receive oral
1937 medication orders.

1938 (D) ASC pharmacies shall be exempt from the labeling provisions and patient notification
1939 requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to
1940 medication orders.

1941 (E) In ASCs with a full-time pharmacist, if a practitioner orders a drug for administration
1942 to a bona fide patient of the facility when the pharmacy is closed, the following is applicable.

1943 (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic
1944 needs of a patient may be removed from the ASC pharmacy.

1945 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

1946 (iii) A record shall be made at the time of withdrawal by the authorized person removing
1947 the drugs and devices. The record shall contain the following information:

1948 (I) name of the patient;
1949 (II) name of device or drug, strength, and dosage form;
1950 (III) dose prescribed;
1951 (IV) quantity taken;
1952 (V) time and date; and
1953 (VI) signature or electronic signature of person making withdrawal.

1954 (iv) The original or direct copy of the medication order may substitute for such record,
1955 provided the medication order meets all the requirements of clause (iii) of this subparagraph.

1956 (v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more
1957 than 72 hours from the time of such withdrawal.

1958 (F) In ASCs with a part-time or consultant pharmacist, if a practitioner orders a drug for
1959 administration to a bona fide patient of the ASC when the pharmacist is not on duty, or when
1960 the pharmacy is closed, the following is applicable.

1961 (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may
1962 be removed from the ASC pharmacy.

1963 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

1964 (iii) A record shall be made at the time of withdrawal by the authorized person removing
1965 the drugs and devices; the record shall meet the same requirements as specified in
1966 subparagraph (E)(iii) of this paragraph.

1967 (iv) The pharmacist shall verify each distribution after a reasonable interval, but in no
1968 event may such interval exceed seven days.

1969 (7) Floor stock. In facilities using a floor stock method of drug distribution, the following is
1970 applicable for removing drugs or devices in the absence of a pharmacist.

1971 (A) Prescription drugs and devices may be removed from the pharmacy only in the
1972 original manufacturer's container or prepackaged container.

1973 (B) Only a designated licensed nurse or practitioner may remove such drugs and devices.

1974 (C) A record shall be made at the time of withdrawal by the authorized person removing
1975 the drug or device; the record shall contain the following information:

1976 (i) name of the drug, strength, and dosage form;
1977 (ii) quantity removed;
1978 (iii) location of floor stock;
1979 (iv) date and time; and

1980 (v) signature or electronic signature of person making the withdrawal.

1981 (D) A pharmacist shall verify the withdrawal according to the following schedule.

1982 (i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as

1983 practical, but in no event more than 72 hours from the time of such withdrawal.

1984 (ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified

1985 after a reasonable interval, but in no event may such interval exceed seven days.

1986 (8) Policies and procedures. Written policies and procedures for a drug distribution system,

1987 appropriate for the ambulatory surgical center, shall be developed and implemented by the

1988 pharmacist-in-charge with the advice of the appropriate committee. The written policies and

1989 procedures for the drug distribution system shall include, but not be limited to, procedures

1990 regarding the following:

1991 (A) controlled substances;

1992 (B) investigational drugs;

1993 (C) prepackaging and manufacturing;

1994 (D) medication errors;

1995 (E) orders of physician or other practitioner;

1996 (F) floor stocks;

1997 (G) adverse drug reactions;

1998 (H) drugs brought into the facility by the patient;

1999 (I) self-administration;

2000 (J) emergency drug tray;

2001 (K) formulary, if applicable;

2002 (L) drug storage areas;

2003 (M) drug samples;

2004 (N) drug product defect reports;

2005 (O) drug recalls;

2006 (P) outdated drugs;

2007 (Q) preparation and distribution of IV admixtures;

2008 (R) procedures for supplying drugs for postoperative use, if applicable;

2009 (S) use of automated drug dispensing systems; and

2010 (T) use of data processing systems.

2011 (9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use

2012 shall be supplied according to the following procedures.

2013 (A) Drugs may only be supplied to patients who have been admitted to the ambulatory
2014 surgical center.

2015 (B) Drugs may only be supplied in accordance with the system of control and
2016 accountability established for drugs supplied from the ambulatory surgical center; such
2017 system shall be developed and supervised by the pharmacist-in-charge or staff pharmacist
2018 designated by the pharmacist-in-charge.

2019 (C) Only drugs listed on the approved postoperative drug list may be supplied; such list
2020 shall be developed by the pharmacist-in-charge and the medical staff and shall consist of
2021 drugs of the nature and type to meet the immediate postoperative needs of the ambulatory
2022 surgical center patient.

2023 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply
2024 in suitable containers and appropriately pre-labeled (including necessary auxiliary labels) by
2025 the pharmacy, provided, however that topicals and ophthalmics in original manufacturer's
2026 containers may be supplied in a quantity exceeding a 72-hour supply.

2027 (E) At the time of delivery of the drug, the practitioner shall complete the label, such that
2028 the prescription container bears a label with at least the following information:

2029 (i) date supplied;

2030 (ii) name of practitioner;

2031 (iii) name of patient;

2032 (iv) directions for use;

2033 (v) brand name and strength of the drug; or if no brand name, then the generic name of
2034 the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

2035 (vi) unique identification number.

2036 (F) After the drug has been labeled by the practitioner, the practitioner or a licensed nurse
2037 under the supervision of the practitioner shall give the appropriately labeled, prepackaged
2038 medication to the patient.

2039 (G) A perpetual record of drugs which are supplied from the ASC shall be maintained
2040 which includes:

2041 (i) name, address, and phone number of the facility;

2042 (ii) date supplied;

2043 (iii) name of practitioner;

2044 (iv) name of patient;

2045 (v) directions for use;

2046 (vi) brand name and strength of the drug; or if no brand name, then the generic name of
2047 the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and
2048 (vii) unique identification number.

2049 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge,
2050 shall review the records at least once every seven days.

2051 (e) Records.

2052 (1) Maintenance of records.

2053 (A) Every inventory or other record required to be kept under the provisions of this section
2054 (relating to Institutional Pharmacy (Class C)) shall be:

2055 (i) kept by the pharmacy and be available, for at least two years from the date of such
2056 inventory or record, for inspecting and copying by the board or its representative, and other
2057 authorized local, state, or federal law enforcement agencies; and

2058 (ii) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
2059 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
2060 format, the requested records must be provided in a mutually agreeable electronic format if
2061 specifically requested by the board or its representative. Failure to provide the records set out
2062 in this subsection, either on site or within 72 hours, constitutes prima facie evidence of
2063 failure to keep and maintain records in violation of the Act.

2064 (B) Records of controlled substances listed in Schedules I and II shall be maintained
2065 separately from all other records of the pharmacy.

2066 (C) Records of controlled substances listed in Schedules III - V shall be maintained
2067 separately or readily retrievable from all other records of the pharmacy. For purposes of this
2068 subsection, readily retrievable means that the controlled substances shall be asterisked, red-
2069 lined, or in some other manner readily identifiable apart from all other items appearing on the
2070 record.

2071 (D) Records, except when specifically required to be maintained in original or hard-copy
2072 form, may be maintained in an alternative data retention system, such as a data processing or
2073 direct imaging system, e.g., microfilm or microfiche, provided:

2074 (i) the records in the alternative data retention system contain all of the information
2075 required on the manual record; and

2076 (ii) the alternative data retention system is capable of producing a hard copy of the record
2077 upon the request of the board, its representative, or other authorized local, state, or federal
2078 law enforcement or regulatory agencies.

2079 (2) Outpatient records.

2080 (A) Only a registered pharmacist may receive, certify, and receive prescription drug
2081 orders.

2082 (B) Outpatient records shall be maintained as provided in §291.34 and §291.35 of this title
2083 contained in Community Pharmacy (Class A).

2084 (C) Outpatient prescriptions, including, but not limited to, discharge prescriptions, that are
2085 written by the practitioner, must be written on a form which meets the requirements of the
2086 Act, §562.006. Medication order forms or copies thereof do not meet the requirements for
2087 outpatient forms.

2088 (D) Controlled substances listed in Schedule II must be written on an electronic
2089 prescription form in accordance with the Texas Controlled Substances Act, §481.075, and
2090 rules promulgated pursuant to the Texas Controlled Substances Act, unless exempted by the
2091 Texas Controlled Substances Rules, 37 TAC §13.74. Outpatient prescriptions for Schedule II
2092 controlled substances that are exempted from the official prescription requirement must be
2093 manually signed by the practitioner.

2094 (3) **Patient** [~~Inpatient~~] records.

2095 (A) Each original medication order or set of orders issued together shall bear the following
2096 information:

2097 (i) patient name;

2098 (ii) drug name, strength, and dosage form;

2099 (iii) directions for use;

2100 (iv) date; and

2101 (v) signature or electronic signature of the practitioner or that of his or her authorized
2102 agent, defined as a licensed nurse employee or consultant/full or part-time pharmacist of the
2103 ASC.

2104 (B) Original medication orders shall be maintained with the medication administration
2105 record in the medical records of the patient.

2106 (C) Controlled substances records shall be maintained as follows.

2107 (i) All records for controlled substances shall be maintained in a readily retrievable
2108 manner.

2109 (ii) Controlled substances records shall be maintained in a manner to establish receipt and
2110 distribution of all controlled substances.

2111 (D) Records of controlled substances listed in Schedule II shall be maintained as follows.

2112 (i) Records of controlled substances listed in Schedule II shall be maintained separately
2113 from records of controlled substances in Schedules III, IV, and V, and all other records.

2114 (ii) An ASC pharmacy shall maintain a perpetual inventory of any controlled substance
2115 listed in Schedule II.

2116 (iii) Distribution records for Schedule II - V controlled substances floor stock shall
2117 include the following information:

2118 (I) patient's name;

2119 (II) practitioner who ordered drug;

2120 (III) name of drug, dosage form, and strength;

2121 (IV) time and date of administration to patient and quantity administered;

2122 (V) signature or electronic signature of individual administering controlled substance;

2123 (VI) returns to the pharmacy; and

2124 (VII) waste (waste is required to be witnessed and cosigned, manually or electronically,
2125 by another individual).

2126 (E) Floor stock records shall be maintained as follows.

2127 (i) Distribution records for Schedules III - V controlled substances floor stock shall
2128 include the following information:

2129 (I) patient's name;

2130 (II) practitioner who ordered controlled substance;

2131 (III) name of controlled substance, dosage form, and strength;

2132 (IV) time and date of administration to patient;

2133 (V) quantity administered;

2134 (VI) signature or electronic signature of individual administering drug;

2135 (VII) returns to the pharmacy; and

2136 (VIII) waste (waste is required to be witnessed and cosigned, manually or electronically,
2137 by another individual).

2138 (ii) The record required by clause (i) of this subparagraph shall be maintained separately
2139 from patient records.

2140 (iii) A pharmacist shall review distribution records with medication orders on a periodic
2141 basis to verify proper usage of drugs, not to exceed 30 days between such reviews.

2142 (F) General requirements for records maintained in a data processing system are as
2143 follows.

2144 (i) If an ASC pharmacy's data processing system is not in compliance with the board's
2145 requirements, the pharmacy must maintain a manual recordkeeping system.

2146 (ii) Requirements for backup systems. The facility shall maintain a backup copy of
2147 information stored in the data processing system using disk, tape, or other electronic backup

2148 system and update this backup copy on a regular basis to assure that data is not lost due to
2149 system failure.

2150 (iii) Change or discontinuance of a data processing system.

2151 (I) Records of distribution and return for all controlled substances, nalbuphine (Nubain),
2152 and **carisoprodol (Soma)** [~~tripleannamine (PBZ)~~]. A pharmacy that changes or discontinues
2153 use of a data processing system must:

2154 (-a-) transfer the records to the new data processing system; or

2155 (-b-) purge the records to a printout which contains the same information as required
2156 on the audit trail printout as specified in subparagraph (G)(ii) of this paragraph. The
2157 information on this printout shall be sorted and printed by drug name and list all
2158 distributions/returns chronologically.

2159 (II) Other records. A pharmacy that changes or discontinues use of a data processing
2160 system must:

2161 (-a-) transfer the records to the new data processing system; or

2162 (-b-) purge the records to a printout which contains all of the information required on
2163 the original document.

2164 (III) Maintenance of purged records. Information purged from a data processing system
2165 must be maintained by the pharmacy for two years from the date of initial entry into the data
2166 processing system.

2167 (iv) Loss of data. The pharmacist-in-charge shall report to the board in writing any
2168 significant loss of information from the data processing system within 10 days of discovery
2169 of the loss.

2170 (G) Data processing system maintenance of records for the distribution and return of all
2171 controlled substances, nalbuphine (Nubain), or **carisoprodol (Soma)** [~~tripleannamine (PBZ)~~]
2172 to the pharmacy.

2173 (i) Each time a controlled substance, nalbuphine (Nubain), or **carisoprodol (Soma)**
2174 [~~tripleannamine (PBZ)~~] is distributed from or returned to the pharmacy, a record of such
2175 distribution or return shall be entered into the data processing system.

2176 (ii) The data processing system shall have the capacity to produce a hard-copy printout of
2177 an audit trail of drug distribution and return for any strength and dosage form of a drug (by
2178 either brand or generic name or both) during a specified time period. This printout shall
2179 contain the following information:

2180 (I) patient's name and room number or patient's facility identification number;

2181 (II) prescribing or attending practitioner's name;

2182 (III) name, strength, and dosage form of the drug product actually distributed;
2183 (IV) total quantity distributed from and returned to the pharmacy;
2184 (V) if not immediately retrievable via **electronic image** [~~CRT display~~], the following
2185 shall also be included on the printout:

- 2186 (-a-) prescribing or attending practitioner's address; and
- 2187 (-b-) practitioner's DEA registration number, if the medication order is for a controlled
2188 substance.

2189 (iii) An audit trail printout for each strength and dosage form of these drugs distributed
2190 during the preceding month shall be produced at least monthly and shall be maintained in a
2191 separate file at the facility. The information on this printout shall be sorted by drug name and
2192 list all distributions/returns for that drug chronologically.

2193 (iv) The pharmacy may elect not to produce the monthly audit trail printout if the data
2194 processing system has a workable (electronic) data retention system which can produce an
2195 audit trail of drug distribution and returns for the preceding two years. The audit trail
2196 required in this clause shall be supplied by the pharmacy within 72 hours, if requested by an
2197 authorized agent of the Texas State Board of Pharmacy, or other authorized local, state, or
2198 federal law enforcement or regulatory agencies.

2199 (H) Failure to maintain records. Failure to provide records set out in this subsection, either
2200 on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to
2201 keep and maintain records.

2202 (I) Data processing system downtime. In the event that an ASC pharmacy which uses a
2203 data processing system experiences system downtime, the pharmacy must have an auxiliary
2204 procedure which will ensure that all data is retained for on-line data entry as soon as the
2205 system is available for use again.

2206 (4) Distribution of controlled substances to another registrant. A pharmacy may distribute
2207 controlled substances to a practitioner, another pharmacy, or other registrant, without being
2208 registered to distribute, under the following conditions.

2209 (A) The registrant to whom the controlled substance is to be distributed is registered under
2210 the Controlled Substances Act to dispense that controlled substance.

2211 (B) The total number of dosage units of controlled substances distributed by a pharmacy
2212 may not exceed 5.0% of all controlled substances dispensed by the pharmacy during the 12-
2213 month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the
2214 pharmacy is required to obtain an additional registration to distribute controlled substances.

2215 (C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be
2216 maintained which indicates:

- 2217 (i) the actual date of distribution;
- 2218 (ii) the name, strength, and quantity of controlled substances distributed;
- 2219 (iii) the name, address, and DEA registration number of the distributing pharmacy; and
- 2220 (iv) the name, address, and DEA registration number of the pharmacy, practitioner, or
2221 other registrant to whom the controlled substances are distributed.

2222 (D) If the distribution is for a Schedule I or II controlled substance, the following is
2223 applicable.

- 2224 (i) The pharmacy, practitioner, or other registrant who is receiving the controlled
2225 substances shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222C) to the
2226 distributing pharmacy.
- 2227 (ii) The distributing pharmacy shall:
 - 2228 (I) complete the area on the DEA order form (DEA 222C) titled "To Be Filled in by
2229 Supplier";
 - 2230 (II) maintain Copy 1 of the DEA order form (DEA 222C) at the pharmacy for two years;
2231 and
 - 2232 (III) forward Copy 2 of the DEA order form (DEA 222C) to the divisional office of the
2233 Drug Enforcement Administration.
- 2234 (5) Other records. Other records to be maintained by the pharmacy include:
 - 2235 (A) a permanent log of the initials or identification codes which will identify each
2236 pharmacist by name. The initials or identification code shall be unique to ensure that each
2237 pharmacist can be identified, i.e., identical initials or identification codes cannot be used;
 - 2238 (B) Copy 3 of DEA order form (DEA 222C), which has been properly dated, initialed, and
2239 filed, and all copies of each unaccepted or defective order form and any attached statements
2240 or other documents;
 - 2241 (C) a hard copy of the power of attorney to sign DEA 222C order forms (if applicable);
 - 2242 (D) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall
2243 verify that the controlled drugs listed on the invoices were actually received by clearly
2244 recording his/her initials and the actual date of receipt of the controlled substances;
 - 2245 (E) supplier's credit memos for controlled substances and dangerous drugs;
 - 2246 (F) a hard copy of inventories required by §291.17 of this title (relating to Inventory
2247 Requirements) except that a perpetual inventory of controlled substances listed in Schedule II

2248 may be kept in a data processing system if the data processing system is capable of producing
2249 a hard copy of the perpetual inventory on-site;

2250 (G) hard-copy reports of surrender or destruction of controlled substances and/or
2251 dangerous drugs to an appropriate state or federal agency;

2252 (H) a hard-copy Schedule V nonprescription register book;

2253 (I) records of distribution of controlled substances and/or dangerous drugs to other
2254 pharmacies, practitioners, or registrants; and

2255 (J) a hard copy of any notification required by the Texas Pharmacy Act or these rules,
2256 including, but not limited to, the following:

2257 (i) reports of theft or significant loss of controlled substances to DEA, DPS, and the
2258 board;

2259 (ii) notification of a change in pharmacist-in-charge of a pharmacy; and

2260 (iii) reports of a fire or other disaster which may affect the strength, purity, or labeling of
2261 drugs, medications, devices, or other materials used in the diagnosis or treatment of injury,
2262 illness, and disease.

2263 (6) Permission to maintain central records. Any pharmacy that uses a centralized
2264 recordkeeping system for invoices and financial data shall comply with the following
2265 procedures.

2266 (A) Controlled substance records. Invoices and financial data for controlled substances
2267 may be maintained at a central location provided the following conditions are met.

2268 (i) Prior to the initiation of central recordkeeping, the pharmacy submits written
2269 notification by registered or certified mail to the divisional director of the Drug Enforcement
2270 Administration as required by the Code of Federal Regulations, Title 21, §1304(a), and
2271 submits a copy of this written notification to the Texas State Board of Pharmacy. Unless the
2272 registrant is informed by the divisional director of the Drug Enforcement Administration that
2273 permission to keep central records is denied, the pharmacy may maintain central records
2274 commencing 14 days after receipt of notification by the divisional director.

2275 (ii) The pharmacy maintains a copy of the notification required in this subparagraph.

2276 (iii) The records to be maintained at the central record location shall not include executed
2277 DEA order forms, prescription drug orders, or controlled substance inventories, which shall
2278 be maintained at the pharmacy.

2279 (B) Dangerous drug records. Invoices and financial data for dangerous drugs may be
2280 maintained at a central location.

2281 (C) Access to records. If the records are kept on microfilm, computer media, or in any
2282 form requiring special equipment to render the records easily readable, the pharmacy shall
2283 provide access to such equipment with the records.

2284 (D) Delivery of records. The pharmacy agrees to deliver all or any part of such records to
2285 the pharmacy location within two business days of written request of a board agent or any
2286 other authorized official.

2287 ~~[(7) Confidentiality.~~

2288

2289 ~~—(A) A pharmacist shall provide adequate security of prescription drug orders, medication~~
2290 ~~orders, and patient medication records to prevent indiscriminate or unauthorized access to~~
2291 ~~confidential health information.~~

2292 ~~—(B) Confidential records are privileged and may be released only to:~~

2293 ~~—(i) the patient or the patient's agent;~~

2294 ~~—(ii) a practitioner or another pharmacist if, in the pharmacist's professional judgement, the~~
2295 ~~release is necessary to protect the patient's health and well being;~~

2296 ~~—(iii) the board or to a person or another state or federal agency authorized by law to~~
2297 ~~receive the confidential record;~~

2298 ~~—(iv) a law enforcement agency engaged in investigation of a suspected violation of~~
2299 ~~Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention~~
2300 ~~and Control Act of 1970 (21 U.S.C. Section 801 et seq.);~~

2301 ~~—(v) a person employed by a state agency that licenses a practitioner, if the person is~~
2302 ~~performing the person's official duties; or~~

2303 ~~—(vi) an insurance carrier or other third party payor authorized by a patient to receive such~~
2304 ~~information.~~