

RULE ANALYSIS

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

Short Title: Concerning Class C Pharmacies Located in Freestanding Ambulatory Surgical Centers and Class F Pharmacies Located in Freestanding Emergency Medical Care Centers

Rule Numbers: §§291.76, 291.151

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

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

Purpose: The amendments to §291.76, if adopted, update the rules for pharmacies in Freestanding Ambulatory Surgical Centers to be consistent with other sections; eliminate language that is no longer necessary; and correct grammar. The amendments, if adopted, update the rules for pharmacies in Freestanding Emergency Medical Care Centers to be consistent with other sections; eliminate language that is no longer necessary; and correct grammar.

The Board reviewed and voted to propose the amendments during the August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register* at 40 TexReg 6517 and 6531.

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

2 **22 TAC §291.73, §291.76**

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

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

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

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

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

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

31 *§291.73.Personnel.*

32 (a) Requirements for pharmacist services.

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

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

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

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

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

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

47 (b) Pharmacist-in-charge.

48 (1) General.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

131 (c) (No change.)

132 (d) Pharmacists.

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

134 (3) Special requirements for compounding.

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

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

141 (e) Pharmacy technicians and pharmacy technician trainees.

142 (1) General.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

289 (19) Prescription drug--

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

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

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

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

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

360 (3) Pharmacists.

361 (A) General.

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

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

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

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

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

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

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

377 (iii) interpreting patient profiles.

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

381 (4) Pharmacy technicians and pharmacy technician trainees.

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

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

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

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

393 (iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy
394 technicians or pharmacy technician trainees have completed the training specified in §291.131 of
395 this title;

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

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

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

404 (vii) maintaining inventories of drug supplies;

405 (viii) maintaining pharmacy records; and

406 (ix) loading ~~bulk unlabeled~~ drugs into an automated medication supply system. For the purpose
407 of this clause, direct supervision may be accomplished by physically present supervision or
408 electronic monitoring by a pharmacist. [drug dispensing system provided a pharmacist
409 supervises, verifies that the system was properly loaded prior to use, and affixes his or her name,
410 initials or electronic signature to the appropriate quality control records.]

411 (C) Procedures.

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

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

417 (D) Special requirements for compounding non-sterile preparations. All pharmacy technicians
418 and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet
419 the training requirements specified in §291.131 of this title.

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

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

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

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

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

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

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

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

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

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

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

450 (d) Operational standards.

451 (1) Licensing requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

503 (2) Environment.

504 (A) General requirements.

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

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

510 (B) Special requirements.

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

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

515 (C) Security.

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

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

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

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

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

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

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

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

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

536 (A) current copies of the following:

537 (i) Texas Pharmacy Act and rules;

538 (ii) Texas Dangerous Drug Act and rules;

539 (iii) Texas Controlled Substances Act and rules;

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

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

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

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

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

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

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

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

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

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

557 (C) ~~[(D)]~~ basic antidote information and the telephone number of the nearest regional poison
558 control center.[:]

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

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

564 (5) Drugs.

565 (A) Procurement, preparation, and storage.

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

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

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

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

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

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

579 (B) Formulary.

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

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

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

586 (I) a formulary has been developed;

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

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

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

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

594 (i) Prepackaging of drugs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

648 (6) Medication orders.

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

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

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

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

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

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

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

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

666 (I) name of the patient;

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

668 (III) dose prescribed;

669 (IV) quantity taken;

670 (V) time and date; and

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

672 (iv) The ~~[original or direct copy of the]~~ medication order in the patient's chart may substitute for
673 such record, provided the medication order meets all the requirements of clause (iii) of this
674 subparagraph.

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

677 (E) ~~[(F)]~~ In ASCs with a part-time or consultant pharmacist, if a practitioner orders a drug for
678 administration to a bona fide patient of the ASC when the pharmacist is not on duty, or when the
679 pharmacy is closed, the following is applicable.

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

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

683 (iii) A record shall be made at the time of withdrawal by the authorized person removing the
684 drugs and devices; the record shall meet the same requirements as specified in subparagraph (D)
685 ~~[(E)]~~ of this paragraph.

686 (iv) The pharmacist shall conduct an audit of patient's medical record according to the schedule
687 set out in the policy and procedures at [verify each distribution after] a reasonable interval, but
688 ~~[in no event may]~~ such interval must occur at least once in every calendar week that the
689 pharmacy is open [exceed seven days].

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

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

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

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

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

698 (ii) quantity removed;

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

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

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

783 (v) duplication of therapy;
784 (vi) drug-drug interactions;
785 (vii) drug-food interactions;
786 (viii) drug-disease interactions;
787 (ix) adverse drug reactions;
788 (x) proper utilization, including overutilization or underutilization; and
789 (xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug
790 effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of
791 the drug in its current regimen.

792 (B) A retrospective, random drug regimen review as specified in the pharmacy's policies and
793 procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed
794 31 days between such reviews.

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

797 (e) Records.

798 (1) Maintenance of records.

799 (A) Every inventory or other record required to be kept under the provisions of this section
800 (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center
801 [Institutional Pharmacy (Class C)]) shall be:

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

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

811 (B) Records of controlled substances listed in Schedule [Schedules I and] II shall be maintained
812 separately and readily retrievable from all other records of the pharmacy.

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

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

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

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

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

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

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

833 (i) patient's name;

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

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

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

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

838 (vi) returns to the pharmacy; and

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

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

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

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

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

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

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

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

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

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

863 (i) patient name;

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

865 (iii) directions for use;

866 (iv) date; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

985 (i) the actual date of distribution;

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

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

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

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

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

993 (ii) The distributing pharmacy shall:

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

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

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

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

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

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

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

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

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

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

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

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

1054 Filed with the Office of the Secretary of State on September 14, 2015.

1055 TRD-201503752

1056 Gay Dodson, R.Ph.

1057 Executive Director

1058 Texas State Board of Pharmacy

1059 Earliest possible date of adoption: October 25, 2015

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

1061

1 **SUBCHAPTER H. OTHER CLASSES OF PHARMACY**

2 **22 TAC §291.151**

3 The Texas State Board of Pharmacy proposes amendments to §291.151 concerning Pharmacies
4 Located in a Freestanding Emergency Medical Care Center (Class F). The amendments, if
5 adopted, update the rules for pharmacies in Freestanding Emergency Medical Care Centers to be
6 consistent with other sections; eliminate language that is no longer necessary; and correct
7 grammar.

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

11 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
12 effect, the public benefit anticipated as a result of enforcing the amendments will ensure the
13 public health and safety of pharmacies located in freestanding emergency medical care centers.
14 There is no fiscal impact for individuals, small or large businesses, or to other entities which are
15 required to comply with this section.

16 Comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of
17 Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,
18 Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., October
19 30, 2015.

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

25 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 -
26 569, Texas Occupations Code.

27 ***§291.151. Pharmacies Located in a Freestanding Emergency Medical Care Facility [~~Center~~]***
28 ***(Class F).***

29 (a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities,
30 and operation of a pharmacy located in a freestanding emergency medical care facilities [~~center~~]
31 that is licensed by the Texas Department of State Health Services or in a freestanding emergency
32 medical care facility [~~center~~] operated by a hospital that is exempt from registration as provided
33 by §254.052, Health and Safety Code. Class F pharmacies located in a freestanding emergency
34 medical care facility [~~center~~] shall comply with this section.

35 (b) Definitions. The following words and terms, when used in this section, shall have the
36 following meanings, unless the context clearly indicates otherwise.

- 37 (1) Act--The Texas Pharmacy Act, [~~Chapters 551—566 and 568—569,~~] Occupations Code,
38 Subtitle J, as amended.
- 39 (2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion,
40 or any other means to the body of a patient by:
- 41 (A) a practitioner, an authorized agent under his supervision, or other person authorized by law;
42 or
- 43 (B) the patient at the direction of a practitioner.
- 44 (3) Automated medication supply system--A mechanical system that performs operations or
45 activities relative to the storage and distribution of medications for administration and which
46 collects, controls, and maintains all transaction information.
- 47 ~~[(2) Automated drug dispensing system--An automated device that measures, counts, and/or~~
48 ~~packages a specified quantity of dosage units for a designated drug product.]~~
- 49 (4) [(3)] Board--The Texas State Board of Pharmacy.
- 50 (5) [(4)] Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult
51 with the FEMCF [~~FEMCC~~] in areas that pertain to the practice of pharmacy.
- 52 (6) [(5)] Controlled substance--A drug, immediate precursor, or other substance listed in
53 Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or
54 a drug immediate precursor, or other substance included in Schedule I - V of the Federal
55 Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-
56 513).
- 57 ~~[(6) Direct copy--Electronic copy or carbonized copy of a medication order including a facsimile~~
58 ~~(FAX) or digital image.]~~
- 59 (7) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or
60 device in the course of professional practice to an ultimate user or his agent by or pursuant to the
61 lawful order of a practitioner.
- 62 (8) Distribute--The delivery of a prescription drug or device other than by administering or
63 dispensing.
- 64 (9) Downtime--Period of time during which a data processing system is not operable.
- 65 (10) Electronic signature--A unique security code or other identifier which specifically identifies
66 the person entering information into a data processing system. A facility which utilizes electronic
67 signatures must:

- 68 (A) maintain a permanent list of the unique security codes assigned to persons authorized to use
69 the data processing system; and
- 70 (B) have an ongoing security program which is capable of identifying misuse and/or
71 unauthorized use of electronic signatures.
- 72 (11) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained
73 at a nursing station or other FEMCF [~~FEMCC~~] department (excluding the pharmacy) for the
74 purpose of administration to a patient of the FEMCF [~~FEMCC~~].
- 75 (12) Formulary--List of drugs approved for use in the FEMCF [~~FEMCC~~] by an appropriate
76 committee of the FEMCF [~~freestanding emergency medical care center~~].
- 77 (13) Freestanding emergency medical care facility (FEMCF) [~~center (FEMCC)~~]~~--~~A freestanding
78 facility that is licensed by the Texas Department of State Health Services pursuant to Chapter
79 254, Health and Safety Code, to provide emergency care to patients.
- 80 (14) Hard copy--A physical document that is readable without the use of a special device (i.e.,
81 data processing system, computer, etc.).
- 82 (15) Investigational new drug--New drug intended for investigational use by experts qualified to
83 evaluate the safety and effectiveness of the drug as authorized by the federal Food and Drug
84 Administration.
- 85 (16) Medication order--~~An~~ [~~A written order from a practitioner or a verbal~~] order from a
86 practitioner or his authorized agent for administration of a drug or device.
- 87 (17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who
88 has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to
89 the practice of pharmacy.
- 90 (18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are
91 stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other areas or
92 departments of the FEMCF [~~FEMCC~~], or dispensed to an ultimate user or his or her agent.
- 93 (19) Prescription drug--
- 94 (A) A substance for which federal or state law requires a prescription before it may be legally
95 dispensed to the public;
- 96 (B) A drug or device that under federal law is required, prior to being dispensed or delivered, to
97 be labeled with either of the following statements:
- 98 (i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend
99 that complies with federal law; or

- 100 (ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or
- 101 (C) A drug or device that is required by any applicable federal or state law or regulation to be
102 dispensed on prescription only or is restricted to use by a practitioner only.
- 103 (20) Prescription drug order--
- 104 (A) An [~~A written order from a practitioner or verbal~~] order from a practitioner or his authorized
105 agent to a pharmacist for a drug or device to be dispensed; or
- 106 (B) An [~~A written order or a verbal~~] order pursuant to Subtitle B, Chapter 157, Occupations
107 Code.
- 108 (21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week
109 or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is
110 open.
- 111 (22) Part-time pharmacist--A pharmacist who works less than full-time.
- 112 (23) Pharmacy technician--An individual who is registered with the board as a pharmacy
113 technician and whose responsibility in a pharmacy is to provide technical services that do not
114 require professional judgment regarding preparing and distributing drugs and who works under
115 the direct supervision of and is responsible to a pharmacist.
- 116 (24) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy
117 technician trainee and is authorized to participate in a pharmacy's technician training program.
- 118 (25) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and
119 Safety Code, Chapter 481, as amended.
- 120 (c) Personnel.
- 121 (1) Pharmacist-in-charge.
- 122 (A) General. Each FEMCF [~~freestanding emergency medical care center~~] shall have one
123 pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time
124 basis, but may be employed on a full-time basis.
- 125 (B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum,
126 the following:
- 127 (i) establishing [~~establishment of~~] specifications for procurement and storage of all materials,
128 including drugs, chemicals, and biologicals;
- 129 (ii) participating [~~participation~~] in the development of a formulary for the FEMCF [~~FEMCC~~],
130 subject to approval of the appropriate committee of the FEMCF [~~FEMCC~~];

- 131 (iii) distributing [~~distribution of~~] drugs to be administered to patients pursuant to [~~an original or~~
132 ~~direct copy of~~] the practitioner's medication order;
- 133 (iv) filling and labeling all containers from which drugs are to be distributed or dispensed;
- 134 (v) maintaining and making available a sufficient inventory of antidotes and other emergency
135 drugs, both in the pharmacy and patient care areas, as well as current antidote information,
136 telephone numbers of regional poison control center and other emergency assistance
137 organizations, and such other materials and information as may be deemed necessary by the
138 appropriate committee of the FEMCF [~~FEMCC~~];
- 139 (vi) maintaining records of all transactions of the FEMCF [~~FEMCC~~] pharmacy as may be
140 required by applicable state and federal law, and as may be necessary to maintain accurate
141 control over and accountability for all pharmaceutical materials;
- 142 (vii) participating [~~participation~~] in those aspects of the FEMCF's [~~FEMCC's~~] patient care
143 evaluation program which relate to pharmaceutical material utilization and effectiveness;
- 144 (viii) participating [~~participation~~] in teaching and/or research programs in the FEMCF [~~FEMCC~~];
- 145 (ix) implementing [~~implementation of~~] the policies and decisions of the appropriate committee(s)
146 relating to pharmaceutical services of the FEMCF [~~FEMCC~~];
- 147 (x) providing effective and efficient messenger and delivery service to connect the FEMCF
148 [~~FEMCC~~] pharmacy with appropriate areas of the FEMCF [~~FEMCC~~] on a regular basis
149 throughout the normal workday of the FEMCF [~~FEMCC~~];
- 150 (xi) labeling, storing, and distributing [~~storage, and distribution of~~] investigational new drugs,
151 including maintaining [~~maintenance of~~] information in the pharmacy and nursing station where
152 such drugs are being administered, concerning the dosage form, route of administration, strength,
153 actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of
154 investigational new drugs;
- 155 (xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this section;
156 and
- 157 (xiii) maintain [~~maintenance of~~] records in a data processing system such that the data processing
158 system is in compliance with the requirements for a FEMCF [~~FEMCC~~].
- 159 (2) Consultant pharmacist.
- 160 (A) The consultant pharmacist may be the pharmacist-in-charge.
- 161 (B) A written contract shall exist between the FEMCF [~~FEMCC~~] and any consultant pharmacist,
162 and a copy of the written contract shall be made available to the board upon request.

163 (3) Pharmacists.

164 (A) General.

165 (i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed
166 pharmacists as may be required to operate the FEMCF [~~FEMCC~~] pharmacy competently, safely,
167 and adequately to meet the needs of the patients of the facility.

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

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

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

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

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

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

180 (iii) interpreting patient profiles.

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

184 (4) Pharmacy technicians and pharmacy technician trainees.

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

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

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

- 194 (ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication
195 orders, provided a pharmacist supervises and checks the preparation;
- 196 (iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy
197 technicians or pharmacy technician trainees have completed the training specified in §291.131 of
198 this title;
- 199 (iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final
200 checks and affixes his or her name, initials, or electronic signature to the appropriate quality
201 control records prior to distribution;
- 202 (v) distributing routine orders for stock supplies to patient care areas;
- 203 (vi) entering medication order and drug distribution information into a data processing system,
204 provided judgmental decisions are not required and a pharmacist checks the accuracy of the
205 information entered into the system prior to releasing the order or in compliance with the
206 absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section;
- 207 (vii) maintaining inventories of drug supplies;
- 208 (viii) maintaining pharmacy records; and
- 209 (ix) loading ~~bulk unlabeled~~ drugs into an automated medication supply system. For the purpose
210 of this clause, direct supervision may be accomplished by physically present supervision or
211 electronic monitoring by a pharmacist. [drug dispensing system provided a pharmacist
212 supervises, verifies that the system was properly loaded prior to use, and affixes his or her name,
213 initials or electronic signature to the appropriate quality control records.]
- 214 (C) Procedures.
- 215 (i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in
216 accordance with standard written procedures and guidelines.
- 217 (ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders
218 in the same manner as pharmacy technicians or pharmacy technician trainees working in a Class
219 A pharmacy.
- 220 (D) Special requirements for compounding non-sterile preparations. All pharmacy technicians
221 and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet
222 the training requirements specified in §291.131 of this title.
- 223 (5) Owner. The owner of a FEMCF ~~[FEMCC]~~ pharmacy shall have responsibility for all
224 administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise
225 the owner on administrative and operational concerns. The owner shall have responsibility for, at
226 a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall
227 consult with the pharmacist-in-charge or another Texas licensed pharmacist:

- 228 (A) ~~establishing~~ [establishment of] policies for procurement of prescription drugs and devices
229 and other products dispensed from the FEMCF [~~FEMCC~~] pharmacy;
- 230 (B) ~~establishing and maintaining~~ [establishment and maintenance of] effective controls against
231 the theft or diversion of prescription drugs;
- 232 (C) if the pharmacy uses an automated medication supply [~~pharmacy dispensing~~] system,
233 reviewing and approving all policies and procedures for system operation, safety, security,
234 accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;
- 235 (D) providing the pharmacy with the necessary equipment and resources commensurate with its
236 level and type of practice; and
- 237 (E) ~~establishing~~ [establishment of] policies and procedures regarding maintenance, storage, and
238 retrieval of records in a data processing system such that the system is in compliance with state
239 and federal requirements.
- 240 (6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows:
- 241 (A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge
242 that bears the person's name and identifies him or her as a pharmacy technician [~~trainee-a~~
243 ~~registered pharmacy technician, or a certified pharmacy technician, if the technician maintains~~
244 ~~current certification with the Pharmacy Technician Certification Board or any other entity~~
245 ~~providing an examination approved by the board~~].
- 246 (B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification
247 tag or badge that bears the person's name and identifies him or her as a pharmacy technician
248 trainee.
- 249 (C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears
250 the person's name and identifies him or her as a pharmacist intern.
- 251 (D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's
252 name and identifies him or her as a pharmacist.
- 253 (d) Operational standards.
- 254 (1) Licensing requirements.
- 255 (A) A FEMCF [~~FEMCC~~] pharmacy shall register annually or biennially with the board on a
256 pharmacy license application provided by the board, following the procedures specified in
257 §291.1 of this title (relating to Pharmacy License Application).
- 258 [~~(B) If the FEMCC pharmacy is owned or operated by a pharmacy management or consulting~~
259 ~~firm, the following conditions apply.~~]

260 ~~{(i) The pharmacy license application shall list the pharmacy management or consulting firm as~~
261 ~~the owner or operator.}~~

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

264 ~~{(I) the pharmacy management or consulting firm and the facility cosign a contractual pharmacy~~
265 ~~service agreement which assigns overall responsibility for controlled substances to the facility;~~
266 ~~and}~~

267 ~~{(H) such pharmacy management or consulting firm maintains dual responsibility for the~~
268 ~~controlled substances.}~~

269 (B) ~~{(C)}~~ A FEMCF ~~[FEMCC-]~~ pharmacy which changes ownership shall notify the board within
270 10 days of the change of ownership and apply for a new and separate license as specified in
271 §291.3 of this title (relating to Required Notifications).

272 (C) ~~{(D)}~~ A FEMCF ~~[FEMCC-]~~ pharmacy which changes location and/or name shall notify the
273 board of the change within 10 days and file for an amended license as specified in §291.3 of this
274 title.

275 (D) ~~{(E)}~~ A FEMCF ~~[FEMCC-]~~ pharmacy owned by a partnership or corporation which changes
276 managing officers shall notify the board in writing of the names of the new managing officers
277 within 10 days of the change, following the procedures in §291.3 of this title.

278 (E) ~~{(F)}~~ A FEMCF ~~[FEMCC-]~~ pharmacy shall notify the board in writing within 10 days of
279 closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

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

282 (G) ~~{(H)}~~ A separate license is required for each principal place of business and only one
283 pharmacy license may be issued to a specific location.

284 (H) A FEMCF pharmacy, which also operates another type of pharmacy which would otherwise
285 be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy
286 (Class A), is not required to secure a license for the other type of pharmacy; provided, however,
287 such license is required to comply with the provisions of §291.31 of this title (relating to
288 Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to
289 Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title
290 (relating to Official Prescription Records), to the extent such sections are applicable to the
291 operation of the pharmacy.

292 (I) A FEMCF [FEMCC] pharmacy engaged in the compounding of non-sterile preparations shall
293 comply with the provisions of §291.131 of this title.

- 294 (2) Environment.
- 295 (A) General requirements.
- 296 (i) Each FEMCF [~~freestanding emergency medical care center~~] shall have a designated work area
297 separate from patient areas, and which shall have space adequate for the size and scope of
298 pharmaceutical services and shall have adequate space and security for the storage of drugs.
- 299 (ii) The FEMCF [~~FEMCC~~] pharmacy shall be arranged in an orderly fashion and shall be kept
300 clean. All required equipment shall be clean and in good operating condition.
- 301 (B) Special requirements.
- 302 (i) The FEMCF [~~FEMCC~~] pharmacy shall have locked storage for Schedule II controlled
303 substances and other controlled drugs requiring additional security.
- 304 (ii) The FEMCF [~~FEMCC~~] pharmacy shall have a designated area for the storage of poisons and
305 externals separate from drug storage areas.
- 306 (C) Security.
- 307 (i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed and
308 capable of being locked by key, combination, or other mechanical or electronic means, so as to
309 prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-
310 charge may enter the pharmacy or [~~authorized personnel may~~] have access to storage areas for
311 prescription drugs and/or devices.
- 312 [~~(ii) All storage areas for prescription drugs and/or devices shall be locked by key or~~
313 ~~combination, so as to prevent access by unauthorized personnel.~~]
- 314 (ii) [(iii)] The pharmacist-in-charge shall consult with FEMCF [~~ASC~~] personnel with respect to
315 security of the drug storage areas, including provisions for adequate safeguards against theft or
316 diversion of dangerous drugs, controlled substances, and records for such drugs. [~~prescription~~
317 ~~drugs and/or devices.~~]
- 318 (iii) The pharmacy shall have locked storage for Schedule II controlled substances and other
319 drugs requiring additional security.
- 320 (3) Equipment and supplies. FEMCFs [~~freestanding emergency medical care centers~~] supplying
321 drugs for outpatient use shall have the following equipment and supplies:
- 322 (A) data processing system including a printer or comparable equipment;
- 323 (B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and
- 324 (C) adequate supply of prescription labels and other applicable identification labels.

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

327 (A) current copies of the following:

328 (i) Texas Pharmacy Act and rules;

329 (ii) Texas Dangerous Drug Act and rules;

330 (iii) Texas Controlled Substances Act and rules; and

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

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

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

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

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

341 [~~(II) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the~~
342 ~~Healthcare Provider);~~]

343 [~~(III) AHFS Drug Information with current supplements;~~]

344 [~~(IV) Remington's Pharmaceutical Sciences; or~~]

345 [~~(V) Clinical Pharmacology;~~]

346 [~~(C) a current or updated reference on injectable drug products, such as Handbook of Injectable~~
347 ~~Drugs;~~]

348 (C) [~~(D)~~] basic antidote information and the telephone number of the nearest regional poison
349 control center. [~~;~~]

350 [~~(E) if the pharmacy compounds sterile preparations, specialty references appropriate for the~~
351 ~~scope of services provided by the pharmacy, e.g., if the pharmacy prepares cytotoxic drugs, a~~
352 ~~reference text on the preparation of cytotoxic drugs, such as Procedures for Handling Cytotoxic~~
353 ~~Drugs; and~~]

354 ~~[(F) metric-apothecary weight and measure conversion charts.]~~

355 (5) Drugs.

356 (A) Procurement, preparation, and storage.

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

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

362 (iii) FEMCF ~~[FEMCC]~~ pharmacies may not sell, purchase, trade, or possess prescription drug
363 samples, unless the pharmacy meets the requirements as specified in §291.16 of this title
364 (relating to Samples).

365 (iv) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in
366 §291.15 of this title (relating to Storage of Drugs).

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

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

371 (B) Formulary.

372 (i) A formulary may be developed by an appropriate committee of the FEMCF ~~[freestanding
373 emergency medical center]~~.

374 (ii) The pharmacist-in-charge, ~~[or]~~ consultant pharmacist, or designee shall be a full voting
375 member of any committee which involves pharmaceutical services.

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

379 (I) a formulary has been developed;

380 (II) the formulary has been approved by the medical staff of the FEMCF;

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

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

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

387 (i) Prepackaging of drugs.

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

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

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

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

395 (-c-) expiration date; and

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

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

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

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

400 (-c-) manufacturer or distributor;

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

402 (-e-) expiration date;

403 (-f-) quantity per prepackaged unit;

404 (-g-) number of prepackaged units;

405 (-h-) date packaged;

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

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

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

410 (ii) Loading bulk unit of use [~~unlabeled~~] drugs into automated medication supply [~~drug~~
411 ~~dispensing~~] systems.

412 [~~(I)~~] Automated medication supply [~~drug dispensing~~] systems may be loaded with bulk unit of
413 use [~~unlabeled~~] drugs only by a pharmacist or by pharmacy technicians or pharmacy technician
414 trainees under the direction and direct supervision of a pharmacist. For the purpose of this clause,
415 direct supervision may be accomplished by physically present supervision or electronic
416 monitoring by a pharmacist. In order for the pharmacist to electronically monitor, the medication
417 supply system must allow for bar code scanning to verify the loading of drugs, and a record of
418 the loading must be maintained by the system and accessible for electronic review by the
419 pharmacist.

420 [~~(II) The label of an automated drug dispensing system container shall indicate the brand name~~
421 ~~and strength of the drug; or if no brand name, then the generic name, strength, and name of the~~
422 ~~manufacturer or distributor.]~~

423 [~~(III) Records of loading bulk unlabeled drugs into an automated drug dispensing system shall be~~
424 ~~maintained to show:]~~

425 [~~(a) name of the drug, strength, and dosage form;]~~

426 [~~(b) manufacturer or distributor;]~~

427 [~~(c) manufacturer's lot number;]~~

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

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

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

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

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

436 (6) Medication orders.

437 (A) Drugs may be administered to patients in FEMCFs [~~FEMCCs~~] only on the order of a
438 practitioner. No change in the order for drugs may be made without the approval of a practitioner
439 except as authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.

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

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

444 (C) [~~(D)~~] FEMCF [~~FEMCC~~] pharmacies shall be exempt from the labeling provisions and
445 patient notification requirements of §562.006 and §562.009 of the Act, as respects drugs
446 distributed pursuant to medication orders.

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

450 (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of
451 a patient may be removed from the FEMCF [~~FEMCC~~] pharmacy.

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

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

455 (I) name of the patient;

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

457 (III) dose prescribed;

458 (IV) quantity taken;

459 (V) time and date; and

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

461 (iv) The [~~original or direct copy of the~~] medication order in the patient's chart may substitute for
462 such record, provided the medication order meets all the requirements of clause (iii) of this
463 subparagraph.

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

466 (E) [~~(F)~~] In FEMCFs [~~FEMCCs~~] with a part-time or consultant pharmacist, if a practitioner
467 orders a drug for administration to a bona fide patient of the FEMCF [~~FEMCC~~] when the
468 pharmacist is not on duty, or when the pharmacy is closed, the following is applicable.

- 469 (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be
470 removed from the FEMCF [~~FEMCC~~] pharmacy.
- 471 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.
- 472 (iii) A record shall be made at the time of withdrawal by the authorized person removing the
473 drugs and devices; the record shall meet the same requirements as specified in subparagraph (D)
474 [~~(E)(iii)~~] of this paragraph.
- 475 (iv) The pharmacist shall conduct an audit of patient's medical record according to the schedule
476 set out in the policy and procedures at [~~verify each distribution after~~] a reasonable interval, but
477 [~~in no event may~~] such interval must occur at least once in every calendar week that the
478 pharmacy is open [~~exceed seven days~~].
- 479 (7) Floor stock. In facilities using a floor stock method of drug distribution, the following is
480 applicable for removing drugs or devices in the absence of a pharmacist.
- 481 (A) Prescription drugs and devices may be removed from the pharmacy only in the original
482 manufacturer's container or prepackaged container.
- 483 (B) Only a designated licensed nurse or practitioner may remove such drugs and devices.
- 484 (C) A record shall be made at the time of withdrawal by the authorized person removing the drug
485 or device; the record shall contain the following information:
- 486 (i) name of the drug, strength, and dosage form;
- 487 (ii) quantity removed;
- 488 (iii) location of floor stock;
- 489 (iv) date and time; and
- 490 (v) signature or electronic signature of person making the withdrawal.
- 491 (D) A pharmacist shall verify the withdrawal according to the following schedule.
- 492 (i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as practical,
493 but in no event more than 72 hours from the time of such withdrawal.
- 494 (ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after a
495 reasonable interval, but [~~in no event may~~] such interval must occur at least once in every
496 calendar week that the pharmacy is open [~~exceed seven days~~].
- 497 (8) Policies and procedures. Written policies and procedures for a drug distribution system,
498 appropriate for the freestanding emergency medical facility [~~center~~], shall be developed and

499 implemented by the pharmacist-in-charge with the advice of the appropriate committee. The
500 written policies and procedures for the drug distribution system shall include, but not be limited
501 to, procedures regarding the following:

502 (A) controlled substances;

503 (B) investigational drugs;

504 (C) prepackaging and manufacturing;

505 (D) medication errors;

506 (E) orders of physician or other practitioner;

507 (F) floor stocks;

508 (G) adverse drug reactions;

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

510 (I) self-administration;

511 (J) emergency drug tray;

512 (K) formulary, if applicable;

513 (L) drug storage areas;

514 (M) drug samples;

515 (N) drug product defect reports;

516 (O) drug recalls;

517 (P) outdated drugs;

518 (Q) preparation and distribution of IV admixtures;

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

520 (S) use of automated medication supply [~~drug dispensing~~] systems; [~~and~~]

521 (T) use of data processing systems; and [-]

522 (U) drug regimen review.

523 (9) Drugs supplied for outpatient use. Drugs provided to patients for take home use [~~supplied to~~
524 ~~patients for outpatient use~~] shall be supplied according to the following procedures.

525 (A) Drugs may only be supplied to patients who have been admitted to the FEMCF [~~freestanding~~
526 ~~emergency medical center~~].

527 (B) Drugs may only be supplied in accordance with the system of control and accountability
528 established for drugs supplied from the FEMCF [~~freestanding emergency medical center~~]; such
529 system shall be developed and supervised by the pharmacist-in-charge or staff pharmacist
530 designated by the pharmacist-in-charge.

531 (C) Only drugs listed on the approved outpatient drug list may be supplied; such list shall be
532 developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the
533 nature and type to meet the immediate postoperative needs of the FEMCF [~~freestanding~~
534 ~~emergency medical center~~] patient.

535 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in
536 suitable containers and appropriately prelabeled (including name, address, and phone number of
537 the facility and necessary auxiliary labels) by the pharmacy, provided, however that topicals and
538 ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-
539 hour supply.

540 (E) At the time of delivery of the drug, the practitioner or licensed nurse under the practitioner's
541 supervision shall complete the label, such that the prescription container bears a label with at
542 least the following information:

543 (i) date supplied;

544 (ii) name of practitioner;

545 (iii) name of patient;

546 (iv) directions for use;

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

549 (vi) unique identification number.

550 (F) After the drug has been labeled [~~by the practitioner~~], the practitioner or a licensed nurse
551 under the supervision of the practitioner shall give the appropriately labeled, prepackaged
552 medication to the patient.

553 (G) A perpetual record of drugs which are supplied from the FEMCF [~~FEMCC~~] shall be
554 maintained which includes:

- 555 (i) name, address, and phone number of the facility;
- 556 (ii) date supplied;
- 557 (iii) name of practitioner;
- 558 (iv) name of patient;
- 559 (v) directions for use;
- 560 (vi) brand name and strength of the drug; or if no brand name, then the generic name of the drug
561 dispensed, strength, and the name of the manufacturer or distributor of the drug; and
- 562 (vii) unique identification number.
- 563 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall
564 review the records at least once in every calendar week that the pharmacy is open [~~every seven~~
565 ~~days~~].
- 566 (10) Drug regimen review.
- 567 (A) A pharmacist shall evaluate medication orders and patient medication records for:
- 568 (i) known allergies;
- 569 (ii) rational therapy--contraindications;
- 570 (iii) reasonable dose and route of administration;
- 571 (iv) reasonable directions for use;
- 572 (v) duplication of therapy;
- 573 (vi) drug-drug interactions;
- 574 (vii) drug-food interactions;
- 575 (viii) drug-disease interactions;
- 576 (ix) adverse drug reactions;
- 577 (x) proper utilization, including overutilization or underutilization; and
- 578 (xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug
579 effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of
580 the drug in its current regimen.

581 (B) A retrospective, random drug regimen review as specified in the pharmacy's policies and
582 procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed
583 31 days between such reviews.

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

586 (e) Records.

587 (1) Maintenance of records.

588 (A) Every inventory or other record required to be kept under the provisions of this section
589 (relating to Pharmacies Located in a Freestanding Emergency Medical Care Facility (Class F)
590 [~~Center~~]) shall be:

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

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

600 (B) Records of controlled substances listed in Schedule [~~Schedules I and~~] II shall be maintained
601 separately and readily retrievable from all other records of the pharmacy.

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

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

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

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

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

617 (F) A FEMCF pharmacy shall maintain a perpetual inventory of controlled substances listed in
618 Schedule II - V which shall be verified for completeness and reconciled at least once in every
619 calendar week that the pharmacy is open.

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

622 (i) patient's name;

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

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

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

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

627 (vi) returns to the pharmacy; and

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

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

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

635 ~~{(2) Outpatient records.}~~

636 ~~{(A) Only a registered pharmacist may receive, certify, and receive prescription drug orders.}~~

637 ~~{(B) Outpatient records shall be maintained as provided in §291.34 and §291.35 of this title~~
638 ~~contained in Community Pharmacy (Class A).}~~

639 ~~{(C) Outpatient prescriptions, including, but not limited to, discharge prescriptions, that are~~
640 ~~written by the practitioner, must be written on a form which meets the requirements of the Act,~~
641 ~~§562.006. Medication order forms or copies thereof do not meet the requirements for outpatient~~
642 ~~forms.}~~

643 ~~{(D) Controlled substances listed in Schedule II must be written on an official prescription form~~
644 ~~in accordance with the Texas Controlled Substances Act, §481.075, and rules promulgated~~

645 ~~pursuant to the Texas Controlled Substances Act, unless exempted by the Texas Controlled~~
646 ~~Substances Rules, 37 TAC §13.74. Outpatient prescriptions for Schedule II controlled substances~~
647 ~~that are exempted from the official prescription requirement must be manually signed by the~~
648 ~~practitioner.]~~

649 (2) ~~[(3)]~~ Patient records.

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

652 (i) patient name;

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

654 (iii) directions for use;

655 (iv) date; and

656 (v) signature or electronic signature of the practitioner or that of his or her authorized agent,
657 defined as a licensed nurse employee or consultant/full or part-time pharmacist of the FEMCF
658 ~~[FEMCC]~~.

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

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

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

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

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

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

668 ~~[(ii) A FEMCC pharmacy shall maintain a perpetual inventory of any controlled substance listed~~
669 ~~in Schedule II.]~~

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

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

673 ~~[(H) practitioner who ordered drug;]~~

674 ~~{(III) name of drug, dosage form, and strength;~~

675 ~~{(IV) time and date of administration to patient and quantity administered;}~~

676 ~~{(V) signature or electronic signature of individual administering controlled substance;}~~

677 ~~{(VI) returns to the pharmacy; and}~~

678 ~~{(VII) waste (waste is required to be witnessed and cosigned, manually or electronically, by~~
679 ~~another individual).}~~

680 ~~{(E) Floor stock records shall be maintained as follows.}~~

681 ~~{(i) Distribution records for Schedules III—V controlled substances floor stock shall include the~~
682 ~~following information:}~~

683 ~~{(I) patient's name;}~~

684 ~~{(II) practitioner who ordered controlled substance;}~~

685 ~~{(III) name of controlled substance, dosage form, and strength;}~~

686 ~~{(IV) time and date of administration to patient;}~~

687 ~~{(V) quantity administered;}~~

688 ~~{(VI) signature or electronic signature of individual administering drug;}~~

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

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

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

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

696 (3) ~~(F)~~ General requirements for records maintained in a data processing system are as follows.

697 (A) ~~(i)~~ If an FEMCF ~~FEMCC~~ pharmacy's data processing system is not in compliance with
698 the board's requirements, the pharmacy must maintain a manual recordkeeping system.

699 (B) ~~(ii)~~ ~~[Requirements for backup systems.]~~ The facility shall maintain a backup copy of
700 information stored in the data processing system using disk, tape, or other electronic backup

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

703 ~~[(iii) Change or discontinuance of a data processing system.]~~

704 ~~(C) [(F)] [Records of distribution and return for all controlled substances and nalbuphine~~
705 ~~(Nubain).] A pharmacy that changes or discontinues use of a data processing system must:~~

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

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

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

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

716 ~~[(II) Other records. A pharmacy that changes or discontinues use of a data processing system~~
717 ~~must:]~~

718 ~~[(a) transfer the records to the new data processing system; or]~~

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

721 (D) [(III)] [Maintenance of purged records.] Information purged from a data processing system
722 must be maintained by the pharmacy for two years from the date of initial entry into the data
723 processing system.

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

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

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

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

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

737 (ii) [(ii)] prescribing or attending practitioner's name;

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

739 (iv) [(iv)] total quantity distributed from and returned to the pharmacy;

740 (v) [(v)] if not immediately retrievable via electronic image, the following shall also be included
741 on the printout:

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

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

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

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

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

758 (I) [~~Data processing system downtime.~~] In the event that an FEMCF [FEMCC] pharmacy which
759 uses a data processing system experiences system downtime, the pharmacy must have an
760 auxiliary procedure which will ensure that all data is retained for on-line data entry as soon as the
761 system is available for use again.

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

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

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

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

773 (i) the actual date of distribution;

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

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

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

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

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

781 (ii) The distributing pharmacy shall:

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

783 (II) maintain Copy 1 of the DEA order form (DEA 222[~~€~~]) at the pharmacy for two years; and

784 (III) forward Copy 2 of the DEA order form (DEA 222[~~€~~]) to the divisional office of the Drug
785 Enforcement Administration.

786 (5) Other records. Other records to be maintained by the pharmacy include:

787 (A) a permanent log of the initials or identification codes which will identify each pharmacist by
788 name. The initials or identification code shall be unique to ensure that each pharmacist can be
789 identified, i.e., identical initials or identification codes cannot be used;

790 (B) Copy 3 of DEA order form (DEA 222[~~€~~]), which has been properly dated, initialed, and
791 filed, and all copies of each unaccepted or defective order form and any attached statements or
792 other documents and/or for each order filled using the DEA Controlled Substance Ordering
793 System (CSOS), the original signed order and all linked records for that order;

794 (C) a [~~hard~~] copy of the power of attorney to sign DEA 222C order forms (if applicable);

795 (D) suppliers' invoices of dangerous drugs and controlled substances dated and initialed or
796 signed by the person receiving the drugs; a pharmacist shall verify that the controlled drugs listed
797 on the invoices were added to the pharmacy's perpetual inventory [~~actually received~~] by clearly
798 recording his/her initials and the [~~actual~~] date of review [~~receipt~~] of the perpetual inventory
799 [~~controlled substances~~];

800 (E) supplier's credit memos for controlled substances and dangerous drugs;

801 (F) a [~~hard~~] copy of inventories required by §291.17 of this title (relating to Inventory
802 Requirements) except that a perpetual inventory of controlled substances listed in Schedule II
803 may be kept in a data processing system if the data processing system is capable of producing a
804 hard copy of the perpetual inventory on-site;

805 (G) [~~hard copy~~] reports of surrender or destruction of controlled substances and/or dangerous
806 drugs to an appropriate state or federal agency;

807 [~~(H) a hard copy Schedule V nonprescription register book;~~]

808 (H) [~~(H)~~] records of distribution of controlled substances and/or dangerous drugs to other
809 pharmacies, practitioners, or registrants; and

810 (I) [~~(I)~~] a [~~hard~~] copy of any notification required by the Texas Pharmacy Act or these rules,
811 including, but not limited to, the following:

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

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

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

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

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

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

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

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

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

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

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

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

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