

**FINAL REPORT OF THE TEXAS STATE BOARD OF PHARMACY'S
TASK FORCE ON CLASS C PHARMACIES LOCATED IN FREESTANDING AMBULATORY
SURGICAL CENTERS AND CLASS F PHARMACIES LOCATED IN FREESTANDING
EMERGENCY MEDICAL CARE CENTERS**

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The task force met on April 29, 2015, and reviewed the current regulations for both Class C pharmacies located in freestanding ambulatory surgical centers and Class F pharmacies located in freestanding emergency medical care centers. The members of the committee developed recommendations for changes to the regulations.

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER D INSTITUTIONAL PHARMACY (CLASS C)
5

6 **§291.76 Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center**
7

8 (a) Purpose. The purpose of this section is to provide standards in the conduct, practice
9 activities, and operation of a pharmacy located in a freestanding ambulatory surgical center that
10 is licensed by the Texas Department of State Health Services. Class C pharmacies located in a
11 freestanding ambulatory surgical center shall comply with this section, in lieu of §§291.71 -
12 291.75 of this title (relating to Purpose; Definitions; Personnel; Operational Standards; and
13 Records).
14

15 (b) Definitions. The following words and terms, when used in these sections, shall have the
16 following meanings, unless the context clearly indicates otherwise.
17

18 (1) Act--The Texas Pharmacy Act, [~~Chapters 551–566 and 568–569;~~] Occupations Code,
19 **Subtitle J**, as amended.
20

21
22 **(2) Administer--The direct application of a prescription drug by injection, inhalation,**
23 **ingestion, or any other means to the body of a patient by:**
24

25 **(A) a practitioner, an authorized agent under his supervision, or other person**
26 **authorized by law; or**
27

28 **(B) the patient at the direction of a practitioner.**
29

30 **(3)[(2)] Ambulatory surgical center (ASC)-- A freestanding facility that is licensed by the Texas**
31 **Department of State Health Services that primarily provides surgical services to patients**
32 **who do not require overnight hospitalization or extensive recovery, convalescent time or**
33 **observation. The planned total length of stay for an ASC patient shall not exceed 23**
34 **hours. Patient stays of greater than 23 hours shall be the result of an unanticipated**
35 **medical condition and shall occur infrequently. The 23-hour period begins with the**
36 **induction of anesthesia.** [~~to provide surgical services to patients who do not require overnight~~
37 ~~hospital care.]
38~~

39 **(4) Automated medication supply system--A mechanical system that performs operations**
40 **or activities relative to the storage and distribution of medications for administration and**
41 **which collects, controls, and maintains all transaction information.**
42

43 [~~(3) Automated drug dispensing system--An automated device that measures, counts, and/or~~
44 ~~packages a specified quantity of dosage units for a designated drug product.]
45~~

46 **(5) [(4)] Board--The Texas State Board of Pharmacy.**
47

48 **(6) [(5)] Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult**
49 **with the ASC in areas that pertain to the practice of pharmacy.**
50

51 **(7)** ~~[(6)]~~ Controlled substance--A drug, immediate precursor, or other substance listed in
52 Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended,
53 or a drug immediate precursor, or other substance included in Schedule I - V of the Federal
54 Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-
55 513).

56
57 **(8)** ~~[(7)]~~ Direct copy--~~Electronic copy or carbonized copy of a medication order including a~~
58 ~~facsimile (FAX) or digital image.]~~

59
60 **(9)** ~~[(8)]~~ Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription
61 drug or device in the course of professional practice to an ultimate user or his agent by or
62 pursuant to the lawful order of a practitioner.

63
64 **(10)** ~~[(9)]~~ Distribute--The delivery of a prescription drug or device other than by administering or
65 dispensing.

66
67 **(11)** ~~[(10)]~~ Downtime--Period of time during which a data processing system is not operable.

68
69 **(12)** ~~[(11)]~~ Electronic signature--A unique security code or other identifier which specifically
70 identifies the person entering information into a data processing system. A facility which utilizes
71 electronic signatures must:

72
73 (A) maintain a permanent list of the unique security codes assigned to persons authorized to
74 use the data processing system; and

75
76 (B) have an ongoing security program which is capable of identifying misuse and/or
77 unauthorized use of electronic signatures.

78
79 **(13)** ~~[(12)]~~ Floor stock--Prescription drugs or devices not labeled for a specific patient and
80 maintained at a nursing station or other ASC department (excluding the pharmacy) for the
81 purpose of administration to a patient of the ASC.

82
83 **(14)** ~~[(13)]~~ Formulary--List of drugs approved for use in the ASC by an appropriate committee
84 of the ambulatory surgical center.

85
86 **(15)** ~~[(14)]~~ Hard copy--A physical document that is readable without the use of a special device
87 (i.e., data processing system, computer, etc.).

88
89 **(16)** ~~[(15)]~~ Investigational new drug--New drug intended for investigational use by experts
90 qualified to evaluate the safety and effectiveness of the drug as authorized by the federal Food
91 and Drug Administration.

92
93 **(17)** ~~[(16)]~~ Medication order—**An** ~~[A written order from a practitioner or a verbal]~~ order from a
94 practitioner or his authorized agent for administration of a drug or device.

95
96 **(18)** ~~[(17)]~~ Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the
97 pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and
98 rules pertaining to the practice of pharmacy.

99

100 **(19)** ~~[(18)]~~ Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs
101 are stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other
102 areas or departments of the ASC, or dispensed to an ultimate user or his or her agent.

103
104 **(20)** ~~[(19)]~~ Prescription drug--

105
106 (A) A substance for which federal or state law requires a prescription before it may be legally
107 dispensed to the public;

108
109 (B) A drug or device that under federal law is required, prior to being dispensed or delivered,
110 to be labeled with either of the following statements:

111
112 (i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another
113 legend that complies with federal law; or

114
115 (ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or

116
117 (C) A drug or device that is required by any applicable federal or state law or regulation to be
118 dispensed on prescription only or is restricted to use by a practitioner only.

119
120 **(21)** ~~[(20)]~~ Prescription drug order--

121
122 (A) **An** ~~[A written order from a practitioner or verbal]~~ order from a practitioner or his authorized
123 agent to a pharmacist for a drug or device to be dispensed; or

124
125 (B) **An** ~~[A written order or a verbal]~~ order pursuant to Subtitle B, Chapter 157, Occupations
126 Code.

127
128 **(22)** ~~[(21)]~~ Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours
129 per week or if the pharmacy is open less than 60 hours per week, one-half of the time the
130 pharmacy is open.

131
132 **(23)** ~~[(22)]~~ Part-time pharmacist--A pharmacist who works less than full-time.

133
134 **(24)** ~~[(23)]~~ Pharmacy technician--An individual who is registered with the board as a pharmacy
135 technician and whose responsibility in a pharmacy is to provide technical services that do not
136 require professional judgment regarding preparing and distributing drugs and who works under
137 the direct supervision of and is responsible to a pharmacist.

138
139 **(25)** ~~[(24)]~~ Pharmacy technician trainee--An individual who is registered with the board as a
140 pharmacy technician trainee and is authorized to participate in a pharmacy's technician training
141 program.

142
143 **(26)** ~~[(25)]~~ Texas Controlled Substances Act--The Texas Controlled Substances Act, the
144 Health and Safety Code, Chapter 481, as amended.

145
146 (c) Personnel.

147
148 (1) Pharmacist-in-charge.

149

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

153
154 (B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum,
155 the following:

156
157 (i) **establishing** [~~establishment of~~] specifications for procurement and storage of all
158 materials, including drugs, chemicals, and biologicals;

159
160 (ii) **participating** [~~participation~~] in the development of a formulary for the ASC, subject to
161 approval of the appropriate committee of the ASC;

162
163 (iii) **distributing** [~~distribution of~~] drugs to be administered to patients pursuant to [~~an original~~
164 ~~or direct copy of~~] the practitioner's medication order;

165
166 (iv) filling and labeling all containers from which drugs are to be distributed or dispensed;

167
168 (v) maintaining and making available a sufficient inventory of antidotes and other emergency
169 drugs, both in the pharmacy and patient care areas, as well as current antidote information,
170 telephone numbers of regional poison control center and other emergency assistance
171 organizations, and such other materials and information as may be deemed necessary by the
172 appropriate committee of the ASC;

173
174 (vi) **maintaining** records of all transactions of the ASC pharmacy as may be required by
175 applicable state and federal law, and as may be necessary to maintain accurate control over
176 and accountability for all pharmaceutical materials;

177
178 (vii) **participating** [~~participation~~] in those aspects of the ASC's patient care evaluation
179 program which relate to pharmaceutical material utilization and effectiveness;

180
181 (viii) **participating** [~~participation~~] in teaching and/or research programs in the ASC;

182
183 (ix) **implementing** [~~implementation of~~] the policies and decisions of the appropriate
184 committee(s) relating to pharmaceutical services of the ASC;

185
186 (x) **providing** effective and efficient messenger and delivery service to connect the ASC
187 pharmacy with appropriate areas of the ASC on a regular basis throughout the normal workday
188 of the ASC;

189
190 (xi) labeling, **storing, and distributing** [~~storage, and distribution of~~] investigational new
191 drugs, including **maintaining** [~~maintenance of~~] information in the pharmacy and nursing station
192 where such drugs are being administered, concerning the dosage form, route of administration,
193 strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of
194 investigational new drugs;

195
196 (xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this
197 subsection; and

198

199 (xiii) **maintaining** [~~maintenance of~~] records in a data processing system such that the data
200 processing system is in compliance with the requirements for a Class C (institutional) pharmacy
201 located in a freestanding ASC.

202

203 (2) Consultant pharmacist.

204

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

206

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

209

210 (3) Pharmacists.

211

212 (A) General.

213

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

217

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

221

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

224

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

227

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

230

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

233

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

235

236 (iii) interpreting patient profiles.

237

238 (C) Special requirements for compounding non-sterile preparations. All pharmacists engaged
239 in compounding non-sterile preparations shall meet the training requirements specified in
240 §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

241

242 (4) Pharmacy technicians and pharmacy technician trainees.

243

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

247

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

251
252 (i) prepacking and labeling unit and multiple dose packages, provided a pharmacist
253 supervises and conducts a final check and affixes his or her name, initials, electronic signature
254 to the appropriate quality control records prior to distribution;

255
256 (ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to
257 medication orders, provided a pharmacist supervises and checks the preparation;

258
259 (iii) compounding non-sterile preparations pursuant to medication orders provided the
260 pharmacy technicians or pharmacy technician trainees have completed the training specified in
261 §291.131 of this title;

262
263 (iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final
264 checks and affixes his or her name, initials, or electronic signature to the appropriate quality
265 control records prior to distribution;

266
267 (v) distributing routine orders for stock supplies to patient care areas;

268
269 (vi) entering medication order and drug distribution information into a data processing
270 system, provided judgmental decisions are not required and a pharmacist checks the accuracy
271 of the information entered into the system prior to releasing the order or in compliance with the
272 absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section;

273
274 (vii) maintaining inventories of drug supplies;

275
276 (viii) maintaining pharmacy records; and

277
278 (ix) loading bulk [~~unlabeled~~] drugs into an automated **medication supply system. For the**
279 **purpose of this clause, direct supervision may be accomplished by physically present**
280 **supervision or electronic monitoring by a pharmacist.** [~~drug dispensing system provided a~~
281 ~~pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his~~
282 ~~or her name, initials or electronic signature to the appropriate quality control records].~~

283
284 (C) Procedures.

285
286 (i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders
287 in accordance with standard written procedures and guidelines.

288
289 (ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug
290 orders in the same manner as pharmacy technicians or pharmacy technician trainees working in
291 a Class A pharmacy.

292
293 (D) Special requirements for compounding non-sterile preparations. All pharmacy technicians
294 and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet
295 the training requirements specified in §291.131 of this title.

296
297 (5) Owner. The owner of an ASC pharmacy shall have responsibility for all administrative and
298 operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on

299 administrative and operational concerns. The owner shall have responsibility for, at a minimum,
300 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with
301 the pharmacist-in-charge or another Texas licensed pharmacist:

302
303 (A) **establishing** [~~establishment of~~] policies for procurement of prescription drugs and
304 devices and other products dispensed from the ASC pharmacy;

305
306 (B) **establishing and maintaining** [~~establishment and maintenance of~~] effective controls
307 against the theft or diversion of prescription drugs;

308
309 (C) if the pharmacy uses an automated **medication supply** [~~pharmacy dispensing~~] system,
310 reviewing and approving all policies and procedures for system operation, safety, security,
311 accuracy and access, patient confidentiality, prevention of unauthorized access, and
312 malfunction;

313
314 (D) providing the pharmacy with the necessary equipment and resources commensurate with
315 its level and type of practice; and

316
317 (E) **establishing** [~~establishment of~~] policies and procedures regarding maintenance, storage,
318 and retrieval of records in a data processing system such that the system is in compliance with
319 state and federal requirements.

320
321 (6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows:

322
323 (A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge
324 that bears the person's name and identifies him or her as a pharmacy technician [~~trainee—a~~
325 ~~registered pharmacy technician, or a certified pharmacy technician if the technician maintains~~
326 ~~current certification with the Pharmacy Technician Certification Board or any other entity~~
327 ~~providing an examination approved by the board~~].

328
329 (B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an
330 identification tag or badge that bears the person's name and identifies him or her as a pharmacy
331 technician trainee.

332
333 (C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that
334 bears the person's name and identifies him or her as a pharmacist intern.

335
336 (D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the
337 person's name and identifies him or her as a pharmacist.

338
339 (d) Operational standards.

340
341 (1) Licensing requirements.

342
343 (A) An ASC pharmacy shall register annually **or biennially** with the board on a pharmacy
344 license application provided by the board, following the procedures specified in §291.1 of this
345 title (relating to Pharmacy License Application).

346
347 (B) [~~If the ASC pharmacy is owned or operated by a pharmacy management or consulting~~
348 ~~firm, the following conditions apply.~~

349

350 —(i) The pharmacy license application shall list the pharmacy management or consulting firm
351 as the owner or operator.

352
353 —(ii) The pharmacy management or consulting firm shall obtain DEA and DPS controlled
354 substances registrations that are issued in the name of the firm, unless the following occur:

355
356 —(I) the pharmacy management or consulting firm and the facility cosign a contractual
357 pharmacy service agreement which assigns overall responsibility for controlled substances to
358 the facility; and

359
360 —(II) such pharmacy management or consulting firm maintains dual responsibility for the
361 controlled substances.]

362
363 [(C)] An ASC pharmacy which changes ownership shall notify the board within 10 days of the
364 change of ownership and apply for a new and separate license as specified in §291.3 of this title
365 (relating to Required Notifications).

366
367 (C) [(D)] An ASC pharmacy which changes location and/or name shall notify the board of the
368 change within 10 days and file for an amended license as specified in §291.3 of this title.

369
370 (D) [(E)] An ASC pharmacy owned by a partnership or corporation which changes managing
371 officers shall notify the board in writing of the names of the new managing officers within 10
372 days of the change, following the procedures in §291.3 of this title.

373
374 (E) [(F)] An ASC pharmacy shall notify the board in writing within 10 days of closing, following
375 the procedures in §291.5 of this title (relating to Closing a Pharmacy).

376
377 (F) [(G)] A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
378 charged for issuance and renewal of a license and the issuance of an amended license.

379
380 (G) [(H)] A separate license is required for each principal place of business and only one
381 pharmacy license may be issued to a specific location.

382
383 (H) [(I)] An ASC pharmacy, licensed under the Act, §560.051(a)(3), concerning institutional
384 pharmacy (Class C), which also operates another type of pharmacy which would otherwise be
385 required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class
386 A), or the Act, §560.051(a)(2), concerning nuclear pharmacy (Class B), is not required to secure
387 a license for the other type of pharmacy; provided, however, such license is required to comply
388 with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to
389 Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating
390 to Records), and §291.35 of this title (relating to Official Prescription Records), or §291.51 of
391 this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title
392 (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of
393 this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such
394 sections are applicable to the operation of the pharmacy.

395
396 (I) [(J)] An ASC pharmacy engaged in the compounding of non-sterile preparations shall
397 comply with the provisions of §291.131 of this title.

398
399 (J) [(K) Effective August 31, 2014, an] ASC pharmacy **personnel** shall not compound sterile
400 preparations unless the pharmacy has applied for and obtained a Class C-S pharmacy.

401
402 **(K)** ~~[(L)]~~ An ASC pharmacy engaged in the provision of remote pharmacy services, including
403 storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of
404 this title (relating to Remote Pharmacy Services).

405
406 **(L)** ~~[(M)]~~ An ASC pharmacy engaged in centralized prescription dispensing and/or
407 prescription drug or medication order processing shall comply with the provisions of §291.123 of
408 this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or
409 §291.125 of this title (relating to Centralized Prescription Dispensing).

410
411 (2) Environment.

412
413 (A) General requirements.

414
415 (i) Each ambulatory surgical center shall have a designated work area separate from patient
416 areas, and which shall have space adequate for the size and scope of pharmaceutical services
417 and shall have adequate space and security for the storage of drugs.

418
419 (ii) The ASC pharmacy shall be arranged in an orderly fashion and shall be kept clean. All
420 required equipment shall be clean and in good operating condition.

421
422 (B) Special requirements.

423
424 (i) The ASC pharmacy shall have locked storage for Schedule II controlled substances and
425 other controlled drugs requiring additional security.

426
427 (ii) The ASC pharmacy shall have a designated area for the storage of poisons and
428 externals separate from drug storage areas.

429
430 (C) Security.

431
432 (i) **The pharmacy and storage areas for prescription drugs and/or devices shall be**
433 **enclosed and capable of being locked by key, combination, or other mechanical or**
434 **electronic means, so as to prohibit access by unauthorized individuals.** Only individuals
435 authorized by the pharmacist-in-charge may enter the pharmacy or ~~[authorized personnel may]~~
436 have access to storage areas for prescription drugs and/or devices.

437
438 (ii) ~~[All storage areas for prescription drugs and/or devices shall be locked by key or~~
439 ~~combination, so as to prevent access by unauthorized personnel.]~~

440
441 ~~[(iii)]~~ The pharmacist-in-charge shall consult with ASC personnel with respect to security of
442 the drug storage areas, including provisions for adequate safeguards against theft or diversion
443 of **dangerous drugs and controlled substances, and to security of records for such**
444 **drugs.** ~~[prescription drugs and/or devices.]~~

445
446 **(iii) The pharmacy shall have locked storage for Schedule II controlled substances**
447 **and other drugs requiring additional security.**

448
449 (3) Equipment and supplies. Ambulatory surgical centers supplying drugs for postoperative use
450 shall have the following equipment and supplies:

- 452 (A) data processing system including a printer or comparable equipment;
453
454 (B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and
455
456 (C) adequate supply of prescription labels and other applicable identification labels.;

457
458 (4) Library. A reference library shall be maintained that includes the following in hard-copy or
459 electronic format and that pharmacy personnel shall be capable of accessing at all times:

460 (A) current copies of the following:

- 461
462 (i) Texas Pharmacy Act and rules;
463
464 (ii) Texas Dangerous Drug Act and rules;
465
466 (iii) Texas Controlled Substances Act and rules;

467
468 (iv) Federal Controlled Substances Act and rules or official publication describing the
469 requirements of the Federal Controlled Substances Act and rules;

470
471 (B) at least one current or updated **general drug information** reference **which is required**
472 **to** ~~[from each of the following categories:]~~

473
474
475 ~~[(i) Drug interactions. A reference text on drug interactions, such as Drug Interaction Facts.~~
476 ~~A separate reference is not required if other references maintained by the pharmacy] contain~~
477 ~~drug interaction information including information needed to determine severity or significance of~~
478 ~~the interaction and appropriate recommendations or actions to be taken; and~~

479
480 ~~[(ii) General information. A general information reference text, such as:~~

- 481
482 ~~—(I) Facts and Comparisons with current supplements;~~
483
484 ~~—(II) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the~~
485 ~~Healthcare Provider);~~
486
487 ~~—(III) AHFS Drug Information with current supplements;~~
488
489 ~~—(IV) Remington's Pharmaceutical Sciences; or~~
490
491 ~~—(V) Clinical Pharmacology;]~~

492
493 (C) ~~[a current or updated reference on injectable drug products, such as Handbook of~~
494 ~~Injectable Drugs;]~~

495
496 ~~[(D)] basic antidote information and the [telephone number of the nearest regional poison~~
497 ~~control center.]~~

498
499 ~~—(E) if the pharmacy compounds sterile preparations, specialty references appropriate for the~~
500 ~~scope of services provided by the pharmacy, e.g., if the pharmacy prepares cytotoxic drugs, a~~
501 ~~reference text on the preparation of cytotoxic drugs, such as Procedures for Handling Cytotoxic~~
502 ~~Drugs; and~~

503
504 —(F) metric apothecary weight and measure conversion charts.]

505
506 (5) Drugs.

507
508 (A) Procurement, preparation, and storage.

509
510 (i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of
511 drugs, but may receive input from other appropriate staff of the facility, relative to such
512 responsibility.

513
514 (ii) The pharmacist-in-charge shall have the responsibility for determining specifications of
515 all drugs procured by the facility.

516
517 (iii) ASC pharmacies may not sell, purchase, trade, or possess prescription drug samples,
518 unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to
519 Samples).

520
521 (iv) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in
522 §291.15 of this title (relating to Storage of Drugs).

523
524 (v) Any drug bearing an expiration date may not be dispensed or distributed beyond the
525 expiration date of the drug.

526
527 (vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined
528 together until such drugs are disposed of.

529
530 (B) Formulary.

531
532 (i) A formulary may be developed by an appropriate committee of the **ASC** [~~ambulatory~~
533 ~~surgical center~~].

534
535 (ii) The pharmacist-in-charge or consultant pharmacist shall be a full voting member of any
536 committee which involves pharmaceutical services.

537
538 **(iii) A practitioner may grant approval for pharmacists at the ASC to interchange, in**
539 **accordance with the facility's formulary, for the drugs on the practitioner's medication**
540 **orders provided:**

541
542 **(I) a formulary has been developed;**

543
544 **(II) the formulary has been approved by the medical staff of the ASC;**

545
546 **(III) there is a reasonable method for the practitioner to override any interchange; and**

547
548 **(IV) the practitioner authorizes pharmacist in the ACS to interchange on his/her**
549 **medication orders in accordance with the facility's formulary through his/her written**
550 **agreement to abide by the policies and procedures of the medical staff and facility.**

551
552 (C) Prepackaging [~~of drugs~~] and loading [~~of bulk unlabeled~~] drugs into automated **medication**
553 **supply** [~~drug dispensing~~] system.

554
555 (i) Prepackaging of drugs.
556
557 (I) Drugs may be prepackaged in quantities suitable for **distribution to other Class C**
558 **pharmacies under common ownership or for** internal distribution only by a pharmacist or by
559 pharmacy technicians or pharmacy technician trainees under the direction and direct
560 supervision of a pharmacist.
561
562 (II) The label of a prepackaged unit shall indicate:
563
564 (-a-) brand name and strength of the drug; or if no brand name, then the generic name,
565 strength, and name of the manufacturer or distributor;
566
567 (-b-) facility's lot number;
568
569 (-c-) expiration date; [~~and~~]
570
571 (-d-) quantity of the drug, if quantity is greater than one; **and**
572
573 **(-e-) if the drug is distributed to another Class C pharmacy, name of the facility**
574 **responsible for prepackaging the drug.**
575
576 (III) Records of prepackaging shall be maintained to show:
577
578 (-a-) the name of the drug, strength, and dosage form;
579
580 (-b-) facility's lot number;
581
582 (-c-) manufacturer or distributor;
583
584 (-d-) manufacturer's lot number;
585
586 (-e-) expiration date;
587
588 (-f-) quantity per prepackaged unit;
589
590 (-g-) number of prepackaged units;
591
592 (-h-) date packaged;
593
594 (-i-) name, initials, or electronic signature of the prepacker; [~~and~~]
595
596 (-j-) signature or electronic signature of the responsible pharmacist; **and**
597
598 **(-k-) if the drug is distributed to another Class C pharmacy, name of the facility**
599 **receiving the prepackaged drug.**
600
601 (IV) Stock packages, repackaged units, and control records shall be quarantined together
602 until checked/released by the pharmacist.
603

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

606
607 ~~[(I)]~~ Automated medication supply [drug dispensing] systems may be loaded with bulk
608 unit of use [unlabeled] drugs only by a pharmacist or by pharmacy technicians or pharmacy
609 technician trainees under the direction and direct supervision of a pharmacist. **For the purpose**
610 **of this clause, direct supervision may be accomplished by physically present**
611 **supervision or electronic monitoring by a pharmacist. In order for the pharmacist to**
612 **electronically monitor, the medication supply system must allow for bar code scanning**
613 **to verify the loading of drugs, and a record of the loading must be maintained by the**
614 **system and accessible for electronic review by the pharmacist.**

615
616 ~~[(II)]~~ The label of an automated drug dispensing system container shall indicate the brand
617 name and strength of the drug; or if no brand name, then the generic name, strength, and name
618 of the manufacturer or distributor.

619
620 ~~[(III)]~~ Records of loading bulk unlabeled drugs into an automated drug dispensing system
621 shall be maintained to show:

622
623 ~~— (a) name of the drug, strength, and dosage form;~~

624
625 ~~— (b) manufacturer or distributor;~~

626
627 ~~— (c) manufacturer's lot number;~~

628
629 ~~— (d) expiration date;~~

630
631 ~~— (e) date of loading;~~

632
633 ~~— (f) name, initials, or electronic signature of the person loading the automated drug~~
634 ~~dispensing system; and~~

635
636 ~~— (g) signature or electronic signature of the responsible pharmacist.~~

637
638 ~~[(IV)]~~ The automated drug dispensing system shall not be used until a pharmacist verifies
639 that the system is properly loaded and affixes his or her signature or electronic signature to the
640 record specified in subclause (III) of this clause.]

641
642 (6) Medication orders.

643
644 (A) Drugs may be administered to patients in ASCs only on the order of a practitioner. No
645 change in the order for drugs may be made without the approval of a practitioner **except as**
646 **authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.**

647
648 (B) Drugs may be distributed only pursuant to the [original or a direct copy of the]
649 practitioner's medication order.

650
651 (C) [Pharmacy technicians and pharmacy technician trainees may not receive oral medication
652 orders.]

653

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

657

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

660

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

663

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

665

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

668

669 (I) name of the patient;

670

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

672

673 (III) dose prescribed;

674

675 (IV) quantity taken;

676

677 (V) time and date; and

678

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

680

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

684

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

687

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

691

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

694

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

696

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

700

701 (iv) The pharmacist shall **conduct an audit of patient charts according to the schedule**
702 **set out in the policy and procedures at [verify each distribution after] a reasonable interval,**
703 **but [in no event may] such interval must occur at least once in every calendar week that the**
704 **pharmacy is open [exceed seven days].**

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

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

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

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

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

(ii) quantity removed;

(iii) location of floor stock;

(iv) date and time; and

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

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

(i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as practical, but in no event more than 72 hours from the time of such withdrawal.

(ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after a reasonable interval, but ~~[in no event may]~~ such interval **must occur at least once in every calendar week that the pharmacy is open** ~~[exceed seven days]~~.

(8) Policies and procedures. Written policies and procedures for a drug distribution system, appropriate for the ambulatory surgical center, shall be developed and implemented by the pharmacist-in-charge with the advice of the appropriate committee. The written policies and procedures for the drug distribution system shall include, but not be limited to, procedures regarding the following:

(A) controlled substances;

(B) investigational drugs;

(C) prepackaging and manufacturing;

(D) medication errors;

(E) orders of physician or other practitioner;

(F) floor stocks;

(G) adverse drug reactions;

- 756 (H) drugs brought into the facility by the patient;
757
758 (I) self-administration;
759
760 (J) emergency drug tray;
761
762 (K) formulary, if applicable;
763
764 (L) drug storage areas;
765
766 (M) drug samples;
767
768 (N) drug product defect reports;
769
770 (O) drug recalls;
771
772 (P) outdated drugs;
773
774 (Q) preparation and distribution of IV admixtures;
775
776 (R) procedures for supplying drugs for postoperative use, if applicable;
777
778 (S) use of automated **medication supply** ~~[drug dispensing]~~ systems; ~~[and]~~
779
780 (T) use of data processing systems; **and**
781
782 **(U) drug regimen review.**

783
784 (9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall
785 be supplied according to the following procedures.

786
787 (A) Drugs may only be supplied to patients who have been admitted to the **ASC** ~~[ambulatory~~
788 ~~surgical center]~~.

789
790 (B) Drugs may only be supplied in accordance with the system of control and accountability
791 established for drugs supplied from the ambulatory surgical center; such system shall be
792 developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the
793 pharmacist-in-charge.

794
795 (C) Only drugs listed on the approved postoperative drug list may be supplied; such list shall
796 be developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the
797 nature and type to meet the immediate postoperative needs of the ambulatory surgical center
798 patient.

799
800 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in
801 suitable containers and appropriately pre-labeled (including name, address, and phone number
802 of the facility, and necessary auxiliary labels) by the pharmacy, provided, however that topicals
803 and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a
804 72-hour supply.
805

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

809 (i) date supplied;

810 (ii) name of practitioner;

811 (iii) name of patient;

812 (iv) directions for use;

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

815 (vi) unique identification number.

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

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

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

822 (ii) date supplied;

823 (iii) name of practitioner;

824 (iv) name of patient;

825 (v) directions for use;

826 (vi) brand name and strength of the drug; or if no brand name, then the generic name of the
827 drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

828 (vii) unique identification number.

829 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall
830 review the records at least once in every calendar week that the pharmacy is open [every
831 seven days].

832 **(10) Drug regimen review.**

833 **(A) A pharmacist shall evaluate medication orders and patient medication records for:**

834 **(i) known allergies;**

835 **(ii) rational therapy--contraindications;**

836

857 (iii) reasonable dose and route of administration;
858
859 (iv) reasonable directions for use;
860
861 (v) duplication of therapy;
862
863 (vi) drug-drug interactions;
864
865 (vii) drug-food interactions;
866
867 (viii) drug-disease interactions;
868
869 (ix) adverse drug reactions;
870
871 (x) proper utilization, including overutilization or underutilization; and
872
873 (xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug
874 effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued
875 use of the drug in its current regimen.
876
877 (B) A retrospective, random drug regimen review as specified in the pharmacy's
878 policies and procedures shall be conducted on a periodic basis to verify proper usage of
879 drugs not to exceed 31 days between such reviews.
880
881 (iii) Any questions regarding the order must be resolved with the prescriber and a
882 written notation of these discussions made and maintained.
883
884 (e) Records.
885
886 (1) Maintenance of records.
887
888 (A) Every inventory or other record required to be kept under the provisions of this section
889 (relating to **Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center**
890 ~~[Institutional Pharmacy (Class C)]~~) shall be:
891
892 (i) kept by the pharmacy and be available, for at least two years from the date of such
893 inventory or record, for inspecting and copying by the board or its representative, and other
894 authorized local, state, or federal law enforcement agencies; and
895
896 (ii) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
897 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,
898 the requested records must be provided in a mutually agreeable electronic format if specifically
899 requested by the board or its representative. Failure to provide the records set out in this
900 subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep
901 and maintain records in violation of the Act.
902
903 (B) Records of controlled substances listed in **Schedule** ~~[Schedules I and]~~ II shall be
904 maintained separately **and readily retrievable** from all other records of the pharmacy.
905
906 (C) Records of controlled substances listed in Schedules III - V shall be maintained
907 separately or readily retrievable from all other records of the pharmacy. For purposes of this

908 **subparagraph** [subsection], readily retrievable means that the controlled substances shall be
909 asterisked, red-lined, or in some other manner readily identifiable apart from all other items
910 appearing on the record.

911
912 (D) Records, except when specifically required to be maintained in original or hard-copy form,
913 may be maintained in an alternative data retention system, such as a data processing or direct
914 imaging system[, e.g., microfilm or microfiche,] provided:

915
916 (i) the records in the alternative data retention system contain all of the information required
917 on the manual record; and

918
919 (ii) the alternative data retention system is capable of producing a hard copy of the record
920 upon the request of the board, its representative, or other authorized local, state, or federal law
921 enforcement or regulatory agencies.

922
923 **(E) Controlled substance records shall be maintained in a manner to establish receipt**
924 **and distribution of all controlled substances.**

925
926 **(F) An ASC pharmacy shall maintain a perpetual inventory of controlled substances**
927 **listed in Schedule II – V which shall be verified for completeness and reconciled at least**
928 **once in every calendar week that the pharmacy is open.**

929
930 **(G) Distribution records for controlled substances, listed in Schedule II – V, shall**
931 **include the following information:**

932
933 **(i) patient's name;**
934 **(ii) practitioner's name who order the drug;**
935 **(iii) name of drug, dosage form, and strength;**
936 **(iv) time and date of administration to patient and quantity administered;**
937 **(v) signature or electronic signature of individual administering the controlled**
938 **substance;**
939 **(vi) returns to the pharmacy; and**
940 **(vii) waste (waste is required to be witnessed and cosigned, manually or**
941 **electronically, by another individual).**

942
943 **(H) The record required by subparagraph (G) of this paragraph shall be maintained**
944 **separately from patient records.**

945
946 **(I) A pharmacist shall conduct an audit by randomly comparing the distribution**
947 **records required by subparagraph (G) with the medication orders in the patient record on**
948 **a periodic basis to verify proper administration of drugs not to exceed 30 days between**
949 **such reviews.**

950
951 (2) [Outpatient records.

952
953 ~~—(A) Only a registered pharmacist may receive, certify, and receive prescription drug orders.~~

954
955 ~~—(B) Outpatient records shall be maintained as provided in §291.34 and §291.35 of this title~~
956 ~~contained in Community Pharmacy (Class A).~~

957

958 ~~—(C) Outpatient prescriptions, including, but not limited to, discharge prescriptions, that are~~
959 ~~written by the practitioner, must be written on a form which meets the requirements of the Act,~~
960 ~~§562.006. Medication order forms or copies thereof do not meet the requirements for outpatient~~
961 ~~forms.~~

962
963 ~~—(D) Controlled substances listed in Schedule II must be written on an electronic prescription~~
964 ~~form in accordance with the Texas Controlled Substances Act, §481.075, and rules promulgated~~
965 ~~pursuant to the Texas Controlled Substances Act, unless exempted by the Texas Controlled~~
966 ~~Substances Rules, 37 TAC §13.74. Outpatient prescriptions for Schedule II controlled~~
967 ~~substances that are exempted from the official prescription requirement must be manually~~
968 ~~signed by the practitioner.]~~

969
970 [(3)] Patient records.

971
972 (A) Each [original] medication order or set of orders issued together shall bear the following
973 information:

- 974 (i) patient name;
975
976 (ii) drug name, strength, and dosage form;
977
978 (iii) directions for use;
979
980 (iv) date; and
981
982 (v) signature or electronic signature of the practitioner or that of his or her authorized agent,
983 defined as a licensed nurse employee or consultant/full or part-time pharmacist of the ASC.
984

985
986 (B) **Medication** [Original medication] orders shall be maintained with the medication
987 administration record in the medical records of the patient.
988

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

990
991 ~~—(i) All records for controlled substances shall be maintained in a readily retrievable manner.~~

992
993 ~~—(ii) Controlled substances records shall be maintained in a manner to establish receipt and~~
994 ~~distribution of all controlled substances.~~

995
996 ~~—(D) Records of controlled substances listed in Schedule II shall be maintained as follows.~~

997
998 ~~—(i) Records of controlled substances listed in Schedule II shall be maintained separately~~
999 ~~from records of controlled substances in Schedules III, IV, and V, and all other records.~~

1000
1001 ~~—(ii) An ASC pharmacy shall maintain a perpetual inventory of any controlled substance listed~~
1002 ~~in Schedule II.~~

1003
1004 ~~—(iii) Distribution records for Schedule II–V controlled substances floor stock shall include the~~
1005 ~~following information:~~

1006
1007 ~~—(l) patient's name;~~

1008

1009 —(II) practitioner who ordered drug;
1010
1011 —(III) name of drug, dosage form, and strength;
1012
1013 —(IV) time and date of administration to patient and quantity administered;
1014
1015 —(V) signature or electronic signature of individual administering controlled substance;
1016
1017 —(VI) returns to the pharmacy; and
1018
1019 —(VII) waste (waste is required to be witnessed and cosigned, manually or electronically, by
1020 another individual).
1021
1022 —(E) Floor stock records shall be maintained as follows.
1023
1024 —(i) Distribution records for Schedules III - V controlled substances floor stock shall include
1025 the following information:
1026
1027 —(I) patient's name;
1028
1029 —(II) practitioner who ordered controlled substance;
1030
1031 —(III) name of controlled substance, dosage form, and strength;
1032
1033 —(IV) time and date of administration to patient;
1034
1035 —(V) quantity administered;
1036
1037 —(VI) signature or electronic signature of individual administering drug;
1038
1039 —(VII) returns to the pharmacy; and
1040
1041 —(VIII) waste (waste is required to be witnessed and cosigned, manually or electronically, by
1042 another individual).
1043
1044 —(ii) The record required by clause (i) of this subparagraph shall be maintained separately
1045 from patient records.
1046
1047 —(iii) A pharmacist shall review distribution records with medication orders on a periodic basis
1048 to verify proper usage of drugs, not to exceed 30 days between such reviews.]
1049
1050 **(3)** [(F)] General requirements for records maintained in a data processing system [are as
1051 follows].
1052
1053 **(A)** [(i)] If an ASC pharmacy's data processing system is not in compliance with the board's
1054 requirements, the pharmacy must maintain a manual recordkeeping system.
1055
1056 **(B)** [(ii) Requirements for backup systems.] The facility shall maintain a backup copy of
1057 information stored in the data processing system using disk, tape, or other electronic backup
1058 system and update this backup copy on a regular basis to assure that data is not lost due to
1059 system failure.

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

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

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

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

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

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

~~—— ~~[-a-]~~ transfer the records to the new data processing system; or~~

~~—— ~~[-b-]~~ purge the records to a printout which contains all of the information required on the original document.]~~

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

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

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

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

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

(i) ~~[(4)]~~ patient's name and room number or patient's facility identification number;

(ii) ~~[(4)]~~ prescribing or attending practitioner's name;

1111
1112 **(iii)** ~~[(iii)]~~ name, strength, and dosage form of the drug product actually distributed;
1113
1114 **(iv)** ~~[(iv)]~~ total quantity distributed from and returned to the pharmacy;
1115
1116 **(v)** ~~[(v)]~~ if not immediately retrievable via electronic image, the following shall also be
1117 included on the printout:
1118
1119 **(i)** ~~[(a)]~~ prescribing or attending practitioner's address; and
1120
1121 **(ii)** ~~[(b)]~~ practitioner's DEA registration number, if the medication order is for a controlled
1122 substance.
1123
1124 **(G)** ~~[(iii)]~~ An audit trail printout for each strength and dosage form of these drugs distributed
1125 during the preceding month shall be produced at least monthly and shall be maintained in a
1126 separate file at the facility. The information on this printout shall be sorted by drug name and list
1127 all distributions/returns for that drug chronologically.
1128
1129 **(H)** ~~[(iv)]~~ The pharmacy may elect not to produce the monthly audit trail printout if the data
1130 processing system has a workable (electronic) data retention system which can produce an
1131 audit trail of drug distribution and returns for the preceding two years. The audit trail required in
1132 this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized
1133 agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law
1134 enforcement or regulatory agencies.
1135
1136 ~~[(H) Failure to maintain records. Failure to provide records set out in this subsection, either on~~
1137 ~~site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep~~
1138 ~~and maintain records.]~~
1139
1140 **(I)** ~~[Data processing system downtime.]~~ In the event that an ASC pharmacy which uses a data
1141 processing system experiences system downtime, the pharmacy must have an auxiliary
1142 procedure which will ensure that all data is retained for on-line data entry as soon as the system
1143 is available for use again.
1144
1145 (4) Distribution of controlled substances to another registrant. A pharmacy may distribute
1146 controlled substances to a practitioner, another pharmacy, or other registrant, without being
1147 registered to distribute, under the following conditions.
1148
1149 (A) The registrant to whom the controlled substance is to be distributed is registered under
1150 the Controlled Substances Act to **possess** ~~[dispense]~~ that controlled substance.
1151
1152 (B) The total number of dosage units of controlled substances distributed by a pharmacy may
1153 not exceed 5.0% of all controlled substances dispensed by the pharmacy during the 12-month
1154 period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is
1155 required to obtain an additional registration to distribute controlled substances.
1156
1157 (C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be
1158 maintained which indicates:
1159
1160 (i) the actual date of distribution;
1161

1162 (ii) the name, strength, and quantity of controlled substances distributed;
1163
1164 (iii) the name, address, and DEA registration number of the distributing pharmacy; and
1165
1166 (iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other
1167 registrant to whom the controlled substances are distributed.
1168
1169 (D) If the distribution is for a Schedule II controlled substance, the following is applicable.
1170
1171 (i) The pharmacy, practitioner, or other registrant who is receiving the controlled substances
1172 shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222[G]) to the distributing pharmacy.
1173
1174 (ii) The distributing pharmacy shall:
1175
1176 (I) complete the area on the DEA order form (DEA 222[G]) titled "To Be Filled in by
1177 Supplier";
1178
1179 (II) maintain Copy 1 of the DEA order form (DEA 222[G]) at the pharmacy for two years;
1180 and
1181
1182 (III) forward Copy 2 of the DEA order form (DEA 222[G]) to the divisional office of the Drug
1183 Enforcement Administration.
1184
1185 (5) Other records. Other records to be maintained by the pharmacy include:
1186
1187 (A) a permanent log of the initials or identification codes which will identify each pharmacist
1188 by name. The initials or identification code shall be unique to ensure that each pharmacist can
1189 be identified, i.e., identical initials or identification codes cannot be used;
1190
1191 (B) Copy 3 of DEA order form (DEA 222[G]), which has been properly dated, initialed, and
1192 filed, and all copies of each unaccepted or defective order form and any attached statements or
1193 other documents **and/or for each order filled using the DEA Controlled Substance**
1194 **Ordering System (CSOS), the original signed order and all linked records for that order;**
1195
1196 (C) a [~~hard~~] copy of the power of attorney to sign DEA 222[G] order forms (if applicable);
1197
1198 (D) suppliers' invoices of dangerous drugs and controlled substances **dated and initialed or**
1199 **signed by the person receiving the drugs;** a pharmacist shall verify that the controlled drugs
1200 listed on the invoices were **added to the pharmacy's perpetual inventory** [~~actually received~~]
1201 by clearly recording his/her initials and the [~~actual~~] date of **review** [~~receipt~~] of the **perpetual**
1202 **inventory** [~~controlled substances~~];
1203
1204 (E) supplier's credit memos for controlled substances and dangerous drugs;
1205
1206 (F) a [~~hard~~] copy of inventories required by §291.17 of this title (relating to Inventory
1207 Requirements) except that a perpetual inventory of controlled substances listed in Schedule II
1208 may be kept in a data processing system if the data processing system is capable of producing
1209 a [~~hard~~] copy of the perpetual inventory on-site;
1210
1211 (G) [~~hard copy~~] reports of surrender or destruction of controlled substances and/or dangerous
1212 drugs to an appropriate state or federal agency;

1213
1214 (H) [~~a hard copy Schedule V nonprescription register book;~~
1215
1216 [(+)] records of distribution of controlled substances and/or dangerous drugs to other
1217 pharmacies, practitioners, or registrants; and
1218
1219 ~~(I)~~[(+)] a [hard] copy of any notification required by the Texas Pharmacy Act or these rules,
1220 including, but not limited to, the following:
1221
1222 (i) reports of theft or significant loss of controlled substances to DEA, DPS, and the board;
1223
1224 (ii) notification of a change in pharmacist-in-charge of a pharmacy; and
1225
1226 (iii) reports of a fire or other disaster which may affect the strength, purity, or labeling of
1227 drugs, medications, devices, or other materials used in the diagnosis or treatment of injury,
1228 illness, and disease.
1229
1230 (6) Permission to maintain central records. Any pharmacy that uses a centralized
1231 recordkeeping system for invoices and financial data shall comply with the following procedures.
1232
1233 (A) Controlled substance records. Invoices and financial data for controlled substances may
1234 be maintained at a central location provided the following conditions are met.
1235
1236 (i) Prior to the initiation of central recordkeeping, the pharmacy submits written notification
1237 by registered or certified mail to the divisional director of the Drug Enforcement Administration
1238 as required by the Code of Federal Regulations, Title 21, §1304(a), and submits a copy of this
1239 written notification to the Texas State Board of Pharmacy. Unless the registrant is informed by
1240 the divisional director of the Drug Enforcement Administration that permission to keep central
1241 records is denied, the pharmacy may maintain central records commencing 14 days after
1242 receipt of notification by the divisional director.
1243
1244 (ii) The pharmacy maintains a copy of the notification required in this subparagraph.
1245
1246 (iii) The records to be maintained at the central record location shall not include executed
1247 DEA order forms, prescription drug orders, or controlled substance inventories, which shall be
1248 maintained at the pharmacy.
1249
1250 (B) Dangerous drug records. Invoices and financial data for dangerous drugs may be
1251 maintained at a central location.
1252
1253 (C) Access to records. If the records are kept [~~on microfilm, computer media, or~~] in any form
1254 requiring special equipment to render the records easily readable, the pharmacy shall provide
1255 access to such equipment with the records.
1256
1257 (D) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the
1258 pharmacy location within two business days of written request of a board agent or any other
1259 authorized official.

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER H OTHER CLASSES OF PHARMACY

5 **§291.151 Pharmacies Located in a Freestanding Emergency Medical Care Facility [Center]**
6 **(Class F)**
7

8 (a) Purpose. The purpose of this section is to provide standards in the conduct, practice
9 activities, and operation of a pharmacy located in a freestanding emergency medical care
10 **facilities** [center] that is licensed by the Texas Department of State Health Services or in a
11 freestanding emergency medical care **facility** [center] operated by a hospital that is exempt
12 from registration as provided by §254.052, Health and Safety Code. Class F pharmacies located
13 in a freestanding emergency medical care **facility** [center] shall comply with this section.
14

15 (b) Definitions. The following words and terms, when used in this section, shall have the
16 following meanings, unless the context clearly indicates otherwise.
17

18 (1) Act--The Texas Pharmacy Act, [~~Chapters 551 – 566 and 568 – 569,~~] Occupations Code,
19 **Subtitle J**, as amended.
20

21 **(2) Administer--The direct application of a prescription drug by injection, inhalation,**
22 **ingestion, or any other means to the body of a patient by:**
23

24 **(A) a practitioner, an authorized agent under his supervision, or other person**
25 **authorized by law; or**
26

27 **(B) the patient at the direction of a practitioner.**
28

29 **(3) Automated medication supply system--A mechanical system that performs operations**
30 **or activities relative to the storage and distribution of medications for administration and**
31 **which collects, controls, and maintains all transaction information.**
32

33 [~~(2) Automated drug dispensing system--An automated device that measures, counts, and/or~~
34 ~~packages a specified quantity of dosage units for a designated drug product.]~~
35

36 **(4) [(3)]-Board--The Texas State Board of Pharmacy.**
37

38 **(5) [(4)] Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult**
39 **with the FEMCF [FEMCC] in areas that pertain to the practice of pharmacy.**
40

41 **(6) [(5)] Controlled substance--A drug, immediate precursor, or other substance listed in**
42 **Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended,**
43 **or a drug immediate precursor, or other substance included in Schedule I - V of the Federal**
44 **Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-**
45 **513).**
46

47 [~~(6) Direct copy --Electronic copy or carbonized copy of a medication order including a facsimile~~
48 ~~(FAX) or digital image.]~~
49

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

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

56
57 (9) Downtime--Period of time during which a data processing system is not operable.

58
59 (10) Electronic signature--A unique security code or other identifier which specifically identifies
60 the person entering information into a data processing system. A facility which utilizes electronic
61 signatures must:

62
63 (A) maintain a permanent list of the unique security codes assigned to persons authorized to
64 use the data processing system; and

65
66 (B) have an ongoing security program which is capable of identifying misuse and/or
67 unauthorized use of electronic signatures.

68
69 (11) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained
70 at a nursing station or other **FEMCF** [~~FEMCC~~] department (excluding the pharmacy) for the
71 purpose of administration to a patient of the **FEMCF** [~~FEMCC~~].

72
73 (12) Formulary--List of drugs approved for use in the **FEMCF** [~~FEMCC~~] by an appropriate
74 committee of the freestanding emergency medical care center.

75
76 (13) Freestanding emergency medical care **facility (FEMCF)** [~~center (FEMCC)~~]-A
77 freestanding facility that is licensed by the Texas Department of State Health Services pursuant
78 to Chapter 254, Health and Safety Code, to provide emergency care to patients.

79
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
83 (15) Investigational new drug--New drug intended for investigational use by experts qualified to
84 evaluate the safety and effectiveness of the drug as authorized by the federal Food and Drug
85 Administration.

86
87 (16) Medication order—~~An [A written order from a practitioner or a verbal]~~ order from a
88 practitioner or his authorized agent for administration of a drug or device.

89
90 (17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist
91 who has the authority or responsibility for a pharmacy's compliance with laws and rules
92 pertaining to the practice of pharmacy.

93
94 (18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are
95 stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other areas
96 or departments of the **FEMCF** [~~FEMCC~~], or dispensed to an ultimate user or his or her agent.

97
98 (19) Prescription drug--
99

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

102
103 (B) A drug or device that under federal law is required, prior to being dispensed or delivered,
104 to be labeled with either of the following statements:

105
106 (i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another
107 legend that complies with federal law; or

108
109 (ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or
110

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

113
114 (20) Prescription drug order--

115
116 (A) An ~~[A written order from a practitioner or verbal]~~ order from a practitioner or his authorized
117 agent to a pharmacist for a drug or device to be dispensed; or

118
119 (B) An ~~[A written order or a verbal]~~ order pursuant to Subtitle B, Chapter 157, Occupations
120 Code.

121
122 (21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per
123 week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy
124 is open.

125
126 (22) Part-time pharmacist--A pharmacist who works less than full-time.

127
128 (23) Pharmacy technician--An individual who is registered with the board as a pharmacy
129 technician and whose responsibility in a pharmacy is to provide technical services that do not
130 require professional judgment regarding preparing and distributing drugs and who works under
131 the direct supervision of and is responsible to a pharmacist.

132
133 (24) Pharmacy technician trainee--An individual who is registered with the board as a
134 pharmacy technician trainee and is authorized to participate in a pharmacy's technician training
135 program.

136
137 (25) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and
138 Safety Code, Chapter 481, as amended.

139
140 (c) Personnel.

141
142 (1) Pharmacist-in-charge.

143
144 (A) General. Each freestanding emergency medical care center shall have one pharmacist-in-
145 charge who is employed or under contract, at least on a consulting or part-time basis, but may
146 be employed on a full-time basis.

147
148 (B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum,
149 the following:

150

- 151 (i) **establishing** [~~establishment of~~] specifications for procurement and storage of all
152 materials, including drugs, chemicals, and biologicals;
153
- 154 (ii) **participating** [~~participation~~] in the development of a formulary for the **FEMCF** [FEMCG],
155 subject to approval of the appropriate committee of the **FEMCF** [FEMCG];
156
- 157 (iii) **distributing** [~~distribution of~~] drugs to be administered to patients pursuant to [~~an original~~
158 ~~or direct copy of~~] the practitioner's medication order;
159
- 160 (iv) filling and labeling all containers from which drugs are to be distributed or dispensed;
161
- 162 (v) maintaining and making available a sufficient inventory of antidotes and other emergency
163 drugs, both in the pharmacy and patient care areas, as well as current antidote information,
164 telephone numbers of regional poison control center and other emergency assistance
165 organizations, and such other materials and information as may be deemed necessary by the
166 appropriate committee of the **FEMCF** [FEMCG];
167
- 168 (vi) **maintaining** records of all transactions of the **FEMCF** [FEMCG] pharmacy as may be
169 required by applicable state and federal law, and as may be necessary to maintain accurate
170 control over and accountability for all pharmaceutical materials;
171
- 172 (vii) **participating** [~~participation~~] in those aspects of the **FEMCF** [FEMCG]'s patient care
173 evaluation program which relate to pharmaceutical material utilization and effectiveness;
174
- 175 (viii) **participating** [~~participation~~] in teaching and/or research programs in the **FEMCF**
176 [FEMCG];
177
- 178 (ix) **implementing** [~~implementation of~~] the policies and decisions of the appropriate
179 committee(s) relating to pharmaceutical services of the **FEMCF** [FEMCG];
180
- 181 (x) **providing** effective and efficient messenger and delivery service to connect the **FEMCF**
182 [FEMCG] pharmacy with appropriate areas of the **FEMCF** [FEMCG] on a regular basis
183 throughout the normal workday of the **FEMCF** [FEMCG];
184
- 185 (xi) labeling, **storing, and distributing** [~~storage, and distribution of~~] investigational new
186 drugs, including **maintaining** [~~maintenance of~~] information in the pharmacy and nursing station
187 where such drugs are being administered, concerning the dosage form, route of administration,
188 strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of
189 investigational new drugs;
190
- 191 (xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this
192 section; and
193
- 194 (xiii) **maintain** [~~maintenance of~~] records in a data processing system such that the data
195 processing system is in compliance with the requirements for a **FEMCF** [FEMCG].
196
- 197 (2) Consultant pharmacist.
198
- 199 (A) The consultant pharmacist may be the pharmacist-in-charge.
200

201 (B) A written contract shall exist between the **FEMCF** [~~FEMCC~~] and any consultant
202 pharmacist, and a copy of the written contract shall be made available to the board upon
203 request.

204

205 (3) Pharmacists.

206

207 (A) General.

208

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

212

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

216

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

219

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

222

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

225

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

228

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

230

231 (iii) interpreting patient profiles.

232

233 (C) Special requirements for compounding non-sterile preparations. All pharmacists engaged
234 in compounding non-sterile preparations shall meet the training requirements specified in
235 §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

236

237 (4) Pharmacy technicians and pharmacy technician trainees.

238

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

242

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

246

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

250

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

253
254 (iii) compounding non-sterile preparations pursuant to medication orders provided the
255 pharmacy technicians or pharmacy technician trainees have completed the training specified in
256 §291.131 of this title;

257
258 (iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final
259 checks and affixes his or her name, initials, or electronic signature to the appropriate quality
260 control records prior to distribution;

261
262 (v) distributing routine orders for stock supplies to patient care areas;

263
264 (vi) entering medication order and drug distribution information into a data processing
265 system, provided judgmental decisions are not required and a pharmacist checks the accuracy
266 of the information entered into the system prior to releasing the order or in compliance with the
267 absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section;

268
269 (vii) maintaining inventories of drug supplies;

270
271 (viii) maintaining pharmacy records; and

272
273 (ix) loading bulk [unlabeled] drugs into an automated **medication supply system. For the**
274 **purpose of this clause, direct supervision may be accomplished by physically present**
275 **supervision or electronic monitoring by a pharmacist.** [~~drug dispensing system provided a~~
276 ~~pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his~~
277 ~~or her name, initials or electronic signature to the appropriate quality control records].~~

278
279 (C) Procedures.

280
281 (i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders
282 in accordance with standard written procedures and guidelines.

283
284 (ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug
285 orders in the same manner as pharmacy technicians or pharmacy technician trainees working in
286 a Class A pharmacy.

287
288 (D) Special requirements for compounding non-sterile preparations. All pharmacy technicians
289 and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet
290 the training requirements specified in §291.131 of this title.

291
292 (5) Owner. The owner of a **FEMCF** [~~FEMCC~~] pharmacy shall have responsibility for all
293 administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise
294 the owner on administrative and operational concerns. The owner shall have responsibility for,
295 at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner
296 shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

297
298 (A) **establishing** [~~establishment of~~] policies for procurement of prescription drugs and
299 devices and other products dispensed from the FEMCF [~~FEMCC~~] pharmacy;

300

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

303
304 (C) if the pharmacy uses an automated **medication supply** ~~[pharmacy dispensing]~~ system,
305 reviewing and approving all policies and procedures for system operation, safety, security,
306 accuracy and access, patient confidentiality, prevention of unauthorized access, and
307 malfunction;

308
309 (D) providing the pharmacy with the necessary equipment and resources commensurate with
310 its level and type of practice; and

311
312 (E) **establishing** ~~[establishment of]~~ policies and procedures regarding maintenance, storage,
313 and retrieval of records in a data processing system such that the system is in compliance with
314 state and federal requirements.

315
316 (6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows:

317
318 (A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge
319 that bears the person's name and identifies him or her as a pharmacy technician ~~[trainee a~~
320 ~~registered pharmacy technician, or a certified pharmacy technician, if the technician maintains~~
321 ~~current certification with the Pharmacy Technician Certification Board or any other entity~~
322 ~~providing an examination approved by the board].~~

323
324 (B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an
325 identification tag or badge that bears the person's name and identifies him or her as a pharmacy
326 technician trainee.

327
328 (C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that
329 bears the person's name and identifies him or her as a pharmacist intern.

330
331 (D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the
332 person's name and identifies him or her as a pharmacist.

333
334 (d) Operational standards.

335
336 (1) Licensing requirements.

337
338 (A) A **FEMCF** ~~[FEMCC]~~ pharmacy shall register annually or biennially with the board on a
339 pharmacy license application provided by the board, following the procedures specified in
340 §291.1 of this title (relating to Pharmacy License Application).

341
342 (B) ~~[If the FEMCC pharmacy is owned or operated by a pharmacy management or consulting~~
343 ~~firm, the following conditions apply.~~

344
345 ~~—(i) The pharmacy license application shall list the pharmacy management or consulting firm~~
346 ~~as the owner or operator.~~

347
348 ~~—(ii) The pharmacy management or consulting firm shall obtain DEA and DPS controlled~~
349 ~~substances registrations that are issued in the name of the firm, unless the following occur:~~

350

351 ——— (I) ~~the pharmacy management or consulting firm and the facility cosign a contractual~~
352 ~~pharmacy service agreement which assigns overall responsibility for controlled substances to~~
353 ~~the facility; and~~

354 ——— (II) ~~such pharmacy management or consulting firm maintains dual responsibility for the~~
355 ~~controlled substances.]~~

356
357
358 [(C)] A **FEMCF** [FEMCG] pharmacy which changes ownership shall notify the board within 10
359 days of the change of ownership and apply for a new and separate license as specified in
360 §291.3 of this title (relating to Required Notifications).

361
362 (C) [(D)] A **FEMCF** [FEMCG] pharmacy which changes location and/or name shall notify the
363 board of the change within 10 days and file for an amended license as specified in §291.3 of
364 this title.

365
366 (D) [(E)] A **FEMCF** [FEMCG] pharmacy owned by a partnership or corporation which changes
367 managing officers shall notify the board in writing of the names of the new managing officers
368 within 10 days of the change, following the procedures in §291.3 of this title.

369
370 (E) [(F)] A **FEMCF** [FEMCG] pharmacy shall notify the board in writing within 10 days of
371 closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

372
373 (F) [(G)] A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
374 charged for issuance and renewal of a license and the issuance of an amended license.

375
376 (G) [(H)] A separate license is required for each principal place of business and only one
377 pharmacy license may be issued to a specific location.

378
379 (H) **A FEMCF pharmacy, which also operates another type of pharmacy which would**
380 **otherwise be required to be licensed under the Act, §560.051(a)(1), concerning**
381 **community pharmacy (Class A), is not required to secure a license for the other type of**
382 **pharmacy; provided, however, such license is required to comply with the provisions of**
383 **§291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel),**
384 **§291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to**
385 **Records), and §291.35 of this title (relating to Official Prescription Records), to the extent**
386 **such sections are applicable to the operation of the pharmacy.**

387
388 (I) A **FEMCF** [FEMCG] pharmacy engaged in the compounding of non-sterile preparations shall
389 comply with the provisions of §291.131 of this title.

390
391 (2) Environment.

392
393 (A) General requirements.

394
395 (i) Each freestanding emergency medical care center shall have a designated work area
396 separate from patient areas, and which shall have space adequate for the size and scope of
397 pharmaceutical services and shall have adequate space and security for the storage of drugs.

398
399 (ii) The **FEMCF** [FEMCG] pharmacy shall be arranged in an orderly fashion and shall be
400 kept clean. All required equipment shall be clean and in good operating condition.

401

402 (B) Special requirements.

403

404 (i) The **FEMCF** [~~FEMCC~~] pharmacy shall have locked storage for Schedule II controlled
405 substances and other controlled drugs requiring additional security.

406

407 (ii) The **FEMCF** [~~FEMCC~~] pharmacy shall have a designated area for the storage of poisons
408 and externals separate from drug storage areas.

409

410 (C) Security.

411

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

417

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

420

421 [~~(iii)~~] The pharmacist-in-charge shall consult with **FEMCF** [~~ASG~~] personnel with respect to
422 security of the drug storage areas, including provisions for adequate safeguards against theft or
423 diversion of **dangerous drugs, controlled substances, and records for such drugs.**
424 [~~prescription drugs and/or devices.~~]

425

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

428

429

430 (3) Equipment and supplies. Freestanding emergency medical care centers supplying drugs
431 for outpatient use shall have the following equipment and supplies:

432

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

434

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

436

437 (C) adequate supply of prescription labels and other applicable identification labels.

438

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

441

442 (A) current copies of the following:

443

444 (i) Texas Pharmacy Act and rules;

445

446 (ii) Texas Dangerous Drug Act and rules;

447

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

449

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

452

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

455
456 [(i) ~~Drug interactions. A reference text on drug interactions, such as Drug Interaction Facts.~~
457 ~~A separate reference is not required if other references maintained by the pharmacy]~~ contain
458 drug interaction information including information needed to determine severity or significance of
459 the interaction and appropriate recommendations or actions to be taken; **and**

460
461 [(ii) ~~General information. A general information reference text, such as:~~

462
463 — (I) ~~Facts and Comparisons with current supplements;~~

464
465 — (II) ~~United States Pharmacopeia Dispensing Information Volume I (Drug Information for the~~
466 ~~Healthcare Provider);~~

467
468 — (III) ~~AHFS Drug Information with current supplements;~~

469
470 — (IV) ~~Remington's Pharmaceutical Sciences; or~~

471
472 — (V) ~~Clinical Pharmacology;]~~

473
474 (C) [~~a current or updated reference on injectable drug products, such as Handbook of~~
475 ~~Injectable Drugs;]~~

476
477 [~~Ⓓ] basic antidote information and the telephone number of the nearest regional poison~~
478 ~~control center.];~~

479
480 — (E) ~~if the pharmacy compounds sterile preparations, specialty references appropriate for the~~
481 ~~scope of services provided by the pharmacy, e.g., if the pharmacy prepares cytotoxic drugs, a~~
482 ~~reference text on the preparation of cytotoxic drugs, such as Procedures for Handling Cytotoxic~~
483 ~~Drugs; and~~

484
485 — (F) ~~metric-apothecary weight and measure conversion charts.]~~

486
487 (5) Drugs.

488
489 (A) Procurement, preparation, and storage.

490
491 (i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of
492 drugs, but may receive input from other appropriate staff of the facility, relative to such
493 responsibility.

494
495 (ii) The pharmacist-in-charge shall have the responsibility for determining specifications of
496 all drugs procured by the facility.

497
498 (iii) **FEMCF** [~~FEMCG~~] pharmacies may not sell, purchase, trade, or possess prescription
499 drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title
500 (relating to Samples).

501
502 (iv) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in
503 §291.15 of this title (relating to Storage of Drugs).

504
505 (v) Any drug bearing an expiration date may not be dispensed or distributed beyond the
506 expiration date of the drug.

507
508 (vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined
509 together until such drugs are disposed of.

510
511 (B) Formulary.

512
513 (i) A formulary may be developed by an appropriate committee of the **FEMCF** [~~freestanding~~
514 ~~emergency medical center~~].

515
516 (ii) The pharmacist-in-charge, [~~or~~] consultant pharmacist, **or designee** shall be a full voting
517 member of any committee which involves pharmaceutical services.

518
519 **(iii) A practitioner may grant approval for pharmacists at the FEMCF to interchange, in**
520 **accordance with the facility's formulary, for the drugs on the practitioner's medication**
521 **orders provided:**

522
523 **(I) a formulary has been developed;**

524
525 **(II) the formulary has been approved by the medical staff of the FEMCF;**

526
527 **(III) there is a reasonable method for the practitioner to override any interchange; and**

528
529 **(IV) the practitioner authorizes pharmacist in the FEMCF to interchange on his/her**
530 **medication orders in accordance with the facility's formulary through his/her written**
531 **agreement to abide by the policies and procedures of the medical staff and facility.**

532
533
534 (C) Prepackaging [~~of drugs~~] and loading [~~of bulk unlabeled~~] drugs into automated **medication**
535 **supply** [~~drug dispensing~~] system.

536
537 (i) Prepackaging of drugs.

538
539 (I) Drugs may be prepackaged in quantities suitable for internal distribution only by a
540 pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and
541 direct supervision of a pharmacist.

542
543 (II) The label of a prepackaged unit shall indicate:

544
545 (-a-) brand name and strength of the drug; or if no brand name, then the generic name,
546 strength, and name of the manufacturer or distributor;

547
548 (-b-) facility's lot number;

549
550 (-c-) expiration date; and

551
552 (-d-) quantity of the drug, if quantity is greater than one.

553
554 (III) Records of prepackaging shall be maintained to show:

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- (-a-) the name of the drug, strength, and dosage form;
- (-b-) facility's lot number;
- (-c-) manufacturer or distributor;
- (-d-) manufacturer's lot number;
- (-e-) expiration date;
- (-f-) quantity per prepackaged unit;
- (-g-) number of prepackaged units;
- (-h-) date packaged;
- (-i-) name, initials, or electronic signature of the prepacker; and
- (-j-) signature or electronic signature of the responsible pharmacist.

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

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

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

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

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

- ~~— (a) name of the drug, strength, and dosage form;~~
- ~~— (b) manufacturer or distributor;~~
- ~~— (c) manufacturer's lot number;~~
- ~~— (d) expiration date;~~

606 ~~—— (e) date of loading;~~

607

608 ~~—— (f) name, initials, or electronic signature of the person loading the automated drug~~
609 ~~dispensing system; and~~

610

611 ~~—— (g) signature or electronic signature of the responsible pharmacist.~~

612

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

616

617 (6) Medication orders.

618

619 (A) Drugs may be administered to patients in **FEMCF** [FEMCC]s only on the order of a
620 practitioner. No change in the order for drugs may be made without the approval of a
621 practitioner **except as authorized by the practitioner in compliance with paragraph (5)(B)**
622 **of this subsection.**

623

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

626

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

629

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

633

634 **(D)** [~~(E)~~] In **FEMCF** [FEMCC]s with a full-time pharmacist, if a practitioner orders a drug for
635 administration to a bona fide patient of the facility when the pharmacy is closed, the following is
636 applicable.

637

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

640

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

642

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

645

646 (I) name of the patient;

647

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

649

650 (III) dose prescribed;

651

652 (IV) quantity taken;

653

654 (V) time and date; and

655

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

657
658 (iv) The ~~original or direct copy of the~~ medication order **in the patient's chart** may
659 substitute for such record, provided the medication order meets all the requirements of clause
660 (iii) of this subparagraph.

661
662 (v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more
663 than 72 hours from the time of such withdrawal.

664
665 **(E) [(F)]** In **FEMCF [FEMCC]**s with a part-time or consultant pharmacist, if a practitioner
666 orders a drug for administration to a bona fide patient of the **FEMCF [FEMCC]** when the
667 pharmacist is not on duty, or when the pharmacy is closed, the following is applicable.

668
669 (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be
670 removed from the **FEMCF [FEMCC]** pharmacy.

671
672 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

673
674 (iii) A record shall be made at the time of withdrawal by the authorized person removing the
675 drugs and devices; the record shall meet the same requirements as specified in subparagraph
676 **(D) [(E)(iii)]** of this paragraph.

677
678 (iv) The pharmacist shall **conduct an audit of patient charts according to the schedule**
679 **set out in the policy and procedures at [verify each distribution after] a reasonable interval,**
680 **but [in no event may] such interval must occur at least once in every calendar week that the**
681 **pharmacy is open [exceed seven days].**

682
683 (7) Floor stock. In facilities using a floor stock method of drug distribution, the following is
684 applicable for removing drugs or devices in the absence of a pharmacist.

685
686 (A) Prescription drugs and devices may be removed from the pharmacy only in the original
687 manufacturer's container or prepackaged container.

688
689 (B) Only a designated licensed nurse or practitioner may remove such drugs and devices.

690
691 (C) A record shall be made at the time of withdrawal by the authorized person removing the
692 drug or device; the record shall contain the following information:

693
694 (i) name of the drug, strength, and dosage form;

695
696 (ii) quantity removed;

697
698 (iii) location of floor stock;

699
700 (iv) date and time; and

701
702 (v) signature or electronic signature of person making the withdrawal.

703
704 (D) A pharmacist shall verify the withdrawal according to the following schedule.

705
706 (i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as
707 practical, but in no event more than 72 hours from the time of such withdrawal.

708
709 (ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after
710 a reasonable interval, but ~~[in no event may]~~ such interval **must occur at least once in every**
711 **calendar week that the pharmacy is open** ~~[exceed seven days]~~.

712
713 (8) Policies and procedures. Written policies and procedures for a drug distribution system,
714 appropriate for the freestanding emergency medical center, shall be developed and
715 implemented by the pharmacist-in-charge with the advice of the appropriate committee. The
716 written policies and procedures for the drug distribution system shall include, but not be limited
717 to, procedures regarding the following:

- 718 (A) controlled substances;
719
720 (B) investigational drugs;
721
722 (C) prepackaging and manufacturing;
723
724 (D) medication errors;
725
726 (E) orders of physician or other practitioner;
727
728 (F) floor stocks;
729
730 (G) adverse drug reactions;
731
732 (H) drugs brought into the facility by the patient;
733
734 (I) self-administration;
735
736 (J) emergency drug tray;
737
738 (K) formulary, if applicable;
739
740 (L) drug storage areas;
741
742 (M) drug samples;
743
744 (N) drug product defect reports;
745
746 (O) drug recalls;
747
748 (P) outdated drugs;
749
750 (Q) preparation and distribution of IV admixtures;
751
752 (R) procedures for supplying drugs for postoperative use, if applicable;
753
754 (S) use of automated **medication supply** ~~[drug dispensing]~~ systems; ~~[and]~~
755
756 (T) use of data processing systems; **and**
757
758

759 (U) drug regimen review.

760

761 (9) Drugs supplied for outpatient use. Drugs supplied to patients for outpatient use shall be
762 supplied according to the following procedures.

763

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

766

767 (B) Drugs may only be supplied in accordance with the system of control and accountability
768 established for drugs supplied from the freestanding emergency medical center; such system
769 shall be developed and supervised by the pharmacist-in-charge or staff pharmacist designated
770 by the pharmacist-in-charge.

771

772 (C) Only drugs listed on the approved outpatient drug list may be supplied; such list shall be
773 developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the
774 nature and type to meet the immediate postoperative needs of the freestanding emergency
775 medical center patient.

776

777 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in
778 suitable containers and appropriately pre-labeled (including name, address, and phone number
779 of the facility and necessary auxiliary labels) by the pharmacy, provided, however that topicals
780 and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a
781 72-hour supply.

782

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

786

787 (i) date supplied;

788

789 (ii) name of practitioner;

790

791 (iii) name of patient;

792

793 (iv) directions for use;

794

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

797

798 (vi) unique identification number.

799

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

803

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

806

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

808

809 (ii) date supplied;

- 810
811 (iii) name of practitioner;
812
813 (iv) name of patient;
814
815 (v) directions for use;
816
817 (vi) brand name and strength of the drug; or if no brand name, then the generic name of the
818 drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and
819
820 (vii) unique identification number.

821
822 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall
823 review the records at least once **in every calendar week that the pharmacy is open** [every
824 seven days].

825
826 **(10) Drug regimen review.**

827
828 **(A) A pharmacist shall evaluate medication orders and patient medication records for:**

829
830 **(i) known allergies;**

831
832 **(ii) rational therapy--contraindications;**

833
834 **(iii) reasonable dose and route of administration;**

835
836 **(iv) reasonable directions for use;**

837
838 **(v) duplication of therapy;**

839
840 **(vi) drug-drug interactions;**

841
842 **(vii) drug-food interactions;**

843
844 **(viii) drug-disease interactions;**

845
846 **(ix) adverse drug reactions;**

847
848 **(x) proper utilization, including overutilization or underutilization; and**

849
850 **(xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug**
851 **effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued**
852 **use of the drug in its current regimen.**

853
854 **(B) A retrospective, random drug regimen review as specified in the pharmacy's**
855 **policies and procedures shall be conducted on a periodic basis to verify proper usage of**
856 **drugs not to exceed 31 days between such reviews.**

857
858 **(iii) Any questions regarding the order must be resolved with the prescriber and a**
859 **written notation of these discussions made and maintained.**

860

861 (e) Records.

862

863 (1) Maintenance of records.

864

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

868

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

872

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

879

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

882

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

888

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

892

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

895

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

899

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

902

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

906

907 **(G) Distribution records for controlled substances, listed in Schedule II – V shall**
908 **include the following information:**

909

910 **(i) patient's name;**

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

- 912 (iii) name of drug, dosage form, and strength;
913 (iv) time and date of administration to patient and quantity administered;
914 (v) signature or electronic signature of individual administering the controlled
915 substance;
916 (vi) returns to the pharmacy; and
917 (vii) waste (waste is required to be witnessed and cosigned, manually or
918 electronically, by another individual).

919
920 (H) The record required by subparagraph (G) of this paragraph shall be maintained
921 separately from patient records.

922
923 (I) A pharmacist shall conduct an audit by randomly comparing the distribution
924 records required by subparagraph (G) with the medication orders in the patient record on
925 a periodic basis to verify proper administration of drugs not to exceed 30 days between
926 such reviews.

927
928 (2) [Outpatient records.

929
930 ~~—(A) Only a registered pharmacist may receive, certify, and receive prescription drug orders.~~

931
932 ~~—(B) Outpatient records shall be maintained as provided in §291.34 and §291.35 of this title~~
933 ~~contained in Community Pharmacy (Class A).~~

934
935 ~~—(C) Outpatient prescriptions, including, but not limited to, discharge prescriptions, that are~~
936 ~~written by the practitioner, must be written on a form which meets the requirements of the Act,~~
937 ~~§562.006. Medication order forms or copies thereof do not meet the requirements for outpatient~~
938 ~~forms.~~

939
940 ~~—(D) Controlled substances listed in Schedule II must be written on an official prescription form~~
941 ~~in accordance with the Texas Controlled Substances Act, §481.075, and rules promulgated~~
942 ~~pursuant to the Texas Controlled Substances Act, unless exempted by the Texas Controlled~~
943 ~~Substances Rules, 37 TAC §13.74. Outpatient prescriptions for Schedule II controlled~~
944 ~~substances that are exempted from the official prescription requirement must be manually~~
945 ~~signed by the practitioner.]~~

946
947 (3) Patient records.

948
949 (A) Each [original] medication order or set of orders issued together shall bear the following
950 information:

951
952 (i) patient name;

953
954 (ii) drug name, strength, and dosage form;

955
956 (iii) directions for use;

957
958 (iv) date; and

959
960 (v) signature or electronic signature of the practitioner or that of his or her authorized agent,
961 defined as a licensed nurse employee or consultant/full or part-time pharmacist of the **FEMCF**
962 **[FEMCG]**.

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

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

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

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

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

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

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

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

~~—(I) patient's name;~~

~~—(II) practitioner who ordered drug;~~

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

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

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

~~—(VI) returns to the pharmacy; and~~

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

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

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

~~—(I) patient's name;~~

~~—(II) practitioner who ordered controlled substance;~~

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

~~—(IV) time and date of administration to patient;~~

~~—(V) quantity administered;~~

1014
1015 —(VI) signature or electronic signature of individual administering drug;
1016
1017 —(VII) returns to the pharmacy; and
1018
1019 —(VIII) waste (waste is required to be witnessed and cosigned, manually or electronically, by
1020 another individual).
1021
1022 —(ii) The record required by clause (i) of this subparagraph shall be maintained separately
1023 from patient records.
1024
1025 —(iii) A pharmacist shall review distribution records with medication orders on a periodic basis
1026 to verify proper usage of drugs, not to exceed 30 days between such reviews.]
1027
1028 **(3)** [(F)] General requirements for records maintained in a data processing system are as
1029 follows.
1030
1031 **(A)** [(i)] If an **FEMCF** [FEMCG] pharmacy's data processing system is not in compliance with
1032 the board's requirements, the pharmacy must maintain a manual recordkeeping system.
1033
1034 **(B)** [(ii) Requirements for backup systems.] The facility shall maintain a backup copy of
1035 information stored in the data processing system using disk, tape, or other electronic backup
1036 system and update this backup copy on a regular basis to assure that data is not lost due to
1037 system failure.
1038
1039 **(C)** [(iii) Change or discontinuance of a data processing system.]
1040
1041 [(I) Records of distribution and return for all controlled substances and nalbuphine
1042 (Nubain).] A pharmacy that changes or discontinues use of a data processing system must:
1043
1044 **(i)** [(a)] transfer the records to the new data processing system; or
1045
1046 **(ii)** [(b)] purge the records to a printout which contains: [the same information as required
1047 on the audit trail printout as specified in subparagraph (G)(ii) of this paragraph. The information
1048 on this printout shall be sorted and printed by drug name and list all distributions/returns
1049 chronologically.]
1050
1051 **(I) all of the information required on the original document; or**
1052 **(II) for records of distribution and return for all controlled substances, the same**
1053 **information as required on the audit trail printout as specified in subparagraph (F) of this**
1054 **paragraph. The information on the printout shall be sorted and printed by drug name and**
1055 **list all distributions and returns chronologically.**
1056
1057 [(II) Other records. A pharmacy that changes or discontinues use of a data processing
1058 system must:
1059
1060 —(a) transfer the records to the new data processing system; or
1061
1062 —(b) purge the records to a printout which contains all of the information required on the
1063 original document.]
1064

1065 ~~(D) [(III) Maintenance of purged records.]~~ Information purged from a data processing
1066 system must be maintained by the pharmacy for two years from the date of initial entry into the
1067 data processing system.

1068 ~~(E) [(iv) Loss of data.]~~ The pharmacist-in-charge shall report to the board in writing any
1069 significant loss of information from the data processing system within 10 days of discovery of
1070 the loss.

1071
1072
1073 ~~[(G) Data processing system maintenance of records for the distribution and return of all
1074 controlled substances, tramadol (Ultram), and nalbuphine (Nubain) to the pharmacy.~~

1075
1076 ~~—(i) Each time a controlled substance, tramadol (Ultram), or nalbuphine (Nubain) is distributed
1077 from or returned to the pharmacy, a record of such distribution or return shall be entered into the
1078 data processing system.]~~

1079
1080 ~~(F) [(ii)]~~ The data processing system shall have the capacity to produce a hard-copy printout
1081 of an audit trail of drug distribution and return for any strength and dosage form of a drug (by
1082 either brand or generic name or both) during a specified time period. This printout shall contain
1083 the following information:

1084 ~~(i) [(i)]~~ patient's name and room number or patient's facility identification number;

1085 ~~(ii) [(ii)]~~ prescribing or attending practitioner's name;

1086 ~~(iii) [(iii)]~~ name, strength, and dosage form of the drug product actually distributed;

1087 ~~(iv) [(iv)]~~ total quantity distributed from and returned to the pharmacy;

1088
1089 ~~(v) [(v)]~~ if not immediately retrievable via electronic image, the following shall also be
1090 included on the printout:

1091 ~~(I) [(a)]~~ prescribing or attending practitioner's address; and

1092 ~~(II) [(b)]~~ practitioner's DEA registration number, if the medication order is for a controlled
1093 substance.

1094
1095
1096 ~~(G) [(iii)]~~ An audit trail printout for each strength and dosage form of these drugs distributed
1097 during the preceding month shall be produced at least monthly and shall be maintained in a
1098 separate file at the facility. The information on this printout shall be sorted by drug name and list
1099 all distributions/returns for that drug chronologically.

1100
1101 ~~(H) [(iv)]~~ The pharmacy may elect not to produce the monthly audit trail printout if the data
1102 processing system has a workable (electronic) data retention system which can produce an
1103 audit trail of drug distribution and returns for the preceding two years. The audit trail required in
1104 this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized
1105 agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law
1106 enforcement or regulatory agencies.

1107
1108
1109 ~~[(H) Failure to maintain records. Failure to provide records set out in this subsection, either on
1110 site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep
1111 and maintain records.]~~

1116
1117 (l) [~~Data processing system downtime.~~] In the event that an FEMCF [FEMCC] pharmacy
1118 which uses a data processing system experiences system downtime, the pharmacy must have
1119 an auxiliary procedure which will ensure that all data is retained for on-line data entry as soon
1120 as the system is available for use again.

1121
1122 (4) Distribution of controlled substances to another registrant. A pharmacy may distribute
1123 controlled substances to a practitioner, another pharmacy, or other registrant, without being
1124 registered to distribute, under the following conditions.

1125
1126 (A) The registrant to whom the controlled substance is to be distributed is registered under
1127 the Controlled Substances Act to possess [~~dispense~~] that controlled substance.

1128
1129 (B) The total number of dosage units of controlled substances distributed by a pharmacy may
1130 not exceed 5.0% of all controlled substances dispensed by the pharmacy during the 12-month
1131 period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is
1132 required to obtain an additional registration to distribute controlled substances.

1133
1134 (C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be
1135 maintained which indicates:

1136
1137 (i) the actual date of distribution;

1138
1139 (ii) the name, strength, and quantity of controlled substances distributed;

1140
1141 (iii) the name, address, and DEA registration number of the distributing pharmacy; and

1142
1143 (iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other
1144 registrant to whom the controlled substances are distributed.

1145
1146 (D) If the distribution is for a Schedule II controlled substance, the following is applicable.

1147
1148 (i) The pharmacy, practitioner, or other registrant who is receiving the controlled substances
1149 shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222[G]) to the distributing pharmacy.

1150
1151 (ii) The distributing pharmacy shall:

1152
1153 (I) complete the area on the DEA order form (DEA 222[G]) titled "To Be Filled in by
1154 Supplier";

1155
1156 (II) maintain Copy 1 of the DEA order form (DEA 222[G]) at the pharmacy for two years;
1157 and

1158
1159 (III) forward Copy 2 of the DEA order form (DEA 222[G]) to the divisional office of the Drug
1160 Enforcement Administration.

1161
1162 (5) Other records. Other records to be maintained by the pharmacy include:

1163
1164 (A) a permanent log of the initials or identification codes which will identify each pharmacist
1165 by name. The initials or identification code shall be unique to ensure that each pharmacist can
1166 be identified, i.e., identical initials or identification codes cannot be used;

1167
1168 (B) Copy 3 of DEA order form (DEA 222[G]), which has been properly dated, initialed, and
1169 filed, and all copies of each unaccepted or defective order form and any attached statements or
1170 other documents **and/or for each order filled using the DEA Controlled Substance**
1171 **Ordering System (CSOS), the original signed order and all linked records for that order;**
1172

1173 (C) a [~~hard~~] copy of the power of attorney to sign DEA 222C order forms (if applicable);
1174

1175 (D) suppliers' invoices of dangerous drugs and controlled substances **dated and initialed or**
1176 **signed by the person receiving the drugs;** a pharmacist shall verify that the controlled drugs
1177 listed on the invoices were **added to the pharmacy's perpetual inventory** [~~actually received~~]
1178 by clearly recording his/her initials and the [~~actual~~] date of **review** [~~receipt~~] of the **perpetual**
1179 **inventory** [~~controlled substances~~];
1180

1181 (E) supplier's credit memos for controlled substances and dangerous drugs;
1182

1183 (F) a [~~hard~~] copy of inventories required by §291.17 of this title (relating to Inventory
1184 Requirements) except that a perpetual inventory of controlled substances listed in Schedule II
1185 may be kept in a data processing system if the data processing system is capable of producing
1186 a hard copy of the perpetual inventory on-site;
1187

1188 (G) [~~hard copy~~] reports of surrender or destruction of controlled substances and/or dangerous
1189 drugs to an appropriate state or federal agency;
1190

1191 (H) [~~a hard copy Schedule V nonprescription register book;~~]
1192

1193 [~~(I)~~] records of distribution of controlled substances and/or dangerous drugs to other
1194 pharmacies, practitioners, or registrants; and
1195

1196 **(I)** [~~(J)~~] a [~~hard~~] copy of any notification required by the Texas Pharmacy Act or these rules,
1197 including, but not limited to, the following:
1198

1199 (i) reports of theft or significant loss of controlled substances to DEA, DPS, and the board;
1200

1201 (ii) notification of a change in pharmacist-in-charge of a pharmacy; and
1202

1203 (iii) reports of a fire or other disaster which may affect the strength, purity, or labeling of
1204 drugs, medications, devices, or other materials used in the diagnosis or treatment of injury,
1205 illness, and disease.
1206

1207 (6) Permission to maintain central records. Any pharmacy that uses a centralized
1208 recordkeeping system for invoices and financial data shall comply with the following procedures.
1209

1210 (A) Controlled substance records. Invoices and financial data for controlled substances may
1211 be maintained at a central location provided the following conditions are met.
1212

1213 (i) Prior to the initiation of central recordkeeping, the pharmacy submits written notification
1214 by registered or certified mail to the divisional director of the Drug Enforcement Administration
1215 as required by the Code of Federal Regulations, Title 21, §1304(a), and submits a copy of this
1216 written notification to the Texas State Board of Pharmacy. Unless the registrant is informed by
1217 the divisional director of the Drug Enforcement Administration that permission to keep central

1218 records is denied, the pharmacy may maintain central records commencing 14 days after
1219 receipt of notification by the divisional director.

1220
1221 (ii) The pharmacy maintains a copy of the notification required in this subparagraph.
1222

1223 (iii) The records to be maintained at the central record location shall not include executed
1224 DEA order forms, prescription drug orders, or controlled substance inventories, which shall be
1225 maintained at the pharmacy.

1226
1227 (B) Dangerous drug records. Invoices and financial data for dangerous drugs may be
1228 maintained at a central location.

1229
1230 (C) Access to records. If the records are kept on microfilm, computer media, or in any form
1231 requiring special equipment to render the records easily readable, the pharmacy shall provide
1232 access to such equipment with the records.

1233
1234 (D) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the
1235 pharmacy location within two business days of written request of a board agent or any other
1236 authorized official.