

RULE REVIEW ANALYSIS

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

Short Title: Services Provided by Pharmacies

Rule Number: Chapter 291, Subchapter H (§§291.151, 291.153, 291.155)

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

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

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

5
6 **§291.151 Pharmacies Located in a Freestanding Emergency Medical Care Facility**
7 **(Class F)**
8
9

10 (a) Purpose. The purpose of this section is to provide standards in the conduct, practice
11 activities, and operation of a pharmacy located in a freestanding emergency medical care
12 facilities that is licensed by the Texas Department of State Health Services or in a freestanding
13 emergency medical care facility operated by a hospital that is exempt from registration as
14 provided by §254.052, Health and Safety Code. Class F pharmacies located in a freestanding
15 emergency medical care facility shall comply with this section.
16

17 (b) Definitions. The following words and terms, when used in this section, shall have the
18 following meanings, unless the context clearly indicates otherwise.
19

20 (1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.
21

22 (2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion,
23 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 authorized by
26 law; or
27

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

30 (3) Automated medication supply system--A mechanical system that performs operations or
31 activities relative to the storage and distribution of medications for administration and which
32 collects, controls, and maintains all transaction information.
33

34 (4) Board--The Texas State Board of Pharmacy.
35

36 (5) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with
37 the FEMCF in areas that pertain to the practice of pharmacy.
38

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

45 (7) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug
46 or device in the course of professional practice to an ultimate user or his agent by or pursuant to
47 the lawful order of a practitioner.
48

49 (8) Distribute--The delivery of a prescription drug or device other than by administering or
50 dispensing.

51
52
53
54
55
56
57
58
59
60
61
62
63
64
65
66
67
68
69
70
71
72
73
74
75
76
77
78
79
80
81
82
83
84
85
86
87
88
89
90
91
92
93
94
95
96
97
98
99
100

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

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

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

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

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

(12) Formulary--List of drugs approved for use in the FEMCF by an appropriate committee of the FEMCF.

(13) Freestanding emergency medical care facility (FEMCF)--A freestanding facility that is licensed by the Texas Department of State Health Services pursuant to Chapter 254, Health and Safety Code, to provide emergency care to patients.

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

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

(16) Medication order--An order from a practitioner or his authorized agent for administration of a drug or device.

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

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

(19) Prescription drug--

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

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

101 (i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another
102 legend that complies with federal law; or
103
104 (ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or
105
106 (C) A drug or device that is required by any applicable federal or state law or regulation to be
107 dispensed on prescription only or is restricted to use by a practitioner only.
108
109 (20) Prescription drug order--
110
111 (A) An order from a practitioner or his authorized agent to a pharmacist for a drug or device to
112 be dispensed; or
113
114 (B) An order pursuant to Subtitle B, Chapter 157, Occupations Code.
115
116 (21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per
117 week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy
118 is open.
119
120 (22) Part-time pharmacist--A pharmacist who works less than full-time.
121
122 (23) Pharmacy technician--An individual who is registered with the board as a pharmacy
123 technician and whose responsibility in a pharmacy is to provide technical services that do not
124 require professional judgment regarding preparing and distributing drugs and who works under
125 the direct supervision of and is responsible to a pharmacist.
126
127 (24) Pharmacy technician trainee--An individual who is registered with the board as a
128 pharmacy technician trainee and is authorized to participate in a pharmacy's technician training
129 program.
130
131 (25) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and
132 Safety Code, Chapter 481, as amended.
133
134 (c) Personnel.
135
136 (1) Pharmacist-in-charge.
137
138 (A) General. Each FEMCF shall have one pharmacist-in-charge who is employed or under
139 contract, at least on a consulting or part-time basis, but may be employed on a full-time basis.
140
141 (B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum,
142 the following:
143
144 (i) establishing specifications for procurement and storage of all materials, including drugs,
145 chemicals, and biologicals;
146
147 (ii) participating in the development of a formulary for the FEMCF, subject to approval of the
148 appropriate committee of the FEMCF;
149

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

199 (i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed
200 pharmacists as may be required to operate the FEMCF pharmacy competently, safely, and
201 adequately to meet the needs of the patients of the facility.
202

203 (ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as
204 outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for
205 pharmaceutical materials.
206

207 (iii) All pharmacists shall be responsible for any delegated act performed by pharmacy
208 technicians or pharmacy technician trainees under his or her supervision.
209

210 (iv) All pharmacists while on duty shall be responsible for complying with all state and
211 federal laws or rules governing the practice of pharmacy.
212

213 (B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but
214 need not be limited to, the following:
215

216 (i) receiving and interpreting prescription drug orders and oral medication orders and
217 reducing these orders to writing either manually or electronically;
218

219 (ii) selecting prescription drugs and/or devices and/or suppliers; and
220

221 (iii) interpreting patient profiles.
222

223 (C) Special requirements for compounding non-sterile preparations. All pharmacists engaged
224 in compounding non-sterile preparations shall meet the training requirements specified in
225 §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).
226

227 (4) Pharmacy technicians and pharmacy technician trainees.
228

229 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the
230 training requirements specified in §297.6 of this title (relating to Pharmacy Technician and
231 Pharmacy Technician Trainee Training).
232

233 (B) Duties. Pharmacy technicians and pharmacy technician trainees may not perform any of
234 the duties listed in paragraph (3)(B) of this subsection. Duties may include, but need not be
235 limited to, the following functions, under the direct supervision of a pharmacist:
236

237 (i) prepacking and labeling unit and multiple dose packages, provided a pharmacist
238 supervises and conducts a final check and affixes his or her name, initials, electronic signature
239 to the appropriate quality control records prior to distribution;
240

241 (ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to
242 medication orders, provided a pharmacist supervises and checks the preparation;
243

244 (iii) compounding non-sterile preparations pursuant to medication orders provided the
245 pharmacy technicians or pharmacy technician trainees have completed the training specified in
246 §291.131 of this title;
247

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

251
252 (v) distributing routine orders for stock supplies to patient care areas;

253
254 (vi) entering medication order and drug distribution information into a data processing
255 system, provided judgmental decisions are not required and a pharmacist checks the accuracy
256 of the information entered into the system prior to releasing the order or in compliance with the
257 absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section;

258
259 (vii) maintaining inventories of drug supplies;

260
261 (viii) maintaining pharmacy records; and

262
263 (ix) loading drugs into an automated medication supply system. For the purpose of this
264 clause, direct supervision may be accomplished by physically present supervision or electronic
265 monitoring by a pharmacist.

266
267 (C) Procedures.

268
269 (i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in
270 accordance with standard written procedures and guidelines.

271
272 (ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug
273 orders in the same manner as pharmacy technicians or pharmacy technician trainees working in
274 a Class A pharmacy.

275
276 (D) Special requirements for compounding non-sterile preparations. All pharmacy technicians
277 and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet
278 the training requirements specified in §291.131 of this title.

279
280 (5) Owner. The owner of a FEMCF pharmacy shall have responsibility for all administrative
281 and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on
282 administrative and operational concerns. The owner shall have responsibility for, at a minimum,
283 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with
284 the pharmacist-in-charge or another Texas licensed pharmacist:

285
286 (A) establishing policies for procurement of prescription drugs and devices and other products
287 dispensed from the FEMCF pharmacy;

288
289 (B) establishing and maintaining effective controls against the theft or diversion of prescription
290 drugs;

291
292 (C) if the pharmacy uses an automated medication supply system, reviewing and approving
293 all policies and procedures for system operation, safety, security, accuracy and access, patient
294 confidentiality, prevention of unauthorized access, and malfunction;

295
296 (D) providing the pharmacy with the necessary equipment and resources commensurate with
297 its level and type of practice; and

298
299
300
301
302
303
304
305
306
307
308
309
310
311
312
313
314
315
316
317
318
319
320
321
322
323
324
325
326
327
328
329
330
331
332
333
334
335
336
337
338
339
340
341
342
343
344
345
346
347

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

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

(A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician.

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

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

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

(d) Operational standards.

(1) Licensing requirements.

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

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

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

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

(E) A FEMCF pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

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

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

(H) A FEMCF pharmacy, which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community

348 pharmacy (Class A), is not required to secure a license for the other type of pharmacy;
349 provided, however, such license is required to comply with the provisions of §291.31 of this title
350 (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating
351 to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title
352 (relating to Official Prescription Records), to the extent such sections are applicable to the
353 operation of the pharmacy.

354
355 (1) A FEMCF pharmacy engaged in the compounding of non-sterile preparations shall comply
356 with the provisions of §291.131 of this title.

357
358 (2) Environment.

359
360 (A) General requirements.

361
362 (i) Each FEMCF shall have a designated work area separate from patient areas, and which
363 shall have space adequate for the size and scope of pharmaceutical services and shall have
364 adequate space and security for the storage of drugs.

365
366 (ii) The FEMCF pharmacy shall be arranged in an orderly fashion and shall be kept clean.
367 All required equipment shall be clean and in good operating condition.

368
369 (B) Special requirements.

370
371 (i) The FEMCF pharmacy shall have locked storage for Schedule II controlled substances
372 and other controlled drugs requiring additional security.

373
374 (ii) The FEMCF pharmacy shall have a designated area for the storage of poisons and
375 externals separate from drug storage areas.

376
377 (C) Security.

378
379 (i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed
380 and capable of being locked by key, combination, or other mechanical or electronic means, so
381 as to prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-
382 in-charge may enter the pharmacy or have access to storage areas for prescription drugs and/or
383 devices.

384
385 (ii) The pharmacist-in-charge shall consult with FEMCF personnel with respect to security of
386 the drug storage areas, including provisions for adequate safeguards against theft or diversion
387 of dangerous drugs, controlled substances, and records for such drugs.

388
389 (iii) The pharmacy shall have locked storage for Schedule II controlled substances and other
390 drugs requiring additional security.

391
392 (3) Equipment and supplies. FEMCFs supplying drugs for outpatient use shall have the
393 following equipment and supplies:

394
395 (A) data processing system including a printer or comparable equipment;

396
397 (B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and

398
399
400
401
402
403
404
405
406
407
408
409
410
411
412
413
414
415
416
417
418
419
420
421
422
423
424
425
426
427
428
429
430
431
432
433
434
435
436
437
438
439
440
441
442
443
444
445
446
447

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

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

(A) current copies of the following:

(i) Texas Pharmacy Act and rules;

(ii) Texas Dangerous Drug Act and rules;

(iii) Texas Controlled Substances Act and rules; and

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

(B) at least one current or updated general drug information reference which is required to contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken; and

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

(5) Drugs.

(A) Procurement, preparation, and storage.

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

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

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

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

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

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

(B) Formulary.

- 448 (i) A formulary may be developed by an appropriate committee of the FEMCF.
449
- 450 (ii) The pharmacist-in-charge, consultant pharmacist, or designee shall be a full voting
451 member of any committee which involves pharmaceutical services.
452
- 453 (iii) A practitioner may grant approval for pharmacists at the FEMCF to interchange, in
454 accordance with the facility's formulary, for the drugs on the practitioner's medication orders
455 provided:
- 456 (I) a formulary has been developed;
457
458 (II) the formulary has been approved by the medical staff of the FEMCF;
459
460 (III) there is a reasonable method for the practitioner to override any interchange; and
461
462 (IV) the practitioner authorizes pharmacist in the FEMCF to interchange on his/her
463 medication orders in accordance with the facility's formulary through his/her written agreement
464 to abide by the policies and procedures of the medical staff and facility.
465
466 (C) Prepackaging and loading drugs into automated medication supply system.
- 467 (i) Prepackaging of drugs.
468
- 469 (I) Drugs may be prepackaged in quantities suitable for internal distribution only by a
470 pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and
471 direct supervision of a pharmacist.
472
473 (II) The label of a prepackaged unit shall indicate:
474
- 475 (-a-) brand name and strength of the drug; or if no brand name, then the generic name,
476 strength, and name of the manufacturer or distributor;
477
478 (-b-) facility's lot number;
479
480 (-c-) expiration date; and
481
482 (-d-) quantity of the drug, if quantity is greater than one.
483
484 (III) Records of prepackaging shall be maintained to show:
485
- 486 (-a-) the name of the drug, strength, and dosage form;
487
488 (-b-) facility's lot number;
489
490 (-c-) manufacturer or distributor;
491
492 (-d-) manufacturer's lot number;
493
494 (-e-) expiration date;
495
496
497

- 498 (-f-) quantity per prepackaged unit;
499
500 (-g-) number of prepackaged units;
501
502 (-h-) date packaged;
503
504 (-i-) name, initials, or electronic signature of the prepacker; and
505
506 (-j-) signature or electronic signature of the responsible pharmacist.
507

508 (IV) Stock packages, repackaged units, and control records shall be quarantined together
509 until checked/released by the pharmacist.
510

511 (ii) Loading bulk unit of use drugs into automated medication supply systems. Automated
512 medication supply systems may be loaded with bulk unit of use drugs only by a pharmacist or
513 by pharmacy technicians or pharmacy technician trainees under the direction and direct
514 supervision of a pharmacist. For the purpose of this clause, direct supervision may be
515 accomplished by physically present supervision or electronic monitoring by a pharmacist. In
516 order for the pharmacist to electronically monitor, the medication supply system must allow for
517 bar code scanning to verify the loading of drugs, and a record of the loading must be maintained
518 by the system and accessible for electronic review by the pharmacist.
519

520 (6) Medication orders.
521

522 (A) Drugs may be administered to patients in FEMCFs only on the order of a practitioner. No
523 change in the order for drugs may be made without the approval of a practitioner except as
524 authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.
525

526 (B) Drugs may be distributed only pursuant to the copy of the practitioner's medication order.
527

528 (C) FEMCF pharmacies shall be exempt from the labeling provisions and patient notification
529 requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to
530 medication orders.
531

532 (D) In FEMCFs with a full-time pharmacist, if a practitioner orders a drug for administration to
533 a bona fide patient of the facility when the pharmacy is closed, the following is applicable.
534

535 (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic
536 needs of a patient may be removed from the FEMCF pharmacy.
537

538 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.
539

540 (iii) A record shall be made at the time of withdrawal by the authorized person removing the
541 drugs and devices. The record shall contain the following information:
542

543 (I) name of the patient;

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

545 (III) dose prescribed;
546
547

548
549 (IV) quantity taken;
550
551 (V) time and date; and
552
553 (VI) signature or electronic signature of person making withdrawal.
554
555 (iv) The medication order in the patient's chart may substitute for such record, provided the
556 medication order meets all the requirements of clause (iii) of this subparagraph.
557
558 (v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more
559 than 72 hours from the time of such withdrawal.
560
561 (E) In FEMCFs with a part-time or consultant pharmacist, if a practitioner orders a drug for
562 administration to a bona fide patient of the FEMCF when the pharmacist is not on duty, or when
563 the pharmacy is closed, the following is applicable.
564
565 (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be
566 removed from the FEMCF pharmacy.
567
568 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.
569
570 (iii) A record shall be made at the time of withdrawal by the authorized person removing the
571 drugs and devices; the record shall meet the same requirements as specified in subparagraph
572 (D) of this paragraph.
573
574 (iv) The pharmacist shall conduct an audit of patient's medical record according to the
575 schedule set out in the policy and procedures at a reasonable interval, but such interval must
576 occur at least once in every calendar week that the pharmacy is open.
577
578 (7) Floor stock. In facilities using a floor stock method of drug distribution, the following is
579 applicable for removing drugs or devices in the absence of a pharmacist.
580
581 (A) Prescription drugs and devices may be removed from the pharmacy only in the original
582 manufacturer's container or prepackaged container.
583
584 (B) Only a designated licensed nurse or practitioner may remove such drugs and devices.
585
586 (C) A record shall be made at the time of withdrawal by the authorized person removing the
587 drug or device; the record shall contain the following information:
588
589 (i) name of the drug, strength, and dosage form;
590
591 (ii) quantity removed;
592
593 (iii) location of floor stock;
594
595 (iv) date and time; and
596
597 (v) signature or electronic signature of person making the withdrawal.

598
599
600
601
602
603
604
605
606
607
608
609
610
611
612
613
614
615
616
617
618
619
620
621
622
623
624
625
626
627
628
629
630
631
632
633
634
635
636
637
638
639
640
641
642
643
644
645
646
647

(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 such interval must occur at least once in every calendar week that the pharmacy is open.

(iii) The medication order in the patient's chart may substitute for the record required in subparagraph (C) of this paragraph, provided the medication order meets all the requirements of subparagraph (C) of this paragraph.

(8) Policies and procedures. Written policies and procedures for a drug distribution system, appropriate for the freestanding emergency medical facility, 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;
- (H) drugs brought into the facility by the patient;
- (I) self-administration;
- (J) emergency drug tray;
- (K) formulary, if applicable;
- (L) drug storage areas;
- (M) drug samples;
- (N) drug product defect reports;
- (O) drug recalls;

- 648 (P) outdated drugs;
649
650 (Q) preparation and distribution of IV admixtures;
651
652 (R) procedures for supplying drugs for postoperative use, if applicable;
653
654 (S) use of automated medication supply systems;
655
656 (T) use of data processing systems; and
657
658 (U) drug regimen review.
659
- 660 (9) Drugs supplied for outpatient use. Drugs provided to patients for take home use shall be
661 supplied according to the following procedures.
662
- 663 (A) Drugs may only be supplied to patients who have been admitted to the FEMCF.
664
- 665 (B) Drugs may only be supplied in accordance with the system of control and accountability
666 established for drugs supplied from the FEMCF; such system shall be developed and
667 supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-
668 charge.
669
- 670 (C) Only drugs listed on the approved outpatient drug list may be supplied; such list shall be
671 developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the
672 nature and type to meet the immediate postoperative needs of the FEMCF patient.
673
- 674 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in
675 suitable containers and appropriately prelabeled (including name, address, and phone number
676 of the facility and necessary auxiliary labels) by the pharmacy, provided, however that topicals
677 and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a
678 72-hour supply.
679
- 680 (E) At the time of delivery of the drug, the practitioner shall complete the label, such that the
681 prescription container bears a label with at least the following information:
682
- 683 (i) date supplied;
684
685 (ii) name of practitioner;
686
687 (iii) name of patient;
688
689 (iv) directions for use;
690
691 (v) brand name and strength of the drug; or if no brand name, then the generic name of the
692 drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and
693
694 (vi) unique identification number.
695
- 696 (F) After the drug has been labeled, the practitioner or a licensed nurse under the supervision
697 of the practitioner shall give the appropriately labeled, prepackaged medication to the patient.

698
699 (G) A perpetual record of drugs which are supplied from the FEMCF shall be maintained
700 which includes:
701
702 (i) name, address, and phone number of the facility;
703
704 (ii) date supplied;
705
706 (iii) name of practitioner;
707
708 (iv) name of patient;
709
710 (v) directions for use;
711
712 (vi) brand name and strength of the drug; or if no brand name, then the generic name of the
713 drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and
714
715 (vii) unique identification number.
716
717 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall
718 review the records at least once in every calendar week that the pharmacy is open.
719
720 (10) Drug regimen review.
721
722 (A) A pharmacist shall evaluate medication orders and patient medication records for:
723
724 (i) known allergies;
725
726 (ii) rational therapy--contraindications;
727
728 (iii) reasonable dose and route of administration;
729
730 (iv) reasonable directions for use;
731
732 (v) duplication of therapy;
733
734 (vi) drug-drug interactions;
735
736 (vii) drug-food interactions;
737
738 (viii) drug-disease interactions;
739
740 (ix) adverse drug reactions;
741
742 (x) proper utilization, including overutilization or underutilization; and
743
744 (xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug
745 effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of
746 the drug in its current regimen.
747

748 (B) A retrospective, random drug regimen review as specified in the pharmacy's policies and
749 procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed
750 31 days between such reviews.

751
752 (C) Any questions regarding the order must be resolved with the prescriber and a written
753 notation of these discussions made and maintained.

754
755 (e) Records.

756
757 (1) Maintenance of records.

758
759 (A) Every inventory or other record required to be kept under the provisions of this section
760 (relating to Pharmacies Located in a Freestanding Emergency Medical Care Facility (Class F))
761 shall be:

762
763 (i) kept by the pharmacy and be available, for at least two years from the date of such
764 inventory or record, for inspecting and copying by the board or its representative, and other
765 authorized local, state, or federal law enforcement agencies; and

766
767 (ii) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
768 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,
769 the requested records must be provided in a mutually agreeable electronic format if specifically
770 requested by the board or its representative. Failure to provide the records set out in this
771 subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep
772 and maintain records in violation of the Act.

773
774 (B) Records of controlled substances listed in Schedule II shall be maintained separately and
775 readily retrievable from all other records of the pharmacy.

776
777 (C) Records of controlled substances listed in Schedules III - V shall be maintained
778 separately or readily retrievable from all other records of the pharmacy. For purposes of this
779 subparagraph, readily retrievable means that the controlled substances shall be asterisked, red-
780 lined, or in some other manner readily identifiable apart from all other items appearing on the
781 record.

782
783 (D) Records, except when specifically required to be maintained in original or hard-copy form,
784 may be maintained in an alternative data retention system, such as a data processing or direct
785 imaging system, e.g., microfilm or microfiche, provided:

786
787 (i) the records in the alternative data retention system contain all of the information required
788 on the manual record; and

789
790 (ii) the alternative data retention system is capable of producing a hard copy of the record
791 upon the request of the board, its representative, or other authorized local, state, or federal law
792 enforcement or regulatory agencies.

793
794 (E) Controlled substance records shall be maintained in a manner to establish receipt and
795 distribution of all controlled substances.

796

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

800
801 (G) Distribution records for controlled substances, listed in Schedule II - V shall include the
802 following information:

- 803 (i) patient's name;
804
805 (ii) practitioner's name who ordered the drug;
806
807 (iii) name of drug, dosage form, and strength;
808
809 (iv) time and date of administration to patient and quantity administered;
810
811 (v) signature or electronic signature of individual administering the controlled substance;
812
813 (vi) returns to the pharmacy; and
814
815 (vii) waste (waste is required to be witnessed and cosigned, manually or electronically, by
816 another individual).

817
818 (H) The record required by subparagraph (G) of this paragraph shall be maintained
819 separately from patient records.
820

821
822 (I) A pharmacist shall conduct an audit by randomly comparing the distribution records
823 required by subparagraph (G) with the medication orders in the patient record on a periodic
824 basis to verify proper administration of drugs not to exceed 30 days between such reviews.
825

826 (2) Patient records.

827
828 (A) Each medication order or set of orders issued together shall bear the following
829 information:

- 830 (i) patient name;
831
832 (ii) drug name, strength, and dosage form;
833
834 (iii) directions for use;
835
836 (iv) date; and
837
838 (v) signature or electronic signature of the practitioner or that of his or her authorized agent,
839 defined as a licensed nurse employee or consultant/full or part-time pharmacist of the FEMCF.
840

841
842 (B) Medication orders shall be maintained with the medication administration record in the
843 medical records of the patient.

844
845 (3) General requirements for records maintained in a data processing system are as follows.
846

847 (A) If an FEMCF pharmacy's data processing system is not in compliance with the board's
848 requirements, the pharmacy must maintain a manual recordkeeping system.

849
850 (B) The facility shall maintain a backup copy of information stored in the data processing
851 system using disk, tape, or other electronic backup system and update this backup copy on a
852 regular basis to assure that data is not lost due to system failure.

853
854 (C) A pharmacy that changes or discontinues use of a data processing system must:

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

856
857 (ii) purge the records to a printout which contains:

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

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

865
866 (D) Information purged from a data processing system must be maintained by the pharmacy
867 for two years from the date of initial entry into the data processing system.

868
869 (E) The pharmacist-in-charge shall report to the board in writing any significant loss of
870 information from the data processing system within 10 days of discovery of the loss.

871
872 (F) The data processing system shall have the capacity to produce a hard-copy printout of an
873 audit trail of drug distribution and return for any strength and dosage form of a drug (by either
874 brand or generic name or both) during a specified time period. This printout shall contain the
875 following information:

876
877 (i) patient's name or patient's facility identification number;

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

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

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

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

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

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

886
887 (G) An audit trail printout for each strength and dosage form of these drugs distributed during
888 the preceding month shall be produced at least monthly and shall be maintained in a separate
889
890
891
892
893

896 file at the facility. The information on this printout shall be sorted by drug name and list all
897 distributions/returns for that drug chronologically.

898
899 (H) The pharmacy may elect not to produce the monthly audit trail printout if the data
900 processing system has a workable (electronic) data retention system which can produce an
901 audit trail of drug distribution and returns for the preceding two years. The audit trail required in
902 this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized
903 agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law
904 enforcement or regulatory agencies.

905
906 (I) In the event that an FEMCF pharmacy which uses a data processing system experiences
907 system downtime, the pharmacy must have an auxiliary procedure which will ensure that all
908 data is retained for on-line data entry as soon as the system is available for use again.

909
910 (4) Distribution of controlled substances to another registrant. A pharmacy may distribute
911 controlled substances to a practitioner, another pharmacy, or other registrant, without being
912 registered to distribute, under the following conditions.

913
914 (A) The registrant to whom the controlled substance is to be distributed is registered under
915 the Controlled Substances Act to possess that controlled substance.

916
917 (B) The total number of dosage units of controlled substances distributed by a pharmacy may
918 not exceed 5.0% of all controlled substances dispensed by the pharmacy during the 12-month
919 period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is
920 required to obtain an additional registration to distribute controlled substances.

921
922 (C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be
923 maintained which indicates:

- 924 (i) the actual date of distribution;
- 925 (ii) the name, strength, and quantity of controlled substances distributed;
- 926 (iii) the name, address, and DEA registration number of the distributing pharmacy; and
- 927 (iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other
928 registrant to whom the controlled substances are distributed.

929
930 (D) If the distribution is for a Schedule II controlled substance, the following is applicable.

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

- 933 (ii) The distributing pharmacy shall:
- 934 (I) complete the area on the DEA order form (DEA 222) titled "To Be Filled in by Supplier";
- 935 (II) maintain Copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and

944

945 (III) forward Copy 2 of the DEA order form (DEA 222) to the divisional office of the Drug
946 Enforcement Administration.

947
948 (5) Other records. Other records to be maintained by the pharmacy include:

949
950 (A) a permanent log of the initials or identification codes which will identify each pharmacist
951 by name. The initials or identification code shall be unique to ensure that each pharmacist can
952 be identified, i.e., identical initials or identification codes cannot be used;

953
954 (B) Copy 3 of DEA order form (DEA 222), which has been properly dated, initialed, and filed,
955 and all copies of each unaccepted or defective order form and any attached statements or other
956 documents and/or for each order filled using the DEA Controlled Substance Ordering System
957 (CSOS), the original signed order and all linked records for that order;

958
959 (C) a copy of the power of attorney to sign DEA 222 order forms (if applicable);

960
961 (D) suppliers' invoices of dangerous drugs and controlled substances dated and initialed or
962 signed by the person receiving the drugs; a pharmacist shall verify that the controlled drugs
963 listed on the invoices were added to the pharmacy's perpetual inventory by clearly recording
964 his/her initials and the date of review of the perpetual inventory;

965
966 (E) supplier's credit memos for controlled substances and dangerous drugs;

967
968 (F) a copy of inventories required by §291.17 of this title (relating to Inventory Requirements)
969 except that a perpetual inventory of controlled substances listed in Schedule II may be kept in a
970 data processing system if the data processing system is capable of producing a hard copy of
971 the perpetual inventory on-site;

972
973 (G) reports of surrender or destruction of controlled substances and/or dangerous drugs to an
974 appropriate state or federal agency;

975
976 (H) records of distribution of controlled substances and/or dangerous drugs to other
977 pharmacies, practitioners, or registrants; and

978
979 (I) a copy of any notification required by the Texas Pharmacy Act or these rules, including,
980 but not limited to, the following:

981
982 (i) reports of theft or significant loss of controlled substances to DEA, DPS, and the board;

983
984 (ii) notification of a change in pharmacist-in-charge of a pharmacy; and

985
986 (iii) reports of a fire or other disaster which may affect the strength, purity, or labeling of
987 drugs, medications, devices, or other materials used in the diagnosis or treatment of injury,
988 illness, and disease.

989
990 (6) Permission to maintain central records. Any pharmacy that uses a centralized
991 recordkeeping system for invoices and financial data shall comply with the following procedures.

992
993 (A) Controlled substance records. Invoices and financial data for controlled substances may
994 be maintained at a central location provided the following conditions are met.

995
996
997
998
999
1000
1001
1002
1003
1004
1005
1006
1007
1008
1009
1010
1011
1012
1013
1014
1015
1016
1017
1018
1019
1020
1021
1022
1023
1024
1025
1026
1027
1028
1029
1030
1031
1032
1033
1034
1035
1036
1037
1038
1039
1040
1041
1042
1043

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

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

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

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

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

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

§291.153 Central Prescription Drug or Medication Order Processing Pharmacy (Class G)

(a) Purpose.

(1) The purpose of this section is to provide standards for a centralized prescription drug or medication order processing pharmacy.

(2) Any facility established for the primary purpose of processing prescription drug or medication drug orders shall be licensed as a Class G pharmacy under the Act. A Class G pharmacy shall not store bulk drugs, or dispense a prescription drug order. Nothing in this subsection shall prohibit an individual pharmacist employee who is licensed in Texas from remotely accessing the pharmacy's electronic data base from a location other than a licensed pharmacy in order to process prescription or medication drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records, and the Texas-licensed pharmacist does not engage in the receiving of written prescription or medication orders or the maintenance of prescription or medication drug orders at the non-licensed remote location.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act.

1044 (1) Centralized prescription drug or medication order processing--The processing of a
1045 prescription drug or medication orders by a Class G pharmacy on behalf of another pharmacy, a
1046 health care provider, or a payor. Centralized prescription drug or medication order processing
1047 does not include the dispensing of a prescription drug but includes any of the following:

- 1048 (A) receiving, interpreting, or clarifying prescription drug or medication drug orders;
- 1049 (B) data entering and transferring of prescription drug or medication order information;
- 1050 (C) performing drug regimen review;
- 1051 (D) obtaining refill and substitution authorizations;
- 1052 (E) verifying accurate prescription data entry;
- 1053 (F) interpreting clinical data for prior authorization for dispensing;
- 1054 (G) performing therapeutic interventions; and
- 1055 (H) providing drug information concerning a patient's prescription.

1056 (2) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week
1057 or, if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is
1058 open.

1059 (c) Personnel.

1060 (1) Pharmacist-in-charge.

1061 (A) General. Each Class G pharmacy shall have one pharmacist-in-charge who is employed
1062 on a full-time basis, who may be the pharmacist-in-charge for only one such pharmacy.

1063 (B) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of
1064 pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-
1065 charge may advise the owner on administrative or operational concerns. The pharmacist-in-
1066 charge shall have responsibility for, at a minimum, the following:

- 1067 (i) education and training of pharmacy technicians and pharmacy technician trainees;
- 1068 (ii) maintaining records of all transactions of the Class G pharmacy required by applicable
1069 state and federal laws and sections;
- 1070 (iii) adherence to policies and procedures regarding the maintenance of records in a data
1071 processing system such that the data processing system is in compliance with Class G
1072 pharmacy requirements; and
- 1073 (iv) legal operation of the pharmacy, including meeting all inspection and other requirements
1074 of all state and federal laws or sections governing the practice of pharmacy.

1093 (2) Owner. The owner of a Class G pharmacy shall have responsibility for all administrative
1094 and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on
1095 administrative and operational concerns. The owner shall have responsibility for, at a minimum,
1096 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with
1097 the pharmacist-in-charge or another Texas licensed pharmacist:

1098
1099 (A) providing the pharmacy with the necessary equipment and resources commensurate with
1100 its level and type of practice; and

1101
1102 (B) establishment of policies and procedures regarding maintenance, storage, and retrieval of
1103 records in a data processing system such that the system is in compliance with state and
1104 federal requirements.

1105
1106 (3) Pharmacists.

1107
1108 (A) General.

1109
1110 (i) The pharmacist-in-charge shall be assisted by sufficient number of additional licensed
1111 pharmacists as may be required to operate the Class G pharmacy competently, safely, and
1112 adequately to meet the needs of the patients of the pharmacy.

1113
1114 (ii) All pharmacists shall assist the pharmacist-in-charge in meeting his or her
1115 responsibilities.

1116
1117 (iii) Pharmacists are solely responsible for the direct supervision of pharmacy technicians
1118 and pharmacy technician trainees and for designating and delegating duties, other than those
1119 listed in subparagraph (B) of this paragraph, to pharmacy technicians and pharmacy technician
1120 trainees. Each pharmacist shall be responsible for any delegated act performed by pharmacy
1121 technicians and pharmacy technician trainees under his or her supervision.

1122
1123 (iv) Pharmacists shall directly supervise pharmacy technicians and pharmacy technician
1124 trainees who are entering prescription data into the pharmacy's data processing system by one
1125 of the following methods.

1126
1127 (I) Physically present supervision. A pharmacist shall be physically present to directly
1128 supervise a pharmacy technician or pharmacy technician trainee who is entering prescription
1129 order or medication order data into the data processing system. Each prescription or medication
1130 order entered into the data processing system shall be verified at the time of data entry.

1131
1132 (II) Electronic supervision. A pharmacist may electronically supervise a pharmacy
1133 technician or pharmacy technician trainee who is entering prescription order or medication order
1134 data into the data processing system provided the pharmacist:

1135
1136 (-a-) is on-site, in the pharmacy where the technician/trainee is located;

1137
1138 (-b-) has immediate access to any original document containing prescription or
1139 medication order information or other information related to the dispensing of the prescription or
1140 medication order. Such access may be through imaging technology provided the pharmacist
1141 has the ability to review the original, hardcopy documents if needed for clarification; and
1142

1143 (-c-) verifies the accuracy of the data entered information prior to the release of the
1144 information to the system for storage.

1145
1146 (III) Electronic verification of data entry by pharmacy technicians or pharmacy technician
1147 trainees. A pharmacist may electronically verify the data entry of prescription information into a
1148 data processing system provided:

1149
1150 (-a-) a pharmacist is on-site in the pharmacy where the pharmacy technicians/trainees are
1151 located;

1152
1153 (-b-) the pharmacist electronically conducting the verification is either a:

1154
1155 (-1-) Texas licensed pharmacist; or

1156
1157 (-2-) pharmacist employed by a Class E pharmacy that has the same owner as the
1158 Class G pharmacy where the pharmacy technicians/trainees are located or that has entered into
1159 a written contract or agreement with the Class G pharmacy, which outlines the services to be
1160 provided and the responsibilities and accountabilities of each pharmacy in compliance with
1161 federal and state laws and regulations;

1162
1163 (-c-) the pharmacy establishes controls to protect the privacy and security of confidential
1164 records; and

1165
1166 (-d-) the pharmacy keeps permanent records of prescriptions electronically verified for a
1167 period of two years.

1168
1169 (v) All pharmacists while on duty, shall be responsible for complying with all state and
1170 federal laws or rules governing the practice of pharmacy.

1171
1172 (B) Duties. Duties which may only be performed by a pharmacist are as follows:

1173
1174 (i) receiving oral prescription drug or medication orders and reducing these orders to writing,
1175 either manually or electronically;

1176
1177 (ii) interpreting prescription drug or medication orders;

1178
1179 (iii) selecting drug products;

1180
1181 (iv) verifying the data entry of the prescription drug or medication order information at the
1182 time of data entry prior to the release of the information to a Class A, Class C, or Class E
1183 pharmacy for dispensing;

1184
1185 (v) communicating to the patient or patient's agent information about the prescription drug or
1186 device which in the exercise of the pharmacist's professional judgment, the pharmacist deems
1187 significant, as specified in §291.33(c) of this title (relating to Operational Standards);

1188
1189 (vi) communicating to the patient or the patient's agent on his or her request information
1190 concerning any prescription drugs dispensed to the patient by the pharmacy;

1191

1192 (vii) assuring that a reasonable effort is made to obtain, record, and maintain patient
1193 medication records;

1194
1195 (viii) interpreting patient medication records and performing drug regimen reviews; and
1196

1197 (ix) performing a specific act of drug therapy management for a patient delegated to a
1198 pharmacist by a written protocol from a physician licensed in this state in compliance with the
1199 Medical Practice Act.

1200
1201 (4) Pharmacy Technicians and Pharmacy Technician Trainees.
1202

1203 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the
1204 training requirements specified in §297.6 of this title (relating to Pharmacy Technician and
1205 Pharmacy Technician Trainee Training).

1206
1207 (B) Duties.
1208

1209 (i) Pharmacy technicians and pharmacy technician trainees may not perform any of the
1210 duties listed in paragraph (3)(B) of this subsection.

1211
1212 (ii) A pharmacist may delegate to pharmacy technicians and pharmacy technician trainees
1213 any nonjudgmental technical duty associated with the preparation and distribution of
1214 prescription drugs provided:

1215
1216 (I) a pharmacist verifies the accuracy of all acts, tasks, and functions performed by
1217 pharmacy technicians and pharmacy technician trainees;

1218
1219 (II) pharmacy technicians and pharmacy technician trainees are under the direct
1220 supervision of and responsible to a pharmacist; and

1221
1222 (iii) Pharmacy technicians and pharmacy technician trainees may perform only
1223 nonjudgmental technical duties associated with the preparation of prescription drugs, as follows:

1224
1225 (I) initiating and receiving refill authorization requests; and

1226
1227 (II) entering prescription or medication order data into a data processing system.
1228

1229 (C) Ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees.
1230 A Class G pharmacy may have a ratio of on-site pharmacists to pharmacy technicians and
1231 pharmacy technician trainees of 1:8 provided:

1232
1233 (i) at least seven are pharmacy technicians and not pharmacy technician trainees; and
1234

1235 (ii) the pharmacy has written policies and procedures regarding the supervision of pharmacy
1236 technicians and pharmacy technician trainees.
1237

1238 (5) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows.
1239

1240 (A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge
1241 that bears the person's name and identifies him or her as a pharmacy technician, or a certified

1242 pharmacy technician, if the technician maintains current certification with the Pharmacy
1243 Technician Certification Board or any other entity providing an examination approved by the
1244 board.

1245
1246 (B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an
1247 identification tag or badge that bears the person's name and identifies him or her as a pharmacy
1248 technician trainee.

1249
1250 (C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that
1251 bears the person's name and identifies him or her as a pharmacist intern.

1252
1253 (D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the
1254 person's name and identifies him or her as a pharmacist.

1255
1256 (d) Operational Standards.

1257
1258 (1) General requirements.

1259
1260 (A) A Class A, Class C, or Class E Pharmacy may outsource prescription drug or medication
1261 order processing to a Class G pharmacy provided the pharmacies:

1262
1263 (i) have:

1264
1265 (I) the same owner; or

1266
1267 (II) entered into a written contract or agreement which outlines the services to be provided
1268 and the responsibilities and accountabilities of each pharmacy in compliance with federal and
1269 state laws and regulations; and

1270
1271 (ii) share a common electronic file or have appropriate technology to allow access to
1272 sufficient information necessary or required to perform a non-dispensing function.

1273
1274 (B) A Class G pharmacy shall comply with the provisions applicable to the class of pharmacy
1275 contained in either §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational
1276 Standards, Records, and Official Prescription Requirements in Class A (Community
1277 Pharmacies), or §§291.72 - 291.75 of this title (relating to Definitions, Personnel, Operational
1278 Standards, and Records in a Class C (Institutional) Pharmacy), or §§291.102 - 291.105 of this
1279 title (relating to Definitions, Personnel, Operational Standards, and Records in a Class E (Non-
1280 Resident) Pharmacy) to the extent applicable for the specific processing activity and this section
1281 including:

1282
1283 (i) duties which must be performed by a pharmacist; and

1284
1285 (ii) supervision requirements for pharmacy technicians and pharmacy technician trainees.

1286
1287 (2) Licensing requirements.

1288
1289 (A) A Class G pharmacy shall register with the board on a pharmacy license application
1290 provided by the board, following the procedures specified in §291.1 of this title (relating to
1291 Pharmacy License Application).

1292
1293 (B) A Class G pharmacy which changes ownership shall notify the board within 10 days of the
1294 change of ownership and apply for a new and separate license as specified in §291.3 of this title
1295 (relating to Required Notifications).
1296

1297 (C) A Class G pharmacy which changes location and/or name shall notify the board of the
1298 change within 10 days and file for an amended license as specified in §291.3 of this title.
1299

1300 (D) A Class G pharmacy owned by a partnership or corporation which changes managing
1301 officers shall notify the board in writing of the names of the new managing officers within 10
1302 days of the change, following the procedures in §291.3 of this title.
1303

1304 (E) A Class G pharmacy shall notify the board in writing within 10 days of closing, following
1305 the procedures in §291.5 of this title (relating to Closing a Pharmacy).
1306

1307 (F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
1308 charged for issuance and renewal of a license and the issuance of an amended license.
1309

1310 (G) A separate license is required for each principal place of business and only one
1311 pharmacy license may be issued to a specific location.
1312

1313 (3) Environment.
1314

1315 (A) General requirements.
1316

1317 (i) The pharmacy shall be arranged in an orderly fashion and kept clean. All required
1318 equipment shall be in good operating condition.
1319

1320 (ii) The pharmacy shall be properly lighted and ventilated.
1321

1322 (B) Security.
1323

1324 (i) Each pharmacist while on duty shall be responsible for the security of the prescription
1325 department, including provisions for effective control against theft or diversion of prescription
1326 drug records.
1327

1328 (ii) Pharmacies shall employ appropriate measures to ensure that security of prescription
1329 drug records is maintained at all times to prohibit unauthorized access.
1330

1331 (4) Policy and Procedures. A policy and procedure manual shall be maintained by the Class G
1332 pharmacy and be available for inspection. The manual shall:
1333

1334 (A) outline the responsibilities of each of the pharmacies;
1335

1336 (B) include a list of the name, address, telephone numbers, and all license/registration
1337 numbers of the pharmacies involved in centralized prescription drug or medication order
1338 processing; and
1339

1340 (C) include policies and procedures for:
1341

- 1342 (i) protecting the confidentiality and integrity of patient information;
1343
1344 (ii) maintenance of appropriate records to identify the name(s), initials, or identification
1345 code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any
1346 processing;
1347
1348 (iii) complying with federal and state laws and regulations;
1349
1350 (iv) operating a continuous quality improvement program for pharmacy services designed to
1351 objectively and systematically monitor and evaluate the quality and appropriateness of patient
1352 care, pursue opportunities to improve patient care, and resolve identified problems; and
1353
1354 (v) annually reviewing the written policies and procedures and documenting such review.
1355

1356 (e) Records.

1357
1358 (1) every record required to be kept under the provisions this section shall be:
1359

1360 (A) kept by the pharmacy and be available, for at least two years from the date of such
1361 inventory or record, for inspecting and copying by the board or its representative and to other
1362 authorized local, state, or federal law enforcement agencies; and
1363

1364 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
1365 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,
1366 the requested records must be provided in a mutually agreeable electronic format if specifically
1367 requested by the board or its representative. Failure to provide the records set out in this
1368 section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and
1369 maintain records in violation of the Act.
1370

1371 (2) The pharmacy shall maintain appropriate records which identify, by prescription drug or
1372 medication order, the name(s), initials, or identification code(s) of each pharmacist, pharmacy
1373 technician, or pharmacy technician trainee who performs a processing function for a prescription
1374 drug or medication order. Such records may be maintained:
1375

1376 (A) separately by each pharmacy and pharmacist; or
1377

1378 (B) in a common electronic file as long as the records are maintained in such a manner that
1379 the data processing system can produce a printout which lists the functions performed by each
1380 pharmacy and pharmacist.
1381

1382 (3) In addition, the pharmacy shall comply with the record keeping requirements applicable to
1383 the class of pharmacy to the extent applicable for the specific processing activity and this
1384 section.
1385

1386 **§291.155 Limited Prescription Delivery Pharmacy (Class H)**
1387

1388 (a) Purpose.

1389
1390 (1) The purpose of this section is to provide standards for a limited prescription delivery
1391 pharmacy.

1392
1393 (2) Any facility established for the primary purpose of limited prescription delivery by a Class A
1394 pharmacy shall be licensed as a Class H pharmacy under the Act. A Class H pharmacy shall
1395 not store bulk drugs, or dispense a prescription drug order.

1396
1397 (3) A Class H pharmacy may deliver prescription drug orders for dangerous drugs. A Class H
1398 pharmacy may not deliver prescription drug orders for controlled substances.

1399
1400 (b) Definitions. Any term not defined in this chapter shall have the definition set out in the Act,
1401 §551.003.

1402
1403 (c) Personnel.

1404
1405 (1) Pharmacist-in-charge.

1406
1407 (A) General. Each Class H pharmacy shall have one pharmacist-in-charge who is employed
1408 or under written agreement, at least on a part-time basis, but may be employed on a full-time
1409 basis, and who may be the pharmacist-in-charge for more than one limited prescription delivery
1410 pharmacy.

1411
1412 (B) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of
1413 pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-
1414 charge may advise the owner on administrative or operational concerns. The pharmacist-in-
1415 charge shall have responsibility for, at a minimum, the following:

1416
1417 (i) education and training of pharmacy technicians and pharmacy technician trainees;

1418
1419 (ii) maintaining records of all transactions of the Class H pharmacy required by applicable
1420 state and federal laws and sections;

1421
1422 (iii) adherence to policies and procedures regarding the maintenance of records; and

1423
1424 (iv) legal operation of the pharmacy, including meeting all inspection and other requirements
1425 of all state and federal laws or sections governing the practice of pharmacy.

1426
1427 (2) Owner. The owner of a Class H pharmacy shall have responsibility for all administrative
1428 and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on
1429 administrative and operational concerns. The owner shall have responsibility for, at a minimum,
1430 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with
1431 the pharmacist-in-charge or another Texas licensed pharmacist:

1432
1433 (A) providing the pharmacy with the necessary equipment and resources commensurate with
1434 its level and type of practice; and

1435
1436 (B) establishment of policies and procedures regarding maintenance, storage, and retrieval of
1437 records in compliance with state and federal requirements.

1438
1439 (3) Pharmacists.

1440

1441 (A) The pharmacist-in-charge shall be assisted by sufficient number of additional licensed
1442 pharmacists as may be required to operate the Class H pharmacy competently, safely, and
1443 adequately to meet the needs of the patients of the pharmacy.
1444

1445 (B) All pharmacists shall assist the pharmacist-in-charge in meeting his or her responsibilities.
1446

1447 (C) Pharmacists shall be responsible for any delegated act performed by the pharmacy
1448 technicians under his or her supervision.
1449

1450 (4) Pharmacy Technicians and Pharmacy Technician Trainees.
1451

1452 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the
1453 training requirements specified in §297.6 of this title (relating to Pharmacy Technician and
1454 Pharmacy Technician Trainee Training).
1455

1456 (B) Duties. Duties include:
1457

1458 (i) delivery of previously verified prescription drug orders to a patient or patient's agent
1459 provided a record of prescriptions delivered is maintained; and
1460

1461 (ii) maintaining pharmacy records.
1462

1463 (5) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows.
1464

1465 (A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge
1466 that bears the person's name and identifies him or her as a pharmacy technician, or a certified
1467 pharmacy technician, if the technician maintains current certification with the Pharmacy
1468 Technician Certification Board or any other entity providing an examination approved by the
1469 board.
1470

1471 (B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an
1472 identification tag or badge that bears the person's name and identifies him or her as a pharmacy
1473 technician trainee.
1474

1475 (C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that
1476 bears the person's name and identifies him or her as a pharmacist intern.
1477

1478 (D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the
1479 person's name and identifies him or her as a pharmacist.
1480

1481 (d) Operational Standards.
1482

1483 (1) General requirements. A Class A or Class E Pharmacy may outsource limited prescription
1484 delivery to a Class H pharmacy provided the pharmacies have entered into a written contract or
1485 agreement which outlines the services to be provided and the responsibilities and
1486 accountabilities of each pharmacy in compliance with federal and state laws and regulations.
1487

1488 (2) Licensing requirements.
1489

1490 (A) A Class H pharmacy shall register with the board on a pharmacy license application
1491 provided by the board, following the procedures specified in §291.1 of this title (relating to
1492 Pharmacy License Application).

1493
1494 (B) A Class H pharmacy must be owned by a hospital district and located in a county without
1495 another pharmacy.

1496
1497 (C) A Class H pharmacy which changes ownership shall notify the board within 10 days of the
1498 change of ownership and apply for a new and separate license as specified in §291.3 of this title
1499 (relating to Required Notifications).

1500
1501 (D) A Class H pharmacy which changes location and/or name shall notify the board of the
1502 change within 10 days and file for an amended license as specified in §291.3 of this title.

1503
1504 (E) A Class H pharmacy shall notify the board in writing within 10 days of closing, following
1505 the procedures in §291.5 of this title (relating to Closing a Pharmacy).

1506
1507 (F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
1508 charged for issuance and renewal of a license and the issuance of an amended license.
1509 However, a pharmacy operated by the state or a political subdivision of the state that qualifies
1510 for a Class H license is not required to pay a fee to obtain a license.

1511
1512 (G) A separate license is required for each principal place of business and only one
1513 pharmacy license may be issued to a specific location.

1514
1515 (3) Environment.

1516
1517 (A) General requirements.

1518
1519 (i) The pharmacy shall have a designated area for the storage of previously verified
1520 prescription drug orders.

1521
1522 (ii) The pharmacy shall be arranged in an orderly fashion and kept clean.

1523
1524 (iii) A sink with hot and cold running water shall be available to all pharmacy personnel and
1525 shall be maintained in a sanitary condition at all times.

1526
1527 (B) Security.

1528
1529 (i) Only authorized personnel may have access to storage areas for dangerous drugs.

1530
1531 (ii) When a pharmacist, pharmacy technician or pharmacy technician trainee is not present
1532 all storage areas for dangerous drugs devices shall be locked by key, combination, or other
1533 mechanical or electronic means, so as to prohibit access by unauthorized individuals.

1534
1535 (iii) The pharmacist-in-charge shall be responsible for the security of all storage areas for
1536 dangerous drugs including provisions for adequate safeguards against theft or diversion of
1537 dangerous drugs, and records for such drugs.

1538

1539 (iv) Housekeeping and maintenance duties shall be carried out in the pharmacy, while the
1540 pharmacist-in-charge, consultant pharmacist, staff pharmacist, or pharmacy technician/trainee is
1541 on the premises.
1542

1543 (4) Library. A reference library shall be maintained which includes current copies of the
1544 following in hard copy or electronic format:
1545

1546 (A) Texas Pharmacy Act and rules;
1547

1548 (B) Texas Dangerous Drug Act;
1549

1550 (C) at least one current or updated patient information reference such as:
1551

1552 (i) United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient); or
1553

1554 (ii) a reference text or information leaflets which provide patient information; and
1555

1556 (D) basic antidote information and the telephone number of the nearest Regional Poison
1557 Control Center.
1558

1559 (5) Delivery of Drugs.
1560

1561 (A) The pharmacist-in-charge, consultant pharmacist, staff pharmacist, pharmacy technician,
1562 or pharmacy technician trainee must be present at the pharmacy to deliver prescriptions.
1563

1564 (B) Prescriptions for controlled substances may not be stored or delivered by the pharmacy.
1565

1566 (C) Prescriptions may be stored at the pharmacy for no more than 15 days. If prescriptions
1567 are not picked up by the patient, the medications are to be destroyed utilizing a reverse
1568 distribution service.
1569

1570 (D) The pharmacist-in-charge, consultant pharmacist, or staff pharmacist shall personally visit
1571 the pharmacy on at least a weekly basis and conduct monthly audits of prescriptions received
1572 and delivered by the pharmacy.
1573

1574 (e) Records.
1575

1576 (1) Every record required to be kept under the provisions this section shall be:
1577

1578 (A) kept by the pharmacy and be available, for at least two years from the date of such
1579 inventory or record, for inspecting and copying by the board or its representative and to other
1580 authorized local, state, or federal law enforcement agencies; and
1581

1582 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
1583 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,
1584 the requested records must be provided in a mutually agreeable electronic format if specifically
1585 requested by the board or its representative. Failure to provide the records set out in this
1586 section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and
1587 maintain records in violation of the Act.
1588

- 1589 (2) A record of on-site visits by the pharmacist-in-charge, consultant pharmacist, or staff
1590 pharmacist shall be maintained and include the following information:
1591
1592 (A) date of the visit;
1593
1594 (B) pharmacist's evaluation of findings; and
1595
1596 (C) signature of the visiting pharmacist.
1597
1598 (3) Records of prescription drug orders delivered to the Class H pharmacy shall include:
1599
1600 (A) patient name;
1601
1602 (B) name and quantity of drug delivered;
1603
1604 (C) name of pharmacy and address delivering the prescription drug order; and
1605
1606 (D) date received at the Class H pharmacy.
1607
1608 (4) Records of drugs delivered to a patient or patient's agent shall include:
1609
1610 (A) patient name;
1611
1612 (B) name, signature, or electronic signature of the person who picks up the prescription drug;
1613
1614 (C) date delivered; and
1615
1616 (D) the name of the drug and quantity delivered.
1617
1618 (5) Ownership of pharmacy records. For the purposes of these sections, a pharmacy licensed
1619 under the Act is the only entity which may legally own and maintain prescription drug records.