

RULE REVIEW ANALYSIS

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

Short Title: Class D Pharmacies

Rule Number: Chapter 291, Subchapter E

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 E CLINIC PHARMACY (CLASS D)**

5
6 **§291.91 Definitions**
7

8 The following words and terms, when used in this chapter, shall have the following meanings,
9 unless the context clearly indicates otherwise.

10
11 (1) Act--The Texas Pharmacy Act, Chapters 551 - 566, 568 - 569, Occupations Code as
12 amended.

13
14 (2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion,
15 or any other means to the body of a patient by:

16
17 (A) a practitioner or an authorized agent under his supervision; or

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

20
21 (3) Board--The Texas State Board of Pharmacy.

22
23 (4) Clinic--A facility/location other than a physician's office, where limited types of dangerous
24 drugs or devices restricted to those listed in and approved for the clinic's formulary are stored,
25 administered, provided, or dispensed to outpatients.

26
27 (5) Consultant pharmacist--A pharmacist retained by a clinic on a routine basis to consult with
28 the clinic in areas that pertain to the practice of pharmacy.

29
30 (6) Continuous supervision--Supervision provided by the pharmacist-in-charge, consultant
31 pharmacist, and/or staff pharmacist, and consists of on-site and telephone supervision, routine
32 inspection, and a policy and procedure manual.

33
34 (7) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules
35 I-V or Penalty Groups 1-4 of the Texas Controlled Substances Act, as amended, or a drug,
36 immediate precursor, or other substance included in Schedule I, II, III, IV, or V of the Federal
37 Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-
38 513).

39
40 (8) Dangerous drug--Any drug or device that is not included in Penalty Groups 1-4 of the
41 Controlled Substances Act and that is unsafe for self-medication or any drug or device that
42 bears or is required to bear the legend:

43
44 (A) "Caution: federal law prohibits dispensing without prescription" or "Rx only";

45
46 (B) "Caution: federal law restricts this drug to use by or on the order of a licensed
47 veterinarian."

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

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
101
102

(10) Indigent--Person who meets or falls below 185% of federal poverty income guidelines as established from time to time by the United States Department of Health and Human Services.

(11) Limited type of device--An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner, that is contained in the clinic formulary and is to be administered, dispensed, or provided according to the objectives of the clinic.

(12) Limited type of drug--A dangerous drug contained in the clinic formulary, and to be administered, dispensed, or provided according to the objectives of the clinic.

(13) Outpatient--An ambulatory patient who comes to a clinic to receive services related to the objectives of the clinic and departs the same day.

(14) Pharmacist--A person licensed by the board to practice pharmacy.

(15) Pharmacist-in-charge--The pharmacist designated on a pharmacy license as the pharmacist who is responsible for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(16) Practitioner--

(A) a person licensed or registered to prescribe, distribute, administer, or dispense a prescription drug or device in the course of professional practice in this state, including a physician, dentist, podiatrist, or veterinarian but excluding a person licensed under the Act;

(B) a person licensed by another state, Canada, or the United Mexican States in a health field in which, under the law of this state, a license holder in this state may legally prescribe a dangerous drug;

(C) a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration registration number and who may legally prescribe a Schedule II, III, IV, or V controlled substance, as specified under Chapter 481, Health and Safety Code, in that other state; or

(D) an advanced practice nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders under §§157.0511, 157.052, 157.053, 157.054, 157.0541, or 157.0542, Occupations Code.

(17) Prepackaging--A method of packaging a drug product into a single container which contains more than one dosage unit and usually contains sufficient quantity of medication for one normal course of therapy.

(18) Provide--To supply one or more units of use of a nonprescription drug or dangerous drug to a patient.

(19) Standing delegation order--Written orders from a physician and designed for a patient population with specific diseases, disorders, health problems, or sets of symptoms, which provide authority for and a plan for use with patients presenting themselves prior to being

103 examined or evaluated by a physician to assure that such acts are carried out correctly and are
104 distinct from specific orders written for a particular patient.

105
106 (20) Standing medical order--Written orders from a physician or the medical staff of an
107 institution for patients which have been examined or evaluated by a physician and which are
108 used as a guide in preparation for and carrying out medical and/or surgical procedures.

109
110 (21) Supportive personnel--Individuals under the supervision of a pharmacist-in-charge,
111 designated by the pharmacist-in-charge, and for whom the pharmacist-in-charge assumes legal
112 responsibility, who function and perform under the instructions of the pharmacist-in-charge.

113
114 (22) Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and
115 Safety Code, Chapter 481, as amended.

116
117 (23) Unit of use--A sufficient quantity of a drug product for one normal course of therapy.

118
119

120 **§291.92 Personnel**

121
122

(a) Pharmacist-in-charge.

123
124

(1) General.

125
126

(A) Each Class D pharmacy shall have one pharmacist-in-charge who is employed or under
127 written agreement, at least on a part-time basis, but may be employed on a full-time basis if
128 desired, and who may be pharmacist-in-charge of more than one clinic pharmacy.

129
130

(B) A written agreement shall exist between the clinic and the pharmacist-in-charge, and a
131 copy of the written agreement shall be made available to the board upon request.

132
133

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

135
136

(A) continuous supervision of registered nurses, licensed vocational nurses, physician
137 assistants, pharmacy technicians, pharmacy technician trainees, and assistants carrying out the
138 pharmacy related aspects of provision;

139
140

(B) documented periodic on-site visits as specified in §291.93(h) and §291.94(b) of this title
141 (relating to Operational Standards and Records), either personally or by the consultant
142 pharmacist or staff pharmacist, to insure that the clinic is following set policies and procedures;
143 documentation shall be as specified in §291.94(b) of this title;

144
145

(C) development of a formulary for the clinic, in conjunction with the clinic's pharmacy and
146 therapeutics committee, consisting of drugs and/or devices needed to meet the objectives of the
147 clinic;

148
149

(D) procurement and storage of drugs and/or devices, but he or she may receive input from
150 other appropriate staff of the clinic;

151
152

(E) determining specifications of all drugs and/or devices procured by the clinic;

153

154 (F) maintenance of records of all transactions of the pharmacy as may be required by
155 applicable law and as may be necessary to maintain accurate control over and accountability for
156 all drugs and/or devices;

157
158 (G) development and at least annual review of a policy and procedure manual for the
159 pharmacy in conjunction with the clinic's pharmacy and therapeutics committee;

160
161 (H) meeting inspection and other requirements of the Texas Pharmacy Act and these
162 sections;

163
164 (I) dispensing of prescription orders; and

165
166 (J) conducting inservice training at least annually for supportive personnel who provide drugs;
167 such training shall be related to actions, contraindications, adverse reactions, and
168 pharmacology of drugs contained in the formulary.

169
170 (b) Consultant pharmacist.

171
172 (1) The consultant pharmacist may be the pharmacist-in-charge.

173
174 (2) The consultant pharmacist may be retained by more than one clinic.

175
176 (c) Staff pharmacists.

177
178 (1) The pharmacist-in-charge may be assisted by a sufficient number of additional pharmacists
179 as may be required to operate the clinic pharmacy competently, safely, and adequately to meet
180 the needs of the patients of the clinic.

181
182 (2) Staff pharmacists and/or the consultant pharmacist shall assist the pharmacist-in-charge in
183 meeting the responsibilities as outlined in subsection (a)(2) of this section and in ordering,
184 supervising, and accounting for drugs and/or devices.

185
186 (3) Staff pharmacists and/or the consultant pharmacist shall be responsible for any delegated
187 act performed by supportive personnel under his or her supervision.

188
189 (d) Supportive personnel.

190
191 (1) Qualifications.

192
193 (A) Supportive personnel shall possess education and training necessary to carry out their
194 responsibilities.

195
196 (B) Supportive personnel shall be qualified to perform the pharmacy tasks assigned to them.

197
198 (2) Duties. Duties may include:

199
200 (A) prepackaging and labeling unit of use packages, under the direct supervision of a
201 pharmacist with the pharmacist conducting in-process and final checks and affixing his or her
202 signature to the appropriate quality control records;

203
204 (B) maintaining inventories of drugs and/or devices; and

205
206 (C) maintaining pharmacy records.

207
208 (3) Absence of the pharmacist. The pharmacist-in-charge shall designate from among the
209 supportive personnel a person to supervise the day-to-day pharmacy-related operations of the
210 clinic.

211
212 (e) Owner. The owner of a Class D pharmacy shall have responsibility for all administrative and
213 operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on
214 administrative and operational concerns. The owner shall have responsibility for, at a minimum,
215 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with
216 the pharmacist-in-charge or another Texas licensed pharmacist:

217
218 (1) establishment of policies for procurement of prescription drugs and devices and other
219 products provided or dispensed from the Class D pharmacy;

220
221 (2) establishment and maintenance of effective controls against the theft or diversion of
222 prescription drugs;

223
224 (3) providing the pharmacy with the necessary equipment and resources commensurate with
225 its level and type of practice; and

226
227 (4) establishment of policies and procedures regarding maintenance, storage, and retrieval of
228 records in a data processing system such that the system is in compliance with state and
229 federal requirements.

230
231
232 **§291.93 Operational Standards**

233
234 (a) Registration.

235
236 (1) General requirements.

237
238 (A) All clinic pharmacies shall register with the board on a form provided by the board,
239 following the procedures specified in §291.1 of this title (relating to Pharmacy License
240 Application).

241
242 (B) All clinic pharmacies shall provide a copy of their policy and procedure manual, which
243 includes the formulary, to the board with the initial license application.

244
245 (C) The registration form shall be signed by the pharmacist-in-charge of the clinic pharmacy.

246
247 (D) The owner or managing officer of the clinic shall sign the registration form and shall agree
248 to comply with the rules adopted by the board governing clinic pharmacies.

249
250 (E) The registration form shall be certified and state whether the clinic pharmacy is a sole
251 ownership and give the name of the owner, or if a partnership, name all the managing partners,
252 or if a corporation, name all the managing officers.

253
254 (F) The following fees will be charged.

256 (i) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
257 charged for the issuance of a new license and for each renewal.
258
259 (ii) A pharmacy operated by the state or a local government that qualifies for a Class D
260 license is not required to pay a fee to obtain a license.
261
262 (G) When a clinic pharmacy changes ownership, a new and separate license application
263 must be filed with the board and the old license returned to the board's office.
264
265 (H) A clinic pharmacy shall notify the board in writing of any change in name or location within
266 10 days.
267
268 (I) A separate license is required for each principal place of business and only one pharmacy
269 license may be issued to a specific location.
270
271 (J) A clinic pharmacy shall notify the board in writing within 10 days of a change of the
272 pharmacist-in-charge or staff pharmacist or consultant pharmacist.
273
274 (K) A clinic pharmacy shall notify the board in writing within 10 days of permanent closing.
275
276 (2) Registration requirements for facilities that operate at temporary clinic sites. A facility that
277 operates a clinic at one or more temporary locations may be licensed as a Class D (clinic)
278 pharmacy and provide dangerous drugs from these temporary locations provided:
279
280 (A) the clinic pharmacy complies with the registration requirements in paragraph (1) of this
281 subsection;
282
283 (B) the clinic pharmacy has a permanent location where all dangerous drugs and records are
284 stored;
285
286 (C) no dangerous drugs are stored or left for later pickup by the patient at the temporary
287 location(s), and all drugs are returned to the permanent location each day and stored:
288
289 (i) within the clinic pharmacy; or
290
291 (ii) within the pharmacy's mobile unit provided the mobile clinic is parked at the location of
292 the clinic pharmacy in a secure area with adequate measures to prevent unauthorized access,
293 and the drugs are maintained at proper temperatures;
294
295 (D) the permanent location is the address of record for the pharmacy;
296
297 (E) the facility has no more than six temporary locations in operation simultaneously;
298
299 (F) the clinic pharmacy notifies the board of the locations of the temporary locations where
300 drugs will be provided and the schedule for operation of such clinics; and
301
302 (G) the clinic pharmacy notifies the board within 10 days of a change in address or closing of
303 a temporary location or a change in schedule of operation of a clinic.
304
305 (b) Environment.
306

307 (1) General requirements.

308

309 (A) The clinic pharmacy shall have a designated area(s) for the storage of dangerous drugs
310 and/or devices.

311

312 (B) No person may operate a pharmacy which is unclean, unsanitary, or under any condition
313 which endangers the health, safety, or welfare of the public.

314

315 (C) The pharmacy shall comply with all federal, state, and local health laws and ordinances.

316

317 (D) A sink with hot and cold running water shall be available to all pharmacy personnel and
318 shall be maintained in a sanitary condition at all times.

319

320 (2) Security.

321

322 (A) Only authorized personnel may have access to storage areas for dangerous drugs and/or
323 devices.

324

325 (B) All storage areas for dangerous drugs and/or devices shall be locked by key, combination,
326 or other mechanical or electronic means, so as to prohibit access by unauthorized individuals.

327

328 (C) The pharmacist-in-charge shall be responsible for the security of all storage areas for
329 dangerous drugs and/or devices including provisions for adequate safeguards against theft or
330 diversion of dangerous drugs and devices, and records for such drugs and devices.

331

332 (D) The pharmacist-in-charge shall consult with clinic personnel with respect to security of the
333 pharmacy, including provisions for adequate safeguards against theft or diversion of dangerous
334 drugs and/or devices, and records for such drugs and/or devices.

335

336 (E) Housekeeping and maintenance duties shall be carried out in the pharmacy, while the
337 pharmacist-in-charge, consultant pharmacist, staff pharmacist, or supportive personnel is on the
338 premises.

339

340 (c) Equipment. Each clinic pharmacy shall maintain the following equipment and supplies:

341

342 (1) if the clinic pharmacy prepackages drugs for provision:

343

344 (A) a typewriter or comparable equipment; and

345

346 (B) an adequate supply of child-resistant, moisture-proof, and light-proof containers and
347 prescription, poison, and other applicable identification labels used in dispensing and providing
348 of drugs;

349

350 (2) if the clinic pharmacy maintains dangerous drugs requiring refrigeration and/or freezing, a
351 refrigerator and/or freezer;

352

353 (3) if the clinic pharmacy compounds prescription drug orders, a properly maintained Class A
354 prescription balance (with weights) or equivalent analytical balance. It is the responsibility of the
355 pharmacist-in-charge to have such balance inspected at least every three years by the
356 appropriate authority as prescribed by local, state, or federal law or regulations.

357

358 (d) Library. A reference library shall be maintained which includes the following in hard copy or
359 electronic format:

360
361 (1) current copies of the following:

362
363 (A) Texas Pharmacy Act and rules; and

364
365 (B) Texas Dangerous Drug Act;

366
367 (2) current copies of at least two of the following references:

368
369 (A) Facts and Comparisons with current supplements;

370
371 (B) AHFS Drug Information;

372
373 (C) United States Pharmacopeia Dispensing Information (USPDI);

374
375 (D) Physician's Desk Reference (PDR);

376
377 (E) American Drug Index;

378
379 (F) a reference text on drug interactions, such as Drug Interaction Facts. A separate
380 reference is not required if other references maintained by the pharmacy contain drug
381 interaction information including information needed to determine severity or significance of the
382 interaction and appropriate recommendations or actions to be taken;

383
384 (G) reference texts in any of the following subjects: toxicology, pharmacology, or drug
385 interactions; or

386
387 (H) reference texts pertinent to the major function(s) of the clinic.

388
389 (e) Drugs and devices.

390
391 (1) Formulary.

392
393 (A) Each Class D pharmacy shall have a formulary which lists all drugs and devices that are
394 administered, dispensed, or provided by the Class D pharmacy.

395
396 (B) The formulary shall be limited to the following types of drugs and devices, exclusive of
397 injectable drugs for administration in the clinic and nonprescription drugs, except as provided in
398 subparagraph (D) of this paragraph:

399
400 (i) anti-infective drugs;

401
402 (ii) musculoskeletal drugs;

403
404 (iii) vitamins;

405
406 (iv) obstetrical and gynecological drugs and devices;

407
408 (v) topical drugs; and

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
448
449
450
451
452
453
454
455
456
457
458
459

(vi) serums, toxoids, and vaccines.

(C) The formulary shall not contain the following drugs or types of drugs:

(i) Nalbuphine (Nubain);

(ii) drugs used to treat erectile dysfunction; and

(iii) Schedule I - V controlled substances.

(D) Clinics with a patient population which consists of at least 80% indigent patients may petition the board to operate with a formulary which includes types of drugs and devices, other than those listed in subparagraph (B) of this paragraph based upon documented objectives of the clinic, under the following conditions.

(i) Such petition shall contain an affidavit with the notarized signatures of the medical director, the pharmacist-in-charge, and the owner/chief executive officer of the clinic, and include the following documentation:

(I) the objectives of the clinic;

(II) the total number of patients served by the clinic during the previous fiscal year or calendar year;

(III) the total number of indigent patients served by the clinic during the previous fiscal year or calendar year;

(IV) the percentage of clinic patients who are indigent, based upon the patient population during the previous fiscal year or calendar year;

(V) the proposed formulary and the need for additional types of drugs based upon objectives of the clinic; and

(VI) if the provision of any drugs on the proposed formulary require special monitoring, the clinic pharmacy shall submit relevant sections of the clinic's policy and procedure manual regarding the provision of drugs that require special monitoring.

(ii) Such petition shall be resubmitted every two years in conjunction with the application for renewal of the pharmacy license.

(I) Such renewal petition shall contain the documentation required in clause (i) of this subparagraph.

(II) If at the time of renewal of the pharmacy license, the patient population for the previous fiscal year or calendar year is below 80% indigent patients, the clinic shall be required to submit an application for a Class A pharmacy license or shall limit the clinic formulary to those types of drugs and devices listed in subparagraph (B) of this paragraph.

(iii) If a clinic pharmacy wishes to add additional drugs to the expanded formulary, the pharmacy shall petition the board in writing prior to adding such drugs to the formulary. The

460 petition shall identify drugs to be added and the need for the additional drugs based upon
461 objectives of the clinic as specified in clause (i) of this subparagraph.

462
463 (iv) The following additional requirements shall be satisfied for clinic pharmacies with
464 expanded formularies.

465 (I) Supportive personnel who are providing drugs shall be licensed nurses or practitioners.
466

467 (II) The pharmacist-in-charge, consultant pharmacist, or staff pharmacist shall make on-site
468 visits to the clinic at least monthly.
469

470 (III) If the pharmacy provides drugs which require special monitoring (i.e., drugs which
471 require follow-up laboratory work or drugs which should not be discontinued abruptly), the
472 pharmacy shall have policies and procedures for the provision of the prescription drugs to
473 patients and the monitoring of patients who receive such drugs.
474

475 (IV) The pharmacist-in-charge, consultant pharmacists, or staff pharmacists shall conduct
476 retrospective drug regimen reviews of a random sample of patients of the clinic on at least a
477 quarterly basis. The pharmacist-in-charge shall be responsible for ensuring that a report
478 regarding the drug regimen review, including the number of patients reviewed, is submitted to
479 the clinic's medical director and the pharmacy and therapeutics committee of the clinic.
480

481 (V) If a pharmacy provides antipsychotic drugs:

482 (-a-) a physician of the clinic shall initiate the therapy;
483

484 (-b-) a practitioner shall monitor and order ongoing therapy; and
485

486 (-c-) the patient shall be physically examined by the physician at least on a yearly basis.
487

488 (v) The board may consider the following items in approving or disapproving a petition for an
489 expanded formulary:

490 (I) the degree of compliance on past compliance inspections;
491

492 (II) the size of the patient population of the clinic;
493

494 (III) the number and types of drugs contained in the formulary; and
495

496 (IV) the objectives of the clinic.
497

498
499
500 (2) Storage.
501

502 (A) Drugs and/or devices which bear the words "Caution, Federal Law Prohibits Dispensing
503 without prescription" or "Rx only" shall be stored in secured storage areas.
504

505 (B) All drugs shall be stored at the proper temperatures, as defined in §291.15 of this title
506 (relating to Storage of Drugs).
507

508 (C) Any drug or device bearing an expiration date may not be provided, dispensed, or
509 administered beyond the expiration date of the drug or device.
510

511
512 (D) Outdated drugs or devices shall be removed from stock and shall be quarantined together
513 until such drugs or devices are disposed.
514
515 (E) Controlled substances may not be stored at the clinic pharmacy.
516
517 (3) Drug samples.
518
519 (A) Drug samples of drugs listed on the clinic pharmacy's formulary and supplied by
520 manufacturers shall be properly stored, labeled, provided, or dispensed by the clinic pharmacy
521 in the same manner as prescribed by these sections for dangerous drugs.
522
523 (B) Samples of controlled substances may not be stored, provided, or dispensed in the clinic
524 pharmacy.
525
526 (4) Prepackaging and labeling for provision.
527
528 (A) Drugs may be prepackaged and labeled for provision in the clinic pharmacy. Such
529 prepackaging shall be performed by a pharmacist or supportive personnel under the direct
530 supervision of a pharmacist and shall be for the internal use of the clinic.
531
532 (B) Drugs must be prepackaged in suitable containers.
533
534 (C) The label of the prepackaged unit shall bear:
535
536 (i) the name, address, and telephone number of the clinic;
537
538 (ii) directions for use, which may include incomplete directions for use provided:
539
540 (I) labeling with incomplete directions for use has been authorized by the pharmacy and
541 therapeutics committee;
542
543 (II) precise requirements for completion of the directions for use are developed by the
544 pharmacy and therapeutics committee and maintained in the pharmacy policy and procedure
545 manual; and
546
547 (III) the directions for use are completed by practitioners, pharmacists, licensed nurses or
548 physician assistants in accordance with the precise requirements developed under subclause
549 (II) of this clause;
550
551 (iii) name and strength of the drug--if generic name, the name of the manufacturer or
552 distributor of the drug;
553
554 (iv) quantity;
555
556 (v) lot number and expiration date; and
557
558 (vi) appropriate ancillary label(s).
559
560 (D) Records of prepackaging shall be maintained according to §291.94(c) of this title (relating
561 to Records).

562
563 (5) Labeling for provision of drugs and/or devices in an original manufacturer's container.
564
565 (A) Drugs and/or devices in an original manufacturer's container shall be labeled prior to
566 provision with the information set out in paragraph (4)(C) of this subsection.
567
568 (B) Drugs and/or devices in an original manufacturer's container may be labeled by:
569
570 (i) a pharmacist in a pharmacy licensed by the board; or
571
572 (ii) supportive personnel in a Class D pharmacy, provided the drugs and/or devices and
573 control records required by §291.94(d) of this title are quarantined together until checked and
574 released by a pharmacist.
575
576 (C) Records of labeling for provision of drugs and/or devices in an original manufacturer's
577 container shall be maintained according to §291.94(d) of this title.
578
579 (6) Provision.
580
581 (A) Drugs and devices may only be provided to patients of the clinic.
582
583 (B) At the time of the initial provision, a licensed nurse or practitioner shall provide verbal and
584 written information to the patient or patient's agent on side effects, interactions, and precautions
585 concerning the drug or device provided. If the provision of subsequent drugs is delivered to the
586 patient at the patient's residence or other designated location, the following is applicable:
587
588 (i) Written information as specified in subparagraph (B) of this paragraph shall be delivered
589 with the medication.
590
591 (ii) The pharmacy shall maintain and use adequate storage or shipment containers and use
592 shipping processes to ensure drug stability and potency. Such shipping processes shall include
593 the use of appropriate packaging material and/or devices to ensure that the drug is maintained
594 at an appropriate temperature range to maintain the integrity of the medication throughout the
595 delivery process.
596
597 (iii) The pharmacy shall use a delivery system which is designed to ensure that the drugs
598 are delivered to the appropriate patient.
599
600 (C) The provision of drugs or devices shall be under the continuous supervision of a
601 pharmacist according to standing delegation orders or standing medical orders and in
602 accordance with written policies and procedures and completion of the label as specified in
603 subparagraph (G) of this paragraph.
604
605 (D) Drugs and/or devices may only be provided in accordance with the system of control and
606 accountability for drugs and/or devices provided by the clinic; such system shall be developed
607 and supervised by the pharmacist-in-charge.
608
609 (E) Only drugs and/or devices listed in the clinic formulary may be provided.
610

611 (F) Drugs and/or devices may only be provided in prepackaged quantities in suitable
612 containers and/or original manufacturer's containers which are appropriately labeled as set out
613 in paragraphs (4) and (5) of this subsection.

614
615 (G) Such drugs and/or devices shall be labeled by a pharmacist licensed by the board;
616 however, when drugs and/or devices are provided under the supervision of a physician
617 according to standing delegation orders or standing medical orders, supportive personnel may
618 at the time of provision print on the label the following information:

619
620 (i) patient's name; however, the patient's partner or family member is not required to be on
621 the label of a drug prescribed for a partner for a sexually transmitted disease or for a patient's
622 family members if the patient has an illness determined by the Centers for Disease Control and
623 Prevention, the World Health Organization, or the Governor's office to be pandemic;

624
625 (ii) any information necessary to complete the directions for use in accordance with
626 paragraph (4)(C)(ii) of this subsection;

627
628 (iii) date of provision; and

629
630 (iv) practitioner's name.

631
632 (H) Records of provision shall be maintained according to §291.94(e) of this title.

633
634 (I) Controlled substances may not be provided or dispensed.

635
636 (J) Non-sterile and sterile preparations may only be provided by the clinic pharmacy in
637 accordance with §291.131 and §291.133 of this title (relating to Pharmacies Compounding Non-
638 sterile Preparations and Pharmacies Compounding Sterile Preparations).

639
640 (7) Dispensing. Dangerous drugs may only be dispensed by a pharmacist pursuant to a
641 prescription order in accordance with §§291.31 - 291.35 of this title (relating to Community
642 Pharmacy (Class A)) and §291.131 and §291.133 of this title.

643
644 (f) Pharmacy and therapeutics committee.

645
646 (1) The clinic pharmacy shall have a pharmacy and therapeutics committee, which shall be
647 composed of at least three persons and shall include the pharmacist-in-charge, the medical
648 director of the clinic, and a person who is responsible for provision of drugs and devices.

649
650 (2) The pharmacy and therapeutics committee shall develop the policy and procedure manual.

651
652 (3) The pharmacy and therapeutics committee shall meet at least annually to:

653
654 (A) review and update the policy and procedure manual; and

655
656 (B) review the retrospective drug utilization review reports submitted by the pharmacist-in-
657 charge if the clinic pharmacy has an expanded formulary.

658
659 (g) Policies and procedures.

660

661 (1) Written policies and procedures shall be developed by the pharmacy and therapeutics
662 committee and implemented by the pharmacist-in-charge.

663
664 (2) The policy and procedure manual shall include, but not be limited to, the following:
665

666 (A) a current list of the names of the pharmacist-in-charge, consultant-pharmacist, staff
667 pharmacist(s), supportive personnel designated to provide drugs or devices, and the supportive
668 personnel designated to supervise the day-to-day pharmacy related operations of the clinic in
669 the absence of the pharmacist;

670
671 (B) functions of the pharmacist-in-charge, consultant pharmacist, staff pharmacist(s), and
672 supportive personnel;

673
674 (C) objectives of the clinic;

675
676 (D) formulary;

677
678 (E) a copy of written agreement between the pharmacist-in-charge and the clinic;

679
680 (F) date of last review/revision of policy and procedure manual; and

681
682 (G) policies and procedures for:

683
684 (i) security;

685
686 (ii) equipment;

687
688 (iii) sanitation;

689
690 (iv) licensing;

691
692 (v) reference materials;

693
694 (vi) storage;

695
696 (vii) packaging-repackaging;

697
698 (viii) dispensing;

699
700 (ix) provision;

701
702 (x) retrospective drug regimen review;

703
704 (xi) supervision;

705
706 (xii) labeling-relabeling;

707
708 (xiii) samples;

709
710 (xiv) drug destruction and returns;

711

- 712 (xv) drug and device procuring;
713
714 (xvi) receiving of drugs and devices;
715
716 (xvii) delivery of drugs and devices;
717
718 (xviii) recordkeeping; and
719
720 (xix) inspection.

721
722 (h) Supervision. The pharmacist-in-charge, consultant pharmacist, or staff pharmacist shall
723 personally visit the clinic on at least a monthly basis to ensure that the clinic is following
724 established policies and procedures. However, clinics operated by state or local governments
725 and clinics funded by government sources money may petition the board for an alternative
726 visitation schedule under the following conditions.

727
728 (1) Such petition shall contain an affidavit with the notarized signatures of the medical director,
729 the pharmacist-in-charge, and the owner/chief executive officer of the clinic, which states that
730 the clinic has a current policy and procedure manual on file, has adequate security to prevent
731 diversion of dangerous drugs, and is in compliance with all rules governing Class D pharmacies.

732
733 (2) The board may consider the following items in determining an alternative schedule:

- 734
735 (A) the degree of compliance on past compliance inspections;
736
737 (B) the size of the patient population of the clinic;
738
739 (C) the number and types of drugs contained in the formulary; and
740
741 (D) the objectives of the clinic.

742
743 (3) Such petition shall be resubmitted every two years in conjunction with the application for
744 renewal of the pharmacy license.

745
746
747 **§291.94 Records**

748
749 (a) Maintenance of records.

750
751 (1) Every inventory or other record required to be kept under the provisions of §291.91 of this
752 title (relating to Definitions), §291.92 of this title (relating to Personnel), §291.93 of this title
753 (relating to Operational Standards), and §291.94 of this title (relating to Records), contained in
754 Clinic Pharmacy (Class D) shall be:

755
756 (A) kept by the pharmacy and be available, for at least two years from the date of such
757 inventory or record, for inspecting and copying by the board or its representative and to other
758 authorized local, state, or federal law enforcement agencies; and

759
760 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
761 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,
762 the requested records must be provided in a mutually agreeable electronic format if specifically

763 requested by the board or its representative. Failure to provide the records set out in this
764 section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and
765 maintain records in violation of the Act.

766
767 (2) Records, except when specifically required to be maintained in original or hard-copy form,
768 may be maintained in an alternative data retention system, such as a data processing system or
769 direct imaging system provided:

770
771 (A) the records maintained in the alternative system contain all of the information required on
772 the manual record; and

773
774 (B) the data processing system is capable of producing a hard copy of the record upon the
775 request of the board, its representative, or other authorized local, state, or federal law
776 enforcement or regulatory agencies.

777
778 (3) Invoices and records of receipt may be kept at a location other than the pharmacy. Any
779 such records not kept at the pharmacy shall be supplied by the pharmacy within 72 hours, if
780 requested by an authorized agent of the Texas State Board of Pharmacy.

781
782 (b) On-site visits. A record of on-site visits by the pharmacist-in-charge, consultant pharmacist,
783 or staff pharmacist shall be maintained and include the following information:

784
785 (1) date of the visit;

786
787 (2) pharmacist's evaluation of findings; and

788
789 (3) signature of the visiting pharmacist.

790
791 (c) Prepackaging. Records of prepackaging shall include the following:

792
793 (1) name, strength, and dosage form of drug;

794
795 (2) name of the manufacturer;

796
797 (3) manufacturer's lot number;

798
799 (4) expiration date;

800
801 (5) facility's lot number;

802
803 (6) quantity per package and number of packages;

804
805 (7) date packaged;

806
807 (8) name(s), signatures, or electronic signatures of the supportive personnel who prepackages
808 the drug under direct supervision of a pharmacist; and

809
810 (9) name, signature, or electronic signature of the pharmacist who prepackages the drug or
811 supervises the prepackaging and checks and releases the drug.

812

813 (d) Labeling. Records of labeling of drugs or devices in original manufacturer's containers shall
814 include the following:

815
816 (1) name and strength of the drug or device labeled;

817
818 (2) name of the manufacturer;

819
820 (3) manufacturer's lot number;

821
822 (4) manufacturer's expiration date;

823
824 (5) quantity per package and number of packages;

825
826 (6) date labeled;

827
828 (7) name of the supportive personnel affixing the label; and

829
830 (8) the signature of the pharmacist who checks and releases the drug.

831
832 (e) Provision. Records of drugs and/or devices provided shall include logs, patient records, or
833 other acceptable methods for documentation. Documentation shall include:

834
835 (1) patient name;

836
837 (2) name, signature, or electronic signature of the person who provides the drug or device;

838
839 (3) date provided; and

840
841 (4) the name of the drug or device and quantity provided.

842
843 (f) Dispensing. Record-keeping requirements for dangerous drugs dispensed by a pharmacist
844 are the same as for a Class A pharmacy as set out in §291.34 of this title (relating to Records).