

## RULE ANALYSIS

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

**Short Title:** Labeling Requirements

**Rule Numbers:** §291.93

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

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

**Purpose:** The amendments, if adopted, update the rules for Class D pharmacies to be consistent with other sections; and clarify the labeling requirements to allow an auxiliary label to be used for adding certain information to the prescription label.

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 **§291.93 Operational Standards**  
7  
8

9 (a) Registration.

10  
11 (1) **Licensing** ~~[General]~~ requirements.

12  
13 (A) All clinic pharmacies shall register with the board on a **pharmacy license application**  
14 ~~[form]~~ provided by the board, following the procedures specified in §291.1 of this title (relating to  
15 Pharmacy License Application).  
16

17 (B) All clinic pharmacies shall provide a copy of their policy and procedure manual, which  
18 includes the formulary, to the board with the initial license application.  
19

20 ~~[(C) The registration form shall be signed by the pharmacist in charge of the clinic pharmacy.]~~  
21

22 ~~[(D) The owner or managing officer of the clinic shall sign the registration form and shall  
23 agree to comply with the rules adopted by the board governing clinic pharmacies.]~~  
24

25 ~~[(E) The registration form shall be certified and state whether the clinic pharmacy is a sole  
26 ownership and give the name of the owner, or if a partnership, name all the managing partners,  
27 or if a corporation, name all the managing officers.]~~  
28

29 (F) The following fees will be charged.

30  
31 (i) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be  
32 charged for the issuance of a new license and for each renewal.  
33

34 (ii) A pharmacy operated by the state or a local government that qualifies for a Class D  
35 license is not required to pay a fee to obtain a license.  
36

37 (G) **A Class D pharmacy which changes ownership shall notify the board within ten**  
38 **days of the change of ownership and apply for a new and separate license as specified in**  
39 **§291.3 of this title (relating to Required Notifications).** ~~[When a clinic pharmacy changes  
40 ownership, a new and separate license application must be filed with the board and the old  
41 license returned to the board's office.]~~  
42

43 (H) A clinic pharmacy shall notify the board in writing of any change in name or location **as**  
44 **specified in §291.3 of this title.** ~~[within 10 days.]~~  
45

46 (I) A separate license is required for each principal place of business and only one pharmacy  
47 license may be issued to a specific location.  
48

49 (J) A clinic pharmacy shall notify the board in writing within 10 days of a change of the  
50 pharmacist-in-charge or staff pharmacist or consultant pharmacist.

51  
52 **(K) A Class D pharmacy shall notify the board in writing within ten days of closing,**  
53 **following the procedures as specified in §291.5 of this title (relating to Closing a**  
54 **Pharmacy).** [~~A clinic pharmacy shall notify the board in writing within 10 days of permanent~~  
55 ~~closing.~~]

56  
57 (2) Registration requirements for facilities that operate at temporary clinic sites. A facility that  
58 operates a clinic at one or more temporary locations may be licensed as a Class D [~~clinic~~]  
59 pharmacy and provide dangerous drugs from these temporary locations provided:

60  
61 (A) the **Class D** [~~clinic~~] pharmacy complies with the registration requirements in paragraph (1)  
62 of this subsection;

63  
64 (B) the **Class D** [~~clinic~~] pharmacy has a permanent location where all dangerous drugs and  
65 records are stored;

66  
67 (C) no dangerous drugs are stored or left for later pickup by the patient at the temporary  
68 location(s), and all drugs are returned to the permanent location each day and stored:

69  
70 (i) within the **Class D** [~~clinic~~] pharmacy; or

71  
72 (ii) within the pharmacy's mobile unit provided the mobile clinic is parked at the location of  
73 the clinic pharmacy in a secure area with adequate measures to prevent unauthorized access,  
74 and the drugs are maintained at proper temperatures;

75  
76 (D) the permanent location is the address of record for the pharmacy;

77  
78 (E) the facility has no more than six temporary locations in operation simultaneously;

79  
80 (F) the **Class D** [~~clinic~~] pharmacy notifies the board of the locations of the temporary locations  
81 where drugs will be provided and the schedule for operation of such clinics; and

82  
83 (G) the **Class D** [~~clinic~~] pharmacy notifies the board within 10 days of a change in address or  
84 closing of a temporary location or a change in schedule of operation of a clinic.

85  
86 (b) Environment.

87  
88 (1) General requirements.

89  
90 (A) The **Class D** [~~clinic~~] pharmacy shall have a designated area(s) for the storage of  
91 dangerous drugs and/or devices.

92  
93 (B) No person may operate a pharmacy which is unclean, unsanitary, or under any condition  
94 which endangers the health, safety, or welfare of the public.

95  
96 (C) The **Class D** pharmacy shall comply with all federal, state, and local health laws and  
97 ordinances.

98  
99 (D) A sink with hot and cold running water shall be available to all pharmacy personnel and  
100 shall be maintained in a sanitary condition at all times.

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(2) Security.

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

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

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

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

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

(c) Equipment. Each **Class D** [clinic] pharmacy shall maintain the following equipment and supplies:

(1) if the **Class D** [clinic] pharmacy prepackages drugs for provision:

(A) a typewriter or comparable equipment; and

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

(2) if the **Class D** [clinic] pharmacy maintains dangerous drugs requiring refrigeration and/or freezing, a refrigerator and/or freezer;

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

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

(1) current copies of the following:

(A) Texas Pharmacy Act and rules; and

(B) Texas Dangerous Drug Act;

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

151  
152 (A) Facts and Comparisons with current supplements;  
153  
154 (B) AHFS Drug Information;  
155  
156 (C) United States Pharmacopeia Dispensing Information (USPDI);  
157  
158 (D) Physician's Desk Reference (PDR);  
159  
160 (E) American Drug Index;  
161  
162 (F) a reference text on drug interactions, such as Drug Interaction Facts. A separate  
163 reference is not required if other references maintained by the pharmacy contain drug  
164 interaction information including information needed to determine severity or significance of the  
165 interaction and appropriate recommendations or actions to be taken;  
166  
167 (G) reference texts in any of the following subjects: toxicology, pharmacology, or drug  
168 interactions; or  
169  
170 (H) reference texts pertinent to the major function(s) of the clinic.  
171  
172 (e) Drugs and devices.  
173  
174 (1) Formulary.  
175  
176 (A) Each Class D pharmacy shall have a formulary which lists all drugs and devices that are  
177 administered, dispensed, or provided by the Class D pharmacy.  
178  
179 (B) The formulary shall be limited to the following types of drugs and devices, exclusive of  
180 injectable drugs for administration in the clinic and nonprescription drugs, except as provided in  
181 subparagraph (D) of this paragraph:  
182  
183 (i) anti-infective drugs;  
184  
185 (ii) musculoskeletal drugs;  
186  
187 (iii) vitamins;  
188  
189 (iv) obstetrical and gynecological drugs and devices;  
190  
191 (v) topical drugs; and  
192  
193 (vi) serums, toxoids, and vaccines.  
194  
195 (C) The formulary shall not contain the following drugs or types of drugs:  
196  
197 (i) Nalbuphine (Nubain);  
198  
199 (ii) drugs used to treat erectile dysfunction; and  
200

201 (iii) Schedule I - V controlled substances.

202

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

207

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

211

212 (I) the objectives of the clinic;

213

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

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

219

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

222

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

225

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

229

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

232

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

235

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

240

241 (iii) If a **Class D** [clinic] pharmacy wishes to add additional drugs to the expanded formulary,  
242 the pharmacy shall petition the board in writing prior to adding such drugs to the formulary. The  
243 petition shall identify drugs to be added and the need for the additional drugs based upon  
244 objectives of the clinic as specified in clause (i) of this subparagraph.

245

246 (iv) The following additional requirements shall be satisfied for clinic pharmacies with  
247 expanded formularies.

248

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

250

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

253  
254 (III) If the pharmacy provides drugs which require special monitoring (i.e., drugs which  
255 require follow-up laboratory work or drugs which should not be discontinued abruptly), the  
256 pharmacy shall have policies and procedures for the provision of the prescription drugs to  
257 patients and the monitoring of patients who receive such drugs.

258  
259 (IV) The pharmacist-in-charge, consultant pharmacists, or staff pharmacists shall conduct  
260 retrospective drug regimen reviews of a random sample of patients of the clinic on at least a  
261 quarterly basis. The pharmacist-in-charge shall be responsible for ensuring that a report  
262 regarding the drug regimen review, including the number of patients reviewed, is submitted to  
263 the clinic's medical director and the pharmacy and therapeutics committee of the clinic.

264  
265 (V) If a pharmacy provides antipsychotic drugs:

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

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

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

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270  
271 (v) The board may consider the following items in approving or disapproving a petition for an  
272 expanded formulary:

273 (I) the degree of compliance on past compliance inspections;

274 (II) the size of the patient population of the clinic;

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

276 (IV) the objectives of the clinic.

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282  
283 (2) Storage.

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

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

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

290 (D) Outdated drugs or devices shall be removed from stock and shall be quarantined together  
291 until such drugs or devices are disposed.

292 (E) Controlled substances may not be stored at the **Class D** [clinic] pharmacy.

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299 (3) Drug samples.  
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302 (A) Drug samples of drugs listed on the **Class D** [clinic] pharmacy's formulary and supplied by  
303 manufacturers shall be properly stored, labeled, provided, or dispensed by the **Class D** [clinic]  
304 pharmacy in the same manner as prescribed by these sections for dangerous drugs.

305  
306 (B) Samples of controlled substances may not be stored, provided, or dispensed in the **Class**  
307 **D** [clinic] pharmacy.

308  
309 (4) Prepackaging and labeling for provision.

310  
311 (A) Drugs may be prepackaged and labeled for provision in the **Class D** [clinic] pharmacy.  
312 Such prepackaging shall be performed by a pharmacist or supportive personnel under the direct  
313 supervision of a pharmacist and shall be for the internal use of the clinic.

314  
315 (B) Drugs must be prepackaged in suitable containers.

316  
317 (C) The label of the prepackaged unit shall bear:

318  
319 (i) the name, address, and telephone number of the clinic;

320  
321 (ii) directions for use, which may include incomplete directions for use provided:

322  
323 (I) labeling with incomplete directions for use has been authorized by the pharmacy and  
324 therapeutics committee;

325  
326 (II) precise requirements for completion of the directions for use are developed by the  
327 pharmacy and therapeutics committee and maintained in the pharmacy policy and procedure  
328 manual; and

329  
330 (III) the directions for use are completed by practitioners, pharmacists, licensed nurses or  
331 physician assistants in accordance with the precise requirements developed under subclause  
332 (II) of this clause;

333  
334 (iii) name and strength of the drug--if generic name, the name of the manufacturer or  
335 distributor of the drug;

336  
337 (iv) quantity;

338  
339 (v) lot number and expiration date; and

340  
341 (vi) appropriate ancillary label(s).

342  
343 (D) Records of prepackaging shall be maintained according to §291.94(c) of this title (relating  
344 to Records).

345  
346 (5) Labeling for provision of drugs and/or devices in an original manufacturer's container.

347  
348 (A) Drugs and/or devices in an original manufacturer's container shall be labeled prior to  
349 provision with the information set out in paragraph (4)(C) of this subsection.

350

351 (B) Drugs and/or devices in an original manufacturer's container may be labeled by:  
352  
353 (i) a pharmacist in a pharmacy licensed by the board; or  
354  
355 (ii) supportive personnel in a Class D pharmacy, provided the drugs and/or devices and  
356 control records required by §291.94(d) of this title are quarantined together until checked and  
357 released by a pharmacist.  
358  
359 (C) Records of labeling for provision of drugs and/or devices in an original manufacturer's  
360 container shall be maintained according to §291.94(d) of this title.  
361  
362 (6) Provision.  
363  
364 (A) Drugs and devices may only be provided to patients of the clinic.  
365  
366 (B) At the time of the initial provision, a licensed nurse or practitioner shall provide verbal and  
367 written information to the patient or patient's agent on side effects, interactions, and precautions  
368 concerning the drug or device provided. If the provision of subsequent drugs is delivered to the  
369 patient at the patient's residence or other designated location, the following is applicable:  
370  
371 (i) Written information as specified in subparagraph (B) of this paragraph shall be delivered  
372 with the medication.  
373  
374 (ii) The pharmacy shall maintain and use adequate storage or shipment containers and use  
375 shipping processes to ensure drug stability and potency. Such shipping processes shall include  
376 the use of appropriate packaging material and/or devices to ensure that the drug is maintained  
377 at an appropriate temperature range to maintain the integrity of the medication throughout the  
378 delivery process.  
379  
380 (iii) The pharmacy shall use a delivery system which is designed to ensure that the drugs  
381 are delivered to the appropriate patient.  
382  
383 (C) The provision of drugs or devices shall be under the continuous supervision of a  
384 pharmacist according to standing delegation orders or standing medical orders and in  
385 accordance with written policies and procedures and completion of the label as specified in  
386 subparagraph (G) of this paragraph.  
387  
388 (D) Drugs and/or devices may only be provided in accordance with the system of control and  
389 accountability for drugs and/or devices provided by the clinic; such system shall be developed  
390 and supervised by the pharmacist-in-charge.  
391  
392 (E) Only drugs and/or devices listed in the clinic formulary may be provided.  
393  
394 (F) Drugs and/or devices may only be provided in prepackaged quantities in suitable  
395 containers and/or original manufacturer's containers which are appropriately labeled as set out  
396 in paragraphs (4) and (5) of this subsection.  
397  
398 (G) Such drugs and/or devices shall be labeled by a pharmacist licensed by the board;  
399 however, when drugs and/or devices are provided under the supervision of a physician  
400 according to standing delegation orders or standing medical orders, supportive personnel may

401 at the time of provision print on the label the following information or affix an ancillary label  
402 containing the following information:

403  
404 (i) patient's name; however, the patient's partner or family member is not required to be on  
405 the label of a drug prescribed for a partner for a sexually transmitted disease or for a patient's  
406 family members if the patient has an illness determined by the Centers for Disease Control and  
407 Prevention, the World Health Organization, or the Governor's office to be pandemic;

408  
409 (ii) any information necessary to complete the directions for use in accordance with  
410 paragraph (4)(C)(ii) of this subsection;

411  
412 (iii) date of provision; and

413  
414 (iv) practitioner's name.

415  
416 (H) Records of provision shall be maintained according to §291.94(e) of this title.

417  
418 (I) Controlled substances may not be provided or dispensed.

419  
420 (J) Non-sterile ~~[and sterile]~~ preparations may only be provided by the clinic pharmacy in  
421 accordance with §291.131 ~~[and §291.133]~~ of this title (relating to Pharmacies Compounding  
422 Non-sterile Preparations ~~[and Pharmacies Compounding Sterile Preparations]~~).

423  
424 (7) Dispensing. Dangerous drugs may only be dispensed by a pharmacist pursuant to a  
425 prescription order in accordance with §§291.31 - 291.35 of this title (relating to Community  
426 Pharmacy (Class A)) and §291.131 ~~[and §291.133]~~ of this title.

427  
428 (f) Pharmacy and therapeutics committee.

429  
430 (1) The clinic pharmacy shall have a pharmacy and therapeutics committee, which shall be  
431 composed of at least three persons and shall include the pharmacist-in-charge, the medical  
432 director of the clinic, and a person who is responsible for provision of drugs and devices.

433  
434 (2) The pharmacy and therapeutics committee shall develop the policy and procedure manual.

435  
436 (3) The pharmacy and therapeutics committee shall meet at least annually to:

437  
438 (A) review and update the policy and procedure manual; and

439  
440 (B) review the retrospective drug utilization review reports submitted by the pharmacist-in-  
441 charge if the clinic pharmacy has an expanded formulary.

442  
443 (g) Policies and procedures.

444  
445 (1) Written policies and procedures shall be developed by the pharmacy and therapeutics  
446 committee and implemented by the pharmacist-in-charge.

447  
448 (2) The policy and procedure manual shall include, but not be limited to, the following:

449

- 450 (A) a current list of the names of the pharmacist-in-charge, consultant-pharmacist, staff  
451 pharmacist(s), supportive personnel designated to provide drugs or devices, and the supportive  
452 personnel designated to supervise the day-to-day pharmacy related operations of the clinic in  
453 the absence of the pharmacist;  
454
- 455 (B) functions of the pharmacist-in-charge, consultant pharmacist, staff pharmacist(s), and  
456 supportive personnel;  
457
- 458 (C) objectives of the clinic;  
459
- 460 (D) formulary;  
461
- 462 (E) a copy of written agreement between the pharmacist-in-charge and the clinic;  
463
- 464 (F) date of last review/revision of policy and procedure manual; and  
465
- 466 (G) policies and procedures for:  
467
- 468 (i) security;
  - 469
  - 470 (ii) equipment;
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  - 472 (iii) sanitation;
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  - 474 (iv) licensing;
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  - 476 (v) reference materials;
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  - 478 (vi) storage;
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  - 480 (vii) packaging-repackaging;
  - 481
  - 482 (viii) dispensing;
  - 483
  - 484 (ix) provision;
  - 485
  - 486 (x) retrospective drug regimen review;
  - 487
  - 488 (xi) supervision;
  - 489
  - 490 (xii) labeling-relabeling;
  - 491
  - 492 (xiii) samples;
  - 493
  - 494 (xiv) drug destruction and returns;
  - 495
  - 496 (xv) drug and device procuring;
  - 497
  - 498 (xvi) receiving of drugs and devices;
  - 499

500 (xvii) delivery of drugs and devices;

501

502 (xviii) recordkeeping; and

503

504 (xix) inspection.

505

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

511

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

516

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

518

519 (A) the degree of compliance on past compliance inspections;

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521 (B) the size of the patient population of the clinic;

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523 (C) the number and types of drugs contained in the formulary; and

524

525 (D) the objectives of the clinic.

526

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