

RULE ANALYSIS

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

Short Title: Floor Stock Documentation

Rule Numbers: §291.76

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, allow pharmacists to record certain information in the patient's chart in lieu of keeping a separate log.

1 **PART 15 TEXAS STATE BOARD OF PHARMACY**
2 **CHAPTER 291 PHARMACIES**
3 **SUBCHAPTER D INSTITUTIONAL PHARMACY (CLASS C)**
4

5 **§291.76 Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center**
6

7
8 (a) – (c) (No change.)
9

10 (d) Operational standards.

11 (1) Licensing requirements.

12 (A) An ASC pharmacy shall register annually or biennially with the board on a pharmacy
13 license application provided by the board, following the procedures specified in §291.1 of this
14 title (relating to Pharmacy License Application).
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17 (B) An ASC pharmacy which changes ownership shall notify the board within 10 days of the
18 change of ownership and apply for a new and separate license as specified in §291.3 of this title
19 (relating to Required Notifications).
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22 (C) An ASC pharmacy which changes location and/or name shall notify the board of the
23 change within 10 days and file for an amended license as specified in §291.3 of this title.
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25 (D) An ASC pharmacy owned by a partnership or corporation which changes managing
26 officers shall notify the board in writing of the names of the new managing officers within 10
27 days of the change, following the procedures in §291.3 of this title.
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29 (E) An ASC pharmacy shall notify the board in writing within 10 days of closing, following the
30 procedures in §291.5 of this title (relating to Closing a Pharmacy).
31

32 (F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
33 charged for issuance and renewal of a license and the issuance of an amended license.
34

35 (G) A separate license is required for each principal place of business and only one
36 pharmacy license may be issued to a specific location.
37

38 (H) An ASC pharmacy, licensed under the Act, §560.051(a)(3), concerning institutional
39 pharmacy (Class C), which also operates another type of pharmacy which would otherwise be
40 required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class
41 A), or the Act, §560.051(a)(2), concerning nuclear pharmacy (Class B), is not required to secure
42 a license for the other type of pharmacy; provided, however, such license is required to comply
43 with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to
44 Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating
45 to Records), and §291.35 of this title (relating to Official Prescription Records), or §291.51 of
46 this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title
47 (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of
48 this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such
49 sections are applicable to the operation of the pharmacy.
50

51 (I) An ASC pharmacy engaged in the compounding of non-sterile preparations shall comply
52 with the provisions of §291.131 of this title.

53
54 (J) ASC pharmacy personnel shall not compound sterile preparations unless the pharmacy
55 has applied for and obtained a Class C-S pharmacy license.

56
57 (K) An ASC pharmacy engaged in the provision of remote pharmacy services, including
58 storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of
59 this title (relating to Remote Pharmacy Services).

60
61 (L) An ASC pharmacy engaged in centralized prescription dispensing and/or prescription drug
62 or medication order processing shall comply with the provisions of §291.123 of this title (relating
63 to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of this title
64 (relating to Centralized Prescription Dispensing).

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66 (2) Environment.

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68 (A) General requirements.

69
70 (i) Each ambulatory surgical center shall have a designated work area separate from patient
71 areas, and which shall have space adequate for the size and scope of pharmaceutical services
72 and shall have adequate space and security for the storage of drugs.

73
74 (ii) The ASC pharmacy shall be arranged in an orderly fashion and shall be kept clean. All
75 required equipment shall be clean and in good operating condition.

76
77 (B) Special requirements.

78
79 (i) The ASC pharmacy shall have locked storage for Schedule II controlled substances and
80 other controlled drugs requiring additional security.

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

84
85 (C) Security.

86
87 (i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed
88 and capable of being locked by key, combination, or other mechanical or electronic means, so
89 as to prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-
90 in-charge may enter the pharmacy or have access to storage areas for prescription drugs and/or
91 devices.

92
93 (ii) The pharmacist-in-charge shall consult with ASC personnel with respect to security of the
94 drug storage areas, including provisions for adequate safeguards against theft or diversion of
95 dangerous drugs and controlled substances, and to security of records for such drugs.

96
97 (iii) The pharmacy shall have locked storage for Schedule II controlled substances and other
98 drugs requiring additional security.

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

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

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

(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;

(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) ASC 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.

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(B) Formulary.

(i) A formulary may be developed by an appropriate committee of the ASC.

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

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

(I) a formulary has been developed;

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

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

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

(C) Prepackaging and loading drugs into automated medication supply system.

(i) Prepackaging of drugs.

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

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

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

(-b-) facility's lot number;

(-c-) expiration date;

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

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

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

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

(-b-) facility's lot number;

- 204 (-c-) manufacturer or distributor;
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206 (-d-) manufacturer's lot number;
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208 (-e-) expiration date;
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210 (-f-) quantity per prepackaged unit;
211
212 (-g-) number of prepackaged units;
213
214 (-h-) date packaged;
215
216 (-i-) name, initials, or electronic signature of the prepacker;
217
218 (-j-) signature or electronic signature of the responsible pharmacist; and
219
220 (-k-) if the drug is distributed to another Class C pharmacy, name of the facility receiving
221 the prepackaged drug.
222

223 (IV) Stock packages, repackaged units, and control records shall be quarantined together
224 until checked/released by the pharmacist.
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226 (ii) Loading bulk unit of use drugs into automated medication supply systems. Automated
227 medication supply systems may be loaded with bulk unit of use drugs only by a pharmacist or
228 by pharmacy technicians or pharmacy technician trainees under the direction and direct
229 supervision of a pharmacist. For the purpose of this clause, direct supervision may be
230 accomplished by physically present supervision or electronic monitoring by a pharmacist. In
231 order for the pharmacist to electronically monitor, the medication supply system must allow for
232 bar code scanning to verify the loading of drugs, and a record of the loading must be maintained
233 by the system and accessible for electronic review by the pharmacist.
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235 (6) Medication orders.
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237 (A) Drugs may be administered to patients in ASCs only on the order of a practitioner. No
238 change in the order for drugs may be made without the approval of a practitioner except as
239 authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.
240

241 (B) Drugs may be distributed only pursuant to the practitioner's medication order.
242

243 (C) ASC pharmacies shall be exempt from the labeling provisions and patient notification
244 requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to
245 medication orders.
246

247 (D) In ASCs with a full-time pharmacist, if a practitioner orders a drug for administration to a
248 bona fide patient of the facility when the pharmacy is closed, the following is applicable.
249

250 (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic
251 needs of a patient may be removed from the ASC pharmacy.
252

253 (ii) Only a designated or practitioner may remove such drugs and devices.
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255 (iii) A record shall be made at the time of withdrawal by the authorized person removing the
256 drugs and devices. The record shall contain the following information:

257
258 (I) name of the patient;

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

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262 (III) dose prescribed;

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264 (IV) quantity taken;

265
266 (V) time and date; and

267
268 (VI) signature or electronic signature of person making withdrawal.

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270 (iv) The medication order in the patient's chart may substitute for such record, provided the
271 medication order meets all the requirements of clause (iii) of this subparagraph.

272
273 (v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more
274 than 72 hours from the time of such withdrawal.

275
276 (E) In ASCs with a part-time or consultant pharmacist, if a practitioner orders a drug for
277 administration to a bona fide patient of the ASC when the pharmacist is not on duty, or when the
278 pharmacy is closed, the following is applicable.

279
280 (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be
281 removed from the ASC pharmacy.

282
283 (ii) Only a designated or practitioner may remove such drugs and devices.

284
285 (iii) A record shall be made at the time of withdrawal by the authorized person removing the
286 drugs and devices; the record shall meet the same requirements as specified in subparagraph
287 (D) of this paragraph.

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290 (iv) The pharmacist shall conduct an audit of patient's medical record according to the
291 schedule set out in the policy and procedures at a reasonable interval, but such interval must
292 occur at least once in every calendar week that the pharmacy is open.

293
294 (7) Floor stock. In facilities using a floor stock method of drug distribution, the following is
295 applicable for removing drugs or devices in the absence of a pharmacist.

296
297 (A) Prescription drugs and devices may be removed from the pharmacy only in the original
298 manufacturer's container or prepackaged container.

299
300 (B) Only a designated or practitioner may remove such drugs and devices.

301
302 (C) A record shall be made at the time of withdrawal by the authorized person removing the
303 drug or device; the record shall contain the following information:

304
305 (i) name of the drug, strength, and dosage form;

306
307 (ii) quantity removed;
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309 (iii) location of floor stock;
310
311 (iv) date and time; and
312
313 (v) signature or electronic signature of person making the withdrawal.
314
315 (D) A pharmacist shall verify the withdrawal according to the following schedule.
316
317 (i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as
318 practical, but in no event more than 72 hours from the time of such withdrawal.
319
320 (ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after
321 a reasonable interval, but such interval must occur at least once in every calendar week that the
322 pharmacy is open.
323
324 **(iii) The medication order in the patient's chart may substitute for such record,**
325 **provided the medication order meets all the requirements of subparagraph (C) of this**
326 **paragraph.**
327
328 (8) Policies and procedures. Written policies and procedures for a drug distribution system,
329 appropriate for the ambulatory surgical center, shall be developed and implemented by the
330 pharmacist-in-charge with the advice of the appropriate committee. The written policies and
331 procedures for the drug distribution system shall include, but not be limited to, procedures
332 regarding the following:
333
334 (A) controlled substances;
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336 (B) investigational drugs;
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338 (C) prepackaging and manufacturing;
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340 (D) medication errors;
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342 (E) orders of physician or other practitioner;
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344 (F) floor stocks;
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346 (G) adverse drug reactions;
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348 (H) drugs brought into the facility by the patient;
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350 (I) self-administration;
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352 (J) emergency drug tray;
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354 (K) formulary, if applicable;
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356 (L) drug storage areas;

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358 (M) drug samples;
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360 (N) drug product defect reports;
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362 (O) drug recalls;
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364 (P) outdated drugs;
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366 (Q) preparation and distribution of IV admixtures;
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368 (R) procedures for supplying drugs for postoperative use, if applicable;
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370 (S) use of automated medication supply systems;
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372 (T) use of data processing systems; and
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374 (U) drug regimen review.
375
376 (9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall
377 be supplied according to the following procedures.
378
379 (A) Drugs may only be supplied to patients who have been admitted to the ASC.
380
381 (B) Drugs may only be supplied in accordance with the system of control and accountability
382 established for drugs supplied from the ambulatory surgical center; such system shall be
383 developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the
384 pharmacist-in-charge.
385
386 (C) Only drugs listed on the approved postoperative drug list may be supplied; such list shall
387 be developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the
388 nature and type to meet the immediate postoperative needs of the ambulatory surgical center
389 patient.
390
391 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in
392 suitable containers and appropriately pre-labeled (including name, address, and phone number
393 of the facility, and necessary auxiliary labels) by the pharmacy, provided, however that topicals
394 and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a
395 72-hour supply.
396
397 (E) At the time of delivery of the drug, the practitioner shall complete the label, such that the
398 prescription container bears a label with at least the following information:
399
400 (i) date supplied;
401
402 (ii) name of practitioner;
403
404 (iii) name of patient;
405
406 (iv) directions for use;
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408 (v) brand name and strength of the drug; or if no brand name, then the generic name of the
409 drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

410
411 (vi) unique identification number.

412
413 (F) After the drug has been labeled, the practitioner or a licensed nurse under the supervision
414 of the practitioner shall give the appropriately labeled, prepackaged medication to the patient.

415
416 (G) A perpetual record of drugs which are supplied from the ASC shall be maintained which
417 includes:

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

420
421 (ii) date supplied;

422
423 (iii) name of practitioner;

424
425 (iv) name of patient;

426
427 (v) directions for use;

428
429 (vi) brand name and strength of the drug; or if no brand name, then the generic name of the
430 drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

431
432 (vii) unique identification number.

433
434 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall
435 review the records at least once in every calendar week that the pharmacy is open.

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437 (10) Drug regimen review.

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

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441 (i) known allergies;

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443 (ii) rational therapy--contraindications;

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445 (iii) reasonable dose and route of administration;

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447 (iv) reasonable directions for use;

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449 (v) duplication of therapy;

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451 (vi) drug-drug interactions;

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453 (vii) drug-food interactions;

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455 (viii) drug-disease interactions;

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457 (ix) adverse drug reactions;

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459 (x) proper utilization, including overutilization or underutilization; and

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461 (xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug
462 effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of
463 the drug in its current regimen.

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465 (B) A retrospective, random drug regimen review as specified in the pharmacy's policies and
466 procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed
467 31 days between such reviews.

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

471

472 (e) (No change.)

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