

## RULE ANALYSIS

**Introduction:** THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED 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.

**The Board reviewed and voted to propose the amendments during the May 3, 2016, meeting. The proposed amendments were published in the June 24, 2016, issue of the *Texas Register* at 41 TexReg 4603.**

1    **SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)**

2    **22 TAC §291.76**

3    The Texas State Board of Pharmacy proposes amendments to §291.76, concerning Class C  
4    Pharmacies Located in a Freestanding Ambulatory Surgical Center. The amendments, if adopted,  
5    clarify recordkeeping requirements and allow pharmacists to record certain information in the  
6    patient's chart in lieu of keeping a separate log.

7    Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year  
8    period the rule is in effect, there will be no fiscal implications for state or local government as a  
9    result of enforcing or administering the rule.

10   Ms. Dodson has determined that, for each year of the first five-year period the rule will be in  
11   effect, the public benefit anticipated as a result of enforcing the amendments will ensure  
12   appropriate records are maintained by Class C Pharmacies located in freestanding ambulatory  
13   surgical centers. There is no fiscal impact for individuals, small or large businesses, or to other  
14   entities which are required to comply with this section.

15   Written comments on the amendments may be submitted to Allison Vordenbaumen Benz, R.Ph.,  
16   M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street,  
17   Suite 3-600, Austin, Texas 78701, FAX (512) 305-6778. Comments must be received by 5:00  
18   p.m., August 1, 2016.

19   The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act  
20   (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the  
21   agency to protect the public through the effective control and regulation of the practice of  
22   pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the  
23   proper administration and enforcement of the Act.

24   The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas  
25   Occupations Code.

26    ***§291.76. Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center.***

27    (a) - (c) (No change.)

28    (d) Operational standards.

29    (1) Licensing requirements.

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

- 33 (B) An ASC pharmacy which changes ownership shall notify the board within 10 days of the  
34 change of ownership and apply for a new and separate license as specified in §291.3 of this title  
35 (relating to Required Notifications).
- 36 (C) An ASC pharmacy which changes location and/or name shall notify the board of the change  
37 within 10 days and file for an amended license as specified in §291.3 of this title.
- 38 (D) An ASC pharmacy owned by a partnership or corporation which changes managing officers  
39 shall notify the board in writing of the names of the new managing officers within 10 days of the  
40 change, following the procedures in §291.3 of this title.
- 41 (E) An ASC pharmacy shall notify the board in writing within 10 days of closing, following the  
42 procedures in §291.5 of this title (relating to Closing a Pharmacy).
- 43 (F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged  
44 for issuance and renewal of a license and the issuance of an amended license.
- 45 (G) A separate license is required for each principal place of business and only one pharmacy  
46 license may be issued to a specific location.
- 47 (H) An ASC pharmacy, licensed under the Act, §560.051(a)(3), concerning institutional  
48 pharmacy (Class C), which also operates another type of pharmacy which would otherwise be  
49 required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class  
50 A), or the Act, §560.051(a)(2), concerning nuclear pharmacy (Class B), is not required to secure  
51 a license for the other type of pharmacy; provided, however, such license is required to comply  
52 with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating  
53 to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title  
54 (relating to Records), and §291.35 of this title (relating to Official Prescription Records), or  
55 §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53  
56 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and  
57 §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent  
58 such sections are applicable to the operation of the pharmacy.
- 59 (I) An ASC pharmacy engaged in the compounding of non-sterile preparations shall comply with  
60 the provisions of §291.131 of this title.
- 61 (J) ASC pharmacy personnel shall not compound sterile preparations unless the pharmacy has  
62 applied for and obtained a Class C-S pharmacy license.
- 63 (K) An ASC pharmacy engaged in the provision of remote pharmacy services, including storage  
64 and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title  
65 (relating to Remote Pharmacy Services).
- 66 (L) An ASC pharmacy engaged in centralized prescription dispensing and/or prescription drug or  
67 medication order processing shall comply with the provisions of §291.123 of this title (relating to

68 Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of this title  
69 (relating to Centralized Prescription Dispensing).

70 (2) Environment.

71 (A) General requirements.

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

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

77 (B) Special requirements.

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

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

82 (C) Security.

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

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

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

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

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

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

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

- 98 (4) Library. A reference library shall be maintained that includes the following in hard-copy or  
99 electronic format and that pharmacy personnel shall be capable of accessing at all times:
- 100 (A) current copies of the following:
- 101 (i) Texas Pharmacy Act and rules;
- 102 (ii) Texas Dangerous Drug Act and rules;
- 103 (iii) Texas Controlled Substances Act and rules;
- 104 (iv) Federal Controlled Substances Act and rules or official publication describing the  
105 requirements of the Federal Controlled Substances Act and rules;
- 106 (B) at least one current or updated general drug information reference which is required to  
107 contain drug interaction information including information needed to determine severity or  
108 significance of the interaction and appropriate recommendations or actions to be taken; and
- 109 (C) basic antidote information and the telephone number of the nearest regional poison control  
110 center.
- 111 (5) Drugs.
- 112 (A) Procurement, preparation, and storage.
- 113 (i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of  
114 drugs, but may receive input from other appropriate staff of the facility, relative to such  
115 responsibility.
- 116 (ii) The pharmacist-in-charge shall have the responsibility for determining specifications of all  
117 drugs procured by the facility.
- 118 (iii) ASC pharmacies may not sell, purchase, trade, or possess prescription drug samples, unless  
119 the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).
- 120 (iv) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in  
121 §291.15 of this title (relating to Storage of Drugs).
- 122 (v) Any drug bearing an expiration date may not be dispensed or distributed beyond the  
123 expiration date of the drug.
- 124 (vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined together  
125 until such drugs are disposed of.
- 126 (B) Formulary.

- 127 (i) A formulary may be developed by an appropriate committee of the ASC.
- 128 (ii) The pharmacist-in-charge or consultant pharmacist shall be a full voting member of any  
129 committee which involves pharmaceutical services.
- 130 (iii) A practitioner may grant approval for pharmacists at the ASC to interchange, in accordance  
131 with the facility's formulary, for the drugs on the practitioner's medication orders provided:
- 132 (I) a formulary has been developed;
- 133 (II) the formulary has been approved by the medical staff of the ASC;
- 134 (III) there is a reasonable method for the practitioner to override any interchange; and
- 135 (IV) the practitioner authorizes pharmacist in the ASC to interchange on his/her medication  
136 orders in accordance with the facility's formulary through his/her written agreement to abide by  
137 the policies and procedures of the medical staff and facility.
- 138 (C) Prepackaging and loading drugs into automated medication supply system.
- 139 (i) Prepackaging of drugs.
- 140 (I) Drugs may be prepackaged in quantities suitable for distribution to other Class C pharmacies  
141 under common ownership or for internal distribution only by a pharmacist or by pharmacy  
142 technicians or pharmacy technician trainees under the direction and direct supervision of a  
143 pharmacist.
- 144 (II) The label of a prepackaged unit shall indicate:
- 145 (-a-) brand name and strength of the drug; or if no brand name, then the generic name, strength,  
146 and name of the manufacturer or distributor;
- 147 (-b-) facility's lot number;
- 148 (-c-) expiration date;
- 149 (-d-) quantity of the drug, if quantity is greater than one; and
- 150 (-e-) if the drug is distributed to another Class C pharmacy, name of the facility responsible for  
151 prepackaging the drug.
- 152 (III) Records of prepackaging shall be maintained to show:
- 153 (-a-) the name of the drug, strength, and dosage form;
- 154 (-b-) facility's lot number;

- 155 (-c-) manufacturer or distributor;
- 156 (-d-) manufacturer's lot number;
- 157 (-e-) expiration date;
- 158 (-f-) quantity per prepackaged unit;
- 159 (-g-) number of prepackaged units;
- 160 (-h-) date packaged;
- 161 (-i-) name, initials, or electronic signature of the prepacker;
- 162 (-j-) signature or electronic signature of the responsible pharmacist; and
- 163 (-k-) if the drug is distributed to another Class C pharmacy, name of the facility receiving the  
164 prepackaged drug.
- 165 (IV) Stock packages, repackaged units, and control records shall be quarantined together until  
166 checked/released by the pharmacist.
- 167 (ii) Loading bulk unit of use drugs into automated medication supply systems. Automated  
168 medication supply systems may be loaded with bulk unit of use drugs only by a pharmacist or by  
169 pharmacy technicians or pharmacy technician trainees under the direction and direct supervision  
170 of a pharmacist. For the purpose of this clause, direct supervision may be accomplished by  
171 physically present supervision or electronic monitoring by a pharmacist. In order for the  
172 pharmacist to electronically monitor, the medication supply system must allow for bar code  
173 scanning to verify the loading of drugs, and a record of the loading must be maintained by the  
174 system and accessible for electronic review by the pharmacist.
- 175 (6) Medication orders.
- 176 (A) Drugs may be administered to patients in ASCs only on the order of a practitioner. No  
177 change in the order for drugs may be made without the approval of a practitioner except as  
178 authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.
- 179 (B) Drugs may be distributed only pursuant to the practitioner's medication order.
- 180 (C) ASC pharmacies shall be exempt from the labeling provisions and patient notification  
181 requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to  
182 medication orders.
- 183 (D) In ASCs with a full-time pharmacist, if a practitioner orders a drug for administration to a  
184 bona fide patient of the facility when the pharmacy is closed, the following is applicable.

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

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

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

190 (I) name of the patient;

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

192 (III) dose prescribed;

193 (IV) quantity taken;

194 (V) time and date; and

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

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

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

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

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

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

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

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

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

- 214 (A) Prescription drugs and devices may be removed from the pharmacy only in the original  
215 manufacturer's container or prepackaged container.
- 216 (B) Only a designated or practitioner may remove such drugs and devices.
- 217 (C) A record shall be made at the time of withdrawal by the authorized person removing the drug  
218 or device; the record shall contain the following information:
- 219 (i) name of the drug, strength, and dosage form;
- 220 (ii) quantity removed;
- 221 (iii) location of floor stock;
- 222 (iv) date and time; and
- 223 (v) signature or electronic signature of person making the withdrawal.
- 224 (D) A pharmacist shall verify the withdrawal according to the following schedule.
- 225 (i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as practical,  
226 but in no event more than 72 hours from the time of such withdrawal.
- 227 (ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after a  
228 reasonable interval, but such interval must occur at least once in every calendar week that the  
229 pharmacy is open.
- 230 (iii) The medication order in the patient's chart may substitute for the record required in  
231 subparagraph (C) of this paragraph, provided the medication order meets all the requirements of  
232 subparagraph (C) of this paragraph.
- 233 (8) Policies and procedures. Written policies and procedures for a drug distribution system,  
234 appropriate for the ambulatory surgical center, shall be developed and implemented by the  
235 pharmacist-in-charge with the advice of the appropriate committee. The written policies and  
236 procedures for the drug distribution system shall include, but not be limited to, procedures  
237 regarding the following:
- 238 (A) controlled substances;
- 239 (B) investigational drugs;
- 240 (C) prepackaging and manufacturing;
- 241 (D) medication errors;
- 242 (E) orders of physician or other practitioner;

- 243 (F) floor stocks;
  - 244 (G) adverse drug reactions;
  - 245 (H) drugs brought into the facility by the patient;
  - 246 (I) self-administration;
  - 247 (J) emergency drug tray;
  - 248 (K) formulary, if applicable;
  - 249 (L) drug storage areas;
  - 250 (M) drug samples;
  - 251 (N) drug product defect reports;
  - 252 (O) drug recalls;
  - 253 (P) outdated drugs;
  - 254 (Q) preparation and distribution of IV admixtures;
  - 255 (R) procedures for supplying drugs for postoperative use, if applicable;
  - 256 (S) use of automated medication supply systems;
  - 257 (T) use of data processing systems; and
  - 258 (U) drug regimen review.
- 259 (9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall  
260 be supplied according to the following procedures.
- 261 (A) Drugs may only be supplied to patients who have been admitted to the ASC.
- 262 (B) Drugs may only be supplied in accordance with the system of control and accountability  
263 established for drugs supplied from the ambulatory surgical center; such system shall be  
264 developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the  
265 pharmacist-in-charge.
- 266 (C) Only drugs listed on the approved postoperative drug list may be supplied; such list shall be  
267 developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the  
268 nature and type to meet the immediate postoperative needs of the ambulatory surgical center  
269 patient.

270 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in  
271 suitable containers and appropriately prelabeled (including name, address, and phone number of  
272 the facility, and necessary auxiliary labels) by the pharmacy, provided, however that topicals and  
273 ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-  
274 hour supply.

275 (E) At the time of delivery of the drug, the practitioner shall complete the label, such that the  
276 prescription container bears a label with at least the following information:

277 (i) date supplied;

278 (ii) name of practitioner;

279 (iii) name of patient;

280 (iv) directions for use;

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

283 (vi) unique identification number.

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

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

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

289 (ii) date supplied;

290 (iii) name of practitioner;

291 (iv) name of patient;

292 (v) directions for use;

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

295 (vii) unique identification number.

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

- 298 (10) Drug regimen review.
- 299 (A) A pharmacist shall evaluate medication orders and patient medication records for:
- 300 (i) known allergies;
- 301 (ii) rational therapy--contraindications;
- 302 (iii) reasonable dose and route of administration;
- 303 (iv) reasonable directions for use;
- 304 (v) duplication of therapy;
- 305 (vi) drug-drug interactions;
- 306 (vii) drug-food interactions;
- 307 (viii) drug-disease interactions;
- 308 (ix) adverse drug reactions;
- 309 (x) proper utilization, including overutilization or underutilization; and
- 310 (xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug  
311 effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of  
312 the drug in its current regimen.
- 313 (B) A retrospective, random drug regimen review as specified in the pharmacy's policies and  
314 procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed  
315 31 days between such reviews.
- 316 (C) Any questions regarding the order must be resolved with the prescriber and a written  
317 notation of these discussions made and maintained.
- 318 (e) (No change.)