

## RULE ANALYSIS

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

**Short Title:** Floor Stock Documentation

**Rule Numbers:** §291.151

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

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

8  
9 (a) – (c) (No change.)

10  
11 (d) Operational standards.

12  
13 (1) Licensing requirements.

14  
15 (A) A FEMCF pharmacy shall register annually or biennially with the board on a pharmacy  
16 license application provided by the board, following the procedures specified in §291.1 of this  
17 title (relating to Pharmacy License Application).

18  
19 (B) A FEMCF pharmacy which changes ownership shall notify the board within 10 days of the  
20 change of ownership and apply for a new and separate license as specified in §291.3 of this title  
21 (relating to Required Notifications).

22  
23 (C) A FEMCF pharmacy which changes location and/or name shall notify the board of the  
24 change within 10 days and file for an amended license as specified in §291.3 of this title.

25  
26 (D) pharmacy owned by a partnership or corporation which changes managing officers shall  
27 notify the board in writing of the names of the new managing officers within 10 days of the  
28 change, following the procedures in §291.3 of this title.

29  
30 (E) A FEMCF pharmacy shall notify the board in writing within 10 days of closing, following  
31 the procedures in §291.5 of this title (relating to Closing a Pharmacy).

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

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

38  
39 (H) A FEMCF pharmacy, which also operates another type of pharmacy which would  
40 otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community  
41 pharmacy (Class A), is not required to secure a license for the other type of pharmacy;  
42 provided, however, such license is required to comply with the provisions of §291.31 of this title  
43 (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating  
44 to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title  
45 (relating to Official Prescription Records), to the extent such sections are applicable to the  
46 operation of the pharmacy.

47  
48 (I) A FEMCF pharmacy engaged in the compounding of non-sterile preparations shall comply  
49 with the provisions of §291.131 of this title.

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51 (2) Environment.

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(A) General requirements.

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

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

(B) Special requirements.

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

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

(C) Security.

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

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

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

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

- (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;

103 (iii) Texas Controlled Substances Act and rules; and

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

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

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

114

115 (5) Drugs.

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117 (A) Procurement, preparation, and storage.

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

122

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

125

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

129

130 (iv) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in  
131 §291.15 of this title (relating to Storage of Drugs).

132

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

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

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139 (B) Formulary.

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

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

145

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

149

150 (I) a formulary has been developed;

151

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

153

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

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

159

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

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162 (i) Prepackaging of drugs.

163

164 (I) Drugs may be prepackaged in quantities suitable for internal distribution only by a  
165 pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and  
166 direct supervision of a pharmacist.

167

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

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

172

173 (-b-) facility's lot number;

174

175 (-c-) expiration date; and

176

177 (-d-) quantity of the drug, if quantity is greater than one.

178

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

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

182

183 (-b-) facility's lot number;

184

185 (-c-) manufacturer or distributor;

186

187 (-d-) manufacturer's lot number;

188

189 (-e-) expiration date;

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191 (-f-) quantity per prepackaged unit;

192

193 (-g-) number of prepackaged units;

194

195 (-h-) date packaged;

196

197 (-i-) name, initials, or electronic signature of the prepacker; and

198

199 (-j-) signature or electronic signature of the responsible pharmacist.

200

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

203

204 (ii) Loading bulk unit of use drugs into automated medication supply systems. Automated  
205 medication supply systems may be loaded with bulk unit of use drugs only by a pharmacist or  
206 by pharmacy technicians or pharmacy technician trainees under the direction and direct  
207 supervision of a pharmacist. For the purpose of this clause, direct supervision may be  
208 accomplished by physically present supervision or electronic monitoring by a pharmacist. In  
209 order for the pharmacist to electronically monitor, the medication supply system must allow for  
210 bar code scanning to verify the loading of drugs, and a record of the loading must be maintained  
211 by the system and accessible for electronic review by the pharmacist.

212  
213 (6) Medication orders.

214  
215 (A) Drugs may be administered to patients in FEMCFs only on the order of a practitioner. No  
216 change in the order for drugs may be made without the approval of a practitioner except as  
217 authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.

218  
219 (B) Drugs may be distributed only pursuant to the copy of the practitioner's medication order.

220  
221 (C) FEMCF pharmacies shall be exempt from the labeling provisions and patient notification  
222 requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to  
223 medication orders.

224  
225 (D) In FEMCFs with a full-time pharmacist, if a practitioner orders a drug for administration to  
226 a bona fide patient of the facility when the pharmacy is closed, the following is applicable.

227  
228 (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic needs  
229 of a patient may be removed from the FEMCF pharmacy.

230  
231 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

232  
233 (iii) A record shall be made at the time of withdrawal by the authorized person removing the  
234 drugs and devices. The record shall contain the following information:

235  
236 (I) name of the patient;

237  
238 (II) name of device or drug, strength, and dosage form;

239  
240 (III) dose prescribed;

241  
242 (IV) quantity taken;

243  
244 (V) time and date; and

245  
246 (VI) signature or electronic signature of person making withdrawal.

247  
248 (iv) The medication order in the patient's chart may substitute for such record, provided the  
249 medication order meets all the requirements of clause (iii) of this subparagraph.

250  
251 (v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more  
252 than 72 hours from the time of such withdrawal.

253

254 (E) In FEMCFs with a part-time or consultant pharmacist, if a practitioner orders a drug for  
255 administration to a bona fide patient of the FEMCF when the pharmacist is not on duty, or when  
256 the pharmacy is closed, the following is applicable.

257  
258 (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be  
259 removed from the FEMCF pharmacy.

260  
261 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

262  
263 (iii) A record shall be made at the time of withdrawal by the authorized person removing the  
264 drugs and devices; the record shall meet the same requirements as specified in subparagraph  
265 (D) of this paragraph.

266  
267 (iv) The pharmacist shall conduct an audit of patient's medical record according to the  
268 schedule set out in the policy and procedures at a reasonable interval, but such interval must  
269 occur at least once in every calendar week that the pharmacy is open.

270  
271 (7) Floor stock. In facilities using a floor stock method of drug distribution, the following is  
272 applicable for removing drugs or devices in the absence of a pharmacist.

273  
274 (A) Prescription drugs and devices may be removed from the pharmacy only in the original  
275 manufacturer's container or prepackaged container.

276  
277 (B) Only a designated licensed nurse or practitioner may remove such drugs and devices.

278  
279 (C) A record shall be made at the time of withdrawal by the authorized person removing the  
280 drug or device; the record shall contain the following information:

281  
282 (i) name of the drug, strength, and dosage form;

283  
284 (ii) quantity removed;

285  
286 (iii) location of floor stock;

287  
288 (iv) date and time; and

289  
290 (v) signature or electronic signature of person making the withdrawal.

291  
292 (D) A pharmacist shall verify the withdrawal according to the following schedule.

293  
294 (i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as  
295 practical, but in no event more than 72 hours from the time of such withdrawal.

296  
297 (ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after  
298 a reasonable interval, but such interval must occur at least once in every calendar week that the  
299 pharmacy is open.

300  
301 **(iii) The medication order in the patient's chart may substitute for such record,**  
302 **provided the medication order meets all the requirements of subparagraph (C) of this**  
303 **paragraph.**

305 (8) Policies and procedures. Written policies and procedures for a drug distribution system,  
306 appropriate for the freestanding emergency medical facility, shall be developed and  
307 implemented by the pharmacist-in-charge with the advice of the appropriate committee. The  
308 written policies and procedures for the drug distribution system shall include, but not be limited  
309 to, procedures regarding the following:

310

(A) controlled substances;

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(B) investigational drugs;

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(C) prepackaging and manufacturing;

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(D) medication errors;

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(E) orders of physician or other practitioner;

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(F) floor stocks;

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(G) adverse drug reactions;

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(H) drugs brought into the facility by the patient;

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(I) self-administration;

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(J) emergency drug tray;

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(K) formulary, if applicable;

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(L) drug storage areas;

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(M) drug samples;

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(N) drug product defect reports;

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(O) drug recalls;

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(P) outdated drugs;

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(Q) preparation and distribution of IV admixtures;

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(R) procedures for supplying drugs for postoperative use, if applicable;

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(S) use of automated medication supply systems;

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(T) use of data processing systems; and

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(U) drug regimen review.

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353 (9) Drugs supplied for outpatient use. Drugs provided to patients for take home use shall be  
354 supplied according to the following procedures.

355

356 (A) Drugs may only be supplied to patients who have been admitted to the FEMCF.

357

358 (B) Drugs may only be supplied in accordance with the system of control and accountability  
359 established for drugs supplied from the FEMCF; such system shall be developed and  
360 supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-  
361 charge.

362

363 (C) Only drugs listed on the approved outpatient drug list may be supplied; such list shall be  
364 developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the  
365 nature and type to meet the immediate postoperative needs of the FEMCF patient.

366

367 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in  
368 suitable containers and appropriately pre-labeled (including name, address, and phone number  
369 of the facility and necessary auxiliary labels) by the pharmacy, provided, however that topicals  
370 and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a  
371 72-hour supply.

372

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

375

376 (i) date supplied;

377

378 (ii) name of practitioner;

379

380 (iii) name of patient;

381

382 (iv) directions for use;

383

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

386

387 (vi) unique identification number.

388

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

391

392 (G) A perpetual record of drugs which are supplied from the FEMCF shall be maintained  
393 which includes:

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

396

397 (ii) date supplied;

398

399 (iii) name of practitioner;

400

401 (iv) name of patient;

402

403 (v) directions for use;

404

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

407  
408 (vii) unique identification number.  
409  
410 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall  
411 review the records at least once in every calendar week that the pharmacy is open.  
412  
413 (10) Drug regimen review.  
414  
415 (A) A pharmacist shall evaluate medication orders and patient medication records for:  
416  
417 (i) known allergies;  
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419 (ii) rational therapy--contraindications;  
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421 (iii) reasonable dose and route of administration;  
422  
423 (iv) reasonable directions for use;  
424  
425 (v) duplication of therapy;  
426  
427 (vi) drug-drug interactions;  
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429 (vii) drug-food interactions;  
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431 (viii) drug-disease interactions;  
432  
433 (ix) adverse drug reactions;  
434  
435 (x) proper utilization, including overutilization or underutilization; and  
436  
437 (xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug  
438 effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of  
439 the drug in its current regimen.  
440  
441 (B) A retrospective, random drug regimen review as specified in the pharmacy's policies and  
442 procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed  
443 31 days between such reviews.  
444  
445 (C) Any questions regarding the order must be resolved with the prescriber and a written  
446 notation of these discussions made and maintained.  
447  
448 (e) (No Change.)