

## RULE ANALYSIS

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

**Short Title:** Labeling and Sterile Compounding

**Rule Numbers:** §§291.76, 291.151

**Statutory Authority:** Texas Pharmacy Act, Chapter 551-566 and 568-569, 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, clarify the labeling requirements for medications provided by ASC pharmacies and Class F pharmacies; and remove references to sterile compounding since this is no longer applicable for these classes of pharmacy.

1 **TITLE 22 EXAMINING BOARDS**  
2 **PART 15 TEXAS STATE BOARD OF PHARMACY**  
3 **CHAPTER 291 PHARMACIES**  
4 **SUBCHAPTER D INSTITUTIONAL PHARMACY (CLASS C)**

5  
6 **§291.76 Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center**  
7

8 (a) – (b) (No change.)  
9

10 (c) Personnel.

11  
12 (1) Pharmacist-in-charge.

13  
14 (A) General. Each ambulatory surgical center shall have one pharmacist-in-charge who is  
15 employed or under contract, at least on a consulting or part-time basis, but may be employed on  
16 a full-time basis.

17  
18 (B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum,  
19 the following:

20  
21 (i) establishment of specifications for procurement and storage of all materials, including  
22 drugs, chemicals, and biologicals;

23  
24 (ii) participation in the development of a formulary for the ASC, subject to approval of the  
25 appropriate committee of the ASC;

26  
27 (iii) distribution of drugs to be administered to patients pursuant to an original or direct copy  
28 of the practitioner's medication order;

29  
30 (iv) filling and labeling all containers from which drugs are to be distributed or dispensed;

31  
32 (v) maintaining and making available a sufficient inventory of antidotes and other emergency  
33 drugs, both in the pharmacy and patient care areas, as well as current antidote information,  
34 telephone numbers of regional poison control center and other emergency assistance  
35 organizations, and such other materials and information as may be deemed necessary by the  
36 appropriate committee of the ASC;

37  
38 (vi) records of all transactions of the ASC pharmacy as may be required by applicable state  
39 and federal law, and as may be necessary to maintain accurate control over and accountability  
40 for all pharmaceutical materials;

41  
42 (vii) participation in those aspects of the ASC's patient care evaluation program which relate  
43 to pharmaceutical material utilization and effectiveness;

44  
45 (viii) participation in teaching and/or research programs in the ASC;

46  
47 (ix) implementation of the policies and decisions of the appropriate committee(s) relating to  
48 pharmaceutical services of the ASC;

49  
50 (x) effective and efficient messenger and delivery service to connect the ASC pharmacy with  
51 appropriate areas of the ASC on a regular basis throughout the normal workday of the ASC;

52  
53 (xi) labeling, storage, and distribution of investigational new drugs, including maintenance of  
54 information in the pharmacy and nursing station where such drugs are being administered,  
55 concerning the dosage form, route of administration, strength, actions, uses, side effects,  
56 adverse effects, interactions, and symptoms of toxicity of investigational new drugs;

57  
58 (xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this  
59 subsection; and

60  
61 (xiii) maintenance of records in a data processing system such that the data processing  
62 system is in compliance with the requirements for a Class C (institutional) pharmacy located in a  
63 freestanding ASC.

64  
65 (2) Consultant pharmacist.

66  
67 (A) The consultant pharmacist may be the pharmacist-in-charge.

68  
69 (B) A written contract shall exist between the ASC and any consultant pharmacist, and a copy  
70 of the written contract shall be made available to the board upon request.

71  
72 (3) Pharmacists.

73  
74 (A) General.

75  
76 (i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed  
77 pharmacists as may be required to operate the ASC pharmacy competently, safely, and  
78 adequately to meet the needs of the patients of the facility.

79  
80 (ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as  
81 outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for  
82 pharmaceutical materials.

83  
84 (iii) All pharmacists shall be responsible for any delegated act performed by pharmacy  
85 technicians or pharmacy technician trainees under his or her supervision.

86  
87 (iv) All pharmacists while on duty shall be responsible for complying with all state and  
88 federal laws or rules governing the practice of pharmacy.

89  
90 (B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but  
91 need not be limited to, the following:

92  
93 (i) receiving and interpreting prescription drug orders and oral medication orders and  
94 reducing these orders to writing either manually or electronically;

95  
96 (ii) selection of prescription drugs and/or devices and/or suppliers; and

97  
98 (iii) interpreting patient profiles.

99  
100 (C) Special requirements for compounding.

101

102 ~~[(i)]~~ Non-Sterile Preparations. All pharmacists engaged in compounding non-sterile  
103 preparations shall meet the training requirements specified in §291.131 of this title (relating to  
104 Pharmacies Compounding Non-Sterile Preparations).

105  
106 ~~[(ii) Sterile Preparations. All pharmacists engaged in compounding sterile preparations shall~~  
107 ~~meet the training requirements specified in §291.133 of this title (relating to Pharmacies~~  
108 ~~Compounding Sterile Preparations).]~~

109  
110 (4) Pharmacy technicians and pharmacy technician trainees.

111  
112 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the  
113 training requirements specified in §297.6 of this title (relating to Pharmacy Technician and  
114 Pharmacy Technician Trainee Training).

115  
116 (B) Duties. Duties may include, but need not be limited to, the following functions, under the  
117 direct supervision of a pharmacist:

118  
119 (i) prepacking and labeling unit and multiple dose packages, provided a pharmacist  
120 supervises and conducts a final check and affixes his or her name, initials, electronic signature  
121 to the appropriate quality control records prior to distribution;

122  
123 (ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to  
124 medication orders, provided a pharmacist supervises and checks the preparation;

125  
126 (iii) compounding non-sterile preparations pursuant to medication orders provided the  
127 pharmacy technicians or pharmacy technician trainees have completed the training specified in  
128 §291.131 of this title;

129  
130 ~~[(iv) compounding sterile preparations pursuant to medication orders provided the pharmacy~~  
131 ~~technicians or pharmacy technician trainees:~~

132  
133 ~~—(I) have completed the training specified in §291.133 of this title; and~~

134  
135 ~~—(II) are supervised by a pharmacist who has completed the sterile preparations training~~  
136 ~~specified in §291.133 of this title, conducts in-process and final checks, and affixes his or her~~  
137 ~~name, initials, or electronic signature to the label or if batch prepared to the appropriate quality~~  
138 ~~control records. (The name, initials, or electronic signature are not required on the label if it is~~  
139 ~~maintained in a permanent record of the pharmacy.)]~~

140  
141 **(iv)** ~~[(v)]~~ bulk compounding, provided a pharmacist supervises and conducts in-process and  
142 final checks and affixes his or her name, initials, or electronic signature to the appropriate  
143 quality control records prior to distribution;

144  
145 **(v)** ~~[(vi)]~~ distributing routine orders for stock supplies to patient care areas;

146  
147 **(vi)** ~~[(vii)]~~ entering medication order and drug distribution information into a data processing  
148 system, provided judgmental decisions are not required and a pharmacist checks the accuracy  
149 of the information entered into the system prior to releasing the order or in compliance with the  
150 absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section;

151  
152 **(vii)** ~~[(viii)]~~ maintaining inventories of drug supplies;

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**(viii)** ~~[(ix)]~~ maintaining pharmacy records; and

**(ix)** ~~[(x)]~~ loading bulk unlabeled drugs into an automated drug dispensing system provided a pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his or her name, initials or electronic signature to the appropriate quality control records.

(C) Procedures.

(i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard written procedures and guidelines.

(ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as pharmacy technicians or pharmacy technician trainees working in a Class A pharmacy.

(D) Special requirements for compounding.

~~[(i)]~~ Non-Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title.

~~[(ii) Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title.]~~

(5) – (6) (No change.)

(d) Operational standards.

(1) Licensing requirements.

(A) – (J) (No change.)

~~[(K) Prior to August 31, 2014, an ASC pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133 of this title.]~~

**(K)** ~~[(L)]~~ Effective August 31, 2014, an ASC pharmacy shall not compound sterile preparations unless the pharmacy has applied for and obtained a Class C-S pharmacy.

**(L)** ~~[(M)]~~ An ASC pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

**(M)** ~~[(N)]~~ An ASC pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

(2) – (8) (No change.)

204 (9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall  
205 be supplied according to the following procedures.

206  
207 (A) Drugs may only be supplied to patients who have been admitted to the ambulatory  
208 surgical center.

209  
210 (B) Drugs may only be supplied in accordance with the system of control and accountability  
211 established for drugs supplied from the ambulatory surgical center; such system shall be  
212 developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the  
213 pharmacist-in-charge.

214  
215 (C) Only drugs listed on the approved postoperative drug list may be supplied; such list shall  
216 be developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the  
217 nature and type to meet the immediate postoperative needs of the ambulatory surgical center  
218 patient.

219  
220 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in  
221 suitable containers and appropriately pre-labeled (including **name, address, phone number,**  
222 **and** necessary auxiliary labels) by the pharmacy, provided, however that topicals and  
223 ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-  
224 hour supply.

225  
226 (E) At the time of delivery of the drug, the practitioner shall complete the label, such that the  
227 prescription container bears a label with at least the following information:

228 (i) date supplied;

229  
230 (ii) name of practitioner;

231  
232 (iii) name of patient;

233  
234 (iv) directions for use;

235  
236 (v) brand name and strength of the drug; or if no brand name, then the generic name of the  
237 drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

238  
239 (vi) unique identification number.

240  
241 (F) After the drug has been labeled by the practitioner, the practitioner or a licensed nurse  
242 under the supervision of the practitioner shall give the appropriately labeled, prepackaged  
243 medication to the patient.

244  
245 (G) A perpetual record of drugs which are supplied from the ASC shall be maintained which  
246 includes:

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

248  
249 (ii) date supplied;

250  
251 (iii) name of practitioner;

252  
253  
254

- 255 (iv) name of patient;  
256  
257 (v) directions for use;  
258  
259 (vi) brand name and strength of the drug; or if no brand name, then the generic name of the  
260 drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and  
261  
262 (vii) unique identification number.  
263

264 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall  
265 review the records at least once every seven days.  
266

267 (e) Records.

268 (1) – (2) (No change.)

269 (3) Patient records.

270 (A) – (F) (No change.)

271 (G) Data processing system maintenance of records for the distribution and return of all  
272 controlled substances, nalbuphine (Nubain), or **tramadol (Ultram)** [~~carisoprodol (Soma)~~] to the  
273 pharmacy.  
274

275 (i) Each time a controlled substance, nalbuphine (Nubain), or **tramadol (Ultram)**  
276 [~~carisoprodol (Soma)~~] is distributed from or returned to the pharmacy, a record of such  
277 distribution or return shall be entered into the data processing system.  
278

279 (ii) The data processing system shall have the capacity to produce a hard-copy printout of  
280 an audit trail of drug distribution and return for any strength and dosage form of a drug (by either  
281 brand or generic name or both) during a specified time period. This printout shall contain the  
282 following information:

283 (I) patient's name and room number or patient's facility identification number;

284 (II) prescribing or attending practitioner's name;

285 (III) name, strength, and dosage form of the drug product actually distributed;

286 (IV) total quantity distributed from and returned to the pharmacy;

287 (V) if not immediately retrievable via electronic image, the following shall also be included  
288 on the printout:

289 (-a-) prescribing or attending practitioner's address; and

290 (-b-) practitioner's DEA registration number, if the medication order is for a controlled  
291 substance.  
292

293 (iii) An audit trail printout for each strength and dosage form of these drugs distributed  
294 during the preceding month shall be produced at least monthly and shall be maintained in a  
295

306 separate file at the facility. The information on this printout shall be sorted by drug name and list  
307 all distributions/returns for that drug chronologically.

308

309 (iv) The pharmacy may elect not to produce the monthly audit trail printout if the data  
310 processing system has a workable (electronic) data retention system which can produce an  
311 audit trail of drug distribution and returns for the preceding two years. The audit trail required in  
312 this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized  
313 agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law  
314 enforcement or regulatory agencies.

315

316 (H) – (I) (No change.)

317

318 (4) Distribution of controlled substances to another registrant. A pharmacy may distribute  
319 controlled substances to a practitioner, another pharmacy, or other registrant, without being  
320 registered to distribute, under the following conditions.

321

322 (A) The registrant to whom the controlled substance is to be distributed is registered under  
323 the Controlled Substances Act to dispense that controlled substance.

324

325 (B) The total number of dosage units of controlled substances distributed by a pharmacy may  
326 not exceed 5.0% of all controlled substances dispensed by the pharmacy during the 12-month  
327 period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is  
328 required to obtain an additional registration to distribute controlled substances.

329

330 (C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be  
331 maintained which indicates:

332

333 (i) the actual date of distribution;

334

335 (ii) the name, strength, and quantity of controlled substances distributed;

336

337 (iii) the name, address, and DEA registration number of the distributing pharmacy; and

338

339 (iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other  
340 registrant to whom the controlled substances are distributed.

341

342 (D) If the distribution is for a Schedule ~~I-IV~~ II controlled substance, the following is  
343 applicable.

344

345 (i) The pharmacy, practitioner, or other registrant who is receiving the controlled substances  
346 shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222C) to the distributing pharmacy.

347

348 (ii) The distributing pharmacy shall:

349

350 (I) complete the area on the DEA order form (DEA 222C) titled "To Be Filled in by  
351 Supplier";

352

353 (II) maintain Copy 1 of the DEA order form (DEA 222C) at the pharmacy for two years; and

354

355 (III) forward Copy 2 of the DEA order form (DEA 222C) to the divisional office of the Drug  
356 Enforcement Administration.

357  
358 (5) – (6) (No change.)  
359

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 Center (Class F)**  
7

8 (a) – (b) (No change.)  
9

10 (c) Personnel.

11  
12 (1) – (2) (No change.)

13  
14 (3) Pharmacists.

15  
16 (A) General.

17  
18 (i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed  
19 pharmacists as may be required to operate the FEMCC pharmacy competently, safely, and  
20 adequately to meet the needs of the patients of the facility.

21  
22 (ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as  
23 outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for  
24 pharmaceutical materials.

25  
26 (iii) All pharmacists shall be responsible for any delegated act performed by pharmacy  
27 technicians or pharmacy technician trainees under his or her supervision.

28  
29 (iv) All pharmacists while on duty shall be responsible for complying with all state and  
30 federal laws or rules governing the practice of pharmacy.

31  
32 (B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but  
33 need not be limited to, the following:

34  
35 (i) receiving and interpreting prescription drug orders and oral medication orders and  
36 reducing these orders to writing either manually or electronically;

37  
38 (ii) selection of prescription drugs and/or devices and/or suppliers; and

39  
40 (iii) interpreting patient profiles.

41  
42 (C) Special requirements for compounding.

43  
44 ~~[(i)]~~ Non-Sterile Preparations. All pharmacists engaged in compounding non-sterile  
45 preparations shall meet the training requirements specified in §291.131 of this title (relating to  
46 Pharmacies Compounding Non-Sterile Preparations).

47  
48 ~~[(ii)]~~ Sterile Preparations. All pharmacists engaged in compounding sterile preparations shall  
49 meet the training requirements specified in §291.133 of this title (relating to Pharmacies  
50 Compounding Sterile Preparations).]  
51

52 (4) Pharmacy technicians and pharmacy technician trainees.

53  
54 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the  
55 training requirements specified in §297.6 of this title (relating to Pharmacy Technician and  
56 Pharmacy Technician Trainee Training).

57  
58 (B) Duties. Duties may include, but need not be limited to, the following functions, under the  
59 direct supervision of a pharmacist:

60  
61 (i) prepacking and labeling unit and multiple dose packages, provided a pharmacist  
62 supervises and conducts a final check and affixes his or her name, initials, electronic signature  
63 to the appropriate quality control records prior to distribution;

64  
65 (ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to  
66 medication orders, provided a pharmacist supervises and checks the preparation;

67  
68 (iii) compounding non-sterile preparations pursuant to medication orders provided the  
69 pharmacy technicians or pharmacy technician trainees have completed the training specified in  
70 §291.131 of this title;

71  
72 ~~[(iv) compounding sterile preparations pursuant to medication orders provided the pharmacy~~  
73 ~~technicians or pharmacy technician trainees:~~

74  
75 ~~—(I) have completed the training specified in §291.133 of this title; and~~

76  
77 ~~—(II) are supervised by a pharmacist who has completed the sterile preparations training~~  
78 ~~specified in §291.133 of this title, conducts in-process and final checks, and affixes his or her~~  
79 ~~name, initials, or electronic signature to the label or if batch prepared to the appropriate quality~~  
80 ~~control records. (The name, initials, or electronic signature are not required on the label if it is~~  
81 ~~maintained in a permanent record of the pharmacy.)]~~

82  
83 **(iv)** ~~[(v)]~~ bulk compounding, provided a pharmacist supervises and conducts in-process and  
84 final checks and affixes his or her name, initials, or electronic signature to the appropriate  
85 quality control records prior to distribution;

86  
87 **(v)** ~~[(vi)]~~ distributing routine orders for stock supplies to patient care areas;

88  
89 **(vi)** ~~[(vii)]~~ entering medication order and drug distribution information into a data processing  
90 system, provided judgmental decisions are not required and a pharmacist checks the accuracy  
91 of the information entered into the system prior to releasing the order or in compliance with the  
92 absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section;

93  
94 **(vii)** ~~[(viii)]~~ maintaining inventories of drug supplies;

95  
96 **(viii)** ~~[(ix)]~~ maintaining pharmacy records; and

97  
98 **(ix)** ~~[(x)]~~ loading bulk unlabeled drugs into an automated drug dispensing system provided a  
99 pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his  
100 or her name, initials or electronic signature to the appropriate quality control records.

101  
102 (C) Procedures.

103  
104 (i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders  
105 in accordance with standard written procedures and guidelines.  
106  
107 (ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug  
108 orders in the same manner as pharmacy technicians or pharmacy technician trainees working in  
109 a Class A pharmacy.  
110  
111 (D) Special requirements for compounding.  
112  
113 ~~[(i)] Non-Sterile Preparations. All pharmacy technicians and pharmacy technician trainees~~  
114 ~~en[ga]ged in compounding non-sterile preparations shall meet the training requirements~~  
115 ~~specified in §291.131 of this title.~~  
116  
117 ~~[(ii)] Sterile Preparations. All pharmacy technicians and pharmacy technician trainees~~  
118 ~~engaged in compounding sterile preparations shall meet the training requirements specified in~~  
119 ~~§291.133 of this title.]~~  
120  
121 (5) – (6) (No change.)  
122  
123 (d) Operational standards.  
124  
125 (1) Licensing requirements.  
126  
127 (A) A FEMCC pharmacy shall register annually or biennially with the board on a pharmacy  
128 license application provided by the board, following the procedures specified in §291.1 of this  
129 title (relating to Pharmacy License Application).  
130  
131 (B) If the FEMCC pharmacy is owned or operated by a pharmacy management or consulting  
132 firm, the following conditions apply.  
133  
134 (i) The pharmacy license application shall list the pharmacy management or consulting firm  
135 as the owner or operator.  
136  
137 (ii) The pharmacy management or consulting firm shall obtain DEA and DPS controlled  
138 substances registrations that are issued in the name of the firm, unless the following occur:  
139  
140 (I) the pharmacy management or consulting firm and the facility cosign a contractual  
141 pharmacy service agreement which assigns overall responsibility for controlled substances to  
142 the facility; and  
143  
144 (II) such pharmacy management or consulting firm maintains dual responsibility for the  
145 controlled substances.  
146  
147 (C) A FEMCC pharmacy which changes ownership shall notify the board within 10 days of  
148 the change of ownership and apply for a new and separate license as specified in §291.3 of this  
149 title (relating to Required Notifications).  
150  
151 (D) A FEMCC pharmacy which changes location and/or name shall notify the board of the  
152 change within 10 days and file for an amended license as specified in §291.3 of this title.  
153

154 (E) A FEMCC pharmacy owned by a partnership or corporation which changes managing  
155 officers shall notify the board in writing of the names of the new managing officers within 10  
156 days of the change, following the procedures in §291.3 of this title.

157  
158 (F) A FEMCC pharmacy shall notify the board in writing within 10 days of closing, following  
159 the procedures in §291.5 of this title (relating to Closing a Pharmacy).

160  
161 (G) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be  
162 charged for issuance and renewal of a license and the issuance of an amended license.

163  
164 (H) A separate license is required for each principal place of business and only one pharmacy  
165 license may be issued to a specific location.

166  
167 (I) A FEMCC pharmacy engaged in the compounding of non-sterile preparations shall comply  
168 with the provisions of §291.131 of this title.

169  
170 ~~[(J) A FEMCC pharmacy engaged in the compounding of sterile preparations shall comply~~  
171 ~~with the provisions of §291.133 of this title.]~~

172  
173 (2) – (8) (No change.)

174  
175 (9) Drugs supplied for outpatient use. Drugs supplied to patients for outpatient use shall be  
176 supplied according to the following procedures.

177  
178 (A) Drugs may only be supplied to patients who have been admitted to the freestanding  
179 emergency medical center.

180  
181 (B) Drugs may only be supplied in accordance with the system of control and accountability  
182 established for drugs supplied from the freestanding emergency medical center; such system  
183 shall be developed and supervised by the pharmacist-in-charge or staff pharmacist designated  
184 by the pharmacist-in-charge.

185  
186 (C) Only drugs listed on the approved outpatient drug list may be supplied; such list shall be  
187 developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the  
188 nature and type to meet the immediate postoperative needs of the freestanding emergency  
189 medical center patient.

190  
191 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in  
192 suitable containers and appropriately pre-labeled (including **name, address, phone number of**  
193 **the facility and** necessary auxiliary labels) by the pharmacy, provided, however that topicals  
194 and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a  
195 72-hour supply.

196  
197 (E) At the time of delivery of the drug, the practitioner shall complete the label, such that the  
198 prescription container bears a label with at least the following information:

199  
200 (i) date supplied;

201  
202 (ii) name of practitioner;

203  
204 (iii) name of patient;

205  
206 (iv) directions for use;  
207  
208 (v) brand name and strength of the drug; or if no brand name, then the generic name of the  
209 drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and  
210  
211 (vi) unique identification number.  
212  
213 (F) After the drug has been labeled by the practitioner, the practitioner or a licensed nurse  
214 under the supervision of the practitioner shall give the appropriately labeled, prepackaged  
215 medication to the patient.  
216  
217 (G) A perpetual record of drugs which are supplied from the FEMCC shall be maintained  
218 which includes:  
219  
220 (i) name, address, and phone number of the facility;  
221  
222 (ii) date supplied;  
223  
224 (iii) name of practitioner;  
225  
226 (iv) name of patient;  
227  
228 (v) directions for use;  
229  
230 (vi) brand name and strength of the drug; or if no brand name, then the generic name of the  
231 drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and  
232  
233 (vii) unique identification number.  
234  
235 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall  
236 review the records at least once every seven days.  
237  
238 (e) (No change.)