

RULE ANALYSIS

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

Short Title: Removing Drugs from the Pharmacy

Rule Numbers: §§291.76 and 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, correct grammar and update record keeping requirements.

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) **establishing** [~~establishment of~~] specifications for procurement and storage of all
22 materials, including drugs, chemicals, and biologicals;

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

26
27 (iii) **distributing** [~~distribution of~~] drugs to be administered to patients pursuant to an original
28 or direct copy 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) **maintaining** records of all transactions of the ASC pharmacy as may be required by
39 applicable state and federal law, and as may be necessary to maintain accurate control over
40 and accountability for all pharmaceutical materials;

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

44
45 (viii) **participating** [~~participation~~] in teaching and/or research programs in the ASC;

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

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

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

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

62
63 (xiii) **maintaining** [~~maintenance of~~] records in a data processing system such that the data
64 processing system is in compliance with the requirements for a Class C ~~[(institutional)]~~
65 pharmacy located in a freestanding ASC.

66
67 (2) (No change.)

68
69 (3) Pharmacists.

70
71 (A) (No change.)

72
73 (B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but
74 need not be limited to, the following:

75
76 (i) receiving and interpreting prescription drug orders and oral medication orders and
77 reducing these orders to writing either manually or electronically;

78
79 (ii) **selecting** [~~selection of~~] prescription drugs and/or devices and/or suppliers; and

80
81 (iii) interpreting patient profiles.

82
83 (C) (No change.)

84
85 (4) (No change.)

86
87 (5) Owner. The owner of an ASC pharmacy shall have responsibility for all administrative and
88 operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on
89 administrative and operational concerns. The owner shall have responsibility for, at a minimum,
90 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with
91 the pharmacist-in-charge or another Texas licensed pharmacist:

92
93 (A) **establishing** [~~establishment of~~] policies for procurement of prescription drugs and
94 devices and other products dispensed from the ASC pharmacy;

95
96 (B) **establishing and maintaining** [~~establishment and maintenance of~~] effective controls
97 against the theft or diversion of prescription drugs;

98

99 (C) if the pharmacy uses an automated pharmacy dispensing system, reviewing and
100 approving all policies and procedures for system operation, safety, security, accuracy and
101 access, patient confidentiality, prevention of unauthorized access, and malfunction;
102

103 (D) providing the pharmacy with the necessary equipment and resources commensurate with
104 its level and type of practice; and
105

106 (E) **establishing** [~~establishment of~~] policies and procedures regarding maintenance, storage,
107 and retrieval of records in a data processing system such that the system is in compliance with
108 state and federal requirements.
109

110 (6) (No change.)
111

112 (d) Operational standards.
113

114 (1) Licensing requirements.
115

116 (A) – (K) (No change.)
117

118 (L) Effective August 31, 2014, an ASC pharmacy shall not compound sterile preparations
119 unless the pharmacy has applied for and obtained a Class C-S pharmacy **license**.
120

121 (M) – (N) (No change.)
122

123 (2) – (3) (No change.)
124

125 (4) Library. A reference library shall be maintained that includes the following in hard-copy or
126 electronic format and that pharmacy personnel shall be capable of accessing at all times:
127

128 (A) current copies of the following:
129

130 (i) Texas Pharmacy Act and rules;
131

132 (ii) Texas Dangerous Drug Act and rules;
133

134 (iii) Texas Controlled Substances Act and rules;
135

136 (iv) Federal Controlled Substances Act and rules or official publication describing the
137 requirements of the Federal Controlled Substances Act and rules;
138

139 (B) at least one current or updated reference from each of the following categories:
140

141 (i) Drug interactions. A reference text on drug interactions, such as Drug Interaction Facts. A
142 separate reference is not required if other references maintained by the pharmacy contain drug
143 interaction information including information needed to determine severity or significance of the
144 interaction and appropriate recommendations or actions to be taken;
145

146 (ii) General information. A general information reference text, such as:
147

148 (l) Facts and Comparisons with current supplements;
149

150 (II) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the
151 Healthcare Provider);

152
153 (III) AHFS Drug Information with current supplements;

154
155 (IV) Remington's Pharmaceutical Sciences; or

156
157 (V) Clinical Pharmacology;

158
159 (C) a current or updated reference on injectable drug products, such as Handbook of
160 Injectable Drugs;

161
162 (D) basic antidote information and the telephone number of the nearest regional poison
163 control center; **and**

164
165 [~~(E) if the pharmacy compounds sterile preparations, specialty references appropriate for the~~
166 ~~scope of services provided by the pharmacy, e.g., if the pharmacy prepares cytotoxic drugs, a~~
167 ~~reference text on the preparation of cytotoxic drugs, such as Procedures for Handling Cytotoxic~~
168 ~~Drugs; and]~~

169
170 (F) metric-apothecary weight and measure conversion charts.

171
172 (5) (No change.)

173
174 (6) Medication orders.

175
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.

178
179 (B) Drugs may be distributed only pursuant to the original or a direct copy of the practitioner's
180 medication order.

181
182 (C) Pharmacy technicians and pharmacy technician trainees may not receive oral medication
183 orders.

184
185 (D) ASC pharmacies shall be exempt from the labeling provisions and patient notification
186 requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to
187 medication orders.

188
189 (E) In ASCs with a full-time pharmacist, if a practitioner orders a drug for administration to a
190 bona fide patient of the facility when the pharmacy is closed, the following is applicable.

191
192 (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic
193 needs of a patient may be removed from the ASC pharmacy.

194
195 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

196
197 (iii) A record shall be made at the time of withdrawal by the authorized person removing the
198 drugs and devices. The record shall contain the following information:

199
200 (I) name of the patient;

201
202 (II) name of device or drug, strength, and dosage form;
203
204 (III) dose prescribed;
205
206 (IV) quantity taken;
207
208 (V) time and date; and
209
210 (VI) signature or electronic signature of person making withdrawal.
211
212 (iv) The original or direct copy of the medication order may substitute for such record,
213 provided the medication order meets all the requirements of clause (iii) of this subparagraph.
214
215 (v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more
216 than 72 hours from the time of such withdrawal.
217
218 (F) In ASCs with a part-time or consultant pharmacist, if a practitioner orders a drug for
219 administration to a bona fide patient of the ASC when the pharmacist is not on duty, or when the
220 pharmacy is closed, the following is applicable.
221
222 (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be
223 removed from the ASC pharmacy.
224
225 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.
226
227 (iii) A record shall be made at the time of withdrawal by the authorized person removing the
228 drugs and devices; the record shall meet the same requirements as specified in subparagraph
229 (E)(iii) of this paragraph.
230
231 (iv) The pharmacist shall verify each distribution after a reasonable interval, but in no event
232 may such interval exceed seven days.
233
234 (7) Floor stock. In facilities using a floor stock method of drug distribution, the following is
235 applicable for removing drugs or devices in the absence of a pharmacist.
236
237 (A) Prescription drugs and devices may be removed from the pharmacy only in the original
238 manufacturer's container or prepackaged container.
239
240 (B) Only a designated licensed nurse or practitioner may remove such drugs and devices.
241
242 (C) A record shall be made at the time of withdrawal by the authorized person removing the
243 drug or device; the record shall contain the following information:
244
245 (i) name of the drug, strength, and dosage form;
246
247 (ii) quantity removed;
248
249 (iii) location of floor stock;
250
251 (iv) date and time; and

252
253 (v) signature or electronic signature of person making the withdrawal.
254
255 (D) A pharmacist shall verify the withdrawal according to the following schedule.
256
257 (i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as
258 practical, but in no event more than 72 hours from the time of such withdrawal.
259
260 (ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after
261 a reasonable interval, but in no event may such interval exceed seven days.
262
263 (8) – (9) (No change.)
264
265 (e) Records.
266
267 (1) Maintenance of records.
268
269 (A) – (C) (No change.)
270
271 (D) Records, except when specifically required to be maintained in original or hard-copy form,
272 may be maintained in an alternative data retention system, such as a data processing or direct
273 imaging system, [e.g., microfilm or microfiche,] provided:
274
275 (i) the records in the alternative data retention system contain all of the information required
276 on the manual record; and
277
278 (ii) the alternative data retention system is capable of producing a hard copy of the record
279 upon the request of the board, its representative, or other authorized local, state, or federal law
280 enforcement or regulatory agencies.
281
282 (2) Outpatient records.
283
284 (A) Only a registered pharmacist may receive, certify, and receive prescription drug orders.
285
286 (B) Outpatient records shall be maintained as provided in **§291.34 of this title (relating to**
287 **Records), and §291.35 of this title (relating to Official Prescription Records)** [~~§291.34 and~~
288 ~~§291.35 of this title contained in Community Pharmacy (Class A)~~].
289
290 (C) Outpatient prescriptions, including, but not limited to, discharge prescriptions, that are
291 written by the practitioner, must be written on a form which meets the requirements of the Act,
292 §562.006. Medication order forms or copies thereof do not meet the requirements for outpatient
293 forms.
294
295 (D) Controlled substances listed in Schedule II must be written on an **official** [electronic]
296 prescription form in accordance with the Texas Controlled Substances Act, §481.075, and rules
297 promulgated pursuant to the Texas Controlled Substances Act, unless exempted by the Texas
298 Controlled Substances Rules, 37 TAC §13.74. Outpatient prescriptions for Schedule II
299 controlled substances that are exempted from the official prescription requirement must be
300 manually signed by the practitioner.
301
302 (3) Patient records.

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(A) – (C) (No change.)

(D) Records of controlled substances listed in Schedule II shall be maintained as follows.

(i) Records of controlled substances listed in Schedule II shall be maintained separately from records of controlled substances in Schedules III, IV, and V, and all other records.

(ii) An ASC pharmacy shall maintain a perpetual inventory of any controlled substance listed in Schedule II.

(iii) Distribution records for Schedule II - V controlled substances floor stock shall include the following information:

(I) patient's name;

(II) practitioner who ordered drug;

(III) name of drug, dosage form, and strength;

(IV) time and date of administration to patient and quantity administered;

(V) signature or electronic signature of individual administering controlled substance;

(VI) returns to the pharmacy; and

(VII) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(iv) The pharmacist shall verify each distribution after a reasonable interval, but in no event shall such interval exceed seven days.

(E) Floor stock records shall be maintained as follows.

(i) Distribution records for Schedules III - V controlled substances floor stock shall include the following information:

(I) patient's name;

(II) practitioner who ordered controlled substance;

(III) name of controlled substance, dosage form, and strength;

(IV) time and date of administration to patient;

(V) quantity administered;

(VI) signature or electronic signature of individual administering drug;

(VII) returns to the pharmacy; and

354 (VIII) waste (waste is required to be witnessed and cosigned, manually or electronically, by
355 another individual).

356
357 (ii) The record required by clause (i) of this subparagraph shall be maintained separately
358 from patient records.

359
360 (iii) A pharmacist shall review distribution records with medication orders on a periodic basis
361 to verify proper usage of drugs, not to exceed 30 days between such reviews.

362
363 **(iv) The pharmacist shall verify each distribution after a reasonable interval, but in no**
364 **event shall such interval exceed seven days.**

365
366 (F) General requirements for records maintained in a data processing system are as follows.

367
368 (i) If an ASC pharmacy's data processing system is not in compliance with the board's
369 requirements, the pharmacy must maintain a manual recordkeeping system.

370
371 (ii) Requirements for backup systems. The facility shall maintain a backup copy of
372 information stored in the data processing system using disk, tape, or other electronic backup
373 system and update this backup copy on a regular basis to assure that data is not lost due to
374 system failure.

375
376 (iii) Change or discontinuance of a data processing system.

377
378 (I) Records of distribution and return for all controlled substances[, ~~nalbuphine (Nubain),~~
379 ~~and carisoprodol (Soma)]. A pharmacy that changes or discontinues use of a data processing
380 system must:~~

381
382 (-a-) transfer the records to the new data processing system; or

383
384 (-b-) purge the records to a printout which contains the same information as required on
385 the audit trail printout as specified in subparagraph (G)(ii) of this paragraph. The information on
386 this printout shall be sorted and printed by drug name and list all distributions/returns
387 chronologically.

388
389 (II) Other records. A pharmacy that changes or discontinues use of a data processing
390 system must:

391
392 (-a-) transfer the records to the new data processing system; or

393
394 (-b-) purge the records to a printout which contains all of the information required on the
395 original document.

396
397 (III) Maintenance of purged records. Information purged from a data processing system
398 must be maintained by the pharmacy for two years from the date of initial entry into the data
399 processing system.

400
401 (iv) Loss of data. The pharmacist-in-charge shall report to the board in writing any significant
402 loss of information from the data processing system within 10 days of discovery of the loss.

403

404 (G) Data processing system maintenance of records for the distribution and return of all
405 controlled substances~~[, nalbuphine (Nubain), or tramadol (Ultram)]~~ to the pharmacy.

406
407 (i) Each time a controlled substance~~[, nalbuphine (Nubain), or tramadol (Ultram)]~~ is
408 distributed from or returned to the pharmacy, a record of such distribution or return shall be
409 entered into the data processing system.

410
411 (ii) The data processing system shall have the capacity to produce a hard-copy printout of
412 an audit trail of drug distribution and return for any strength and dosage form of a drug (by either
413 brand or generic name or both) during a specified time period. This printout shall contain the
414 following information:

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

416
417 (II) prescribing or attending practitioner's name;

418
419 (III) name, strength, and dosage form of the drug product actually distributed;

420
421 (IV) total quantity distributed from and returned to the pharmacy;

422
423 (V) if not immediately retrievable via electronic image, the following shall also be included
424 on the printout:

425
426 (-a-) prescribing or attending practitioner's address; and

427
428 (-b-) practitioner's DEA registration number, if the medication order is for a controlled
429 substance.

430
431 (iii) An audit trail printout for each strength and dosage form of these drugs distributed
432 during the preceding month shall be produced at least monthly and shall be maintained in a
433 separate file at the facility. The information on this printout shall be sorted by drug name and list
434 all distributions/returns for that drug chronologically.

435
436 (iv) The pharmacy may elect not to produce the monthly audit trail printout if the data
437 processing system has a workable (electronic) data retention system which can produce an
438 audit trail of drug distribution and returns for the preceding two years. The audit trail required in
439 this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized
440 agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law
441 enforcement or regulatory agencies.

442
443 (H) – (I) (No change.)

444
445 (4) - (6) (No change.)

446
447 .

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**
7 **F)**
8

9 (a) – (b) (No change.)

10
11 (c) Personnel.

12
13 (1) Pharmacist-in-charge.

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

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

21
22 (i) **establishing** [~~establishment of~~] specifications for procurement and storage of all
23 materials, including drugs, chemicals, and biologicals;

24
25 (ii) **participating** [~~participation~~] in the development of a formulary for the FEMCC, subject to
26 approval of the appropriate committee of the FEMCC;

27
28 (iii) **distributing** [~~distribution of~~] drugs to be administered to patients pursuant to an original
29 or direct copy of the practitioner's medication order;

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

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

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

42
43 (vii) **participating** [~~participation~~] in those aspects of the FEMCC's patient care evaluation
44 program which relate to pharmaceutical material utilization and effectiveness;

45
46 (viii) **participating** [~~participation~~] in teaching and/or research programs in the FEMCC;

47
48 (ix) **implementing** [~~implementation of~~] the policies and decisions of the appropriate
49 committee(s) relating to pharmaceutical services of the FEMCC;

51 (x) **providing** effective and efficient messenger and delivery service to connect the FEMCC
52 pharmacy with appropriate areas of the FEMCC on a regular basis throughout the normal
53 workday of the FEMCC;

54
55 (xi) labeling, **storing and distributing** [~~storage, and distribution of~~] investigational new
56 drugs, including maintenance of information in the pharmacy and nursing station where such
57 drugs are being administered, concerning the dosage form, route of administration, strength,
58 actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of
59 investigational new drugs;

60
61 (xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this
62 section; and

63
64 (xiii) **maintaining** [~~maintenance of~~] records in a data processing system such that the data
65 processing system is in compliance with the requirements for a FEMCC.

66
67 (2) (No change.)

68
69 (3) Pharmacists.

70
71 (A) General.

72
73 (i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed
74 pharmacists as may be required to operate the FEMCC pharmacy competently, safely, and
75 adequately to meet the needs of the patients of the facility.

76
77 (ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as
78 outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for
79 pharmaceutical materials.

80
81 (iii) All pharmacists shall be responsible for any delegated act performed by pharmacy
82 technicians or pharmacy technician trainees under his or her supervision.

83
84 (iv) All pharmacists while on duty shall be responsible for complying with all state and
85 federal laws or rules governing the practice of pharmacy.

86
87 (B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but
88 need not be limited to, the following:

89
90 (i) receiving and interpreting prescription drug orders and oral medication orders and
91 reducing these orders to writing either manually or electronically;

92
93 (ii) **selecting** [~~selection of~~] prescription drugs and/or devices and/or suppliers; and

94
95 (iii) interpreting patient profiles.

96
97 (C) (No change.)

98
99 (4) (No change.)

100

101 (5) Owner. The owner of a FEMCC pharmacy shall have responsibility for all administrative
102 and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on
103 administrative and operational concerns. The owner shall have responsibility for, at a minimum,
104 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with
105 the pharmacist-in-charge or another Texas licensed pharmacist:

106
107 (A) **establishing** [~~establishment of~~] policies for procurement of prescription drugs and
108 devices and other products dispensed from the FEMCC pharmacy;

109
110 (B) **establishing and maintaining** [~~establishment and maintenance of~~] effective controls
111 against the theft or diversion of prescription drugs;

112
113 (C) if the pharmacy uses an automated pharmacy dispensing system, reviewing and
114 approving all policies and procedures for system operation, safety, security, accuracy and
115 access, patient confidentiality, prevention of unauthorized access, and malfunction;

116
117 (D) providing the pharmacy with the necessary equipment and resources commensurate with
118 its level and type of practice; and

119
120 (E) **establishing** [~~establishment of~~] policies and procedures regarding maintenance, storage,
121 and retrieval of records in a data processing system such that the system is in compliance with
122 state and federal requirements.

123
124 (6) (No change.)

125
126 (d) Operational standards.

127
128 (1) – (3) (No change.)

129
130 (4) Library. A reference library shall be maintained that includes the following in hard-copy or
131 electronic format and that pharmacy personnel shall be capable of accessing at all times:

132
133 (A) current copies of the following:

134
135 (i) Texas Pharmacy Act and rules;

136
137 (ii) Texas Dangerous Drug Act and rules;

138
139 (iii) Texas Controlled Substances Act and rules; and

140
141 (iv) Federal Controlled Substances Act and rules or official publication describing the
142 requirements of the Federal Controlled Substances Act and rules;

143
144 (B) at least one current or updated reference from each of the following categories:

145
146 (i) Drug interactions. A reference text on drug interactions, such as Drug Interaction Facts. A
147 separate reference is not required if other references maintained by the pharmacy contain drug
148 interaction information including information needed to determine severity or significance of the
149 interaction and appropriate recommendations or actions to be taken;

150
151 (ii) General information. A general information reference text, such as:

152
153 (I) Facts and Comparisons with current supplements;
154
155 (II) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the
156 Healthcare Provider);
157
158 (III) AHFS Drug Information with current supplements;
159
160 (IV) Remington's Pharmaceutical Sciences; or
161
162 (V) Clinical Pharmacology;
163
164 (C) a current or updated reference on injectable drug products, such as Handbook of
165 Injectable Drugs;
166
167 (D) basic antidote information and the telephone number of the nearest regional poison
168 control center; **and**
169
170 ~~(E) [if the pharmacy compounds sterile preparations, specialty references appropriate for the~~
171 ~~scope of services provided by the pharmacy, e.g., if the pharmacy prepares cytotoxic drugs, a~~
172 ~~reference text on the preparation of cytotoxic drugs, such as Procedures for Handling Cytotoxic~~
173 ~~Drugs; and~~
174
175 ~~—(F)]~~ metric-apothecary weight and measure conversion charts.
176
177 (5) (No change.)
178
179 (6) Medication orders.
180
181 (A) Drugs may be administered to patients in FEMCCs only on the order of a practitioner. No
182 change in the order for drugs may be made without the approval of a practitioner.
183
184 (B) Drugs may be distributed only pursuant to the original or a direct copy of the practitioner's
185 medication order.
186
187 (C) Pharmacy technicians and pharmacy technician trainees may not receive oral medication
188 orders.
189
190 (D) FEMCC pharmacies shall be exempt from the labeling provisions and patient notification
191 requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to
192 medication orders.
193
194 (E) In FEMCCs with a full-time pharmacist, if a practitioner orders a drug for administration to
195 a bona fide patient of the facility when the pharmacy is closed, the following is applicable.
196
197 (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic
198 needs of a patient may be removed from the FEMCC pharmacy.
199
200 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.
201

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

- 204 (I) name of the patient;
- 205
- 206 (II) name of device or drug, strength, and dosage form;
- 207
- 208 (III) dose prescribed;
- 209
- 210 (IV) quantity taken;
- 211
- 212 (V) time and date; and
- 213
- 214 (VI) signature or electronic signature of person making withdrawal.
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- 216

217 (iv) The original or direct copy of the medication order may substitute for such record,
218 provided the medication order meets all the requirements of clause (iii) of this subparagraph.

219
220 (v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more
221 than 72 hours from the time of such withdrawal.

222
223 (F) In FEMCCs with a part-time or consultant pharmacist, if a practitioner orders a drug for
224 administration to a bona fide patient of the FEMCC when the pharmacist is not on duty, or when
225 the pharmacy is closed, the following is applicable.

226
227 (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be
228 removed from the FEMCC pharmacy.

229
230 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

231
232 (iii) A record shall be made at the time of withdrawal by the authorized person removing the
233 drugs and devices; the record shall meet the same requirements as specified in subparagraph
234 (E)(iii) of this paragraph.

235
236 (iv) The pharmacist shall verify each distribution after a reasonable interval, but in no event
237 may such interval exceed seven days.

238
239 (7) Floor stock. In facilities using a floor stock method of drug distribution, the following is
240 applicable for removing drugs or devices in the absence of a pharmacist.

241
242 (A) Prescription drugs and devices may be removed from the pharmacy only in the original
243 manufacturer's container or prepackaged container.

244
245 (B) Only a designated licensed nurse or practitioner may remove such drugs and devices.

246
247 (C) A record shall be made at the time of withdrawal by the authorized person removing the
248 drug or device; the record shall contain the following information:

- 249 (i) name of the drug, strength, and dosage form;
- 250
- 251 (ii) quantity removed;
- 252

253
254 (iii) location of floor stock;
255
256 (iv) date and time; and
257
258 (v) signature or electronic signature of person making the withdrawal.
259
260 (D) A pharmacist shall verify the withdrawal according to the following schedule.
261
262 (i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as
263 practical, but in no event more than 72 hours from the time of such withdrawal.
264
265 (ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after
266 a reasonable interval, but in no event may such interval exceed seven days.
267
268 (8) Policies and procedures. Written policies and procedures for a drug distribution system,
269 appropriate for the freestanding emergency medical center, shall be developed and
270 implemented by the pharmacist-in-charge with the advice of the appropriate committee. The
271 written policies and procedures for the drug distribution system shall include, but not be limited
272 to, procedures regarding the following:
273
274 (A) controlled substances;
275
276 (B) investigational drugs;
277
278 (C) prepackaging and manufacturing;
279
280 (D) medication errors;
281
282 (E) orders of physician or other practitioner;
283
284 (F) floor stocks;
285
286 (G) adverse drug reactions;
287
288 (H) drugs brought into the facility by the patient;
289
290 (I) self-administration;
291
292 (J) emergency drug tray;
293
294 (K) formulary, if applicable;
295
296 (L) drug storage areas;
297
298 (M) drug samples;
299
300 (N) drug product defect reports;
301
302 (O) drug recalls;
303

304 (P) outdated drugs;
305
306 (Q) [~~preparation and distribution of IV admixtures;~~
307
308 [~~(R)~~] procedures for supplying drugs for postoperative use, if applicable;
309
310 **(R)** [~~(S)~~] use of automated drug dispensing systems; and
311
312 **(S)** [~~(T)~~] use of data processing systems.
313
314 (9) (No change.)
315
316 (e) Records.
317
318 (1) Maintenance of records.
319
320 (A) – (C) (No change.)
321
322 (D) Records, except when specifically required to be maintained in original or hard-copy form,
323 may be maintained in an alternative data retention system, such as a data processing or direct
324 imaging system, [~~e.g., microfilm or microfiche,~~] provided:
325
326 (i) the records in the alternative data retention system contain all of the information required
327 on the manual record; and
328
329 (ii) the alternative data retention system is capable of producing a hard copy of the record
330 upon the request of the board, its representative, or other authorized local, state, or federal law
331 enforcement or regulatory agencies.
332
333 (2) Outpatient records.
334
335 (A) Only a registered pharmacist may receive, certify, and receive prescription drug orders.
336
337 (B) Outpatient records shall be maintained as provided in **§291.34 of this title (relating to**
338 **Records) and §291.35 of this title (relating to Official Prescription Records)** [~~§291.34 and~~
339 ~~§291.35 of this title contained in Community Pharmacy (Class A)].
340
341 (C) Outpatient prescriptions, including, but not limited to, discharge prescriptions, that are
342 written by the practitioner, must be written on a form which meets the requirements of the Act,
343 §562.006. Medication order forms or copies thereof do not meet the requirements for outpatient
344 forms.
345
346 (D) Controlled substances listed in Schedule II must be written on an official prescription form
347 in accordance with the Texas Controlled Substances Act, §481.075, and rules promulgated
348 pursuant to the Texas Controlled Substances Act, unless exempted by the Texas Controlled
349 Substances Rules, 37 TAC §13.74. Outpatient prescriptions for Schedule II controlled
350 substances that are exempted from the official prescription requirement must be manually
351 signed by the practitioner.
352
353 (3) Patient records.
354~~

355 (A) – (C) (No change.)
356

357 (D) Records of controlled substances listed in Schedule II shall be maintained as follows.
358

359 (i) Records of controlled substances listed in Schedule II shall be maintained separately
360 from records of controlled substances in Schedules III, IV, and V, and all other records.
361

362 (ii) A FEMCC pharmacy shall maintain a perpetual inventory of any controlled substance
363 listed in Schedule II.
364

365 (iii) Distribution records for Schedule II - V controlled substances floor stock shall include the
366 following information:
367

368 (I) patient's name;
369

370 (II) practitioner who ordered drug;
371

372 (III) name of drug, dosage form, and strength;
373

374 (IV) time and date of administration to patient and quantity administered;
375

376 (V) signature or electronic signature of individual administering controlled substance;
377

378 (VI) returns to the pharmacy; and
379

380 (VII) waste (waste is required to be witnessed and cosigned, manually or electronically, by
381 another individual).
382

383 **(iv) The pharmacist shall verify each distribution after a reasonable interval, but in no**
384 **event may such interval exceed seven days.**
385

386 (E) Floor stock records shall be maintained as follows.
387

388 (i) Distribution records for Schedules III - V controlled substances floor stock shall include
389 the following information:
390

391 (I) patient's name;
392

393 (II) practitioner who ordered controlled substance;
394

395 (III) name of controlled substance, dosage form, and strength;
396

397 (IV) time and date of administration to patient;
398

399 (V) quantity administered;
400

401 (VI) signature or electronic signature of individual administering drug;
402

403 (VII) returns to the pharmacy; and
404

405 (VIII) waste (waste is required to be witnessed and cosigned, manually or electronically, by
406 another individual).

407
408 (ii) The record required by clause (i) of this subparagraph shall be maintained separately
409 from patient records.

410
411 (iii) **The pharmacist shall verify each distribution after a reasonable interval, but in no**
412 **event may such interval exceed seven days.**

413
414 **(iv)** A pharmacist shall review distribution records with medication orders on a periodic basis
415 to verify proper usage of drugs, not to exceed 30 days between such reviews.

416
417 (F) General requirements for records maintained in a data processing system are as follows.

418
419 (i) If an FEMCC pharmacy's data processing system is not in compliance with the board's
420 requirements, the pharmacy must maintain a manual recordkeeping system.

421
422 (ii) Requirements for backup systems. The facility shall maintain a backup copy of
423 information stored in the data processing system using disk, tape, or other electronic backup
424 system and update this backup copy on a regular basis to assure that data is not lost due to
425 system failure.

426
427 (iii) Change or discontinuance of a data processing system.

428
429 (I) Records of distribution and return for all controlled substances [~~and nalbuphine~~
430 (~~Nubain~~)]. A pharmacy that changes or discontinues use of a data processing system must:

431
432 (-a-) transfer the records to the new data processing system; or

433
434 (-b-) purge the records to a printout which contains the same information as required on
435 the audit trail printout as specified in subparagraph (G)(ii) of this paragraph. The information on
436 this printout shall be sorted and printed by drug name and list all distributions/returns
437 chronologically.

438
439 (II) Other records. A pharmacy that changes or discontinues use of a data processing
440 system must:

441
442 (-a-) transfer the records to the new data processing system; or

443
444 (-b-) purge the records to a printout which contains all of the information required on the
445 original document.

446
447 (III) Maintenance of purged records. Information purged from a data processing system
448 must be maintained by the pharmacy for two years from the date of initial entry into the data
449 processing system.

450
451 (iv) Loss of data. The pharmacist-in-charge shall report to the board in writing any significant
452 loss of information from the data processing system within 10 days of discovery of the loss.

453
454 (G) Data processing system maintenance of records for the distribution and return of all
455 controlled substances [~~tramadol (Ultram) and nalbuphine (Nubain)~~] to the pharmacy.

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

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

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

(II) prescribing or attending practitioner's name;

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

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

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

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

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

(iii) An audit trail printout for each strength and dosage form of these drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the facility. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

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

(H) Failure to maintain records. Failure to provide records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

(I) Data processing system downtime. In the event that an FEMCC pharmacy which uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for on-line data entry as soon as the system is available for use again.

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

507 (A) – (C) (No change.)

508

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

511

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

514

515 (ii) The distributing pharmacy shall:

516

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

519

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

521

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

524

525 (5) - (6) (No change.)