

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED 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provided by ASC pharmacies and Class F pharmacies; and remove references to sterile compounding since this is no longer applicable for these classes of pharmacy.

The Board reviewed and voted to propose the amendments during the May 6, 2014, meeting. The proposed amendments were published in the June 13, 2014, issue of the *Texas Register*.

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

2 **22 TAC §291.76**

3 The Texas State Board of Pharmacy proposes amendments to §291.76, concerning Class C
4 Pharmacies Located in a Freestanding Ambulatory Surgical Center. The proposed amendments,
5 if adopted, clarify the labeling requirements for medications provided by ASC pharmacies;
6 remove references to sterile compounding that are no longer necessary; and add tramadol to the
7 record keeping requirements to be consistent with other sections.

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

11 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
12 effect, the public benefit anticipated as a result of enforcing the amendments will ensure out-
13 patient medications provided by the pharmacy are adequately labeled; ensure appropriate records
14 for tramadol are maintained by the pharmacy; and eliminate references to sterile compounding
15 that are no longer necessary.

16 Written comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director
17 of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,
18 Austin, Texas 78701, fax (512) 305-8008. Comments must be received by 5:00 p.m., July 31,
19 2014.

20 The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act
21 (Chapters 551 - 566, 568 and 569, Texas Occupations Code). The Board interprets §551.002 as
22 authorizing the agency to protect the public through the effective control and regulation of the
23 practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules
24 for the proper administration and enforcement of the Act.

25 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566, 568 and
26 569, Texas Occupations Code.

27 ***§291.76. Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center.***

28 (a) - (b) (No change.)

29 (c) Personnel.

30 (1) - (2) (No change.)

31 (3) Pharmacists.

32 (A) - (B) (No change.)

33 (C) Special requirements for compounding non-sterile preparations.

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

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

40 (4) Pharmacy technicians and pharmacy technician trainees.

41 (A) (No change.)

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

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

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

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

52 ~~[(iv) compounding sterile preparations pursuant to medication orders provided the pharmacy~~
53 ~~technicians or pharmacy technician trainees:]~~

54 ~~[(I) have completed the training specified in §291.133 of this title; and]~~

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

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

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

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

68 (vii) [~~(viii)~~] maintaining inventories of drug supplies;

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

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

73 (C) Procedures.

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

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

79 (D) Special requirements for compounding non-sterile preparations.

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

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

86 (5) - (6) (No change.)

87 (d) Operational standards.

88 (1) Licensing requirements.

89 (A) - (J) (No change.)

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

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

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

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

101 (2) - (8) (No change.)

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

104 (A) - (C) (No change.)

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

109 (E) - (H) (No change.)

110 (e) Records.

111 (1) - (2) (No change.)

112 (3) Patient records.

113 (A) - (F) (No change.)

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

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

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

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

- 125 (II) prescribing or attending practitioner's name;
- 126 (III) name, strength, and dosage form of the drug product actually distributed;
- 127 (IV) total quantity distributed from and returned to the pharmacy;
- 128 (V) if not immediately retrievable via electronic image, the following shall also be included on
129 the printout:
- 130 (-a-) prescribing or attending practitioner's address; and
- 131 (-b-) practitioner's DEA registration number, if the medication order is for a controlled
132 substance.
- 133 (iii) An audit trail printout for each strength and dosage form of these drugs distributed during
134 the preceding month shall be produced at least monthly and shall be maintained in a separate file
135 at the facility. The information on this printout shall be sorted by drug name and list all
136 distributions/returns for that drug chronologically.
- 137 (iv) The pharmacy may elect not to produce the monthly audit trail printout if the data processing
138 system has a workable (electronic) data retention system which can produce an audit trail of drug
139 distribution and returns for the preceding two years. The audit trail required in this clause shall
140 be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas
141 State Board of Pharmacy, or other authorized local, state, or federal law enforcement or
142 regulatory agencies.
- 143 (H) - (I) (No change.)
- 144 (4) Distribution of controlled substances to another registrant. A pharmacy may distribute
145 controlled substances to a practitioner, another pharmacy, or other registrant, without being
146 registered to distribute, under the following conditions.
- 147 (A) - (C) (No change.)
- 148 (D) If the distribution is for a Schedule [~~I~~] II controlled substance, the following is applicable.
- 149 (i) The pharmacy, practitioner, or other registrant who is receiving the controlled substances
150 shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222C) to the distributing pharmacy.
- 151 (ii) The distributing pharmacy shall:
- 152 (I) complete the area on the DEA order form (DEA 222C) titled "To Be Filled in by Supplier";
- 153 (II) maintain Copy 1 of the DEA order form (DEA 222C) at the pharmacy for two years; and

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

156 (5) - (6) (No change.)

157 The agency certifies that legal counsel has reviewed the proposal and found it to be within the
158 state agency's legal authority to adopt.

159 Filed with the Office of the Secretary of State on May 30, 2014.

160 TRD-201402547

161 Gay Dodson, R.Ph.

162 Executive Director

163 Texas State Board of Pharmacy

164 Earliest possible date of adoption: July 13, 2014

165 For further information, please call: (512) 305-8073

166

1 **SUBCHAPTER H. OTHER CLASSES OF PHARMACY**

2 **22 TAC §291.151**

3 The Texas State Board of Pharmacy proposes amendments to §291.151, concerning Pharmacies
4 Located in a Freestanding Emergency Medical Care Center (Class F). The proposed
5 amendments, if adopted, clarify the labeling requirements for medications provided by Class F
6 pharmacies; remove references to sterile compounding that are no longer necessary; and add
7 tramadol to the record keeping requirements to be consistent with other sections.

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

11 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
12 effect, the public benefit anticipated as a result of enforcing the amendments will ensure
13 outpatient medications provided by the pharmacy are adequately labeled; ensure appropriate
14 records for tramadol are maintained by the pharmacy; and eliminate references to sterile
15 compounding that are no longer necessary.

16 Written comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director
17 of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,
18 Austin, Texas 78701, fax (512) 305-8008. Comments must be received by 5:00 p.m., July 31,
19 2014.

20 The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act
21 (Chapters 551 - 566, 568 and 569, Texas Occupations Code). The Board interprets §551.002 as
22 authorizing the agency to protect the public through the effective control and regulation of the
23 practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules
24 for the proper administration and enforcement of the Act.

25 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566, 568 and
26 569, Texas Occupations Code.

27 ***§291.151. Pharmacies Located in a Freestanding Emergency Medical Care Center (Class F).***

28 (a) - (b) (No change.)

29 (c) Personnel.

30 (1) - (2) (No change.)

31 (3) Pharmacists.

32 (A) - (B) (No change.)

- 33 (C) Special requirements for compounding non-sterile preparations.
- 34 ~~[(i) [Non-Sterile Preparations.] All pharmacists engaged in compounding non-sterile~~
35 ~~preparations shall meet the training requirements specified in §291.131 of this title (relating to~~
36 ~~Pharmacies Compounding Non-Sterile Preparations).~~
- 37 ~~[(ii) Sterile Preparations. All pharmacists engaged in compounding sterile preparations shall~~
38 ~~meet the training requirements specified in §291.133 of this title (relating to Pharmacies~~
39 ~~Compounding Sterile Preparations).]~~
- 40 (4) Pharmacy technicians and pharmacy technician trainees.
- 41 (A) (No change.)
- 42 (B) Duties. Duties may include, but need not be limited to, the following functions, under the
43 direct supervision of a pharmacist:
- 44 (i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises
45 and conducts a final check and affixes his or her name, initials, electronic signature to the
46 appropriate quality control records prior to distribution;
- 47 (ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication
48 orders, provided a pharmacist supervises and checks the preparation;
- 49 (iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy
50 technicians or pharmacy technician trainees have completed the training specified in §291.131 of
51 this title;
- 52 ~~[(iv) compounding sterile preparations pursuant to medication orders provided the pharmacy~~
53 ~~technicians or pharmacy technician trainees:]~~
- 54 ~~[(I) have completed the training specified in §291.133 of this title; and]~~
- 55 ~~[(II) are supervised by a pharmacist who has completed the sterile preparations training specified~~
56 ~~in §291.133 of this title, conducts in-process and final checks, and affixes his or her name,~~
57 ~~initials, or electronic signature to the label or if batch prepared to the appropriate quality control~~
58 ~~records. (The name, initials, or electronic signature are not required on the label if it is~~
59 ~~maintained in a permanent record of the pharmacy.)]~~
- 60 (iv) ~~[(v)]~~ bulk compounding, provided a pharmacist supervises and conducts in-process and final
61 checks and affixes his or her name, initials, or electronic signature to the appropriate quality
62 control records prior to distribution;
- 63 (v) ~~[(vi)]~~ distributing routine orders for stock supplies to patient care areas;

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

68 (vii) [~~(viii)~~] maintaining inventories of drug supplies;

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

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

73 (C) (No change.)

74 (D) Special requirements for compounding non-sterile preparations.

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

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

81 (5) - (6) (No change.)

82 (d) Operational standards.

83 (1) Licensing requirements.

84 (A) - (I) (No change.)

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

87 (2) - (8) (No change.)

88 (9) Drugs supplied for outpatient use. Drugs supplied to patients for outpatient use shall be
89 supplied according to the following procedures.

90 (A) - (C) (No change.)

91 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in
92 suitable containers and appropriately pre-labeled (including name, address, phone number of the
93 facility and necessary auxiliary labels) by the pharmacy, provided, however that topicals and

94 ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-
95 hour supply.

96 (E) - (H) (No change.)

97 (e) Records.

98 (1) - (2) (No change.)

99 (3) Patient records.

100 (A) - (F) (No change.)

101 (G) Data processing system maintenance of records for the distribution and return of all
102 controlled substances, tramadol (Ultram), and nalbuphine (Nubain) to the pharmacy.

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

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

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

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

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

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

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

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

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

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

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

129 (H) - (I) (No change.)

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

133 (A) - (C) (No change.)

134 (D) If the distribution is for a Schedule [~~I~~] II controlled substance, the following is applicable.

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

137 (ii) The distributing pharmacy shall:

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

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

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

142 (5) - (6) (No change.)

143 The agency certifies that legal counsel has reviewed the proposal and found it to be within the
144 state agency's legal authority to adopt.

145 Filed with the Office of the Secretary of State on May 30, 2014.

146 TRD-201402549

147 Gay Dodson, R.Ph.

148 Executive Director

149 Texas State Board of Pharmacy

150 Earliest possible date of adoption: July 13, 2014

151 For further information, please call: (512) 305-8073