

## RULE ANALYSIS

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

**Short Title:** Written Agreements

**Rule Numbers:** §§291.131, 291.133

**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, clarify the requirements regarding written agreements for supplying compounded preparations for office use and make formatting changes.

1 TITLE 22 EXAMINING BOARDS  
2 PART 15 TEXAS STATE BOARD OF PHARMACY  
3 CHAPTER 291 PHARMACIES  
4 SUBCHAPTER G SERVICES PROVIDED BY PHARMACIES  
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6 **§291.131 Pharmacies Compounding Non-Sterile Preparations**  
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9 (a) – (e) (No change.)  
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11 (f) Office Use Compounding and Distribution of Compounded Preparations to Class C  
12 Pharmacies or Veterinarians in Accordance With §563.054 of the Act.

13 (1) General.

14 (A) A pharmacy may dispense and deliver a reasonable quantity of a compounded  
15 preparation to a practitioner for office use by the practitioner in accordance with this subsection.

16 (B) A Class A ~~[(Community)]~~ pharmacy is not required to register or be licensed under  
17 Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations to a  
18 Class C ~~[(Institutional)]~~ pharmacy.

19 (C) A Class C ~~[(Institutional)]~~ pharmacy is not required to register or be licensed under  
20 Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations that  
21 the Class C pharmacy has compounded for other Class C pharmacies under common  
22 ownership.

23 (D) To dispense and deliver a compounded preparation under this subsection, a pharmacy  
24 must:

25 (i) verify the source of the raw materials to be used in a compounded drug;

26 (ii) comply with applicable United States Pharmacopoeia guidelines, including the testing  
27 requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No.  
28 104-191);

29 (iii) enter into a written agreement with a practitioner for the practitioner's office use of a  
30 compounded preparation;

31 (iv) comply with all applicable competency and accrediting standards as determined by the  
32 board; and

33 (v) comply with the provisions of this subsection.

34 (2) Written Agreement. A pharmacy that provides non-sterile compounded preparations to  
35 practitioners for office use or to another pharmacy shall enter into a written agreement with the  
36 practitioner or pharmacy. The written agreement shall:

37 (A) address acceptable standards of practice for a compounding pharmacy and a practitioner  
38 and receiving pharmacy that enter into the agreement including a statement that the  
39 compounded preparations may only be administered to the patient and may not be dispensed to  
40 the patient or sold to any other person or entity except as authorized by §563.054 of the Act;

41 (B) **state that** ~~[require]~~ the practitioner or receiving pharmacy **should** ~~[to]~~ include on a  
42 **separate log or in a** patient's chart, medication order, or medication administration record, the  
43 lot number and beyond-use date of a compounded preparation administered to a patient; and

44 (C) describe the scope of services to be performed by the pharmacy and practitioner or  
45 receiving pharmacy, including a statement of the process for:

46 (i) a patient to report an adverse reaction or submit a complaint; and

47 (ii) the pharmacy to recall batches of compounded preparations.

48 (3) Recordkeeping.

49 (A) Maintenance of Records.

50 (i) Records of orders and distribution of non-sterile compounded preparations to a  
51 practitioner for office use or to a Class C ~~[(Institutional)]~~ pharmacy for administration to a patient  
52 shall:

53 (I) be kept by the pharmacy and be available, for at least two years from the date of the  
54 record, for inspecting and copying by the board or its representative and to other authorized  
55 local, state, or federal law enforcement agencies;

56 (II) maintained separately from the records of products dispensed pursuant to a  
57 prescription or medication order; and

58 (III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the  
59 Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in  
60 an electronic format, the requested records must be provided in an electronic format. Failure to  
61 provide the records set out in this subsection, either on site or within 72 hours for whatever  
62 reason, constitutes prima facie evidence of failure to keep and maintain records.

63 (ii) Records may be maintained in an alternative data retention system, such as a data  
64 processing system or direct imaging system provided the data processing system is capable of  
65 producing a hard copy of the record upon the request of the board, its representative, or other  
66 authorized local, state, or federal law enforcement or regulatory agencies.

67 (B) Orders. The pharmacy shall maintain a record of all non-sterile compounded  
68 preparations ordered by a practitioner for office use or by a Class C pharmacy for administration  
69 to a patient. The record shall include the following information:

70 (i) date of the order;

71 (ii) name, address, and phone number of the practitioner who ordered the preparation and if  
72 applicable, the name, address and phone number of the Class C pharmacy ordering the  
73 preparation; and

74 (iii) name, strength, and quantity of the preparation ordered.

75 (C) Distributions. The pharmacy shall maintain a record of all non-sterile compounded  
76 preparations distributed pursuant to an order to a practitioner for office use or by a Class C  
77 pharmacy for administration to a patient. The record shall include the following information:

78 (i) date the preparation was compounded;

79 (ii) date the preparation was distributed;

80 (iii) name, strength and quantity in each container of the preparation;

81 (iv) pharmacy's lot number;

82 (v) quantity of containers shipped; and

83 (vi) name, address, and phone number of the practitioner or Class C pharmacy to whom the  
84 preparation is distributed.

85 (D) Audit Trail.

86 (i) The pharmacy shall store the order and distribution records of preparations for all non-  
87 sterile compounded preparations ordered by and or distributed to a practitioner for office use or  
88 by a Class C pharmacy for administration to a patient in such a manner as to be able to provide  
89 a audit trail for all orders and distributions of any of the following during a specified time period.

90 (I) any strength and dosage form of a preparation (by either brand or generic name or  
91 both);

92 (II) any ingredient;

93 (III) any lot number;

94 (IV) any practitioner;

95 (V) any facility; and

96 (VI) any pharmacy, if applicable.

97 (ii) The audit trail shall contain the following information:

98 (I) date of order and date of the distribution;

99 (II) practitioner's name, address, and name of the Class C pharmacy, if applicable;

100 (III) name, strength and quantity of the preparation in each container of the preparation;

- 101 (IV) name and quantity of each active ingredient;  
102 (V) quantity of containers distributed; and  
103 (VI) pharmacy's lot number;  
104 (4) Labeling. The pharmacy shall affix a label to the preparation containing the following  
105 information:  
106 (A) name, address, and phone number of the compounding pharmacy;  
107 (B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation  
108 is distributed to a veterinarian the statement: "Compounded Preparation";  
109 (C) name and strength of the preparation or list of the active ingredients and strengths;  
110 (D) pharmacy's lot number;  
111 (E) beyond-use date as determined by the pharmacist using appropriate documented  
112 criteria;  
113 (F) quantity or amount in the container;  
114 (G) appropriate ancillary instructions, such as storage instructions or cautionary statements,  
115 including hazardous drug warning labels where appropriate; and  
116 (H) device-specific instructions, where appropriate.

117  
118 (g) (No change.)

119  
120 **§291.133 Pharmacies Compounding Sterile Preparations**

121  
122 (a) – (e) (No change.)

123  
124 (f) Office Use Compounding and Distribution of Sterile Compounded Preparations

125 (1) General.

126 (A) A pharmacy may compound, dispense, deliver, and distribute a compounded sterile  
127 preparation as specified in Subchapter D, Texas Pharmacy Act Chapter 562.

128 (B) A Class A-S pharmacy is not required to register or be licensed under Chapter 431,  
129 Health and Safety Code, to distribute sterile compounded preparations to a Class C or Class C-  
130 S pharmacy.

131 (C) A Class C-S pharmacy is not required to register or be licensed under Chapter 431,  
132 Health and Safety Code, to distribute sterile compounded preparations that the Class C-S  
133 pharmacy has compounded for other Class C or Class C-S pharmacies under common  
134 ownership.

135 (D) To compound and deliver a compounded preparation under this subsection, a pharmacy  
136 must:

137 (i) verify the source of the raw materials to be used in a compounded drug;

138 (ii) comply with applicable United States Pharmacopoeia guidelines, including the testing  
139 requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No.  
140 104-191);

141 (iii) enter into a written agreement with a practitioner for the practitioner's office use of a  
142 compounded preparation;

143 (iv) comply with all applicable competency and accrediting standards as determined by the  
144 board; and

145 (v) comply with the provisions of this subsection.

146 (E) This subsection does not apply to Class B pharmacies compounding sterile  
147 radiopharmaceuticals that are furnished for departmental or physicians' use if such authorized  
148 users maintain a Texas radioactive materials license.

149 (2) Written Agreement. A pharmacy that provides sterile compounded preparations to  
150 practitioners for office use or to another pharmacy shall enter into a written agreement with the  
151 practitioner or pharmacy. The written agreement shall:

152 (A) address acceptable standards of practice for a compounding pharmacy and a practitioner  
153 and receiving pharmacy that enter into the agreement including a statement that the  
154 compounded drugs may only be administered to the patient and may not be dispensed to the  
155 patient or sold to any other person or entity except to a veterinarian as authorized by §563.054  
156 of the Act;

157 (B) ) **state that** [~~require~~] the practitioner or receiving pharmacy **should** [~~to~~] include on a  
158 **separate log, or in a** patient's chart, medication order, or medication administration record, the  
159 lot number and beyond-use date of a compounded preparation administered to a patient; and

160 (C) describe the scope of services to be performed by the pharmacy and practitioner or  
161 receiving pharmacy, including a statement of the process for:

162 (i) a patient to report an adverse reaction or submit a complaint; and

163 (ii) the pharmacy to recall batches of compounded preparations.

164 (3) Recordkeeping.

165 (A) Maintenance of Records.

166 (i) Records of orders and distribution of sterile compounded preparations to a practitioner for  
167 office use or to an institutional pharmacy for administration to a patient shall:

168 (I) be kept by the pharmacy and be available, for at least two years from the date of the  
169 record, for inspecting and copying by the board or its representative and to other authorized  
170 local, state, or federal law enforcement agencies;

171 (II) maintained separately from the records of preparations dispensed pursuant to a  
172 prescription or medication order; and

173 (III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the  
174 Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in  
175 an electronic format, the requested records must be provided in an electronic format. Failure to  
176 provide the records set out in this subsection, either on site or within 72 hours for whatever  
177 reason, constitutes prima facie evidence of failure to keep and maintain records.

178 (ii) Records may be maintained in an alternative data retention system, such as a data  
179 processing system or direct imaging system provided the data processing system is capable of  
180 producing a hard copy of the record upon the request of the board, its representative, or other  
181 authorized local, state, or federal law enforcement or regulatory agencies.

182 (B) Orders. The pharmacy shall maintain a record of all sterile compounded preparations  
183 ordered by a practitioner for office use or by an institutional pharmacy for administration to a  
184 patient. The record shall include the following information:

185 (i) date of the order;

186 (ii) name, address, and phone number of the practitioner who ordered the preparation and if  
187 applicable, the name, address and phone number of the institutional pharmacy ordering the  
188 preparation; and

189 (iii) name, strength, and quantity of the preparation ordered.

190 (C) Distributions. The pharmacy shall maintain a record of all sterile compounded  
191 preparations distributed pursuant to an order to a practitioner for office use or by an institutional  
192 pharmacy for administration to a patient. The record shall include the following information:

193 (i) date the preparation was compounded;

194 (ii) date the preparation was distributed;

195 (iii) name, strength and quantity in each container of the preparation;

196 (iv) pharmacy's lot number;

197 (v) quantity of containers shipped; and

198 (vi) name, address, and phone number of the practitioner or institutional pharmacy to whom  
199 the preparation is distributed.

200 (D) Audit Trail.

201 (i) The pharmacy shall store the order and distribution records of preparations for all sterile  
202 compounded preparations ordered by and or distributed to a practitioner for office use or by a

203 pharmacy licensed to compound sterile preparations for administration to a patient in such a  
204 manner as to be able to provide an audit trail for all orders and distributions of any of the  
205 following during a specified time period:  
206 (I) any strength and dosage form of a preparation (by either brand or generic name or  
207 both);  
208 (II) any ingredient;  
209 (III) any lot number;  
210 (IV) any practitioner;  
211 (V) any facility; and  
212 (VI) any pharmacy, if applicable.  
213 (ii) The audit trail shall contain the following information:  
214 (I) date of order and date of the distribution;  
215 (II) practitioner's name, address, and name of the institutional pharmacy, if applicable;  
216 (III) name, strength and quantity of the preparation in each container of the preparation;  
217 (IV) name and quantity of each active ingredient;  
218 (V) quantity of containers distributed; and  
219 (VI) pharmacy's lot number.  
220 (4) Labeling. The pharmacy shall affix a label to the preparation containing the following  
221 information:  
222 (A) name, address, and phone number of the compounding pharmacy;  
223 (B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation  
224 is distributed to a veterinarian the statement: "Compounded Preparation";  
225 (C) name and strength of the preparation or list of the active ingredients and strengths;  
226 (D) pharmacy's lot number;  
227 (E) beyond-use date as determined by the pharmacist using appropriate documented  
228 criteria;  
229 (F) quantity or amount in the container;  
230 (G) appropriate ancillary instructions, such as storage instructions or cautionary statements,  
231 including hazardous drug warning labels where appropriate; and  
232 (H) device-specific instructions, where appropriate.  
233  
234 (g) (No change.)