

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED RULE

Short Title: Controlled Substance Prescriptions

Rule Numbers: §291.104

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, update the requirements for Class E pharmacies to submit prescription to the Texas State Board of Pharmacy instead of the Texas Department of Public Safety.

The Board reviewed and voted to propose the amendments during the May 3, 2016, meeting. The proposed amendments were published in the June 24, 2016, issue of the *Texas Register* at 41 TexReg 4608.

1 **SUBCHAPTER F. NON-RESIDENT PHARMACY (CLASS E)**

2 **22 TAC §291.104**

3 The Texas State Board of Pharmacy proposes amendments to §291.104, concerning Operational
4 Standards. The amendments, if adopted, update the requirements for Class E pharmacies to
5 submit prescription to the Texas State Board of Pharmacy instead of the Texas Department of
6 Public Safety.

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

10 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
11 effect, the public benefit anticipated as a result of enforcing the amendments will ensure
12 prescriptions for residents of Texas are properly submitted to the Texas Prescription Monitoring
13 Program. There is no fiscal impact for individuals, small or large businesses, or to other entities
14 which are required to comply with this section.

15 Written comments on the amendments may be submitted to Allison Vordenbaumen Benz, R.Ph.,
16 M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street,
17 Suite 3-600, Austin, Texas 78701, FAX (512) 305-6778. Comments must be received by 5 p.m.,
18 August 1, 2016.

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

24 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas
25 Occupations Code.

26 **§291.104.Operational Standards.**

27 (a) Licensing requirements.

28 (1) A Class E pharmacy shall register with the board on a pharmacy license application provided
29 by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy
30 License Application).

31 (2) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this
32 title (relating to Pharmacy License Application) and then provide the following additional
33 information specified in §560.052(c) and (f) of the Act (relating to Qualifications):

- 34 (A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the
35 state in which the pharmacy is located;
- 36 (B) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;
- 37 (C) evidence of the applicant's ability to provide to the board a record of a prescription drug
38 order dispensed by the applicant to a resident of this state not later than 72 hours after the time
39 the board requests the record;
- 40 (D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read and
41 understands the laws and rules relating to a Class E pharmacy;
- 42 (E) proof of creditworthiness; and
- 43 (F) an inspection report issued not more than two years before the date the license application is
44 received and conducted by the pharmacy licensing board in the state of the pharmacy's physical
45 location.
- 46 (i) A Class E pharmacy may submit an inspection report issued by an entity other than the
47 pharmacy licensing board of the state in which the pharmacy is physically located if the state's
48 licensing board does not conduct inspections as follows:
- 49 (I) an individual approved by the board who is not employed by the pharmacy but acting as a
50 consultant to inspect the pharmacy;
- 51 (II) an agent of the National Association of Boards of Pharmacy;
- 52 (III) an agent of another State Board of Pharmacy; or
- 53 (IV) an agent of an accrediting body, such as the Joint Commission on Accreditation of
54 Healthcare Organizations.
- 55 (ii) The inspection must be substantively equivalent to an inspection conducted by the board.
- 56 (3) On renewal of a license, the pharmacy shall complete the renewal application provided by the
57 board and, as specified in §561.0031 of the Act, provide an inspection report issued not more
58 than three years before the date the renewal application is received and conducted by the
59 pharmacy licensing board in the state of the pharmacy's physical location.
- 60 (A) A Class E pharmacy may submit an inspection report issued by an entity other than the
61 pharmacy licensing board of the state in which the pharmacy is physically located if the state's
62 licensing board does not conduct inspections as follows:
- 63 (i) an individual approved by the board who is not employed by the pharmacy but acting as a
64 consultant to inspect the pharmacy;

- 65 (ii) an agent of the National Association of Boards of Pharmacy;
- 66 (iii) an agent of another State Board of Pharmacy; or
- 67 (iv) an agent of an accrediting body, such as the Joint Commission on Accreditation of
68 Healthcare Organizations.
- 69 (B) The inspection must be substantively equivalent to an inspection conducted by the board.
- 70 (4) A Class E pharmacy which changes ownership shall notify the board within ten days of the
71 change of ownership and apply for a new and separate license as specified in §291.3 of this title
72 (relating to Required Notifications).
- 73 (5) A Class E pharmacy which changes location and/or name shall notify the board [~~within ten~~
74 ~~days~~] of the change [~~and file for an amended license~~] as specified in §291.3 of this title.
- 75 (6) A Class E pharmacy owned by a partnership or corporation which changes managing officers
76 shall notify the board in writing of the names of the new managing officers within ten days of the
77 change, following the procedures in §291.3 of this title.
- 78 (7) A Class E pharmacy shall notify the board in writing within ten days of closing.
- 79 (8) A separate license is required for each principal place of business and only one pharmacy
80 license may be issued to a specific location.
- 81 (9) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged
82 for the issuance and renewal of a license and the issuance of an amended license.
- 83 (10) The board may grant an exemption from the licensing requirements of this Act on the
84 application of a pharmacy located in a state of the United States other than this state that restricts
85 its dispensing of prescription drugs or devices to residents of this state to isolated transactions.
- 86 (11) A Class E pharmacy engaged in the centralized dispensing of prescription drug or
87 medication orders shall comply with the provisions of §291.125 of this title (relating to
88 Centralized Prescription Dispensing).
- 89 (12) A Class E pharmacy engaged in central processing of prescription drug or medication orders
90 shall comply with the provisions of §291.123 of this title (relating to Central Prescription or
91 Medication Order Processing).
- 92 (13) A Class E pharmacy engaged in the compounding of non-sterile preparations shall comply
93 with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile
94 Preparations).
- 95 (14) Class E pharmacy personnel shall not compound sterile preparations unless the pharmacy
96 has applied for and obtained a Class E-S pharmacy.

97 (15) A Class E pharmacy, which operates as a community type of pharmacy which would
98 otherwise be required to be licensed under the Act §560.051(a)(1) (Community Pharmacy (Class
99 A)), shall comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of
100 this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34
101 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription
102 Records), contained in Community Pharmacy (Class A); or which operates as a nuclear type of
103 pharmacy which would otherwise be required to be licensed under the Act §560.051(a)(2)
104 (Nuclear Pharmacy (Class B)), shall comply with the provisions of §291.51 of this title (relating
105 to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to
106 Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title
107 (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are
108 applicable to the operation of the pharmacy.

109 (b) Prescription dispensing and delivery.

110 (1) General.

111 (A) All prescription drugs and/or devices shall be dispensed and delivered safely and accurately
112 as prescribed.

113 (B) The pharmacy shall maintain adequate storage or shipment containers and use shipping
114 processes to ensure drug stability and potency. Such shipping processes shall include the use of
115 packaging material and devices to ensure that the drug is maintained at an appropriate
116 temperature range to maintain the integrity of the medication throughout the delivery process.

117 (C) The pharmacy shall utilize a delivery system which is designed to assure that the drugs are
118 delivered to the appropriate patient.

119 (D) All pharmacists shall exercise sound professional judgment with respect to the accuracy and
120 authenticity of any prescription drug order they dispense. If the pharmacist questions the
121 accuracy or authenticity of a prescription drug order, he/she shall verify the order with the
122 practitioner prior to dispensing.

123 (E) Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound
124 professional judgment, that the prescription is a valid prescription. A pharmacist may not
125 dispense a prescription drug if the pharmacist knows or should have known that the prescription
126 was issued on the basis of an Internet-based or telephonic consultation without a valid patient-
127 practitioner relationship.

128 (F) Subparagraph (E) of this paragraph does not prohibit a pharmacist from dispensing a
129 prescription when a valid patient-practitioner relationship is not present in an emergency
130 situation (e.g. a practitioner taking calls for the patient's regular practitioner).

131 (2) Drug regimen review.

132 (A) For the purpose of promoting therapeutic appropriateness, a pharmacist shall prior to or at
133 the time of dispensing a prescription drug order, review the patient's medication record. Such
134 review shall at a minimum identify clinically significant:

135 (i) inappropriate drug utilization;

136 (ii) therapeutic duplication;

137 (iii) drug-disease contraindications;

138 (iv) drug-drug interactions;

139 (v) incorrect drug dosage or duration of drug treatment;

140 (vi) drug-allergy interactions; and

141 (vii) clinical abuse/misuse.

142 (B) Upon identifying any clinically significant conditions, situations, or items listed in
143 subparagraph (A) of this paragraph, the pharmacist shall take appropriate steps to avoid or
144 resolve the problem including consultation with the prescribing practitioner. The pharmacist
145 shall document such occurrences.

146 (3) Patient counseling and provision of drug information.

147 (A) To optimize drug therapy, a pharmacist shall communicate to the patient or the patient's
148 agent, information about the prescription drug or device which in the exercise of the pharmacist's
149 professional judgment the pharmacist deems significant, such as the following:

150 (i) the name and description of the drug or device;

151 (ii) dosage form, dosage, route of administration, and duration of drug therapy;

152 (iii) special directions and precautions for preparation, administration, and use by the patient;

153 (iv) common severe side or adverse effects or interactions and therapeutic contraindications that
154 may be encountered, including their avoidance, and the action required if they occur;

155 (v) techniques for self-monitoring of drug therapy;

156 (vi) proper storage;

157 (vii) refill information; and

158 (viii) action to be taken in the event of a missed dose.

159 (B) Such communication shall be:

160 (i) provided to new and existing patients of a pharmacy with each new prescription drug order. A
161 new prescription drug order is one that has not been dispensed by the pharmacy to the patient in
162 the same dosage and strength within the last year;

163 (ii) provided for any prescription drug order dispensed by the pharmacy on the request of the
164 patient or patient's agent;

165 (iii) communicated orally in person unless the patient or patient's agent is not at the pharmacy or
166 a specific communication barrier prohibits such oral communication; and

167 (iv) reinforced with written information. The following is applicable concerning this written
168 information:

169 (I) Written information must be in plain language designed for the patient and printed in an
170 easily readable font comparable to but no smaller than ten-point Times Roman. This information
171 may be provided to the patient in an electronic format, such as by e-mail, if the patient or
172 patient's agent requests the information in an electronic format and the pharmacy documents the
173 request.

174 (II) When a compounded product is dispensed, information shall be provided for the major active
175 ingredient(s), if available.

176 (III) For new drug entities, if no written information is initially available, the pharmacist is not
177 required to provide information until such information is available, provided:

178 (-a-) the pharmacist informs the patient or the patient's agent that the product is a new drug entity
179 and written information is not available;

180 (-b-) the pharmacist documents the fact that no written information was provided; and

181 (-c-) if the prescription is refilled after written information is available, such information is
182 provided to the patient or patient's agent.

183 (IV) The written information accompanying the prescription or the prescription label shall
184 contain the statement "Do not flush unused medications or pour down a sink or drain." A drug
185 product on a list developed by the Federal Food and Drug Administration of medicines
186 recommended for disposal by flushing is not required to bear this statement.

187 (C) Only a pharmacist may orally provide drug information to a patient or patient's agent and
188 answer questions concerning prescription drugs. Non-pharmacist personnel may not ask
189 questions of a patient or patient's agent which are intended to screen and/or limit interaction with
190 the pharmacist.

191 (D) If prescriptions are routinely delivered outside the area covered by the pharmacy's local
192 telephone service, the pharmacy shall provide a toll-free telephone line which is answered during
193 normal business hours to enable communication between the patient and a pharmacist.

194 (E) The pharmacist shall place on the prescription container or on a separate sheet delivered with
195 the prescription container in both English and Spanish the local and toll-free telephone number
196 of the pharmacy and the statement: "Written information about this prescription has been
197 provided for you. Please read this information before you take the medication. If you have
198 questions concerning this prescription, a pharmacist is available during normal business hours to
199 answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."

200 (F) The provisions of this paragraph do not apply to patients in facilities where drugs are
201 administered to patients by a person required to do so by the laws of the state (i.e., nursing
202 homes).

203 (G) Upon delivery of a refill prescription, a pharmacist shall ensure that the patient or patient's
204 agent is offered information about the refilled prescription and that a pharmacist is available to
205 discuss the patient's prescription and provide information.

206 (H) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide
207 consultation when a patient or patient's agent refuses such consultation. The pharmacist shall
208 document such refusal for consultation.

209 (4) Labeling. At the time of delivery, the dispensing container shall bear a label that contains the
210 following information:

211 (A) the name, physical address, and phone number of the pharmacy;

212 (B) if the drug is dispensed in a container other than the manufacturer's original container, the
213 date after which the prescription should not be used or beyond-use-date. Unless otherwise
214 specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is
215 dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may
216 be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is
217 not required on the label of a prescription dispensed to a person at the time of release from prison
218 or jail if the prescription is for not more than a 10-day supply of medication;

219 (C) either on the prescription label or the written information accompanying the prescription, the
220 statement, "Do not flush unused medications or pour down a sink or drain." A drug product on a
221 list developed by the Federal Food and Drug Administration of medicines recommended for
222 disposal by flushing is not required to bear this statement; and

223 (D) any other information that is required by the pharmacy or drug laws or rules in the state in
224 which the pharmacy is located.

225 (c) Substitution requirements.

226 (1) Unless compliance would violate the pharmacy or drug laws or rules in the state in which the
227 pharmacy is located a pharmacist in a Class E pharmacy may dispense a generically equivalent
228 drug or interchangeable biological product and shall comply with the provisions of §309.3 of this
229 title (relating to Substitution Requirements) and §309.7 of this title (relating to Dispensing
230 Responsibilities).

231 (2) The pharmacy must include on the prescription order form completed by the patient or the
232 patient's agent information that clearly and conspicuously:

233 (A) states that if a less expensive generically equivalent drug or interchangeable biological
234 product is available for the brand prescribed, the patient or the patient's agent may choose
235 between the generically equivalent drug or interchangeable biological product and the brand
236 prescribed; and

237 (B) allows the patient or the patient's agent to indicate the choice of the generically equivalent
238 drug or interchangeable biological product or the brand prescribed.

239 (d) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response to
240 the one prescribed shall not be made without prior approval of the prescribing practitioner. This
241 subsection does not apply to generic substitution. For generic substitution, see the requirements
242 of subsection (c) of this section.

243 (1) The patient shall be notified of the therapeutic drug interchange prior to, or upon delivery, of
244 the dispensed prescription to the patient. Such notification shall include:

245 (A) a description of the change;

246 (B) the reason for the change;

247 (C) whom to notify with questions concerning the change; and

248 (D) instructions for return of the drug if not wanted by the patient.

249 (2) The pharmacy shall maintain documentation of patient notification of therapeutic drug
250 interchange which shall include:

251 (A) the date of the notification;

252 (B) the method of notification;

253 (C) a description of the change; and

254 (D) the reason for the change.

255 (e) Transfer of Prescription Drug Order Information. Unless compliance would violate the
256 pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a

257 Class E pharmacy may not refuse to transfer prescriptions to another pharmacy that is making
258 the transfer request on behalf of the patient. The transfer of original prescription information
259 must be done within four business hours of the request.

260 (f) Prescriptions for Schedule II - V controlled substances. Unless compliance would violate the
261 pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a
262 Class E pharmacy who dispenses a prescription for a Schedule II - V controlled substance for a
263 resident of Texas [~~issued by a prescriber registered with the Texas Department of Public Safety~~]
264 shall[~~:~~

265 [~~(1) mail a copy of the prescription to the Texas Department of Public Safety, Texas Prescription~~
266 ~~Program, P.O. Box 4087, Austin, Texas 78773 within 7 days of dispensing; or~~

267 [~~(2)~~] electronically send the prescription information to the Texas State Board of Pharmacy as
268 specified in §315.6 of this title (relating to Pharmacy Responsibility - Electronic Reporting -
269 Effective September 1, 2016.) [~~Texas Department of Public Safety per their requirements for~~
270 ~~electronic submissions~~] within 7 days of dispensing.