

RULE ANALYSIS

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

1 **TITLE 22 EXAMINING BOARDS**
2 **PART 15 TEXAS STATE BOARD OF PHARMACY**
3 **CHAPTER 291 PHARMACIES**
4 **SUBCHAPTER F NON-RESIDENT PHARMACY (CLASS E)**

5
6 **§291.104 Operational Standards**

7
8 (a) Licensing requirements.

9
10 (1) A Class E pharmacy shall register with the board on a pharmacy license application
11 provided by the board, following the procedures specified in §291.1 of this title (relating to
12 Pharmacy License Application).

13
14 (2) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this
15 title (relating to Pharmacy License Application) and then provide the following additional
16 information specified in §560.052(c) and (f) of the Act (relating to Qualifications):

17
18 (A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the
19 state in which the pharmacy is located;

20
21 (B) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;

22
23 (C) evidence of the applicant's ability to provide to the board a record of a prescription drug
24 order dispensed by the applicant to a resident of this state not later than 72 hours after the time
25 the board requests the record;

26
27 (D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read and
28 understands the laws and rules relating to a Class E pharmacy;

29
30 (E) proof of creditworthiness; and

31
32 (F) an inspection report issued not more than two years before the date the license
33 application is received and conducted by the pharmacy licensing board in the state of the
34 pharmacy's physical location.

35
36 (i) A Class E pharmacy may submit an inspection report issued by an entity other than the
37 pharmacy licensing board of the state in which the pharmacy is physically located if the state's
38 licensing board does not conduct inspections as follows:

39
40 (I) an individual approved by the board who is not employed by the pharmacy but acting as
41 a consultant to inspect the pharmacy;

42
43 (II) an agent of the National Association of Boards of Pharmacy;

44
45 (III) an agent of another State Board of Pharmacy; or

46
47 (IV) an agent of an accrediting body, such as the Joint Commission on Accreditation of
48 Healthcare Organizations.

49
50 (ii) The inspection must be substantively equivalent to an inspection conducted by the
51 board.

52
53 (3) On renewal of a license, the pharmacy shall complete the renewal application provided by
54 the board and, as specified in §561.0031 of the Act, provide an inspection report issued not
55 more than three years before the date the renewal application is received and conducted by the
56 pharmacy licensing board in the state of the pharmacy's physical location.
57

58 (A) A Class E pharmacy may submit an inspection report issued by an entity other than the
59 pharmacy licensing board of the state in which the pharmacy is physically located if the state's
60 licensing board does not conduct inspections as follows:
61

62 (i) an individual approved by the board who is not employed by the pharmacy but acting as a
63 consultant to inspect the pharmacy;
64

65 (ii) an agent of the National Association of Boards of Pharmacy;
66

67 (iii) an agent of another State Board of Pharmacy; or
68

69 (iv) an agent of an accrediting body, such as the Joint Commission on Accreditation of
70 Healthcare Organizations.
71

72 (B) The inspection must be substantively equivalent to an inspection conducted by the board.
73

74 (4) A Class E pharmacy which changes ownership shall notify the board within ten days of the
75 change of ownership and apply for a new and separate license as specified in §291.3 of this title
76 (relating to Required Notifications).
77

78 (5) A Class E pharmacy which changes location and/or name shall notify the board [~~within ten~~
79 ~~days~~] of the change [~~and file for an amended license~~] as specified in §291.3 of this title.
80

81 (6) A Class E pharmacy owned by a partnership or corporation which changes managing
82 officers shall notify the board in writing of the names of the new managing officers within ten
83 days of the change, following the procedures in §291.3 of this title.
84

85 (7) A Class E pharmacy shall notify the board in writing within ten days of closing.
86

87 (8) A separate license is required for each principal place of business and only one pharmacy
88 license may be issued to a specific location.
89

90 (9) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged
91 for the issuance and renewal of a license and the issuance of an amended license.
92

93 (10) The board may grant an exemption from the licensing requirements of this Act on the
94 application of a pharmacy located in a state of the United States other than this state that
95 restricts its dispensing of prescription drugs or devices to residents of this state to isolated
96 transactions.
97

98 (11) A Class E pharmacy engaged in the centralized dispensing of prescription drug or
99 medication orders shall comply with the provisions of §291.125 of this title (relating to
100 Centralized Prescription Dispensing).
101

102 (12) A Class E pharmacy engaged in central processing of prescription drug or medication
103 orders shall comply with the provisions of §291.123 of this title (relating to Central Prescription
104 or Medication Order Processing).

105
106 (13) A Class E pharmacy engaged in the compounding of non-sterile preparations shall comply
107 with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile
108 Preparations).

109
110 (14) Class E pharmacy personnel shall not compound sterile preparations unless the
111 pharmacy has applied for and obtained a Class E-S pharmacy.

112
113 (15) A Class E pharmacy, which operates as a community type of pharmacy which would
114 otherwise be required to be licensed under the Act §560.051(a)(1) (Community Pharmacy
115 (Class A)), shall comply with the provisions of §291.31 of this title (relating to Definitions),
116 §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational
117 Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official
118 Prescription Records), contained in Community Pharmacy (Class A); or which operates as a
119 nuclear type of pharmacy which would otherwise be required to be licensed under the Act
120 §560.051(a)(2) (Nuclear Pharmacy (Class B)), shall comply with the provisions of §291.51 of
121 this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title
122 (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of
123 this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such
124 sections are applicable to the operation of the pharmacy.

125
126 (b) Prescription dispensing and delivery.

127
128 (1) General.

129
130 (A) All prescription drugs and/or devices shall be dispensed and delivered safely and
131 accurately as prescribed.

132
133 (B) The pharmacy shall maintain adequate storage or shipment containers and use shipping
134 processes to ensure drug stability and potency. Such shipping processes shall include the use
135 of packaging material and devices to ensure that the drug is maintained at an appropriate
136 temperature range to maintain the integrity of the medication throughout the delivery process.

137
138 (C) The pharmacy shall utilize a delivery system which is designed to assure that the drugs
139 are delivered to the appropriate patient.

140
141 (D) All pharmacists shall exercise sound professional judgment with respect to the accuracy
142 and authenticity of any prescription drug order they dispense. If the pharmacist questions the
143 accuracy or authenticity of a prescription drug order, he/she shall verify the order with the
144 practitioner prior to dispensing.

145
146 (E) Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound
147 professional judgment, that the prescription is a valid prescription. A pharmacist may not
148 dispense a prescription drug if the pharmacist knows or should have known that the prescription
149 was issued on the basis of an Internet-based or telephonic consultation without a valid patient-
150 practitioner relationship.

152 (F) Subparagraph (E) of this paragraph does not prohibit a pharmacist from dispensing a
153 prescription when a valid patient-practitioner relationship is not present in an emergency
154 situation (e.g. a practitioner taking calls for the patient's regular practitioner).
155

156 (2) Drug regimen review.
157

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

- 161 (i) inappropriate drug utilization;
- 162 (ii) therapeutic duplication;
- 163 (iii) drug-disease contraindications;
- 164 (iv) drug-drug interactions;
- 165 (v) incorrect drug dosage or duration of drug treatment;
- 166 (vi) drug-allergy interactions; and
- 167 (vii) clinical abuse/misuse.

175 (B) Upon identifying any clinically significant conditions, situations, or items listed in
176 subparagraph (A) of this paragraph, the pharmacist shall take appropriate steps to avoid or
177 resolve the problem including consultation with the prescribing practitioner. The pharmacist shall
178 document such occurrences.
179

180 (3) Patient counseling and provision of drug information.
181

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

- 185 (i) the name and description of the drug or device;
 - 186 (ii) dosage form, dosage, route of administration, and duration of drug therapy;
 - 187 (iii) special directions and precautions for preparation, administration, and use by the
188 patient;
 - 189 (iv) common severe side or adverse effects or interactions and therapeutic contraindications
190 that may be encountered, including their avoidance, and the action required if they occur;
 - 191 (v) techniques for self-monitoring of drug therapy;
 - 192 (vi) proper storage;
 - 193 (vii) refill information; and
- 194
195
196
197
198
199
200
201
202

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

204

205 (B) Such communication shall be:

206

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

210

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

213

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

216

217 (iv) reinforced with written information. The following is applicable concerning this written
218 information:

219

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

225

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

228

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

231

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

234

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

236

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

239

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

244

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

249

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

253

254 (E) The pharmacist shall place on the prescription container or on a separate sheet delivered
255 with the prescription container in both English and Spanish the local and toll-free telephone
256 number of the pharmacy and the statement: "Written information about this prescription has
257 been provided for you. Please read this information before you take the medication. If you have
258 questions concerning this prescription, a pharmacist is available during normal business hours
259 to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."
260

261 (F) The provisions of this paragraph do not apply to patients in facilities where drugs are
262 administered to patients by a person required to do so by the laws of the state (i.e., nursing
263 homes).
264

265 (G) Upon delivery of a refill prescription, a pharmacist shall ensure that the patient or patient's
266 agent is offered information about the refilled prescription and that a pharmacist is available to
267 discuss the patient's prescription and provide information.
268

269 (H) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide
270 consultation when a patient or patient's agent refuses such consultation. The pharmacist shall
271 document such refusal for consultation.
272

273 (4) Labeling. At the time of delivery, the dispensing container shall bear a label that contains
274 the following information:
275

276 (A) the name, physical address, and phone number of the pharmacy;
277

278 (B) if the drug is dispensed in a container other than the manufacturer's original container, the
279 date after which the prescription should not be used or beyond-use-date. Unless otherwise
280 specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is
281 dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may
282 be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is
283 not required on the label of a prescription dispensed to a person at the time of release from
284 prison or jail if the prescription is for not more than a 10-day supply of medication;
285

286 (C) either on the prescription label or the written information accompanying the prescription,
287 the statement, "Do not flush unused medications or pour down a sink or drain." A drug product
288 on a list developed by the Federal Food and Drug Administration of medicines recommended
289 for disposal by flushing is not required to bear this statement; and
290

291 (D) any other information that is required by the pharmacy or drug laws or rules in the state in
292 which the pharmacy is located.
293

294 (c) Substitution requirements.
295

296 (1) Unless compliance would violate the pharmacy or drug laws or rules in the state in which
297 the pharmacy is located a pharmacist in a Class E pharmacy may dispense a generically
298 equivalent drug or interchangeable biological product and shall comply with the provisions of
299 §309.3 of this title (relating to Substitution Requirements) and §309.7 of this title (relating to
300 Dispensing Responsibilities).
301

302 (2) The pharmacy must include on the prescription order form completed by the patient or the
303 patient's agent information that clearly and conspicuously:
304

305 (A) states that if a less expensive generically equivalent drug or interchangeable biological
306 product is available for the brand prescribed, the patient or the patient's agent may choose
307 between the generically equivalent drug or interchangeable biological product and the brand
308 prescribed; and
309

310 (B) allows the patient or the patient's agent to indicate the choice of the generically equivalent
311 drug or interchangeable biological product or the brand prescribed.
312

313 (d) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response to
314 the one prescribed shall not be made without prior approval of the prescribing practitioner. This
315 subsection does not apply to generic substitution. For generic substitution, see the requirements
316 of subsection (c) of this section.
317

318 (1) The patient shall be notified of the therapeutic drug interchange prior to, or upon delivery, of
319 the dispensed prescription to the patient. Such notification shall include:
320

321 (A) a description of the change;
322

323 (B) the reason for the change;
324

325 (C) whom to notify with questions concerning the change; and
326

327 (D) instructions for return of the drug if not wanted by the patient.
328

329 (2) The pharmacy shall maintain documentation of patient notification of therapeutic drug
330 interchange which shall include:
331

332 (A) the date of the notification;
333

334 (B) the method of notification;
335

336 (C) a description of the change; and
337

338 (D) the reason for the change.
339

340 (e) Transfer of Prescription Drug Order Information. Unless compliance would violate the
341 pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a
342 Class E pharmacy may not refuse to transfer prescriptions to another pharmacy that is making
343 the transfer request on behalf of the patient. The transfer of original prescription information
344 must be done within four business hours of the request.
345

346 (f) Prescriptions for Schedule II - V controlled substances. Unless compliance would violate the
347 pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a
348 Class E pharmacy who dispenses a prescription for a Schedule II - V controlled substance **for a**
349 **resident of Texas** [issued by a prescriber registered with the Texas Department of Public
350 Safety] shall[:
351

352 [~~(1) mail a copy of the prescription to the Texas Department of Public Safety, Texas~~
353 ~~Prescription Program, P.O. Box 4087, Austin, Texas 78773 within 7 days of dispensing; or]~~
354

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