

RULE ANALYSIS

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

Short Title: Inspections of Non-resident Pharmacies

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 rules to require non-resident (Class E) pharmacies to submit an inspection conducted within the last 2 year as part of the pharmacy application. The proposed change makes the requirement consistent with other sections of the rules.

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):
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18 (A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the
19 state in which the pharmacy is located;
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21 (B) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;
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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;
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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;
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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.
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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;
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43 (II) an agent of the National Association of Boards of Pharmacy;
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45 (III) an agent of another State Board of Pharmacy; or
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47 (IV) an agent of an accrediting body, such as the Joint Commission on Accreditation of
48 Healthcare Organizations.
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50 (ii) The inspection must be substantively equivalent to an inspection conducted by the
51 board.

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53 (3) On renewal of a license, the pharmacy shall complete the renewal application provided by
54 the board and, as specified in §561.031 of the Act, provide an inspection report issued not more
55 than two [~~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;
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65 (ii) an agent of the National Association of Boards of Pharmacy;
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67 (iii) an agent of another State Board of Pharmacy; or
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69 (iv) an agent of an accrediting body, such as the Joint Commission on Accreditation of
70 Healthcare Organizations.
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72 (B) The inspection must be substantively equivalent to an inspection conducted by the board.
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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).
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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.
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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.
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85 (7) A Class E pharmacy shall notify the board in writing within ten days of closing.
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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.
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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.
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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).

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110 (14) Prior to August 31, 2014, a Class E pharmacy engaged in the compounding of sterile
111 preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies
112 Compounding Sterile Preparations).

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114 (15) Effective August 31, 2014, a Class E pharmacy shall not compound sterile preparations
115 unless the pharmacy has applied for and obtained a Class E-S pharmacy.

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

129
130 (b) Prescription dispensing and delivery.

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132 (1) General.

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

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

141
142 (C) The pharmacy shall utilize a delivery system which is designed to assure that the drugs
143 are delivered to the appropriate patient.

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

149
150 (E) Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound
151 professional judgment, that the prescription is a valid prescription. A pharmacist may not
152 dispense a prescription drug if the pharmacist knows or should have known that the prescription

153 was issued on the basis of an Internet-based or telephonic consultation without a valid patient-
154 practitioner relationship.

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

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160 (2) Drug regimen review.

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

- 165 (i) inappropriate drug utilization;
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167 (ii) therapeutic duplication;
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169 (iii) drug-disease contraindications;
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171 (iv) drug-drug interactions;
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173 (v) incorrect drug dosage or duration of drug treatment;
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175 (vi) drug-allergy interactions; and
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177 (vii) clinical abuse/misuse.

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

183
184
185 (3) Patient counseling and provision of drug information.

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

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

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

(B) Such communication shall be:

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

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

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

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

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

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

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

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

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

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

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

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

254 (D) If prescriptions are routinely delivered outside the area covered by the pharmacy's local
255 telephone service, the pharmacy shall provide a toll-free telephone line which is answered
256 during normal business hours to enable communication between the patient and a pharmacist.
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258 (E) The pharmacist shall place on the prescription container or on a separate sheet delivered
259 with the prescription container in both English and Spanish the local and toll-free telephone
260 number of the pharmacy and the statement: "Written information about this prescription has
261 been provided for you. Please read this information before you take the medication. If you have
262 questions concerning this prescription, a pharmacist is available during normal business hours
263 to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."
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265 (F) The provisions of this paragraph do not apply to patients in facilities where drugs are
266 administered to patients by a person required to do so by the laws of the state (i.e., nursing
267 homes).
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269 (G) Upon delivery of a refill prescription, a pharmacist shall ensure that the patient or patient's
270 agent is offered information about the refilled prescription and that a pharmacist is available to
271 discuss the patient's prescription and provide information.
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273 (H) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide
274 consultation when a patient or patient's agent refuses such consultation. The pharmacist shall
275 document such refusal for consultation.
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277 (4) Labeling. At the time of delivery, the dispensing container shall bear a label that contains
278 the following information:
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280 (A) the name, physical address, and phone number of the pharmacy;
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282 (B) if the drug is dispensed in a container other than the manufacturer's original container, the
283 date after which the prescription should not be used or beyond-use-date. Unless otherwise
284 specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is
285 dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may
286 be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is
287 not required on the label of a prescription dispensed to a person at the time of release from
288 prison or jail if the prescription is for not more than a 10-day supply of medication;
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290 (C) either on the prescription label or the written information accompanying the prescription,
291 the statement, "Do not flush unused medications or pour down a sink or drain." A drug product
292 on a list developed by the Federal Food and Drug Administration of medicines recommended
293 for disposal by flushing is not required to bear this statement; and
294

295 (D) any other information that is required by the pharmacy or drug laws or rules in the state in
296 which the pharmacy is located.
297

298 (c) Generic Substitution.
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300 (1) Unless compliance would violate the pharmacy or drug laws or rules in the state in which
301 the pharmacy is located a pharmacist in a Class E pharmacy may dispense a generically
302 equivalent drug product and shall comply with the provisions of §309.3 of this title (relating to
303 Generic Substitution) and §309.7 of this title (relating to Dispensing Responsibilities).
304

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

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

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312 (B) allows the patient or the patient's agent to indicate the choice of the generically equivalent
313 drug or the brand prescribed.

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

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

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323 (A) a description of the change;

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325 (B) the reason for the change;

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

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

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

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334 (A) the date of the notification;

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336 (B) the method of notification;

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338 (C) a description of the change; and

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340 (D) the reason for the change.

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

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

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

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356 (2) electronically send the prescription information to the Texas Department of Public Safety
357 per their requirements for electronic submissions within 7 days of dispensing.