

RULE ANALYSIS

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

Short Title: Notifications

Rule Numbers: §291.3

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 a change of name for a pharmacy; update the notification requirements for internet sites verified by NABP; add a requirement for pharmacies and pharmacists to report disciplinary action by another state to TSBP as required by §562.106 of the Act; and clarify requirements to be 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 A ALL CLASSES OF PHARMACIES
5

6 **§291.3 Required Notification**
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8
9 (a) Change of Location [~~and/or Name~~].

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11 (1) When a pharmacy changes location [~~and/or name~~], the following is applicable.
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13 (A) A new completed pharmacy application containing the information outlined in §291.1 of
14 this title (relating to Pharmacy License Application), must be filed with the board not later than
15 30 days before the date of the change of location of the pharmacy.
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17 (B) The previously issued license must be returned to the board office.
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19 (C) An amended license reflecting the new location [~~and/or name~~] of the pharmacy will be
20 issued by the board; and
21

22 (D) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
23 charged for issuance of the amended license.
24

25 (2) At least 14 days prior to the change of location of a pharmacy that dispenses prescription
26 drug orders, the pharmacist-in-charge shall post a sign in a conspicuous place indicating that
27 the pharmacy is changing locations. Such sign shall be in the front of the prescription
28 department and at all public entrance doors to the pharmacy and shall indicate the date the
29 pharmacy is changing locations.
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31 (3) Disasters, accidents, and emergencies which require the pharmacy to change location shall
32 be immediately reported to the board. If a pharmacy changes location suddenly due to
33 disasters, accidents, or other emergency circumstances and the pharmacist-in-charge cannot
34 provide notification 14 days prior to the change of location, the pharmacist-in-charge shall
35 comply with the provisions of paragraph (2) of this subsection as far in advance of the change of
36 location as allowed by the circumstances.
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38 (b) **Change of Name. When a pharmacy changes its name, the following is applicable.**
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40 **(1) A new completed pharmacy application containing the information outlined in**
41 **§291.1 of this title (relating to Pharmacy License Application), must be filed with the**
42 **board within 10 days of the change of name of the pharmacy.**
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44 **(2) The previously issued license must be returned to the board office.**
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46 **(3) An amended license reflecting the new name of the pharmacy will be issued by the**
47 **board; and**
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49 **(4) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be**
50 **charged for issuance of the amended license.**
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52 **(c)** Change of Managing Officers.

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54 (1) The owner of a pharmacy shall notify the board in writing within 10 days of a change of any
55 managing officer of a partnership or corporation which owns a pharmacy. The written
56 notification shall include the effective date of such change and the following information for all
57 managing officers:

58 (A) name and title;

59 (B) home address and telephone number;

60 (C) date of birth;

61 (D) a copy of social security card or other official document showing the social security
62 number as approved by the board; [~~however, if an individual is unable to obtain a social security~~
63 ~~number, an individual taxpayer identification number may be provided in lieu of a social security~~
64 ~~number along with documentation indicating why the individual is unable to obtain a social~~
65 ~~security number;]~~ and

66 (E) a copy of current driver's license, state issued photo identification card, or passport.

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68 (2) For purposes of this subsection, managing officers are defined as the top four executive
69 officers, including the corporate officer in charge of pharmacy operations, who are designated
70 by the partnership or corporation to be jointly responsible for the legal operation of the
71 pharmacy.

72 **(d)** [~~(c)~~] Change of Ownership.

73 (1) When a pharmacy changes ownership, a new pharmacy application must be filed with the
74 board following the procedures as specified in §291.1 of this title (relating to Pharmacy License
75 Application). In addition, a copy of the purchase contract or mutual agreement between the
76 buyer and seller must be submitted.

77 (2) The license issued to the previous owner must be returned to the board.

78 (3) A fee as specified in §291.6 of this title will be charged for issuance of a new license.

79 **(e)** [~~(d)~~] Change of Pharmacist Employment.

80 (1) Change of pharmacist employed in a pharmacy. When a change in pharmacist employment
81 occurs, the pharmacist shall report such change in writing to the board within 10 days.

82 (2) Change of pharmacist-in-charge of a pharmacy. The incoming pharmacist-in-charge shall
83 be responsible for notifying the board within 10 days in writing on a form provided by the board
84 that a change of pharmacist-in-charge has occurred. The notification shall include the following:

85 (A) the name and license number of the departing pharmacist-in-charge;

86 (B) the name and license number of the incoming pharmacist-in-charge;

87 (C) the date the incoming pharmacist-in-charge became the pharmacist-in-charge; and

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(D) a statement signed by the incoming pharmacist-in-charge attesting that:

(i) an inventory, as specified in §291.17 of this title (relating to Inventory Requirements), has been conducted by the departing and incoming pharmacists-in-charge; if the inventory was not taken by both pharmacists, the statement shall provide an explanation; and

(ii) the incoming pharmacist-in-charge has read and understands the laws and rules relating to this class of pharmacy.

(f) [(e)] Notification of Theft or Loss of a Controlled Substance or a Dangerous Drug.

(1) Controlled substances. For the purposes of the Act, §562.106, the theft or significant loss of any controlled substance by a pharmacy shall be reported in writing to the board immediately on discovery of such theft or loss. A pharmacy shall be in compliance with this subsection by submitting to the board a copy of the Drug Enforcement Administration (DEA) report of theft or loss of controlled substances, DEA Form 106, or by submitting a list of all controlled substances stolen or lost.

(2) Dangerous drugs. A pharmacy shall report in writing to the board immediately on discovery the theft or significant loss of any dangerous drug by submitting a list of the name and quantity of all dangerous drugs stolen or lost.

(g) [(f)] Fire or Other Disaster. If a pharmacy experiences a fire or other disaster, the following requirements are applicable.

(1) Responsibilities of the pharmacist-in-charge.

(A) The pharmacist-in-charge shall be responsible for reporting the date of the fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of the injury, illness, and disease; such notification shall be immediately reported to the board, but in no event shall exceed 10 days from the date of the disaster.

(B) The pharmacist-in-charge or designated agent shall comply with the following procedures.

(i) If controlled substances, dangerous drugs, or Drug Enforcement Administration (DEA) order forms are lost or destroyed in the disaster, the pharmacy shall:

(I) notify the DEA, ~~Department of Public Safety (DPS),~~ and **the board** ~~[Texas State Board of Pharmacy (board)]~~ of the loss of the controlled substances or order forms. A pharmacy shall be in compliance with this section by submitting to each of these agencies a copy of the DEA's report of theft or loss of controlled substances, DEA Form-106, immediately on discovery of the loss; and

(II) notify the board in writing of the loss of the dangerous drugs by submitting a list of the dangerous drugs lost.

(ii) If the extent of the loss of controlled substances or dangerous drugs is not able to be determined, the pharmacy shall:

154 (I) take a new, complete inventory of all remaining drugs specified in §291.17(c) of this title
155 (relating to Inventory Requirements);

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157 (II) submit to DEA [~~and DPS~~] a statement attesting that the loss of controlled substances is
158 indeterminable and that a new, complete inventory of all remaining controlled substances was
159 conducted and state the date of such inventory; and

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161 (III) submit to the board a statement attesting that the loss of controlled substances and
162 dangerous drugs is indeterminable and that a new, complete inventory of the drugs specified in
163 §291.17(c) of this title was conducted and state the date of such inventory.

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165 (C) If the pharmacy changes to a new, permanent location, the pharmacist-in-charge shall
166 comply with subsection (a) of this section.

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168 (D) If the pharmacy moves to a temporary location, the pharmacist shall comply with
169 subsection (a) of this section. If the pharmacy returns to the original location, the pharmacist-in-
170 charge shall again comply with subsection (a) of this section.

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172 (E) If the pharmacy closes due to fire or other disaster, the pharmacy may not be closed for
173 longer than 90 days as specified in §291.11 of this title (relating to Operation of a Pharmacy).

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175 (F) If the pharmacy discontinues business (ceases to operate as a pharmacy), the
176 pharmacist-in-charge shall comply with §291.5 of this title (relating to Closing a Pharmacy).

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178 (G) The pharmacist-in-charge shall maintain copies of all inventories, reports, or notifications
179 required by this section for a period of two years.

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181 (2) Drug stock.

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183 (A) Any drug which has been exposed to excessive heat, smoke, or other conditions which
184 may have caused deterioration shall not be dispensed.

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186 (B) Any potentially adulterated or damaged drug shall only be sold, transferred, or otherwise
187 distributed pursuant to the provisions of the Texas Food Drug and Cosmetics Act (Chapter 431,
188 Health and Safety Code) administered by the Bureau of Food and Drug Safety of the Texas
189 Department of State Health Services.

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191 **(h)** [~~(g)~~] Notification to Consumers.

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193 (1) Pharmacy.

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195 (A) Every licensed pharmacy shall provide notification to consumers of the name, mailing
196 address, Internet site address, and telephone number of the board for the purpose of directing
197 complaints concerning the practice of pharmacy to the board. Such notification shall be provided
198 as follows.

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200 (i) If the pharmacy serves walk-in customers, the pharmacy shall either:

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202 (I) post in a prominent place that is in clear public view where prescription drugs are
203 dispensed:

205 (-a) a sign which notifies the consumer that complaints concerning the practice of
206 pharmacy may be filed with the board and list the board's name, mailing address, Internet site
207 address, telephone number, and a toll-free telephone number for filing complaints; or
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209 (-b-) an electronic messaging system in a type size no smaller than ten-point Times
210 Roman which notifies the consumer that complaints concerning the practice of pharmacy may
211 be filed with the board and list the board's name, mailing address, Internet site address,
212 telephone number, and a toll-free number for filing complaints; or
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214 (II) provide with each dispensed prescription a written notification in a type size no smaller
215 than ten-point Times Roman which states the following: "Complaints concerning the practice of
216 pharmacy may be filed with the Texas State Board of Pharmacy at: (list the mailing address,
217 Internet site address, telephone number of the board, and a toll-free telephone number for filing
218 complaints)."
219

220 (ii) If the prescription drug order is delivered to patients at their residence or other
221 designated location, the pharmacy shall provide with each dispensed prescription a written
222 notification in type size no smaller than ten-point Times Roman which states the following:
223 "Complaints concerning the practice of pharmacy may be filed with the Texas State Board of
224 Pharmacy at: (list the mailing address, Internet site address, telephone number, and a toll-free
225 telephone number for filing complaints)." If multiple prescriptions are delivered to the same
226 location, only one such notice shall be required.
227

228 (iii) The provisions of this subsection do not apply to prescriptions for patients in facilities
229 where drugs are administered to patients by a person required to do so by the laws of the state
230 (i.e., nursing homes).
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232 (B) A pharmacy that maintains a generally accessible site on the Internet that is located in
233 Texas or sells or distributes drugs through this site to residents of this state shall post the
234 following information on the pharmacy's initial home page and on the page where a sale of
235 prescription drugs occurs.
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237 (i) Information on the ownership of the pharmacy, to include at a minimum, the:
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239 (I) owner's name or if the owner is a partnership or corporation, the partnership's or
240 corporation's name and the name of the chief operating officer;
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242 (II) owner's address;
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244 (III) owner's telephone number; and
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246 (IV) year the owner began operating pharmacies in the United States.
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248 (ii) The Internet address and toll free telephone number that a consumer may use to:
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250 (I) report medication/device problems to the pharmacy; and
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252 (II) report business compliance problems.
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254 (iii) Information about each pharmacy that dispenses prescriptions for this site, to include at
255 a minimum, the:

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257 (I) pharmacy's name, address, and telephone number;
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259 (II) name of the pharmacist responsible for operation of the pharmacy;
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261 (III) Texas pharmacy license number for the pharmacy and a link to the Internet site
262 maintained by the Texas State Board of Pharmacy; and
263
264 (IV) the names of all other states in which the pharmacy is licensed, the license number in
265 that state, and a link to the Internet site of the entity that regulates pharmacies in that state, if
266 available.
267
268 (C) A pharmacy whose Internet site has been **verified** [~~awarded a Verified Internet Pharmacy~~
269 ~~Practice Sites (VIPPS), Veterinary Verified Internet Pharmacy Practice Sites (Vet-VIPPS)~~
270 ~~accreditation, or e-Advertiser Approval Program~~] by the National Association of Boards of
271 Pharmacy **to be in compliance with the laws of this state, as well as in all other states in**
272 **which the pharmacy is licensed** shall be in compliance with subparagraph (B) of this
273 paragraph [~~by displaying the VIPPS, Vet-VIPPS, or e-Advertiser seal on the pharmacy internet~~
274 ~~site~~].
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276 (2) Texas State Board of Pharmacy. On or before January 1, 2005, the board shall establish a
277 pharmacy profile system as specified in §2054.2606, Government Code.
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279 (A) The board shall make the pharmacy profiles available to the public on the agency's
280 Internet site.
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282 (B) A pharmacy profile shall contain at least the following information:
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284 (i) name, address, and telephone number of the pharmacy;
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286 (ii) pharmacy license number, licensure status, and expiration date of the license;
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288 (iii) the class and type of the pharmacy;
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290 (iv) ownership information for the pharmacy;
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292 (v) names and license numbers of all pharmacists working at the pharmacy;
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294 (vi) whether the pharmacy has had prior disciplinary action by the board;
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296 (vii) whether the pharmacy's consumer service areas are accessible to disabled persons, as
297 defined by law;
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299 (viii) the type of language translating services, including translating services for persons with
300 impairment of hearing, that the pharmacy provides for consumers; and
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302 (ix) insurance information including whether the pharmacy participates in the state Medicaid
303 program.
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305 (C) The board shall gather this information on initial licensing and update the information in
306 conjunction with the license renewal for the pharmacy.

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308 **(i) ~~[(h)]~~ Notification of Licensees or Registrants Obtaining Controlled Substances or Dangerous**
309 **Drugs by Forged Prescriptions.** If a licensee or registrant obtains controlled substances or
310 dangerous drugs from a pharmacy by means of a forged prescription, the pharmacy shall report
311 in writing to the board immediately on discovery of such forgery. A pharmacy shall be in
312 compliance with this subsection by submitting to the board the following:

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314 (1) name of licensee or registrant obtaining controlled substances or dangerous drugs by
315 forged prescription;

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317 (2) date(s) of forged prescription(s);

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319 (3) name(s) and amount(s) of drug(s); and

320
321 (4) copies of forged prescriptions.

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323 **(j) Notification of Disciplinary Action. For the purpose of the Act, §562.106, pharmacy**
324 **shall report in writing to the board not later than the 10th day after the date of:**

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326 **(1) a final order against the pharmacy license holder by the regulatory or licensing**
327 **agency of the state in which the pharmacy is located if the pharmacy is located in**
328 **another state; or**

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330 **(2) a final order against a pharmacist who is designated as the pharmacist-in-charge of**
331 **the pharmacy by the regulatory or licensing agency of the state in which the pharmacy is**
332 **located if the pharmacy is located in another state.**