

RULE ANALYSIS

Introduction: THE NEW RULE AND AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS A ADOPTED RULE

Short Title: Interchangeable Biological Products

Rule Numbers: §§ 309.1 – 309.8, 291.33, 291.34, 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 new rule and amendments, if adopted, implement the provisions of HB 751 regarding interchangeable biological products.

The Board reviewed and voted to propose the amendments during the August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register* at 40 TexReg 6510, 6530, and 6545.

1 **CHAPTER 309. SUBSTITUTION OF DRUG PRODUCTS**

2 **22 TAC §§309.1 - 309.8**

3 The Texas State Board of Pharmacy proposes amendments to §309.1 concerning Objective,
4 §309.2 concerning Definitions, §309.3 concerning Generic Substitution, §309.4 concerning
5 Patient Notification, §309.6 concerning Records, §309.7 concerning Dispensing Responsibilities,
6 and §309.8 concerning Advertising of Generic Drugs by Pharmacies and new §309.5 concerning
7 Communication with Prescriber. The new rule and amendments, if adopted, implement the
8 provisions of HB 751 regarding interchangeable biological products; and SB 460 regarding
9 posting of the generic substitution sign.

10 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
11 period the rules are in effect, there will be no fiscal implications for state or local government as
12 a result of enforcing or administering the rules.

13 Ms. Dodson has determined that, for each year of the first five-year period the rules will be in
14 effect, the public benefit anticipated as a result of enforcing the amendments and new rule will
15 ensure pharmacists are substituting interchangeable biological products appropriately. There is
16 no fiscal impact for individuals, small or large businesses, or to other entities which are required
17 to comply with these sections.

18 Comments on the amendments and new rule may be submitted to Allison Benz, R.Ph., M.S.,
19 Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite
20 3-600, Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m.,
21 October 30, 2015.

22 The amendments and new rule are proposed under §551.002 and §554.051 of the Texas
23 Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board
24 interprets §551.002 as authorizing the agency to protect the public through the effective control
25 and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the
26 agency to adopt rules for the proper administration and enforcement of the Act.

27 The statutes affected by these amendments and new rule: Texas Pharmacy Act, Chapters 551 -
28 566 and 568 - 569, Texas Occupations Code.

29 **§309.1. Objective.**

30 These sections govern the substitution of lower-priced generically equivalent drug products for
31 certain brand name drug products and the substitution of interchangeable biological products for
32 certain biological products.

33 **§309.2. Definitions.**

34 The following words and terms, when used in this chapter, shall have the following meanings,
35 unless the context clearly indicates otherwise. Any term not defined in this section shall have the
36 definition set out in the Act, §551.003 and Chapter 562.

37 (1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.

38 (2) Biological product--A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood
39 component or derivative, allergenic product, protein (except any chemically synthesized
40 polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other
41 trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease
42 or condition of human beings.

43 (3) Biosimilar--A biological product that is highly similar to the reference product
44 notwithstanding minor differences in clinically inactive components and there are no clinically
45 meaningful differences between the biological product and the reference product in terms of the
46 safety, purity, and potency of the product.

47 (4) [(2)] Data communication device--An electronic device that receives electronic information
48 from one source and transmits or routes it to another (e.g., bridge, router, switch, or gateway).

49 (5) [(3)] Electronic prescription drug order--A prescription drug order which is transmitted by an
50 electronic device to the receiver (pharmacy).

51 (6) [(4)] Generically equivalent--A drug that is pharmaceutically equivalent and therapeutically
52 equivalent to the drug prescribed.

53 (7) Interchangeable--Referencing a biological product that is:

54 (A) biosimilar to the reference product and can be expected to produce the same clinical result as
55 the reference product in any given patient; and if the biological product is administered more
56 than once to an individual, the risk in terms of safety or diminished efficacy of alternating or
57 switching between use of the biological product and the reference product is not greater than the
58 risk of using the reference product without such alternation or switch may be substituted for the
59 reference product without the intervention of the health care provider who prescribed the
60 reference product; or

61 (B) designated as therapeutically equivalent to another product by the United States Food and
62 Drug Administration in the most recent edition or supplement of the United States Food and
63 Drug Administration's references.

64 (8) [(5)] Pharmaceutically equivalent--Drug products that have identical amounts of the same
65 active chemical ingredients in the same dosage form and that meet the identical compendial or
66 other applicable standards of strength, quality, and purity according to the United States
67 Pharmacopoeia or another nationally recognized compendium.

68 (9) Reference product--A single biological product against which a biological product is
69 evaluated and is found to be biosimilar.

70 (10) [(6)] Therapeutically equivalent--Pharmaceutically equivalent drug products that, if
71 administered in the same amounts, will provide the same therapeutic effect, identical in duration
72 and intensity.

73 (11) [(7)] Original prescription--The:

74 (A) original written prescription drug orders; or

75 (B) original verbal or electronic prescription drug orders reduced to writing either manually or
76 electronically by the pharmacist.

77 (12) [(8)] Practitioner--

78 (A) A person licensed or registered to prescribe, distribute, administer, or dispense a prescription
79 drug or device in the course of professional practice in this state, including a physician, dentist,
80 podiatrist, therapeutic optometrist, or veterinarian but excluding a person licensed under this
81 subtitle;

82 (B) A person licensed by another state, Canada, or the United Mexican States in a health field in
83 which, under the law of this state, a license holder in this state may legally prescribe a dangerous
84 drug;

85 (C) A person practicing in another state and licensed by another state as a physician, dentist,
86 veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration
87 registration number and who may legally prescribe a Schedule II, III, IV, or V controlled
88 substance, as specified under Chapter 481, Health and Safety Code, in that other state; or

89 (D) An advanced practice registered nurse or physician assistant to whom a physician has
90 delegated the authority to carry out or sign prescription drug orders under §§157.0511, 157.0512,
91 or [157.052, 157.053,] 157.054, [157.0541, or 157.0542,] Occupations Code.

92 **§309.3.[Generic] Substitution Requirements.**

93 (a) General requirements. In accordance with Chapter 562 of the Act, a pharmacist may dispense
94 a generically equivalent drug or interchangeable biological product if:

95 (1) the generic drug or interchangeable biological product costs the patient less than the
96 prescribed drug product;

97 (2) the patient does not refuse the substitution; and

98 (3) the practitioner does not certify on the prescription form that a specific prescribed brand is
99 medically necessary as specified in a dispensing directive described in subsection (c) of this
100 section.

101 (b) Prescription format for written prescription drug orders.

102 (1) A written prescription drug order issued in Texas may:

103 (A) be on a form containing a single signature line for the practitioner; and

104 (B) contain the following reminder statement on the face of the prescription: "A generically
105 equivalent drug product may be dispensed unless the practitioner hand writes the words 'Brand
106 Necessary' or 'Brand Medically Necessary' on the face of the prescription."

107 (2) A pharmacist may dispense a prescription that is not issued on the form specified in
108 paragraph (1) of this subsection, however, the pharmacist may dispense a generically equivalent
109 drug or interchangeable biological product unless the practitioner has prohibited substitution
110 through a dispensing directive in compliance with subsection (c)(1) of this section.

111 (3) The prescription format specified in paragraph (1) of this subsection does not apply to the
112 following types of prescription drug orders:

113 (A) prescription drug orders issued by a practitioner in a state other than Texas;

114 (B) prescriptions for dangerous drugs issued by a practitioner in the United Mexican States or the
115 Dominion of Canada; or

116 (C) prescription drug orders issued by practitioners practicing in a federal facility provided they
117 are acting in the scope of their employment.

118 (4) In the event of multiple prescription orders appearing on one prescription form, the
119 practitioner shall clearly identify to which prescription(s) the dispensing directive(s) apply. If the
120 practitioner does not clearly indicate to which prescription(s) the dispensing directive(s) apply,
121 the pharmacist may substitute on all prescriptions on the form.

122 (c) Dispensing directive.

123 (1) General requirements. The following is applicable to the dispensing directive outlined in this
124 subsection.

125 (A) When a prescription is issued for a brand name product that has no generic equivalent
126 product, the pharmacist must dispense the brand name product. If a generic equivalent or
127 interchangeable biological product becomes available, a pharmacist may substitute the
128 generically equivalent or interchangeable biological product unless the practitioner has specified
129 on the initial prescription that the brand name product is medically necessary.

130 (B) If the practitioner has prohibited substitution through a dispensing directive in compliance
131 with this subsection, a pharmacist shall not substitute a generically equivalent drug or
132 interchangeable biological product unless the pharmacist obtains verbal or written authorization
133 from the practitioner, notes such authorization on the original prescription drug order, and
134 notifies the patient in accordance with §309.4 of this title (relating to Patient Notification).

135 (2) Written prescriptions.

136 (A) A practitioner may prohibit the substitution of a generically equivalent drug or
137 interchangeable biological product for a brand name drug product by writing across the face of
138 the written prescription, in the practitioner's own handwriting, the phrase "brand necessary" or
139 "brand medically necessary."

140 (B) The dispensing directive shall:

141 (i) be in a format that protects confidentiality as required by the Health Insurance Portability and
142 Accountability Act of 1996 (29 U.S.C. Section 1181 et seq.) and its subsequent amendments; and

143 (ii) comply with federal and state law, including rules, with regard to formatting and security
144 requirements.

145 (C) The dispensing directive specified in this paragraph may not be preprinted, rubber stamped,
146 or otherwise reproduced on the prescription form.

147 (D) A practitioner may prohibit substitution on a written prescription only by following the
148 dispensing directive specified in this paragraph. Two-line prescription forms, check boxes, or
149 other notations on an original prescription drug order which indicate "substitution instructions"
150 are not valid methods to prohibit substitution, and a pharmacist may substitute on these types of
151 written prescriptions.

152 (3) Verbal Prescriptions.

153 (A) If a prescription drug order is transmitted to a pharmacist orally, the practitioner or
154 practitioner's agent shall prohibit substitution by specifying "brand necessary" or "brand
155 medically necessary." The pharmacist [~~pharmacists~~] shall note any substitution instructions by
156 the practitioner or practitioner's agent, on the file copy of the prescription drug order. Such file
157 copy may follow the one-line format indicated in subsection (b)(1) of this section, or any other
158 format that clearly indicates the substitution instructions.

159 (B) If the practitioner's or practitioner's agent does not clearly indicate that the brand name is
160 medically necessary, the pharmacist may substitute a generically equivalent drug or
161 interchangeable biological product.

162 (C) To prohibit substitution on a verbal prescription reimbursed through the medical assistance
163 program specified in 42 C.F.R., §447.331:

164 (i) the practitioner or the practitioner's agent shall verbally indicate that the brand is medically
165 necessary; and

166 (ii) the practitioner shall mail or fax a written prescription to the pharmacy which complies with
167 the dispensing directive for written prescriptions specified in paragraph (1) of this subsection
168 within 30 days.

169 (4) Electronic prescription drug orders.

170 (A) To prohibit substitution, the practitioner or practitioner's agent shall clearly indicate
171 substitution instructions in the electronic prescription drug order.

172 (B) If the practitioner or practitioner's agent does not indicate or does not clearly indicate in the
173 electronic prescription drug order that the brand is necessary, the pharmacist may substitute a
174 generically equivalent drug or interchangeable biological product.

175 (C) To prohibit substitution on an electronic prescription drug order reimbursed through the
176 medical assistance program specified in 42 C.F.R., §447.331, the practitioner shall comply with
177 state and federal laws.

178 (5) Prescriptions issued by out-of-state, Mexican, Canadian, or federal facility practitioners.

179 (A) The dispensing directive specified in this subsection does not apply to the following types of
180 prescription drug orders:

181 (i) prescription drug orders issued by a practitioner in a state other than Texas;

182 (ii) prescriptions for dangerous drugs issued by a practitioner in the United Mexican States or the
183 Dominion of Canada; or

184 (iii) prescription drug orders issued by practitioners practicing in a federal facility provided they
185 are acting in the scope of their employment.

186 (B) A pharmacist may not substitute on prescription drug orders identified in subparagraph (A)
187 of this paragraph unless the practitioner has authorized substitution on the prescription drug
188 order. If the practitioner has not authorized substitution on the written prescription drug order, a
189 pharmacist shall not substitute a generically equivalent drug product unless:

190 (i) the pharmacist obtains verbal or written authorization from the practitioner (such
191 authorization shall be noted on the original prescription drug order); or

192 (ii) the pharmacist obtains written documentation regarding substitution requirements from the
193 State Board of Pharmacy in the state, other than Texas, in which the prescription drug order was
194 issued. The following is applicable concerning this documentation.

195 (I) The documentation shall state that a pharmacist may substitute on a prescription drug order
196 issued in such other state unless the practitioner prohibits substitution on the original prescription
197 drug order.

198 (II) The pharmacist shall note on the original prescription drug order the fact that documentation
199 from such other state board of pharmacy is on file.

200 (III) Such documentation shall be updated yearly.

201 (d) Refills.

202 (1) Original substitution instructions. All refills shall follow the original substitution instructions
203 unless otherwise indicated by the practitioner or practitioner's agent.

204 (2) Narrow therapeutic index drugs.

205 (A) The board and the Texas Medical Board shall establish a joint committee to recommend to
206 the board a list of narrow therapeutic index drugs and the rules, if any, by which this paragraph
207 applies to those drugs. The committee must consist of an equal number of members from each
208 board. The committee members shall select a member of the committee to serve as presiding
209 officer for a one year term. The presiding officer may not represent the same board as the
210 presiding officer's predecessor.

211 (B) The board, on the recommendation of the joint committee, has determined that no drugs shall
212 be included on a list of narrow therapeutic index drugs as defined in §562.014, Occupations
213 Code.

214 (i) The board has specified in §309.7 of this title (relating to dispensing responsibilities) that for
215 drugs listed in the publication, pharmacist shall use as a basis for determining generic
216 equivalency, Approved Drug Products with Therapeutic Equivalence Evaluations and current
217 supplements published by the Federal Food and Drug Administration, within the limitations
218 stipulated in that publication. For drugs listed in the publications, pharmacists may only
219 substitute products that are rated therapeutically equivalent in the Approved Drug Products with
220 Therapeutic Equivalence Evaluations and current supplements.

221 (ii) Practitioners may prohibit substitution through a dispensing directive in compliance with
222 subsection (c) of this section.

223 (C) The board shall reconsider the contents of the list if:

224 (i) the Federal Food and Drug Administration determines a new equivalence classification which
225 indicates that certain drug products are equivalent but special notification to the patient and
226 practitioner is required when substituting these products; or

227 (ii) any interested person petitions the board to reconsider the list. If the board receives a petition
228 to include a drug on the list, the joint committee specified in subparagraph (A) of this paragraph
229 shall review the request and make a recommendation to the board.

230 **§309.4. Patient Notification.**

231 (a) Substitution notification. Before delivery of a prescription for a generically equivalent drug or
232 interchangeable biological product [products] as authorized by Chapter 562, Subchapter A of the
233 Act, a pharmacist must:

234 (1) personally, or through his or her agent or employee inform the patient or the patient's agent
235 that a less expensive generically equivalent drug interchangeable biological product is available
236 for the brand prescribed; and ask the patient or the patient's agent to choose between the
237 generically equivalent drug or biological product and the brand prescribed.

238 ~~[(2) cause to be displayed, in a prominent place that is in clear public view where prescription
239 drugs are dispensed, a sign in block letters not less than one inch in height that reads, in both
240 English and Spanish: "TEXAS LAW REQUIRES A PHARMACIST TO INFORM YOU IF A
241 LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG IS AVAILABLE FOR CERTAIN
242 BRAND NAME DRUGS AND TO ASK YOU TO CHOOSE BETWEEN THE GENERIC
243 AND THE BRAND NAME DRUG. YOU HAVE A RIGHT TO ACCEPT OR REFUSE THE
244 GENERICALLY EQUIVALENT DRUG."}]~~

245 (2) ~~[(3)]~~ A pharmacist shall offer the patient or the patient's agent the option of paying for a
246 prescription drug at a lower price instead of paying the amount of the copayment under the
247 patient's prescription drug insurance plan if the price of the prescribed drug is lower than the
248 amount of the patient's copayment.

249 (b) Exceptions. A pharmacy is not required to comply with the provisions of subsection (a) of
250 this section:

251 (1) in the case of the refill of a prescription for which the pharmacy previously complied with
252 subsection (a) of this section with regard to the same patient or patient's agent; or

253 (2) if the patient's physician or physician's agent advises the pharmacy that:

254 (A) the physician has informed the patient or the patient's agent that a less expensive generically
255 equivalent drug or interchangeable biological product is available for the brand prescribed; and

256 (B) the patient or the patient's agent has chosen either the brand prescribed or the less expensive
257 generically equivalent drug or interchangeable biological product.

258 (c) Notification by pharmacies delivering prescriptions by mail.

259 (1) A pharmacy that supplies a prescription by mail is considered to have complied with the
260 provision of subsection (a) of this section if the pharmacy includes on the prescription order form
261 completed by the patient or the patient's agent language that clearly and conspicuously:

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

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

268 (2) If the patient or patient's agent fails to indicate otherwise to a pharmacy on the prescription
269 order form under paragraph (1) of this subsection, the pharmacy may dispense a generically
270 equivalent drug or interchangeable biological product.

271 (d) Inpatient notification exemption. Institutional pharmacies shall be exempt from the labeling
272 provisions and patient notification requirements of §562.006 and §562.009 of the Act, as respects
273 drugs distributed pursuant to medication orders.

274 **§309.5. Communication with Prescriber.**

275 (a) Not later than the third business day after the date of dispensing a biological product, the
276 dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing
277 practitioner the specific product provided to the patient, including the name of the product and
278 the manufacturer or national drug code number.

279 (b) The communication must be conveyed by making an entry into an interoperable electronic
280 medical records system or through electronic prescribing technology or a pharmacy benefit
281 management system or a pharmacy record, which may include information submitted for the
282 payment of claims, that a pharmacist reasonably concludes is electronically accessible by the
283 prescribing practitioner. Otherwise, the pharmacist or the pharmacist's designee shall
284 communicate the biological product dispensed to the prescribing practitioner, using facsimile,
285 telephone, electronic transmission, or other prevailing means, provided that communication is
286 not required if:

287 (1) there is no interchangeable biological product approved by the United States Food and Drug
288 Administration for the product prescribed; or

289 (2) a refill prescription is not changed from the product dispensed on the prior filling of the
290 prescription.

291 (c) This section expires September 1, 2019.

292 **§309.6. Records.**

293 (a) When the pharmacist dispenses a generically equivalent drug or interchangeable biological
294 product pursuant to the Subchapter A, Chapter 562 of the Act, the following information shall be
295 noted on the original written or hard-copy of the oral prescription drug order:

296 (1) any substitution instructions communicated orally to the pharmacist by the practitioner or
297 practitioner's agent or a notation that no substitution instructions were given; and

298 (2) the name and strength of the actual drug product dispensed shall be noted on the original or
299 hard-copy prescription drug order. The name shall be either:

300 (A) the brand name and strength; or

301 (B) the generic name or the name of the interchangeable biological product, strength, and name
302 of the manufacturer or distributor of such generic drug or interchangeable biological product.
303 (The name of the manufacturer or distributor may be reduced to an abbreviation or initials,
304 provided the abbreviation or initials are sufficient to identify the manufacturer or distributor. For
305 combination drug products having no brand name, the principal active ingredients shall be
306 indicated on the prescription.)

307 (b) If a pharmacist refills a prescription drug order with a generically equivalent product or
308 interchangeable biological product from a different manufacturer or distributor than previously
309 dispensed, the pharmacist shall record on the prescription drug order the information required in
310 subsection (a) of this section for the product dispensed on the refill.

311 (c) If a pharmacy utilizes patient medication records for recording prescription information, the
312 information required in subsections (a) and (b) of this section shall be recorded on the patient
313 medication records.

314 (d) The National Drug Code (NDC) of a drug or any other code may be indicated on the
315 prescription drug order at the discretion of the pharmacist, but such code shall not be used in
316 place of the requirements of subsections (a) and (b) of this section.

317 ***§309.7. Dispensing Responsibilities.***

318 (a) The determination of the drug product to be substituted as authorized by the Subchapter A,
319 Chapter 562 of the Act, is the professional responsibility of the pharmacist, and the pharmacist
320 may not dispense any product that does not meet the requirements of the Subchapter A, Chapter
321 562 of the Act. [~~As specified in Chapter 562 of the Act and §309.2 of this title (relating to~~
322 ~~definitions), a generically equivalent product is one that is pharmaceutically equivalent and~~
323 ~~therapeutically equivalent to the drug prescribed.]~~

324 (b) Pharmacists shall use as a basis for the determination of generic equivalency or
325 interchangeability as defined in the Subchapter A, Chapter 562 of the Act, most recent edition or
326 supplement of the United States Food and Drug Administration's references (e.g., the Orange
327 Book or Purple Book). [~~the following:~~]

328 (c) Pharmacists.

329 ~~[(1) For drugs listed in the publication, pharmacists] shall use Approved Drug Products With~~
330 ~~Therapeutic Equivalence Evaluations (Orange Book) and current supplements published by the~~
331 ~~Federal Food and Drug Administration, within the limitations stipulated in that publication, to~~
332 ~~determine generic equivalency. Pharmacists may only substitute products that are rated~~
333 ~~therapeutically equivalent in the Orange Book and have an "A" rating. "A" rated drug products~~
334 ~~include but are not limited to, those designated AA, AB, AN, AO, AP, or AT in the Orange~~
335 ~~Book.]~~

336 [(2)] For drugs not listed in the Orange Book, pharmacists shall use their professional judgment
337 to determine generic equivalency.

338 (d) Pharmacists shall use Lists of Licensed Biological Products with Reference Product
339 Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book) and current
340 supplements published by the Federal Food and Drug Administration, within the limitations
341 stipulated in that publication, to determine biosimilarity to or interchangeability with a reference
342 biological product.

343 **§309.8. Advertising of Generic Drugs by Pharmacies.**

344 Prescription drug advertising comparing generic drugs or biological products and brand name
345 drugs or biological products is subject to the §554.054 of the Act and in compliance with federal
346 law.

347 The agency certifies that legal counsel has reviewed the proposal and found it to be within the
348 state agency's legal authority to adopt.

349 Filed with the Office of the Secretary of State on September 14, 2015.

350 TRD-201503760

351 Gay Dodson, R.Ph.

352 Executive Director

353 Texas State Board of Pharmacy

354 Earliest possible date of adoption: October 25, 2015

355 For further information, please call: (512) 305-8028

356

1 **SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)**

2 **22 TAC §§291.32 - 291.34**

3 The Texas State Board of Pharmacy proposes amendments to §291.32 concerning Personnel,
4 §291.33 concerning Operational Standards, and §291.34 concerning Records. The amendments,
5 if adopted, clarify that pharmacists may not serve as the pharmacist-in-charge of other
6 pharmacies if the pharmacist is required to be a full time pharmacist; correct grammar; clarify
7 the duties of a pharmacist to include transferring or receiving a transfer of original prescription
8 information on behalf of a patient; clarify that prescriptions must be transferred within four
9 business hours; update the requirements with regard to interchangeable biological products; and
10 update the rules regarding distributions to include dangerous drugs.

11 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
12 period the rules are in effect, there will be no fiscal implications for state or local government as
13 a result of enforcing or administering the rules.

14 Ms. Dodson has determined that, for each year of the first five-year period the rules will be in
15 effect, the public benefit anticipated as a result of enforcing the amendments will ensure the
16 pharmacies are adequately supervised by the pharmacist-in-charge; ensure only pharmacists are
17 performing duties of a pharmacist; ensure patients receive transferred prescriptions in a timely
18 manner; and ensure biologicals are handled appropriately. There is no fiscal impact for
19 individuals, small or large businesses, or to other entities which are required to comply with
20 these sections.

21 Comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of
22 Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,
23 Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., October
24 30, 2015.

25 The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act
26 (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as
27 authorizing the agency to protect the public through the effective control and regulation of the
28 practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules
29 for the proper administration and enforcement of the Act.

30 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 -
31 569, Texas Occupations Code.

32 *§291.32. Personnel.*

33 (a) Pharmacist-in-charge.

34 (1) General.

35 (A) Each Class A pharmacy shall have one pharmacist-in-charge who is employed on a full-time
36 basis, who may be the pharmacist-in-charge for only one such pharmacy; provided, however,
37 such pharmacist-in-charge may be the pharmacist-in-charge of:

38 (i) more than one Class A pharmacy, if the additional Class A pharmacies are not open to
39 provide pharmacy services simultaneously; or

40 (ii) during an emergency, up to two Class A pharmacies open simultaneously if the pharmacist-
41 in-charge works at least 10 hours per week in each pharmacy for no more than a period of 30
42 consecutive days.

43 (B) The pharmacist-in-charge shall comply with the provisions of §291.17 of this title (relating
44 to Inventory Requirements).

45 (C) The pharmacist-in-charge of a Class A pharmacy may not serve as the pharmacist-in-charge
46 of a Class B pharmacy or a Class C pharmacy with 101 beds or more.

47 (2) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of
48 pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-
49 charge may advise the owner on administrative or operational concerns. The pharmacist-in-
50 charge shall have responsibility for, at a minimum, the following:

51 (A) educating and training of pharmacy technicians and pharmacy technician trainees;

52 (B) supervising a system to assure appropriate procurement of prescription drugs and devices
53 and other products dispensed from the Class A pharmacy;

54 (C) disposing of and distributing drugs from the Class A pharmacy;

55 (D) storing all materials, including drugs, chemicals, and biologicals;

56 (E) maintaining records of all transactions of the Class A pharmacy necessary to maintain
57 accurate control over and accountability for all pharmaceutical materials required by applicable
58 state and federal laws and sections;

59 (F) supervising a system to assure maintenance of effective controls against the theft or diversion
60 of prescription drugs, and records for such drugs;

61 (G) adhering to policies and procedures regarding the maintenance of records in a data
62 processing system such that the data processing system is in compliance with Class A
63 (community) pharmacy requirements;

64 (H) legally operating the pharmacy, including meeting all inspection and other requirements of
65 all state and federal laws or sections governing the practice of pharmacy; and

66 (I) if the pharmacy uses an automated pharmacy dispensing system, shall be responsible for the
67 following:

68 (i) consulting with the owner concerning and adherence to the policies and procedures for system
69 operation, safety, security, accuracy and access, patient confidentiality, prevention of
70 unauthorized access, and malfunction;

71 (ii) inspecting medications in the automated pharmacy dispensing system, at least monthly, for
72 expiration date, misbranding, physical integrity, security, and accountability;

73 (iii) assigning, discontinuing, or changing personnel access to the automated pharmacy
74 dispensing system;

75 (iv) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed healthcare
76 professionals performing any services in connection with an automated pharmacy dispensing
77 system have been properly trained on the use of the system and can demonstrate comprehensive
78 knowledge of the written policies and procedures for operation of the system; and

79 (v) ensuring that the automated pharmacy dispensing system is stocked accurately and an
80 accountability record is maintained in accordance with the written policies and procedures of
81 operation.

82 (b) Owner. The owner of a Class A pharmacy shall have responsibility for all administrative and
83 operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on
84 administrative and operational concerns. The owner shall have responsibility for, at a minimum,
85 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with
86 the pharmacist-in-charge or another Texas licensed pharmacist:

87 (1) establishing [~~establishment of~~] policies for procurement of prescription drugs and devices and
88 other products dispensed from the Class A pharmacy;

89 (2) establishing [~~establishment of~~] policies and procedures for the security of the prescription
90 department including the maintenance of effective controls against the theft or diversion of
91 prescription drugs;

92 (3) if the pharmacy uses an automated pharmacy dispensing system, reviewing and approving all
93 policies and procedures for system operation, safety, security, accuracy and access, patient
94 confidentiality, prevention of unauthorized access, and malfunction;

95 (4) providing the pharmacy with the necessary equipment and resources commensurate with its
96 level and type of practice; and

97 (5) establishing [~~establishment of~~] policies and procedures regarding maintenance, storage, and
98 retrieval of records in a data processing system such that the system is in compliance with state
99 and federal requirements.

100 (c) Pharmacists.

101 (1) General.

102 (A) The pharmacist-in-charge shall be assisted by sufficient number of additional licensed
103 pharmacists as may be required to operate the Class A pharmacy competently, safely, and
104 adequately to meet the needs of the patients of the pharmacy.

105 (B) All pharmacists shall assist the pharmacist-in-charge in meeting his or her responsibilities in
106 ordering, dispensing, and accounting for prescription drugs.

107 (C) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and
108 pharmacy technician trainees and for designating and delegating duties, other than those listed in
109 paragraph (2) of this subsection, to pharmacy technicians and pharmacy technician trainees. Each
110 pharmacist shall be responsible for any delegated act performed by pharmacy technicians and
111 pharmacy technician trainees under his or her supervision.

112 (D) Pharmacists shall directly supervise pharmacy technicians and pharmacy technician trainees
113 who are entering prescription data into the pharmacy's data processing system by one of the
114 following methods.

115 (i) Physically present supervision. A pharmacist shall be physically present to directly supervise
116 a pharmacy technician or pharmacy technician trainee who is entering prescription data into the
117 data processing system. Each prescription entered into the data processing system shall be
118 verified at the time of data entry. If the pharmacist is not physically present due to a temporary
119 absence as specified in §291.33(b)(3) of this title (relating to Operational Standards), on return
120 the pharmacist must:

121 (I) conduct a drug regimen review for the prescriptions data entered during this time period as
122 specified in §291.33(c)(2) of this title; and

123 (II) verify that prescription data entered during this time period was entered accurately.

124 (ii) Electronic supervision. A pharmacist may electronically supervise a pharmacy technician or
125 pharmacy technician trainee who is entering prescription data into the data processing system
126 provided the pharmacist:

127 (I) is on-site, in the pharmacy where the technician/trainee is located;

128 (II) has immediate access to any original document containing prescription information or other
129 information related to the dispensing of the prescription. Such access may be through imaging
130 technology provided the pharmacist has the ability to review the original, hardcopy documents if
131 needed for clarification; and

132 (III) verifies the accuracy of the data entered information prior to the release of the information
133 to the system for storage and/or generation of the prescription label.

134 (iii) Electronic verification of data entry by pharmacy technicians or pharmacy technician
135 trainees. A pharmacist may electronically verify the data entry of prescription information into a
136 data processing system provided:

137 (I) a pharmacist is on-site in the pharmacy where the pharmacy technicians/trainees are located;

138 (II) the pharmacist electronically conducting the verification is either a:

139 (-a-) Texas licensed pharmacist; or

140 (-b-) pharmacist employed by a Class E pharmacy that:

141 (-1-) has the same owner as the Class A pharmacy where the pharmacy technicians/trainees are
142 located; or

143 (-2-) has entered into a written contract or agreement with the Class A pharmacy, which outlines
144 the services to be provided and the responsibilities and accountabilities of each pharmacy in
145 compliance with federal and state laws and regulations;

146 (III) the pharmacy establishes controls to protect the privacy and security of confidential records;
147 and

148 (IV) the pharmacy keeps permanent records of prescriptions electronically verified for a period
149 of two years.

150 (E) All pharmacists, while on duty, shall be responsible for the legal operation of the pharmacy
151 and for complying with all state and federal laws or rules governing the practice of pharmacy.

152 (F) A dispensing pharmacist shall be responsible for and ensure that the drug is dispensed and
153 delivered safely, and accurately as prescribed, unless the pharmacy's data processing system can
154 record the identity of each pharmacist involved in a specific portion of the dispensing processing.
155 If the system can track the identity of each pharmacist involved in the dispensing process, each
156 pharmacist involved in the dispensing process shall be responsible for and ensure that the portion
157 of the process the pharmacist is performing results in the safe and accurate dispensing and
158 delivery of the drug as prescribed. The dispensing process shall include, but not be limited to,
159 drug regimen review and verification of accurate prescription data entry, including data entry of
160 prescriptions placed on hold, packaging, preparation, compounding, transferring, ~~and~~ labeling,
161 and performance of the final check of the dispensed prescription. An intern has the same
162 responsibilities described in this subparagraph as a pharmacist but must perform his or her duties
163 under the supervision of a pharmacist.

164 (2) Duties. Duties which may only be performed by a pharmacist are as follows:

165 (A) receiving oral prescription drug orders and reducing these orders to writing, either manually
166 or electronically;

- 167 (B) interpreting prescription drug orders;
- 168 (C) selecting drug products;
- 169 (D) performing the final check of the dispensed prescription before delivery to the patient to
170 ensure that the prescription has been dispensed accurately as prescribed;
- 171 (E) communicating to the patient or patient's agent information about the prescription drug or
172 device which in the exercise of the pharmacist's professional judgment, the pharmacist deems
173 significant, as specified in §291.33(c) of this title;
- 174 (F) communicating to the patient or the patient's agent on his or her request information
175 concerning any prescription drugs dispensed to the patient by the pharmacy;
- 176 (G) assuring that a reasonable effort is made to obtain, record, and maintain patient medication
177 records;
- 178 (H) interpreting patient medication records and performing drug regimen reviews;
- 179 (I) performing a specific act of drug therapy management for a patient delegated to a pharmacist
180 by a written protocol from a physician licensed in this state in compliance with the Medical
181 Practice Act; [~~and~~]
- 182 (J) verifying that controlled substances listed on invoices are received by clearly recording
183 his/her initials and date of receipt of the controlled substances; and[~~-~~]
- 184 (K) transferring or receiving a transfer of original prescription information on behalf of a patient.
- 185 (d) - (e) (No change.)
- 186 **§291.33.Operational Standards.**
- 187 (a) - (b) (No change.)
- 188 (c) Prescription dispensing and delivery.
- 189 (1) - (2) (No change.)
- 190 (3) [~~Generic~~] Substitution of generically equivalent drugs or interchangeable biological products.
191 A pharmacist may dispense a generically equivalent drug or interchangeable biological product
192 and shall comply with the provisions of §309.3 of this title (relating to [~~Generic~~] Substitution
193 Requirements).
- 194 (4) - (6) (No change.)
- 195 (7) Labeling.

- 196 (A) At the time of delivery of the drug, the dispensing container shall bear a label in plain
197 language and printed in an easily readable font size, unless otherwise specified, with at least the
198 following information:
- 199 (i) name, address and phone number of the pharmacy;
 - 200 (ii) unique identification number of the prescription that is printed in an easily readable font size
201 comparable to but no smaller than ten-point Times Roman;
 - 202 (iii) date the prescription is dispensed;
 - 203 (iv) initials or an identification code of the dispensing pharmacist;
 - 204 (v) name of the prescribing practitioner;
 - 205 (vi) if the prescription was signed by a pharmacist, the name of the pharmacist who signed the
206 prescription for a dangerous drug under delegated authority of a physician as specified in Subtitle
207 B, Chapter 157, Occupations Code;
 - 208 (vii) name of the patient or if such drug was prescribed for an animal, the species of the animal
209 and the name of the owner that is printed in an easily readable font size comparable to but no
210 smaller than ten-point Times Roman. The name of the patient's partner or family member is not
211 required to be on the label of a drug prescribed for a partner for a sexually transmitted disease or
212 for a patient's family members if the patient has an illness determined by the Centers for Disease
213 Control and Prevention, the World Health Organization, or the Governor's office to be pandemic;
 - 214 (viii) instructions for use that is printed in an easily readable font [size] comparable to but no
215 smaller than ten-point Times Roman;
 - 216 (ix) quantity dispensed;
 - 217 (x) appropriate ancillary instructions such as storage instructions or cautionary statements such
218 as warnings of potential harmful effects of combining the drug product with any product
219 containing alcohol;
 - 220 (xi) if the prescription is for a Schedules II - IV controlled substance, the statement "Caution:
221 Federal law prohibits the transfer of this drug to any person other than the patient for whom it
222 was prescribed";
 - 223 (xii) if the pharmacist has selected a generically equivalent drug or interchangeable biological
224 product pursuant to the provisions of the Act, Chapter 562, the statement "Substituted for Brand
225 Prescribed" or "Substituted for 'Brand Name'" where "Brand Name" is the actual name of the
226 brand name product prescribed;

227 (xiii) the name and strength of the actual drug or biological product dispensed that is printed in
228 an easily readable font size comparable to but no smaller than ten-point Times Roman, unless
229 otherwise directed by the prescribing practitioner;

230 (I) The name shall be either:

231 (-a-) the brand name; or

232 (-b-) if no brand name, then the generic drug or interchangeable biological product name and
233 name of the manufacturer or distributor of such generic drug or interchangeable biological
234 product. (The name of the manufacturer or distributor may be reduced to an abbreviation or
235 initials, provided the abbreviation or initials are sufficient to identify the manufacturer or
236 distributor. For combination drug products or non-sterile compounded drug preparations having
237 no brand name, the principal active ingredients shall be indicated on the label.)

238 (II) Except as provided in clause (xii) of this subparagraph, the brand name of the prescribed
239 drug or biological product shall not appear on the prescription container label unless it is the drug
240 product actually dispensed.

241 (xiv) if the drug is dispensed in a container other than the manufacturer's original container, the
242 date after which the prescription should not be used or beyond-use-date. Unless otherwise
243 specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is
244 dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may
245 be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is
246 not required on the label of a prescription dispensed to a person at the time of release from prison
247 or jail if the prescription is for not more than a 10-day supply of medication; and

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

252 (B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type
253 size smaller than ten-point Times Roman, the pharmacy shall provide the patient written
254 information containing the information as specified in subparagraph (A) of this paragraph in an
255 easily readable font [size] comparable to but no smaller than ten-point Times Roman.

256 (C) The label is not required to include the initials or identification code of the dispensing
257 pharmacist as specified in subparagraph (A) of this paragraph if the identity of the dispensing
258 pharmacist is recorded in the pharmacy's data processing system. The record of the identity of
259 the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

260 (D) The dispensing container is not required to bear the label as specified in subparagraph (A) of
261 this paragraph if:

262 (i) the drug is prescribed for administration to an ultimate user who is institutionalized in a
263 licensed health care institution (e.g., nursing home, hospice, hospital);

264 (ii) no more than a 90-day supply is dispensed at one time;

265 (iii) the drug is not in the possession of the ultimate user prior to administration;

266 (iv) the pharmacist-in-charge has determined that the institution:

267 (I) maintains medication administration records which include adequate directions for use for the
268 drug(s) prescribed;

269 (II) maintains records of ordering, receipt, and administration of the drug(s); and

270 (III) provides for appropriate safeguards for the control and storage of the drug(s); and

271 (v) the dispensing container bears a label that adequately:

272 (I) identifies the:

273 (-a-) pharmacy by name and address;

274 (-b-) unique identification number of the prescription;

275 (-c-) name and strength of the drug dispensed;

276 (-d-) name of the patient; and

277 (-e-) name of the prescribing practitioner or, if applicable, the name of the advanced practice
278 nurse, physician assistant, or pharmacist who signed the prescription drug order;

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

286 (III) sets forth the directions for use and cautionary statements, if any, contained on the
287 prescription drug order or required by law.

288 (8) (No change.)

289 (d) - (i) (No change.)

290 §291.34.Records.

291 (a) (No change.)

292 (b) Prescriptions.

293 (1) - (6) (No change.)

294 (7) Prescription drug order information.

295 (A) (No change.)

296 (B) At the time of dispensing, a pharmacist is responsible for documenting the following
297 information on either the original hard copy prescription or in the pharmacy's data processing
298 system:

299 (i) unique identification number of the prescription drug order;

300 (ii) initials or identification code of the dispensing pharmacist;

301 (iii) initials or identification code of the pharmacy technician or pharmacy technician trainee
302 performing data entry of the prescription, if applicable;

303 (iv) quantity dispensed, if different from the quantity prescribed;

304 (v) date of dispensing, if different from the date of issuance; and

305 (vi) brand name or manufacturer of the drug or biological product actually dispensed, if the drug
306 was prescribed by generic name or interchangeable biological name or if a drug or
307 interchangeable biological product other than the one prescribed was dispensed pursuant to the
308 provisions of the Act, Chapters 562 and 563.

309 (8) - (10) (No change.)

310 (c) - (f) (No change.)

311 (g) Transfer of prescription drug order information. For the purpose of initial or refill dispensing,
312 the transfer of original prescription drug order information is permissible between pharmacies,
313 subject to the following requirements.

314 (1) The transfer of original prescription drug order information for controlled substances listed in
315 Schedule III, IV, or V is permissible between pharmacies on a one-time basis only. However,
316 pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum
317 refills permitted by law and the prescriber's authorization.

- 318 (2) The transfer of original prescription drug order information for dangerous drugs is
319 permissible between pharmacies without limitation up to the number of originally authorized
320 refills.
- 321 (3) The transfer is communicated orally by telephone or via facsimile directly by a pharmacist to
322 another pharmacist; by a pharmacist to a student-intern, extended-intern, or resident-intern; or by
323 a student-intern, extended-intern, or resident-intern to another pharmacist.
- 324 (4) Both the original and the transferred prescription drug orders are maintained for a period of
325 two years from the date of last refill.
- 326 (5) The individual transferring the prescription drug order information shall ensure the following
327 occurs:
- 328 (A) write the word "void" on the face of the invalidated prescription or the prescription is voided
329 in the data processing system;
- 330 (B) record the name, address, if for a controlled substance, the DEA registration number of the
331 pharmacy to which it was transferred, and the name of the receiving individual on the reverse of
332 the invalidated prescription or stored with the invalidated prescription drug order in the data
333 processing system;
- 334 (C) record the date of the transfer and the name of the individual transferring the information;
335 and
- 336 (D) if the prescription is transferred electronically, provide the following information:
- 337 (i) date of original dispensing and prescription number;
- 338 (ii) number of refills remaining and if a controlled substance, the date(s) and location(s) of
339 previous refills;
- 340 (iii) name, address, and if a controlled substance, the DEA registration number of the transferring
341 pharmacy;
- 342 (iv) name of the individual transferring the prescription; and
- 343 (v) if a controlled substance, name, address and DEA registration number, and prescription
344 number from the pharmacy that originally dispensed the prescription, if different.
- 345 (6) The individual receiving the transferred prescription drug order information shall:
- 346 (A) write the word "transfer" on the face of the prescription or the prescription record indicates
347 the prescription was a transfer; and

348 (B) reduce to writing all of the information required to be on a prescription as specified in
349 subsection (b)(7) of this section (relating to Prescriptions) and including the following
350 information:

351 (i) date of issuance and prescription number;

352 (ii) original number of refills authorized on the original prescription drug order;

353 (iii) date of original dispensing;

354 (iv) number of valid refills remaining and if a controlled substance, date(s) and location(s) of
355 previous refills;

356 (v) name, address, and if for a controlled substance, the DEA registration number of the
357 transferring pharmacy;

358 (vi) name of the individual transferring the prescription; and

359 (vii) name, address, and if for a controlled substance, the DEA registration number, of the
360 pharmacy that originally dispensed the prescription, if different; or

361 (C) if the prescription is transferred electronically, create an electronic record for the prescription
362 that includes the receiving pharmacist's name and all of the information transferred with the
363 prescription including all of the information required to be on a prescription as specified in
364 subsection (b)(7) of this section (relating to Prescriptions) and the following:

365 (i) date of original dispensing;

366 (ii) number of refills remaining and if a controlled substance, the prescription number(s), date(s)
367 and location(s) of previous refills;

368 (iii) name, address, and if for a controlled substance, the DEA registration number;

369 (iv) name of the individual transferring the prescription; and

370 (v) name, address, and if for a controlled substance, the DEA registration number, of the
371 pharmacy that originally filled the prescription.

372 (7) Both the individual transferring the prescription and the individual receiving the prescription
373 must engage in confirmation of the prescription information by such means as:

374 (A) the transferring individual faxes the hard copy prescription to the receiving individual; or

375 (B) the receiving individual repeats the verbal information from the transferring individual and
376 the transferring individual verbally confirms that the repeated information is correct.

377 (8) Pharmacies transferring prescriptions electronically shall comply with the following:

378 (A) Prescription drug orders may not be transferred by non-electronic means during periods of
379 downtime except on consultation with and authorization by a prescribing practitioner; provided
380 however, during downtime, a hard copy of a prescription drug order may be made available for
381 informational purposes only, to the patient or a pharmacist, and the prescription may be read to a
382 pharmacist by telephone.

383 (B) The original prescription drug order shall be invalidated in the data processing system for
384 purposes of filling or refilling, but shall be maintained in the data processing system for refill
385 history purposes.

386 (C) If the data processing system does not have the capacity to store all the information as
387 specified in paragraphs (5) and (6) of this subsection, the pharmacist is required to record this
388 information on the original or transferred prescription drug order.

389 (D) The data processing system shall have a mechanism to prohibit the transfer or refilling of
390 controlled substance prescription drug orders that have been previously transferred.

391 (E) Pharmacies electronically accessing the same prescription drug order records may
392 electronically transfer prescription information if the following requirements are met.

393 (i) The original prescription is voided and the pharmacies' data processing systems shall store all
394 the information as specified in paragraphs (5) and (6) of this subsection.

395 (ii) Pharmacies not owned by the same entity ~~[person]~~ may electronically access the same
396 prescription drug order records, provided the owner, chief executive officer, or designee of each
397 pharmacy signs an agreement allowing access to such prescription drug order records.

398 (iii) An electronic transfer between pharmacies may be initiated by a pharmacist intern,
399 pharmacy technician, or pharmacy technician trainee acting under the direct supervision of a
400 pharmacist.

401 (9) An individual may not refuse to transfer original prescription information to another
402 individual who is acting on behalf of a patient and who is making a request for this information
403 as specified in this subsection. The transfer of original prescription information must be
404 completed within four business hours of the request. ~~[done in a timely manner.]~~

405 (10) When transferring a compounded prescription, a pharmacy is required to provide all of the
406 information regarding the compounded preparation including the formula unless the formula is
407 patented or otherwise protected, in which case, the transferring pharmacy shall, at a minimum,
408 provide the quantity or strength of all of the active ingredients of the compounded preparation.

409 (11) ~~(10)~~ The electronic transfer of multiple or bulk prescription records between two
410 pharmacies is permitted provided:

411 (A) a record of the transfer as specified in paragraph (5) of this section is maintained by the
412 transferring pharmacy;

413 (B) the information specified in paragraph (6) of this subsection is maintained by the receiving
414 pharmacy; and

415 (C) in the event that the patient or patient's agent is unaware of the transfer of the prescription
416 drug order record, the transferring pharmacy must notify the patient or patient's agent of the
417 transfer and must provide the patient or patient's agent with the telephone number of the
418 pharmacy receiving the multiple or bulk prescription drug order records.

419 (h) Distribution of prescription drugs [~~controlled substances~~] to another registrant. A pharmacy
420 may distribute prescription drugs [~~controlled substances~~] to a practitioner, another pharmacy, or
421 other registrant, without being registered to distribute, under the following conditions.

422 (1) If the distribution is for a controlled substance, the [The] registrant to whom the controlled
423 substance is to be distributed is registered under the Controlled Substances Act to possess
424 [~~dispense~~] that controlled substance.

425 (2) The total number of dosage units of prescription drugs [~~controlled substances~~] distributed by
426 a pharmacy may not exceed 5.0% of all prescription drugs [~~controlled substances~~] dispensed and
427 distributed by the pharmacy during the 12-month period in which the pharmacy is registered; if
428 at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to
429 distribute prescription drugs [~~controlled substances~~].

430 (3) If the distribution is for a dangerous drug, a record shall be maintained that indicates the:

431 (A) date of distribution;

432 (B) name, strength, and quantity of dangerous drug distributed;

433 (C) name and address of the distributing pharmacy; and

434 (D) name and address of the pharmacy, practitioner, or other registrant to whom the dangerous
435 drugs are distributed.

436 (4) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be
437 maintained that indicates the:

438 (A) [~~the actual~~] date of distribution;

439 (B) [~~the~~] name, strength, and quantity of controlled substances distributed;

440 (C) [~~the~~] name, address, and DEA registration number of the distributing pharmacy; and

441 (D) ~~the~~ name, address, and DEA registration number of the pharmacy, practitioner, or other
442 registrant to whom the controlled substances are distributed.

443 (5) ~~(4)~~ If the distribution is for a Schedule II controlled substance, the following is applicable.

444 (A) The pharmacy, practitioner, or other registrant who is receiving the controlled substances
445 shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222) to the distributing pharmacy.

446 (B) The distributing pharmacy shall:

447 (i) complete the area on the DEA order form (DEA 222) titled "To Be Filled in by Supplier";

448 (ii) maintain Copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and

449 (iii) forward Copy 2 of the DEA order form (DEA 222) to the Divisional Office of the Drug
450 Enforcement Administration.

451 (i) - (l) (No change.)

452 The agency certifies that legal counsel has reviewed the proposal and found it to be within the
453 state agency's legal authority to adopt.

454 Filed with the Office of the Secretary of State on September 14, 2015.

455 TRD-201503748

456 Gay Dodson, R.Ph.

457 Executive Director

458 Texas State Board of Pharmacy

459 Earliest possible date of adoption: October 25, 2015

460 For further information, please call: (512) 305-8028

461

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

2 **22 TAC §291.103, §291.104**

3 The Texas State Board of Pharmacy proposes amendments to §291.103 concerning Personnel
4 and §291.104 concerning Operational Standards. The amendments, if adopted, implement
5 provisions of S.B. 460 and HB 751 passed by the 84th Texas Legislature. The amendment to
6 §291.103, if adopted, require the pharmacist-in-charge of a non-resident pharmacy (Class E) to
7 be licensed in Texas. The amendments to §291.104, if adopted, update the requirements with
8 regard to interchangeable biological products and correct grammar.

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

12 Ms. Dodson has determined that, for each year of the first five-year period the rules will be in
13 effect, the public benefit anticipated as a result of enforcing the amendments will ensure the non-
14 resident pharmacies are supervised by appropriately licensed pharmacists; and pharmacies
15 appropriately dispense interchangeable biological products. There is no fiscal impact for
16 individuals, small or large businesses, or to other entities which are required to comply with
17 these sections.

18 Comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of
19 Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,
20 Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., October
21 30, 2015.

22 The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act
23 (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as
24 authorizing the agency to protect the public through the effective control and regulation of the
25 practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules
26 for the proper administration and enforcement of the Act.

27 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 -
28 569, Texas Occupations Code.

29 *§291.103.Personnel.*

30 As specified in §562.101(f) of the Act (relating to Supervision of Pharmacy), a Class E
31 pharmacy shall be under the continuous on-site supervision of a pharmacist and shall designate
32 one pharmacist licensed to practice pharmacy by the regulatory or licensing agency of the state
33 in which the Class E pharmacy is located and effective September 1, 2016, is licensed as a
34 pharmacist in Texas to serve as the pharmacist-in-charge of the Class E pharmacy license.

35 **§291.104.Operational Standards.**

- 36 (a) Licensing requirements.
- 37 (1) - (2) (No change.)
- 38 (3) On renewal of a license, the pharmacy shall complete the renewal application provided by the
39 board and, as specified in §561.0031 [~~§561.031~~] of the Act, provide an inspection report issued
40 not more than three years before the date the renewal application is received and conducted by
41 the pharmacy licensing board in the state of the pharmacy's physical location.
- 42 (A) A Class E pharmacy may submit an inspection report issued by an entity other than the
43 pharmacy licensing board of the state in which the pharmacy is physically located if the state's
44 licensing board does not conduct inspections as follows:
- 45 (i) an individual approved by the board who is not employed by the pharmacy but acting as a
46 consultant to inspect the pharmacy;
- 47 (ii) an agent of the National Association of Boards of Pharmacy;
- 48 (iii) an agent of another State Board of Pharmacy; or
- 49 (iv) an agent of an accrediting body, such as the Joint Commission on Accreditation of
50 Healthcare Organizations.
- 51 (B) The inspection must be substantively equivalent to an inspection conducted by the board.
- 52 (4) A Class E pharmacy which changes ownership shall notify the board within ten days of the
53 change of ownership and apply for a new and separate license as specified in §291.3 of this title
54 (relating to Required Notifications).
- 55 (5) A Class E pharmacy which changes location and/or name shall notify the board within ten
56 days of the change and file for an amended license as specified in §291.3 of this title.
- 57 (6) A Class E pharmacy owned by a partnership or corporation which changes managing officers
58 shall notify the board in writing of the names of the new managing officers within ten days of the
59 change, following the procedures in §291.3 of this title.
- 60 (7) A Class E pharmacy shall notify the board in writing within ten days of closing.
- 61 (8) A separate license is required for each principal place of business and only one pharmacy
62 license may be issued to a specific location.
- 63 (9) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged
64 for the issuance and renewal of a license and the issuance of an amended license.

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

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

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

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

77 ~~[(14) Prior to August 31, 2014, a Class E pharmacy engaged in the compounding of sterile
78 preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies
79 Compounding Sterile Preparations).]~~

80 (14) ~~[(15)]~~ ~~[Effective August 31, 2014, a]~~ Class E pharmacy personnel shall not compound
81 sterile preparations unless the pharmacy has applied for and obtained a Class E-S pharmacy.

82 (15) ~~[(16)]~~ A Class E pharmacy, which operates as a community type of pharmacy which would
83 otherwise be required to be licensed under the Act §560.051(a)(1) (Community Pharmacy (Class
84 A)), shall comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of
85 this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34
86 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription
87 Records), contained in Community Pharmacy (Class A); or which operates as a nuclear type of
88 pharmacy which would otherwise be required to be licensed under the Act §560.051(a)(2)
89 (Nuclear Pharmacy (Class B)), shall comply with the provisions of §291.51 of this title (relating
90 to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to
91 Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title
92 (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are
93 applicable to the operation of the pharmacy.

94 (b) (No change.)

95 (c) ~~[Generic]~~ Substitution requirements.

96 (1) Unless compliance would violate the pharmacy or drug laws or rules in the state in which the
97 pharmacy is located a pharmacist in a Class E pharmacy may dispense a generically equivalent
98 drug or interchangeable biological product and shall comply with the provisions of §309.3 of this
99 title (relating to ~~[Generic-]~~ Substitution Requirements) and §309.7 of this title (relating to
100 Dispensing Responsibilities).

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

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

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

109 (d) (No change.)

110 (e) Transfer of Prescription Drug Order Information. Unless compliance would violate the
111 pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a
112 Class E pharmacy may not refuse to transfer prescriptions to another pharmacy that is making
113 the transfer request on behalf of the patient. The transfer of original prescription information
114 must be done within four business hours of the request [~~in a timely manner~~].

115 (f) (No change.)

116 The agency certifies that legal counsel has reviewed the proposal and found it to be within the
117 state agency's legal authority to adopt.

118 Filed with the Office of the Secretary of State on September 14, 2015.

119 TRD-201503753

120 Gay Dodson, R.Ph.

121 Executive Director

122 Texas State Board of Pharmacy

123 Earliest possible date of adoption: October 25, 2015

124 For further information, please call: (512) 305-8028

125

From: Ritchard Engelhardt
Sent: Thursday, October 15, 2015 4:10 PM
To: Allison Benz
Subject: Proposed Rule: Substitution of Drug Products

Dear Ms. Benz,

I am writing to follow up with a conversation that I had with Margarita in your office earlier today regarding the proposed rule that amends 22 TAC §§309.1-309.8, relative to the Substitution of Drug Products. The rule appeared in the Texas Register on September 25, 2015 (Volume 40, Number 39) on pages 6545 – 6549.

When I reviewed the rule, I noticed that there were two errors on page 6548, under “§309.4 Patient Notification.” In paragraph (a)(1), the third line should read, “...equivalent drug or interchangeable biological product is available for the...”. In the current draft, the word “or” is omitted. Next, in the fifth line of the same paragraph, it should read, “...between the generically equivalent drug or interchangeable biological product and the...”. In the current draft, the word “interchangeable” is omitted, even though it correctly appears in every other instance referencing ‘interchangeable biological products’ throughout the proposed rule.

I appreciate your consideration and assistance in correcting this paragraph. Please reply to verify receipt of this email, and feel free to also contact me if you have any questions or concerns.

Best regards,
Ritchard Engelhardt

RITCHARD ENGELHARDT

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