

RULE ANALYSIS

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

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 309 SUBSTITUTION OF DRUG OR BIOLOGICAL PRODUCTS
4

5
6 **§309.1 Objective**
7

8 These sections govern the substitution of lower-priced generically equivalent drug products for
9 certain brand name drug products **and the substitution of interchangeable biological**
10 **products for certain biological products.**
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13 **§309.2 Definitions**
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15 The following words and terms, when used in this chapter, shall have the following meanings,
16 unless the context clearly indicates otherwise. Any term not defined in this section shall have
17 the definition set out in the Act, §551.003 and Chapter 562.
18

19 (1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.
20

21 (2) **Biological product—A virus, therapeutic serum, toxin, antitoxin, vaccine, blood,**
22 **blood component or derivative, allergenic product, protein (except any chemically**
23 **synthesized polypeptide), or analogous product, or arsphenamine or derivative of**
24 **arsphenamine (or any other trivalent organic arsenic compound), applicable to the**
25 **prevention, treatment, or cure of a disease or condition of human beings.**
26

27 **(3) Biosimilar—A biological product that is highly similar to the reference product**
28 **notwithstanding minor differences in clinically inactive components and there are no**
29 **clinically meaningful differences between the biological product and the reference**
30 **product in terms of the safety, purity, and potency of the product.**
31

32 **(4) Data communication device--An electronic device that receives electronic information from**
33 **one source and transmits or routes it to another (e.g., bridge, router, switch, or gateway).**
34

35 **(5) [(3)] Electronic prescription drug order--A prescription drug order which is transmitted by an**
36 **electronic device to the receiver (pharmacy).**
37

38 **(6) [(4)] Generically equivalent--A drug that is pharmaceutically equivalent and therapeutically**
39 **equivalent to the drug prescribed.**
40

41 **(7) Interchangeable- Referencing a biological product that is:**
42

43 **(A) biosimilar to the reference product and can be expected to produce the same**
44 **clinical result as the reference product in any given patient; and if the biological product**
45 **is administered more than once to an individual, the risk in terms of safety or diminished**
46 **efficacy of alternating or switching between use of the biological product and the**
47 **reference product is not greater than the risk of using the reference product without such**
48 **alternation or switch may be substituted for the reference product without the**
49 **intervention of the health care provider who prescribed the reference product; or**
50

51 (B) designated as therapeutically equivalent to another product by the United States
52 Food and Drug Administration in the most recent edition or supplement of the United
53 States Food and Drug Administration’s Approved Drug Products with Therapeutic
54 Equivalence Evaluations, also known as the Orange Book.

55
56 **(8)** [(5)] Pharmaceutically equivalent--Drug products that have identical amounts of the same
57 active chemical ingredients in the same dosage form and that meet the identical compendial or
58 other applicable standards of strength, quality, and purity according to the United States
59 Pharmacopoeia or another nationally recognized compendium.

60
61 **(9) Reference product—a single biological product against which a biological product is**
62 **evaluated and is found to be biosimilar.**

63
64 **(10)** [(6)] Therapeutically equivalent--Pharmaceutically equivalent drug products that, if
65 administered in the same amounts, will provide the same therapeutic effect, identical in duration
66 and intensity.

67
68 **(11)** [(7)] Original prescription--The:

69
70 (A) original written prescription drug orders; or

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

74
75 **(12)** [(8)] Practitioner--

76
77 (A) A person licensed or registered to prescribe, distribute, administer, or dispense a
78 prescription drug or device in the course of professional practice in this state, including a
79 physician, dentist, podiatrist, therapeutic optometrist, or veterinarian but excluding a person
80 licensed under this subtitle;

81
82 (B) A person licensed by another state, Canada, or the United Mexican States in a health
83 field in which, under the law of this state, a license holder in this state may legally prescribe a
84 dangerous drug;

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

90
91 (D) An advanced practice **registered** nurse or physician assistant to whom a physician has
92 delegated the authority to carry out or sign prescription drug orders under §§**157.0511,**
93 **157.0512, or** [157.052, 157.053,] 157.054, [157.0541, or 157.0542,] Occupations Code.

94
95 **§309.3 [Generic] Substitution Requirements**

96
97 (a) General requirements. In accordance with Chapter 562 of the Act, a pharmacist may
98 dispense a generically equivalent drug **or interchangeable biological** product if:

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100 (1) the generic **drug or interchangeable biological** product costs the patient less than the
101 prescribed drug product;

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

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

(b) Prescription format for written prescription drug orders.

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

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

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

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

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

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

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

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

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

(c) Dispensing directive.

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

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

(B) If the practitioner has prohibited substitution through a dispensing directive in compliance with this subsection, a pharmacist shall not substitute a generically equivalent drug **or**

153 **interchangeable biological** product unless the pharmacist obtains verbal or written
154 authorization from the practitioner, notes such authorization on the original prescription drug
155 order, and notifies the patient in accordance with §309.4 of this title (relating to Patient
156 Notification).

157

158 (2) Written prescriptions.

159

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

164

165 (B) The dispensing directive shall:

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

170

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

173

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

176

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

182

183 (3) Verbal Prescriptions.

184

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

191

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

195

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

198

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

201

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

205
206 (4) Electronic prescription drug orders.

207
208 (A) To prohibit substitution, the practitioner or practitioner's agent shall clearly indicate
209 substitution instructions in the electronic prescription drug order.

210
211 (B) If the practitioner or practitioner's agent does not indicate or does not clearly indicate in
212 the electronic prescription drug order that the brand is necessary, the pharmacist may substitute
213 a generically equivalent drug **or interchangeable biological** product.

214
215 (C) To prohibit substitution on an electronic prescription drug order reimbursed through the
216 medical assistance program specified in 42 C.F.R., §447.331, the practitioner shall comply with
217 state and federal laws.

218
219 (5) Prescriptions issued by out-of-state, Mexican, Canadian, or federal facility practitioners.

220
221 (A) The dispensing directive specified in this subsection does not apply to the following types
222 of prescription drug orders:

223
224 (i) prescription drug orders issued by a practitioner in a state other than Texas;

225
226 (ii) prescriptions for dangerous drugs issued by a practitioner in the United Mexican States
227 or the Dominion of Canada; or

228
229 (iii) prescription drug orders issued by practitioners practicing in a federal facility provided
230 they are acting in the scope of their employment.

231
232 (B) A pharmacist may not substitute on prescription drug orders identified in subparagraph
233 (A) of this paragraph unless the practitioner has authorized substitution on the prescription drug
234 order. If the practitioner has not authorized substitution on the written prescription drug order, a
235 pharmacist shall not substitute a generically equivalent drug product unless:

236
237 (i) the pharmacist obtains verbal or written authorization from the practitioner (such
238 authorization shall be noted on the original prescription drug order); or

239
240 (ii) the pharmacist obtains written documentation regarding substitution requirements from
241 the State Board of Pharmacy in the state, other than Texas, in which the prescription drug order
242 was issued. The following is applicable concerning this documentation.

243
244 (I) The documentation shall state that a pharmacist may substitute on a prescription drug
245 order issued in such other state unless the practitioner prohibits substitution on the original
246 prescription drug order.

247
248 (II) The pharmacist shall note on the original prescription drug order the fact that
249 documentation from such other state board of pharmacy is on file.

250
251 (III) Such documentation shall be updated yearly.

252

253 (d) Refills.

254

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

257

258 (2) Narrow therapeutic index drugs.

259

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

266

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

270

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

278

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

281

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

283

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

287

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

291

292

293 **§309.4 Patient Notification**

294

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

298

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

303

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

311
312 [(3)] A pharmacist shall offer the patient or the patient's agent the option of paying for a
313 prescription drug at a lower price instead of paying the amount of the copayment under the
314 patient's prescription drug insurance plan if the price of the prescribed drug is lower than the
315 amount of the patient's copayment.

316
317 (b) Exceptions. A pharmacy is not required to comply with the provisions of subsection (a) of
318 this section:

319
320 (1) in the case of the refill of a prescription for which the pharmacy previously complied with
321 subsection (a) of this section with regard to the same patient or patient's agent; or

322
323 (2) if the patient's physician or physician's agent advises the pharmacy that:

324
325 (A) the physician has informed the patient or the patient's agent that a less expensive
326 generically equivalent drug **or interchangeable biological product** is available for the brand
327 prescribed; and

328
329 (B) the patient or the patient's agent has chosen either the brand prescribed or the less
330 expensive generically equivalent drug **or interchangeable biological product**.

331
332 (c) Notification by pharmacies delivering prescriptions by mail.

333
334 (1) A pharmacy that supplies a prescription by mail is considered to have complied with the
335 provision of subsection (a) of this section if the pharmacy includes on the prescription order form
336 completed by the patient or the patient's agent language that clearly and conspicuously:

337
338 (A) states that if a less expensive generically equivalent drug **or interchangeable biological**
339 **product** is available for the brand prescribed, the patient or the patient's agent may choose
340 between the generically equivalent drug **or interchangeable biological product** and the brand
341 prescribed; and

342
343 (B) allows the patient or the patient's agent to indicate the choice of the generically equivalent
344 drug **or interchangeable biological product** or the brand prescribed.

345
346 (2) If the patient or patient's agent fails to indicate otherwise to a pharmacy on the prescription
347 order form under paragraph (1) of this subsection, the pharmacy may dispense a generically
348 equivalent drug **or interchangeable biological product**.

349
350 (d) Inpatient notification exemption. Institutional pharmacies shall be exempt from the labeling
351 provisions and patient notification requirements of §562.006 and §562.009 of the Act, as
352 respects drugs distributed pursuant to medication orders.

353
354

355 **§309.5 Communication with prescriber**
356

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

361
362 (b) The communication must be conveyed by making an entry into an interoperable
363 electronic medical records system or through electronic prescribing technology or a
364 pharmacy benefit management system or a pharmacy record, which may include
365 information submitted for the payment of claims, that a pharmacist reasonably
366 concludes is electronically accessible by the prescribing practitioner. Otherwise, the
367 pharmacist or the pharmacist's designee shall communicate the biological product
368 dispensed to the prescribing practitioner, using facsimile, telephone, electronic
369 transmission, or other prevailing means, provided that communication is not required if:

370
371 (1) there is no interchangeable biological product approved by the United States Food
372 and Drug Administration for the product prescribed; or

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

375
376 (c) This section expires September 1, 2019.
377

378 **§309.6 Records**
379

380 (a) When the pharmacist dispenses a generically equivalent drug **or interchangeable**
381 **biological product** pursuant to the Subchapter A, Chapter 562 of the Act, the following
382 information shall be noted on the original written or hard-copy of the oral prescription drug order:
383

384 (1) any substitution instructions communicated orally to the pharmacist by the practitioner or
385 practitioner's agent or a notation that no substitution instructions were given; and
386

387 (2) the name and strength of the actual drug product dispensed shall be noted on the original
388 or hard-copy prescription drug order. The name shall be either:
389

390 (A) the brand name and strength; or
391

392 (B) the generic name **or the name of the interchangeable biological product**, strength,
393 and name of the manufacturer or distributor of such generic drug **or interchangeable**
394 **biological product**. (The name of the manufacturer or distributor may be reduced to an
395 abbreviation or initials, provided the abbreviation or initials are sufficient to identify the
396 manufacturer or distributor. For combination drug products having no brand name, the principal
397 active ingredients shall be indicated on the prescription.)
398

399 (b) If a pharmacist refills a prescription drug order with a generically equivalent product **or**
400 **interchangeable biological product** from a different manufacturer or distributor than
401 previously dispensed, the pharmacist shall record on the prescription drug order the information
402 required in subsection (a) of this section for the product dispensed on the refill.
403

404 (c) If a pharmacy utilizes patient medication records for recording prescription information, the
405 information required in subsection (a) and (b) of this section shall be recorded on the patient
406 medication records.

407

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

411

412

413 **§309.7 Dispensing Responsibilities**

414

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

421

422 (b) Pharmacists shall use as a basis for the determination of generic equivalency as defined in
423 the Subchapter A, Chapter 562 of the Act, the following:

424

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

431

432 (2) For drugs not listed in the Orange Book, pharmacists shall use their professional judgment
433 to determine generic equivalency.

434

435

436 **§309.8 Advertising of Generic Drugs by Pharmacies**

437

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

441

442

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER B COMMUNITY PHARMACY (CLASS A)

5
6 **§291.33 Operational Standards**
7

8 (a) – (b) (No change.)
9

10 (c) Prescription dispensing and delivery.

11
12 (1) – (2) (No change.)
13

14 (3) [Generic] Substitution **of generically equivalent drugs or interchangeable biological**
15 **products**. A pharmacist may dispense a generically equivalent drug **or interchangeable**
16 **biological** product and shall comply with the provisions of §309.3 of this title (relating to
17 [Generic] Substitution **Requirements**).
18

19 (4) – (6) (No change.)
20

21 (7) Labeling.
22

23 (A) At the time of delivery of the drug, the dispensing container shall bear a label in plain
24 language and printed in an easily readable font size, unless otherwise specified, with at least
25 the following information:
26

27 (i) name, address and phone number of the pharmacy;
28

29 (ii) unique identification number of the prescription that is printed in an easily readable font
30 size comparable to but no smaller than ten-point Times Roman;
31

32 (iii) date the prescription is dispensed;
33

34 (iv) initials or an identification code of the dispensing pharmacist;
35

36 (v) name of the prescribing practitioner;
37

38 (vi) if the prescription was signed by a pharmacist, the name of the pharmacist who signed
39 the prescription for a dangerous drug under delegated authority of a physician as specified in
40 Subtitle B, Chapter 157, Occupations Code;
41

42 (vii) name of the patient or if such drug was prescribed for an animal, the species of the
43 animal and the name of the owner that is printed in an easily readable font size comparable to
44 but no smaller than ten-point Times Roman. The name of the patient's partner or family member
45 is not required to be on the label of a drug prescribed for a partner for a sexually transmitted
46 disease or for a patient's family members if the patient has an illness determined by the Centers
47 for Disease Control and Prevention, the World Health Organization, or the Governor's office to
48 be pandemic;
49

50 (viii) instructions for use that is printed in an easily readable font [size] comparable to but no
51 smaller than ten-point Times Roman;

52
53 (ix) quantity dispensed;

54
55 (x) appropriate ancillary instructions such as storage instructions or cautionary statements
56 such as warnings of potential harmful effects of combining the drug product with any product
57 containing alcohol;

58
59 (xi) if the prescription is for a Schedules II - IV controlled substance, the statement "Caution:
60 Federal law prohibits the transfer of this drug to any person other than the patient for whom it
61 was prescribed";

62
63 (xii) if the pharmacist has selected a generically equivalent drug **or interchangeable**
64 **biological product** pursuant to the provisions of the Act, Chapter 562, the statement
65 "Substituted for Brand Prescribed" or "Substituted for 'Brand Name'" where "Brand Name" is the
66 actual name of the brand name product prescribed;

67
68 (xiii) the name and strength of the actual drug **or biological** product dispensed that is
69 printed in an easily readable font size comparable to but no smaller than ten-point Times
70 Roman, unless otherwise directed by the prescribing practitioner;

71
72 (I) The name shall be either:

73
74 (-a-) the brand name; or

75
76 (-b-) if no brand name, then the generic **drug or interchangeable biological product**
77 name and name of the manufacturer or distributor of such generic drug **or interchangeable**
78 **biological product**. (The name of the manufacturer or distributor may be reduced to an
79 abbreviation or initials, provided the abbreviation or initials are sufficient to identify the
80 manufacturer or distributor. For combination drug products or non-sterile compounded drug
81 preparations having no brand name, the principal active ingredients shall be indicated on the
82 label.)

83
84 (II) Except as provided in clause (xii) of this subparagraph, the brand name of the
85 prescribed drug **or biological product** shall not appear on the prescription container label
86 unless it is the drug product actually dispensed.

87
88 (xiv) if the drug is dispensed in a container other than the manufacturer's original container,
89 the date after which the prescription should not be used or beyond-use-date. Unless otherwise
90 specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is
91 dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may
92 be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is
93 not required on the label of a prescription dispensed to a person at the time of release from
94 prison or jail if the prescription is for not more than a 10-day supply of medication; and

95
96 (xv) either on the prescription label or the written information accompanying the prescription,
97 the statement "Do not flush unused medications or pour down a sink or drain." A drug product
98 on a list developed by the Federal Food and Drug Administration of medicines recommended
99 for disposal by flushing is not required to bear this statement.

100
101 (B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type
102 size smaller than ten-point Times Roman, the pharmacy shall provide the patient written

103 information containing the information as specified in subparagraph (A) of this paragraph in an
104 easily readable font [size] comparable to but no smaller than ten-point Times Roman.
105

106 (C) The label is not required to include the initials or identification code of the dispensing
107 pharmacist as specified in subparagraph (A) of this paragraph if the identity of the dispensing
108 pharmacist is recorded in the pharmacy's data processing system. The record of the identity of
109 the dispensing pharmacist shall not be altered in the pharmacy's data processing system.
110

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

113
114 (i) the drug is prescribed for administration to an ultimate user who is institutionalized in a
115 licensed health care institution (e.g., nursing home, hospice, hospital);

116
117 (ii) no more than a 90-day supply is dispensed at one time;

118
119 (iii) the drug is not in the possession of the ultimate user prior to administration;

120
121 (iv) the pharmacist-in-charge has determined that the institution:

122
123 (I) maintains medication administration records which include adequate directions for use
124 for the drug(s) prescribed;

125
126 (II) maintains records of ordering, receipt, and administration of the drug(s); and

127
128 (III) provides for appropriate safeguards for the control and storage of the drug(s); and

129
130 (v) the dispensing container bears a label that adequately:

131
132 (I) identifies the:

133
134 (-a-) pharmacy by name and address;

135
136 (-b-) unique identification number of the prescription;

137
138 (-c-) name and strength of the drug dispensed;

139
140 (-d-) name of the patient; and

141
142 (-e-) name of the prescribing practitioner or, if applicable, the name of the advanced
143 practice nurse, physician assistant, or pharmacist who signed the prescription drug order;

144
145 (II) if the drug is dispensed in a container other than the manufacturer's original container,
146 specifies the date after which the prescription should not be used or beyond-use-date. Unless
147 otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date
148 the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-
149 use-date may be placed on the prescription label or on a flag label attached to the bottle. A
150 beyond-use-date is not required on the label of a prescription dispensed to a person at the time
151 of release from prison or jail if the prescription is for not more than a 10-day supply of
152 medication; and
153

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

156
157 (8) (No change.)

158
159 (d) – (i) (No change.)

160
161
162 **§291.34 Records**

163
164 (a) (No change.)

165
166 (b) Prescriptions.

167
168 (1) – (6) (No change.)

169
170 (7) Prescription drug order information.

171
172 (A) (No change.)

173
174 (B) At the time of dispensing, a pharmacist is responsible for documenting the following
175 information on either the original hard copy prescription or in the pharmacy's data processing
176 system:

177
178 (i) unique identification number of the prescription drug order;

179
180 (ii) initials or identification code of the dispensing pharmacist;

181
182 (iii) initials or identification code of the pharmacy technician or pharmacy technician trainee
183 performing data entry of the prescription, if applicable;

184
185 (iv) quantity dispensed, if different from the quantity prescribed;

186
187 (v) date of dispensing, if different from the date of issuance; and

188
189 (vi) brand name or manufacturer of the drug or biological product actually dispensed, if the
190 drug was prescribed by generic name or interchangeable biological name or if a drug or
191 interchangeable biological product other than the one prescribed was dispensed pursuant to
192 the provisions of the Act, Chapters 562 and 563.

193
194 (8) – (10) (No change.)

195
196 (c) – (h) (No change.)

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

5
6 **§291.104 Operational Standards**
7

8 (a) Licensing requirements.
9

10 (1) – (2) (No change.)
11

12 (3) On renewal of a license, the pharmacy shall complete the renewal application provided by
13 the board and, as specified in **§561.0031** [~~§561.031~~] of the Act, provide an inspection report
14 issued not more than three years before the date the renewal application is received and
15 conducted by the pharmacy licensing board in the state of the pharmacy's physical location.
16

17 (A) A Class E pharmacy may submit an inspection report issued by an entity other than the
18 pharmacy licensing board of the state in which the pharmacy is physically located if the state's
19 licensing board does not conduct inspections as follows:
20

21 (i) an individual approved by the board who is not employed by the pharmacy but acting as a
22 consultant to inspect the pharmacy;
23

24 (ii) an agent of the National Association of Boards of Pharmacy;
25

26 (iii) an agent of another State Board of Pharmacy; or
27

28 (iv) an agent of an accrediting body, such as the Joint Commission on Accreditation of
29 Healthcare Organizations.
30

31 (B) The inspection must be substantively equivalent to an inspection conducted by the board.
32

33 (4) A Class E pharmacy which changes ownership shall notify the board within ten days of the
34 change of ownership and apply for a new and separate license as specified in §291.3 of this title
35 (relating to Required Notifications).
36

37 (5) A Class E pharmacy which changes location and/or name shall notify the board within ten
38 days of the change and file for an amended license as specified in §291.3 of this title.
39

40 (6) A Class E pharmacy owned by a partnership or corporation which changes managing
41 officers shall notify the board in writing of the names of the new managing officers within ten
42 days of the change, following the procedures in §291.3 of this title.
43

44 (7) A Class E pharmacy shall notify the board in writing within ten days of closing.
45

46 (8) A separate license is required for each principal place of business and only one pharmacy
47 license may be issued to a specific location.
48

49 (9) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged
50 for the issuance and renewal of a license and the issuance of an amended license.
51

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

56
57 (11) A Class E pharmacy engaged in the centralized dispensing of prescription drug or
58 medication orders shall comply with the provisions of §291.125 of this title (relating to
59 Centralized Prescription Dispensing).

60
61 (12) A Class E pharmacy engaged in central processing of prescription drug or medication
62 orders shall comply with the provisions of §291.123 of this title (relating to Central Prescription
63 or Medication Order Processing).

64
65 (13) A Class E pharmacy engaged in the compounding of non-sterile preparations shall comply
66 with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile
67 Preparations).

68
69 (14) ~~[Prior to August 31, 2014, a Class E pharmacy engaged in the compounding of sterile
70 preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies
71 Compounding Sterile Preparations).]~~

72
73 (15) ~~[Effective August 31, 2014, a]~~ Class E pharmacy **personnel** shall not compound sterile
74 preparations unless the pharmacy has applied for and obtained a Class E-S pharmacy.

75
76 (16) A Class E pharmacy, which operates as a community type of pharmacy which would
77 otherwise be required to be licensed under the Act §560.051(a)(1) (Community Pharmacy
78 (Class A)), shall comply with the provisions of §291.31 of this title (relating to Definitions),
79 §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational
80 Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official
81 Prescription Records), contained in Community Pharmacy (Class A); or which operates as a
82 nuclear type of pharmacy which would otherwise be required to be licensed under the Act
83 §560.051(a)(2) (Nuclear Pharmacy (Class B)), shall comply with the provisions of §291.51 of
84 this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title
85 (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of
86 this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such
87 sections are applicable to the operation of the pharmacy.

88
89 (b) (No change.)

90
91 (c) ~~[Generic]~~ Substitution **requirements**.

92
93 (1) Unless compliance would violate the pharmacy or drug laws or rules in the state in which
94 the pharmacy is located a pharmacist in a Class E pharmacy may dispense a generically
95 equivalent drug **or interchangeable biological** product and shall comply with the provisions of
96 §309.3 of this title (relating to ~~[Generic]~~ Substitution **Requirements**) and §309.7 of this title
97 (relating to Dispensing Responsibilities).

98
99 (2) The pharmacy must include on the prescription order form completed by the patient or the
100 patient's agent information that clearly and conspicuously:

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

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

110 (d) (No change.)
111

112 (e) Transfer of Prescription Drug Order Information. Unless compliance would violate the
113 pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a
114 Class E pharmacy may not refuse to transfer prescriptions to another pharmacy that is making
115 the transfer request on behalf of the patient. The transfer of original prescription information
116 must be done **within four business hours of the request** ~~[in a timely manner]~~.
117

118 (f) (No change.)

AN ACT

relating to the prescription and pharmaceutical substitution of biological products; amending provisions subject to a criminal penalty.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 562.001, Occupations Code, is amended by amending Subdivision (1) and adding Subdivisions (1-a) and (1-b) to read as follows:

(1) "Biological product" has the meaning assigned by Section 351, Public Health Service Act (42 U.S.C. Section 262).

(1-a) "Generically equivalent" means a drug that is pharmaceutically equivalent and therapeutically equivalent to the drug prescribed.

(1-b) "Interchangeable," in reference to a biological product, has the meaning assigned by Section 351, Public Health Service Act (42 U.S.C. Section 262), or means a biological product that is designated as therapeutically equivalent to another product by the United States Food and Drug Administration in the most recent edition or supplement of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.

SECTION 2. Section 562.002, Occupations Code, is amended to read as follows:

Sec. 562.002. LEGISLATIVE INTENT. It is the intent of the

1 legislature to save consumers money by allowing the substitution of
2 lower-priced generically equivalent drug products for certain
3 brand name drug products and the substitution of interchangeable
4 biological products for certain biological products and for
5 pharmacies and pharmacists to pass on the net benefit of the lower
6 costs of the generically equivalent drug product or interchangeable
7 biological product to the purchaser.

8 SECTION 3. Section 562.003, Occupations Code, is amended to
9 read as follows:

10 Sec. 562.003. DISCLOSURE OF PRICE; PATIENT'S OPTION. If
11 the price of a drug or biological product to a patient is lower than
12 the amount of the patient's copayment under the patient's
13 prescription drug insurance plan, the pharmacist shall offer the
14 patient the option of paying for the drug or biological product at
15 the lower price instead of paying the amount of the copayment.

16 SECTION 4. Section 562.005, Occupations Code, is amended to
17 read as follows:

18 Sec. 562.005. RECORD OF DISPENSED DRUG OR BIOLOGICAL
19 PRODUCT. A pharmacist shall record on the prescription form the
20 name, strength, and manufacturer or distributor of a drug or
21 biological product dispensed as authorized by this subchapter.

22 SECTION 5. Subchapter A, Chapter 562, Occupations Code, is
23 amended by adding Section 562.0051 to read as follows:

24 Sec. 562.0051. COMMUNICATION REGARDING CERTAIN DISPENSED
25 BIOLOGICAL PRODUCTS. (a) Not later than the third business day
26 after the date of dispensing a biological product, the dispensing
27 pharmacist or the pharmacist's designee shall communicate to the

1 prescribing practitioner the specific product provided to the
2 patient, including the name of the product and the manufacturer or
3 national drug code number.

4 (b) The communication must be conveyed by making an entry
5 into an interoperable electronic medical records system or through
6 electronic prescribing technology or a pharmacy benefit management
7 system or a pharmacy record, which may include information
8 submitted for the payment of claims, that a pharmacist reasonably
9 concludes is electronically accessible by the prescribing
10 practitioner. Otherwise, the pharmacist or the pharmacist's
11 designee shall communicate the biological product dispensed to the
12 prescribing practitioner, using facsimile, telephone, electronic
13 transmission, or other prevailing means, provided that
14 communication is not required if:

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

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

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

21 SECTION 6. Section 562.006, Occupations Code, is amended to
22 read as follows:

23 Sec. 562.006. LABEL. (a) Unless otherwise directed by the
24 practitioner, the label on the dispensing container must indicate
25 the actual drug or biological product dispensed, indicated by
26 either:

27 (1) the brand name; or

1 (2) if there is not a brand name, the drug's generic
2 name or the name of the biological product, the strength of the drug
3 or biological product, and the name of the manufacturer or
4 distributor of the drug or biological product.

5 **(b)** [~~(a-1)~~] In addition to the information required by
6 Subsection (a), the label on the dispensing container of a drug or
7 biological product dispensed by a Class A or Class E pharmacy must
8 indicate:

9 (1) the name, address, and telephone number of the
10 pharmacy;

11 (2) the date the prescription is dispensed;

12 (3) the name of the prescribing practitioner;

13 (4) the name of the patient or, if the drug or
14 biological product was prescribed for an animal, the species of the
15 animal and the name of the owner;

16 (5) instructions for use;

17 (6) the quantity dispensed;

18 (7) if the drug or biological product is dispensed in a
19 container other than the manufacturer's original container, the
20 date after which the prescription should not be used, determined
21 according to criteria established by board rule based on standards
22 in the United States Pharmacopeia-National Formulary; and

23 (8) any other information required by board rule.

24 **(c)** [~~(a-2)~~] The information required by Subsection (b)(7)
25 [~~(a-1)(7)~~] may be recorded on any label affixed to the dispensing
26 container.

27 **(d)** [~~(a-3)~~] Subsection (b) [~~(a-1)~~] does not apply to a

1 prescription dispensed to a person at the time of release from
2 prison or jail if the prescription is for not more than a 10-day
3 supply of medication.

4 (e) [~~(b)~~] If a drug or biological product has been selected
5 other than the one prescribed, the pharmacist shall place on the
6 container the words "Substituted for brand prescribed" or
7 "Substituted for 'brand name'" where "brand name" is the name of the
8 brand name drug or biological product prescribed.

9 (f) [~~(c)~~] The board shall adopt rules requiring the label on
10 a dispensing container to be in plain language and printed in an
11 easily readable font size for the consumer.

12 SECTION 7. Section 562.008, Occupations Code, is amended to
13 read as follows:

14 Sec. 562.008. GENERIC EQUIVALENT OR INTERCHANGEABLE
15 BIOLOGICAL PRODUCT AUTHORIZED. (a) If a practitioner certifies on
16 the prescription form that a specific prescribed brand is medically
17 necessary, the pharmacist shall dispense the drug or biological
18 product as written by the practitioner. The certification must be
19 made as required by the dispensing directive adopted under Section
20 562.015. This subchapter does not permit a pharmacist to substitute
21 a generically equivalent drug or interchangeable biological
22 product unless the substitution is made as provided by this
23 subchapter.

24 (b) Except as otherwise provided by this subchapter, a
25 pharmacist who receives a prescription for a drug or biological
26 product for which there is one or more generic equivalents or one or
27 more interchangeable biological products may dispense any of the

1 generic equivalents or interchangeable biological products.

2 SECTION 8. The heading to Section 562.009, Occupations
3 Code, is amended to read as follows:

4 Sec. 562.009. REQUIREMENTS CONCERNING SELECTION OF
5 GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT.

6 SECTION 9. Sections 562.009(a), (b), (c), and (d),
7 Occupations Code, are amended to read as follows:

8 (a) Before delivery of a prescription for a generically
9 equivalent drug or interchangeable biological product, a
10 pharmacist must personally, or through the pharmacist's agent or
11 employee:

12 (1) inform the patient or the patient's agent that a
13 less expensive generically equivalent drug or interchangeable
14 biological product is available for the brand prescribed; and

15 (2) ask the patient or the patient's agent to choose
16 between the generically equivalent drug or interchangeable
17 biological product and the brand prescribed.

18 (b) A pharmacy is not required to comply with the provisions
19 of Subsection (a):

20 (1) in the case of the refill of a prescription for
21 which the pharmacy previously complied with Subsection (a) with
22 respect to the same patient or patient's agent; or

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

25 (A) the physician has informed the patient or the
26 patient's agent that a less expensive generically equivalent drug
27 or interchangeable biological product is available for the brand

1 prescribed; and

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

5 (c) A pharmacy that supplies a prescription by mail is
6 considered to have complied with the provisions of Subsection (a)
7 if the pharmacy includes on the prescription order form completed
8 by the patient or the patient's agent language that clearly and
9 conspicuously:

10 (1) states that if a less expensive generically
11 equivalent drug or interchangeable biological product is available
12 for the brand prescribed, the patient or the patient's agent may
13 choose between the generically equivalent drug or interchangeable
14 biological product and the brand prescribed; and

15 (2) allows the patient or the patient's agent to
16 indicate the choice between [~~of~~] the generically equivalent drug or
17 interchangeable biological product and [~~or~~] the brand prescribed.

18 (d) If the patient or the patient's agent fails to indicate
19 otherwise to a pharmacy on the prescription order form under
20 Subsection (c), the pharmacy may dispense a generically equivalent
21 drug or interchangeable biological product.

22 SECTION 10. Section 562.010, Occupations Code, is amended
23 to read as follows:

24 Sec. 562.010. RESPONSIBILITY CONCERNING GENERICALLY
25 EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT; LIABILITY.

26 (a) A pharmacist who selects a generically equivalent drug or
27 interchangeable biological product to be dispensed under this

1 subchapter assumes the same responsibility for selecting the
2 generically equivalent drug or interchangeable biological product
3 as the pharmacist does in filling a prescription for a drug
4 prescribed by generic or biological product name.

5 (b) The prescribing practitioner is not liable for a
6 pharmacist's act or omission in selecting, preparing, or dispensing
7 a drug or biological product under this subchapter.

8 SECTION 11. Section 562.011, Occupations Code, is amended
9 to read as follows:

10 Sec. 562.011. RESTRICTION ON SELECTION OF AND CHARGING FOR
11 GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT.

12 (a) A pharmacist may not select a generically equivalent drug or
13 interchangeable biological product unless the generically
14 equivalent drug or interchangeable biological product selected
15 costs the patient less than the prescribed drug or biological
16 product.

17 (b) A pharmacist may not charge for dispensing a generically
18 equivalent drug or interchangeable biological product a
19 professional fee higher than the fee the pharmacist customarily
20 charges for dispensing the brand name drug or biological product
21 prescribed.

22 SECTION 12. Section 562.013, Occupations Code, is amended
23 to read as follows:

24 Sec. 562.013. APPLICABILITY OF SUBCHAPTER. Unless a drug
25 is determined to be generically equivalent to, or a biological
26 product is determined to be interchangeable with, the brand
27 prescribed, drug or biological product selection as authorized by

1 this subchapter does not apply to:

- 2 (1) an enteric-coated tablet;
- 3 (2) a controlled release product;
- 4 (3) an injectable suspension, other than an
5 antibiotic;
- 6 (4) a suppository containing active ingredients for
7 which systemic absorption is necessary for therapeutic activity; or
- 8 (5) a different delivery system for aerosol or
9 nebulizer drugs.

10 SECTION 13. Section [562.015\(a\)](#), Occupations Code, is
11 amended to read as follows:

12 (a) The board shall adopt rules to provide a dispensing
13 directive to instruct pharmacists on the manner in which to
14 dispense a drug or biological product according to the contents of a
15 prescription. The rules adopted under this section must:

16 (1) require the use of the phrase "brand necessary" or
17 "brand medically necessary" on a prescription form to prohibit the
18 substitution of a generically equivalent drug or interchangeable
19 biological product for a brand name drug or biological product;

20 (2) be in a format that protects confidentiality as
21 required by the Health Insurance Portability and Accountability Act
22 of 1996 (Pub. L. No. 104-191) [~~(29 U.S.C. Section 1181 et seq.)~~] and
23 its subsequent amendments;

24 (3) comply with federal and state law, including
25 rules, with regard to formatting and security requirements;

26 (4) be developed to coordinate with 42 C.F.R. Section
27 447.512 [~~447.331(c)~~]; and

1 (5) include an exemption for electronic prescriptions
2 as provided by Subsection (b).

3 SECTION 14. Subchapter A, Chapter 562, Occupations Code, is
4 amended by adding Section 562.016 to read as follows:

5 Sec. 562.016. LIST OF APPROVED INTERCHANGEABLE BIOLOGICAL
6 PRODUCTS. The board shall maintain on the board's Internet website
7 a link to the United States Food and Drug Administration's list of
8 approved interchangeable biological products.

9 SECTION 15. (a) Chapter 562, Occupations Code, as amended
10 by this Act, applies only to a prescription issued for a biological
11 product on or after December 1, 2015. A prescription issued for a
12 biological product before December 1, 2015, is governed by the law
13 in effect immediately before that date, and the former law is
14 continued in effect for that purpose.

15 (b) The Texas State Board of Pharmacy shall adopt rules
16 necessary to implement the changes in law made by this Act not later
17 than December 1, 2015.

18 SECTION 16. This Act takes effect September 1, 2015.

President of the Senate

Speaker of the House

I certify that H.B. No. 751 was passed by the House on April 14, 2015, by the following vote: Yeas 146, Nays 0, 1 present, not voting; that the House refused to concur in Senate amendments to H.B. No. 751 on May 8, 2015, and requested the appointment of a conference committee to consider the differences between the two houses; and that the House adopted the conference committee report on H.B. No. 751 on May 21, 2015, by the following vote: Yeas 144, Nays 0, 1 present, not voting.

Chief Clerk of the House

H.B. No. 751

I certify that H.B. No. 751 was passed by the Senate, with amendments, on May 6, 2015, by the following vote: Yeas 31, Nays 0; at the request of the House, the Senate appointed a conference committee to consider the differences between the two houses; and that the Senate adopted the conference committee report on H.B. No. 751 on May 29, 2015, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

APPROVED: _____

Date

Governor

AN ACT

relating to the licensing and regulation of pharmacists and pharmacies.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 483.047, Health and Safety Code, is amended by amending Subsection (a) and adding Subsections (b-1) and (b-2) to read as follows:

(a) Except as authorized by Subsections [~~Subsection~~] (b) and (b-1), a pharmacist commits an offense if the pharmacist refills a prescription unless:

(1) the prescription contains an authorization by the practitioner for the refilling of the prescription, and the pharmacist refills the prescription in the manner provided by the authorization; or

(2) at the time of refilling the prescription, the pharmacist is authorized to do so by the practitioner who issued the prescription.

(b-1) Notwithstanding Subsection (b), in the event of a natural or manmade disaster, a pharmacist may dispense not more than a 30-day supply of a dangerous drug without the authorization of the prescribing practitioner if:

(1) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

1 (2) the natural or manmade disaster prohibits the
2 pharmacist from being able to contact the practitioner;

3 (3) the governor has declared a state of disaster
4 under Chapter 418, Government Code; and

5 (4) the board, through the executive director, has
6 notified pharmacies in this state that pharmacists may dispense up
7 to a 30-day supply of a dangerous drug.

8 (b-2) The prescribing practitioner is not liable for an act
9 or omission by a pharmacist in dispensing a dangerous drug under
10 Subsection (b-1).

11 SECTION 2. Section 555.002(a), Occupations Code, is amended
12 to read as follows:

13 (a) The board by rule shall establish methods by which
14 consumers and service recipients are notified of the name, mailing
15 address, and telephone number of the board for the purpose of
16 directing complaints to the board. The board may provide for that
17 notice:

18 (1) on each registration form, application, or written
19 contract for services of a person regulated by the board;

20 (2) on a sign prominently displayed in the place of
21 business of each person regulated by the board; ~~[or]~~

22 (3) on an electronic messaging system in a font
23 specified by board rule prominently displayed in the place of
24 business of each person regulated by the board; or

25 (4) in a bill for service provided by a person
26 regulated by the board.

27 SECTION 3. Section 556.051, Occupations Code, is amended to

1 read as follows:

2 Sec. 556.051. AUTHORIZATION TO ENTER AND INSPECT. (a) The
3 board or a representative of the board may enter and inspect a
4 facility relative to the following:

- 5 (1) drug storage and security;
- 6 (2) equipment;
- 7 (3) components used in compounding, finished and
8 unfinished products, containers, and labeling of any item;

9 (4) sanitary conditions; ~~or~~

10 (5) records, reports, or other documents required to
11 be kept or made under this subtitle, Chapter 481 or 483, Health and
12 Safety Code, or the Comprehensive Drug Abuse Prevention and Control
13 Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under
14 one of those laws; or

15 (6) subject to Subsection (b), financial records
16 relating to the operation of the facility.

17 (b) The board or a representative of the board may inspect
18 financial records under Subsection (a) only in the course of the
19 investigation of a specific complaint. The board or representative
20 may inspect only records related to the specific complaint. The
21 inspection is subject to Section 565.055.

22 SECTION 4. Section 556.054, Occupations Code, is amended to
23 read as follows:

24 Sec. 556.054. CONFIDENTIALITY OF CERTAIN INFORMATION
25 [LIMITATION ON INSPECTION]. The following information obtained by
26 the board during an inspection of a facility is confidential and not
27 subject to disclosure under Chapter 552, Government Code [Unless

1 ~~the owner, pharmacist, or agent in charge of a facility consents in~~
2 ~~writing, an inspection of the facility authorized by this chapter~~
3 ~~may not extend to]:~~

- 4 (1) financial data;
- 5 (2) sales data, other than shipment data; and ~~[or]~~
- 6 (3) pricing data.

7 SECTION 5. Subchapter B, Chapter 556, Occupations Code, is
8 amended by adding Section 556.057 to read as follows:

9 Sec. 556.057. INSPECTION OF PHARMACIST RECORDS. A
10 pharmacist shall provide to the board, on request, records of the
11 pharmacist's practice that occurs outside of a pharmacy. The
12 pharmacist shall provide the records at a time specified by board
13 rule.

14 SECTION 6. Sections 558.055(a) and (b), Occupations Code,
15 are amended to read as follows:

16 (a) An applicant who on the applicant's first attempt fails
17 the examination may take the examination four ~~[two]~~ additional
18 times.

19 (b) Before an applicant who has failed the examination five
20 ~~[three]~~ times is allowed to retake the examination, the applicant
21 must provide documentation from a college of pharmacy that the
22 applicant has successfully completed additional college course
23 work in each examination subject area the applicant failed.

24 SECTION 7. Section 560.052(b), Occupations Code, is amended
25 to read as follows:

26 (b) To qualify for a pharmacy license, an applicant must
27 submit to the board:

1 (1) a license fee set by the board, except as provided
2 by Subsection (d); and

3 (2) a completed application that:

4 (A) is on a form prescribed by the board;

5 (B) is given under oath;

6 (C) includes proof that:

7 (i) a pharmacy license held by the
8 applicant in this state or another state, if applicable, has not
9 been restricted, suspended, revoked, or surrendered for any reason;
10 and

11 (ii) no owner of the pharmacy for which the
12 application is made has held a pharmacist license in this state or
13 another state, if applicable, that has been restricted, suspended,
14 revoked, or surrendered for any reason; and

15 (D) includes a statement of:

16 (i) the ownership;

17 (ii) the location of the pharmacy;

18 (iii) the license number of each pharmacist
19 who is employed by the pharmacy, if the pharmacy is located in this
20 state, or who is licensed to practice pharmacy in this state, if the
21 pharmacy is located in another state;

22 (iv) the pharmacist license number of the
23 pharmacist-in-charge; and

24 (v) any other information the board
25 determines necessary.

26 SECTION 8. Section 561.003(e), Occupations Code, is amended
27 to read as follows:

1 (e) If a pharmacy's license has been expired for 91 days
2 [~~one year~~] or more, the pharmacy may not renew the license. The
3 pharmacy may obtain a new license by complying with the
4 requirements and procedures for obtaining an original license.

5 SECTION 9. Sections 562.056(a) and (a-1), Occupations Code,
6 are amended to read as follows:

7 (a) Before dispensing a prescription, a pharmacist shall
8 determine, in the exercise of sound professional judgment, that the
9 prescription is a valid prescription. A pharmacist may not
10 dispense a prescription drug if the pharmacist knows or should know
11 that the prescription was issued [~~on the basis of an Internet-based~~
12 ~~or telephonic consultation~~] without a valid practitioner-patient
13 relationship.

14 (a-1) To be a valid prescription, a prescription [~~for a~~
15 ~~controlled substance~~] must be issued for a legitimate medical
16 purpose by a practitioner acting in the usual course of the
17 practitioner's professional practice. The responsibility for the
18 proper prescribing and dispensing of prescription drugs
19 [~~controlled substances~~] is on the prescribing practitioner, but a
20 corresponding responsibility rests with the pharmacist who fills
21 the prescription.

22 SECTION 10. Section 562.106, Occupations Code, is amended
23 by amending Subsection (a) and adding Subsection (a-1) to read as
24 follows:

25 (a) A pharmacy shall report in writing to the board not
26 later than the 10th day after the date of:

- 27 (1) a permanent closing of the pharmacy;

- 1 (2) a change of ownership of the pharmacy;
- 2 (3) [~~a change of location of the pharmacy,~~
- 3 [~~(4)~~] a change of the person designated as the
- 4 pharmacist-in-charge of the pharmacy;
- 5 (4) [~~(5)~~] a sale or transfer of any controlled
- 6 substance or dangerous drug as a result of the permanent closing or
- 7 change of ownership of the pharmacy;
- 8 (5) [~~(6)~~] any matter or occurrence that the board
- 9 requires by rule to be reported;
- 10 (6) [~~(7)~~] as determined by the board, an out-of-state
- 11 purchase of any controlled substance;
- 12 (7) [~~(8)~~] a final order against the pharmacy license
- 13 holder by the regulatory or licensing agency of the state in which
- 14 the pharmacy is located if the pharmacy is located in another state;
- 15 or
- 16 (8) [~~(9)~~] a final order against a pharmacist who is
- 17 designated as the pharmacist-in-charge of the pharmacy by the
- 18 regulatory or licensing agency of the state in which the pharmacy is
- 19 located if the pharmacy is located in another state.
- 20 (a-1) A pharmacy shall report in writing to the board not
- 21 later than the 30th day before the date of a change of location of
- 22 the pharmacy.

23 SECTION 11. Section 565.002(a), Occupations Code, is

24 amended to read as follows:

25 (a) The board may discipline an applicant for or the holder

26 of a pharmacy license, including a Class E pharmacy license subject

27 to Section 565.003 [~~565.003(b)~~], if the board finds that the

1 applicant or license holder has:

2 (1) been convicted of or placed on deferred
3 adjudication community supervision or deferred disposition or the
4 applicable federal equivalent for:

5 (A) a misdemeanor:

6 (i) involving moral turpitude; or

7 (ii) under Chapter 481 or 483, Health and
8 Safety Code, or the Comprehensive Drug Abuse Prevention and Control
9 Act of 1970 (21 U.S.C. Section 801 et seq.); or

10 (B) a felony;

11 (2) advertised a prescription drug or device in a
12 deceitful, misleading, or fraudulent manner;

13 (3) violated any provision of this subtitle or any
14 rule adopted under this subtitle or that an owner or employee of a
15 pharmacy has violated any provision of this subtitle or any rule
16 adopted under this subtitle;

17 (4) sold without legal authorization a prescription
18 drug or device to a person other than:

19 (A) a pharmacy licensed by the board;

20 (B) a practitioner;

21 (C) a person who procures a prescription drug or
22 device for lawful research, teaching, or testing, and not for
23 resale;

24 (D) a manufacturer or wholesaler licensed by the
25 commissioner of public health as required by Chapter 431, Health
26 and Safety Code; or

27 (E) a carrier or warehouseman;

1 (5) allowed an employee who is not a pharmacist to
2 practice pharmacy;

3 (6) sold an adulterated or misbranded prescription or
4 nonprescription drug;

5 (7) failed to engage in or ceased to engage in the
6 business described in the application for a license;

7 (8) failed to maintain records as required by this
8 subtitle, Chapter 481 or 483, Health and Safety Code, the
9 Comprehensive Drug Abuse Prevention and Control Act of 1970 (21
10 U.S.C. Section 801 et seq.), or any rule adopted under this subtitle
11 or Chapter 483, Health and Safety Code;

12 (9) failed to establish and maintain effective
13 controls against diversion of prescription drugs into other than a
14 legitimate medical, scientific, or industrial channel as provided
15 by this subtitle, another state statute or rule, or a federal
16 statute or rule;

17 (10) engaged in fraud, deceit, or misrepresentation as
18 defined by board rule in operating a pharmacy or in applying for a
19 license to operate a pharmacy;

20 (11) violated a disciplinary order;

21 (12) been responsible for a drug audit shortage; [~~or~~]

22 (13) been disciplined by the regulatory board of
23 another state for conduct substantially equivalent to conduct
24 described under this subsection; or

25 (14) waived, discounted, or reduced, or offered to
26 waive, discount, or reduce, a patient copayment or deductible for a
27 compounded drug in the absence of:

1 (A) a legitimate, documented financial hardship
2 of the patient; or

3 (B) evidence of a good faith effort to collect
4 the copayment or deductible from the patient.

5 SECTION 12. Section 565.060(d), Occupations Code, is
6 amended to read as follows:

7 (d) If a license holder complies with and successfully
8 completes the terms of a remedial plan, the board shall remove all
9 records of the remedial plan from the board's records at the end of
10 the state fiscal year in which ~~on~~ the fifth anniversary of the
11 date the board issued the terms of the remedial plan occurs.

12 SECTION 13. Section 565.061(a), Occupations Code, is
13 amended to read as follows:

14 (a) Except as provided by Chapter 564, a disciplinary action
15 taken by the board ~~[under Section 565.060 or]~~ on the basis of a
16 ground for discipline under Subchapter A is governed by Chapter
17 2001, Government Code, and the rules of practice and procedure
18 before the board.

19 SECTION 14. The following provisions of the Occupations
20 Code are repealed:

- 21 (1) Section 561.003(d);
22 (2) Section 562.009(a-1); and
23 (3) Section 562.051.

24 SECTION 15. The change in law made by this Act to Section
25 483.047, Health and Safety Code, applies only to an offense
26 committed on or after the effective date of this Act. An offense
27 committed before the effective date of this Act is governed by the

1 law in effect on the date the offense was committed, and the former
2 law is continued in effect for that purpose. For purposes of this
3 section, an offense was committed before the effective date of this
4 Act if any element of the offense occurred before that date.

5 SECTION 16. Section 560.052(b), Occupations Code, as
6 amended by this Act, applies only to an application for a pharmacy
7 license submitted on or after the effective date of this Act. An
8 application submitted before the effective date of this Act is
9 governed by the law in effect on the date the application was
10 submitted, and the former law is continued in effect for that
11 purpose.

12 SECTION 17. Section 561.003(e), Occupations Code, as
13 amended by this Act, and the repeal by this Act of Section
14 561.003(d), Occupations Code, apply only to a pharmacy license that
15 expires on or after the effective date of this Act. A pharmacy
16 license that expired before the effective date of this Act is
17 governed by the law in effect on the date the license expired, and
18 the former law is continued in effect for that purpose.

19 SECTION 18. Section 562.106(a), Occupations Code, as
20 amended by this Act, and Section 562.106(a-1), Occupations Code, as
21 added by this Act, apply only to a pharmacy that changes location on
22 or after October 1, 2015. A pharmacy that changes location before
23 that date is governed by the law in effect immediately before the
24 effective date of this Act, and the former law is continued in
25 effect for that purpose.

26 SECTION 19. The change in law made by this Act to Section
27 565.002(a), Occupations Code, applies only to conduct that occurs

1 on or after the effective date of this Act. Conduct that occurs
2 before that date is governed by the law in effect on the date the
3 conduct occurred, and the former law is continued in effect for that
4 purpose.

5 SECTION 20. The change in law made by this Act to Section
6 565.061(a), Occupations Code, is a clarification of existing law
7 and does not imply that existing law may be construed as
8 inconsistent with the law as amended by this Act.

9 SECTION 21. This Act takes effect September 1, 2015.

S.B. No. 460

President of the Senate

Speaker of the House

I hereby certify that S.B. No. 460 passed the Senate on April 14, 2015, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

I hereby certify that S.B. No. 460 passed the House on May 22, 2015, by the following vote: Yeas 137, Nays 3, two present not voting.

Chief Clerk of the House

Approved:

Date

Governor