

1 **PART 15 TEXAS STATE BOARD OF PHARMACY**  
2 **CHAPTER 309 SUBSTITUTION OF DRUG PRODUCTS**

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4  
5 **§309.1 Objective**

6  
7 These sections govern the substitution of lower-priced generically equivalent drug products for  
8 certain brand name drug products.  
9

10  
11 **§309.2 Definitions**

12  
13 The following words and terms, when used in this chapter, shall have the following meanings,  
14 unless the context clearly indicates otherwise. Any term not defined in this section shall have  
15 the definition set out in the Act, §551.003 and Chapter 562.  
16

17 (1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.  
18

19 (2) Data communication device--An electronic device that receives electronic information from  
20 one source and transmits or routes it to another (e.g., bridge, router, switch, or gateway).  
21

22 (3) Electronic prescription drug order--A prescription drug order which is transmitted by an  
23 electronic device to the receiver (pharmacy).  
24

25 (4) Generically equivalent--A drug that is pharmaceutically equivalent and therapeutically  
26 equivalent to the drug prescribed.  
27

28 (5) Pharmaceutically equivalent--Drug products that have identical amounts of the same active  
29 chemical ingredients in the same dosage form and that meet the identical compendial or other  
30 applicable standards of strength, quality, and purity according to the United States  
31 Pharmacopoeia or another nationally recognized compendium.  
32

33 (6) Therapeutically equivalent--Pharmaceutically equivalent drug products that, if administered  
34 in the same amounts, will provide the same therapeutic effect, identical in duration and intensity.  
35

36 (7) Original prescription--The:  
37

38 (A) original written prescription drug orders; or  
39

40 (B) original verbal or electronic prescription drug orders reduced to writing either manually or  
41 electronically by the pharmacist.  
42

43 (8) Practitioner--  
44

45 (A) A person licensed or registered to prescribe, distribute, administer, or dispense a  
46 prescription drug or device in the course of professional practice in this state, including a  
47 physician, dentist, podiatrist, therapeutic optometrist, or veterinarian but excluding a person  
48 licensed under this subtitle;  
49

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

53  
54 (C) A person practicing in another state and licensed by another state as a physician, dentist,  
55 veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration  
56 registration number and who may legally prescribe a Schedule II, III, IV, or V controlled  
57 substance, as specified under Chapter 481, Health and Safety Code, in that other state; or  
58

59 (D) An advanced practice nurse or physician assistant to whom a physician has delegated  
60 the authority to carry out or sign prescription drug orders under §§157.052, 157.053, 157.054,  
61 157.0541, or 157.0542, Occupations Code.  
62

### 63 **§309.3 Generic Substitution**

64  
65  
66 (a) General requirements. In accordance with Chapter 562 of the Act, a pharmacist may  
67 dispense a generically equivalent drug product if:

68  
69 (1) the generic product costs the patient less than the prescribed drug product;

70  
71 (2) the patient does not refuse the substitution; and  
72

73 (3) the practitioner does not certify on the prescription form that a specific prescribed brand is  
74 medically necessary as specified in a dispensing directive described in subsection (c) of this  
75 section.  
76

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

78  
79 (1) A written prescription drug order issued in Texas may:

80  
81 (A) be on a form containing a single signature line for the practitioner; and  
82

83 (B) contain the following reminder statement on the face of the prescription: "A generically  
84 equivalent drug product may be dispensed unless the practitioner hand writes the words 'Brand  
85 Necessary' or 'Brand Medically Necessary' on the face of the prescription."  
86

87 (2) A pharmacist may dispense a prescription that is not issued on the form specified in  
88 paragraph (1) of this subsection, however, the pharmacist may dispense a generically  
89 equivalent drug product unless the practitioner has prohibited substitution through a dispensing  
90 directive in compliance with subsection (c)(1) of this section.  
91

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

94  
95 (A) prescription drug orders issued by a practitioner in a state other than Texas;  
96

97 (B) prescriptions for dangerous drugs issued by a practitioner in the United Mexican States or  
98 the Dominion of Canada; or  
99

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

102  
103 (4) In the event of multiple prescription orders appearing on one prescription form, the  
104 practitioner shall clearly identify to which prescription(s) the dispensing directive(s) apply. If the  
105 practitioner does not clearly indicate to which prescription(s) the dispensing directive(s) apply,  
106 the pharmacist may substitute on all prescriptions on the form.

107  
108 (c) Dispensing directive.

109  
110 (1) General requirements. The following is applicable to the dispensing directive outlined in this  
111 subsection.

112  
113 (A) When a prescription is issued for a brand name product that has no generic equivalent  
114 product, the pharmacist must dispense the brand name product. If a generic equivalent product  
115 becomes available, a pharmacist may substitute the generically equivalent product unless the  
116 practitioner has specified on the initial prescription that the brand name product is medically  
117 necessary.

118  
119 (B) If the practitioner has prohibited substitution through a dispensing directive in compliance  
120 with this subsection, a pharmacist shall not substitute a generically equivalent drug product  
121 unless the pharmacist obtains verbal or written authorization from the practitioner, notes such  
122 authorization on the original prescription drug order, and notifies the patient in accordance with  
123 §309.4 of this title (relating to Patient Notification).

124  
125 (2) Written prescriptions.

126  
127 (A) A practitioner may prohibit the substitution of a generically equivalent drug product for a  
128 brand name drug product by writing across the face of the written prescription, in the  
129 practitioner's own handwriting, the phrase "brand necessary" or "brand medically necessary."

130  
131 (B) The dispensing directive shall:

132  
133 (i) be in a format that protects confidentiality as required by the Health Insurance Portability  
134 and Accountability Act of 1996 (29 U.S.C. Section 1181 et seq.) and its subsequent  
135 amendments; and

136  
137 (ii) comply with federal and state law, including rules, with regard to formatting and security  
138 requirements.

139  
140 (C) The dispensing directive specified in this paragraph may not be preprinted, rubber  
141 stamped, or otherwise reproduced on the prescription form.

142  
143 (D) A practitioner may prohibit substitution on a written prescription only by following the  
144 dispensing directive specified in this paragraph. Two-line prescription forms, check boxes, or  
145 other notations on an original prescription drug order which indicate "substitution instructions"  
146 are not valid methods to prohibit substitution, and a pharmacist may substitute on these types of  
147 written prescriptions.

148  
149 (3) Verbal Prescriptions.

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

157  
158 (B) If the practitioner's or practitioner's agent does not clearly indicate that the brand name is  
159 medically necessary, the pharmacist may substitute a generically equivalent drug product.

160  
161 (C) To prohibit substitution on a verbal prescription reimbursed through the medical  
162 assistance program specified in 42 C.F.R., §447.331:

163  
164 (i) the practitioner or the practitioner's agent shall verbally indicate that the brand is  
165 medically necessary; and

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

170  
171 (4) Electronic prescription drug orders.

172  
173 (A) To prohibit substitution, the practitioner or practitioner's agent shall clearly indicate  
174 substitution instructions in the electronic prescription drug order.

175  
176 (B) If the practitioner or practitioner's agent does not indicate or does not clearly indicate in  
177 the electronic prescription drug order that the brand is necessary, the pharmacist may substitute  
178 a generically equivalent drug product.

179  
180 (C) To prohibit substitution on an electronic prescription drug order reimbursed through the  
181 medical assistance program specified in 42 C.F.R., §447.331, the practitioner shall comply with  
182 state and federal laws.

183  
184 (5) Prescriptions issued by out-of-state, Mexican, Canadian, or federal facility practitioners.

185  
186 (A) The dispensing directive specified in this subsection does not apply to the following types  
187 of prescription drug orders:

188  
189 (i) prescription drug orders issued by a practitioner in a state other than Texas;

190  
191 (ii) prescriptions for dangerous drugs issued by a practitioner in the United Mexican States  
192 or the Dominion of Canada; or

193  
194 (iii) prescription drug orders issued by practitioners practicing in a federal facility provided  
195 they are acting in the scope of their employment.

196  
197 (B) A pharmacist may not substitute on prescription drug orders identified in subparagraph  
198 (A) of this paragraph unless the practitioner has authorized substitution on the prescription drug  
199 order. If the practitioner has not authorized substitution on the written prescription drug order, a  
200 pharmacist shall not substitute a generically equivalent drug product unless:

201

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

204  
205 (ii) the pharmacist obtains written documentation regarding substitution requirements from  
206 the State Board of Pharmacy in the state, other than Texas, in which the prescription drug order  
207 was issued. The following is applicable concerning this documentation.

208  
209 (I) The documentation shall state that a pharmacist may substitute on a prescription drug  
210 order issued in such other state unless the practitioner prohibits substitution on the original  
211 prescription drug order.

212  
213 (II) The pharmacist shall note on the original prescription drug order the fact that  
214 documentation from such other state board of pharmacy is on file.

215  
216 (III) Such documentation shall be updated yearly.

217  
218 (d) Refills.

219  
220 (1) Original substitution instructions. All refills shall follow the original substitution instructions  
221 unless otherwise indicated by the practitioner or practitioner's agent.

222  
223 (2) Narrow therapeutic index drugs.

224  
225 (A) The board and the Texas Medical Board shall establish a joint committee to recommend  
226 to the board a list of narrow therapeutic index drugs and the rules, if any, by which this  
227 paragraph applies to those drugs. The committee must consist of an equal number of members  
228 from each board. The committee members shall select a member of the committee to serve as  
229 presiding officer for a one year term. The presiding officer may not represent the same board as  
230 the presiding officer's predecessor.

231  
232 (B) The board, on the recommendation of the joint committee, has determined that no drugs  
233 shall be included on a list of narrow therapeutic index drugs as defined in §562.014,  
234 Occupations Code.

235  
236 (i) The board has specified in §309.7 of this title (relating to dispensing responsibilities) that  
237 for drugs listed in the publication, pharmacist shall use as a basis for determining generic  
238 equivalency, Approved Drug Products with Therapeutic Equivalence Evaluations and current  
239 supplements published by the Federal Food and Drug Administration, within the limitations  
240 stipulated in that publication. For drugs listed in the publications, pharmacists may only  
241 substitute products that are rated therapeutically equivalent in the Approved Drug Products with  
242 Therapeutic Equivalence Evaluations and current supplements.

243  
244 (ii) Practitioners may prohibit substitution through a dispensing directive in compliance with  
245 subsection (c) of this section.

246  
247 (C) The board shall reconsider the contents of the list if:

248  
249 (i) the Federal Food and Drug Administration determines a new equivalence classification  
250 which indicates that certain drug products are equivalent but special notification to the patient  
251 and practitioner is required when substituting these products; or

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

256  
257  
258 **§309.4 Patient Notification**  
259

260 (a) Substitution notification. Before delivery of a prescription for a generically equivalent drug  
261 products as authorized by Chapter 562, Subchapter A of the Act, a pharmacist must:

262  
263 (1) personally, or through his or her agent or employee inform the patient or the patient's agent  
264 that a less expensive generically equivalent drug product is available for the brand prescribed;  
265 and ask the patient or the patient's agent to choose between the generically equivalent drug and  
266 the brand prescribed.

267  
268 (2) cause to be displayed, in a prominent place that is in clear public view where prescription  
269 drugs are dispensed, a sign in block letters not less than one inch in height that reads, in both  
270 English and Spanish: "TEXAS LAW REQUIRES A PHARMACIST TO INFORM YOU IF A LESS  
271 EXPENSIVE GENERICALLY EQUIVALENT DRUG IS AVAILABLE FOR CERTAIN BRAND  
272 NAME DRUGS AND TO ASK YOU TO CHOOSE BETWEEN THE GENERIC AND THE  
273 BRAND NAME DRUG. YOU HAVE A RIGHT TO ACCEPT OR REFUSE THE GENERICALLY  
274 EQUIVALENT DRUG."

275  
276 (3) A pharmacist shall offer the patient or the patient's agent the option of paying for a  
277 prescription drug at a lower price instead of paying the amount of the copayment under the  
278 patient's prescription drug insurance plan if the price of the prescribed drug is lower than the  
279 amount of the patient's copayment.

280  
281 (b) Exceptions. A pharmacy is not required to comply with the provisions of subsection (a) of  
282 this section:

283  
284 (1) in the case of the refill of a prescription for which the pharmacy previously complied with  
285 subsection (a) of this section with regard to the same patient or patient's agent; or

286  
287 (2) if the patient's physician or physician's agent advises the pharmacy that:

288  
289 (A) the physician has informed the patient or the patient's agent that a less expensive  
290 generically equivalent drug is available for the brand prescribed; and

291  
292 (B) the patient or the patient's agent has chosen either the brand prescribed or the less  
293 expensive generically equivalent drug.

294  
295 (c) Notification by pharmacies delivering prescriptions by mail.

296  
297 (1) A pharmacy that supplies a prescription by mail is considered to have complied with the  
298 provision of subsection (a) of this section if the pharmacy includes on the prescription order form  
299 completed by the patient or the patient's agent language that clearly and conspicuously:

300  
301 (A) states that if a less expensive generically equivalent drug is available for the brand  
302 prescribed, the patient or the patient's agent may choose between the generically equivalent  
303 drug and the brand prescribed; and

304  
305 (B) allows the patient or the patient's agent to indicate the choice of the generically equivalent  
306 drug or the brand prescribed.

307  
308 (2) If the patient or patient's agent fails to indicate otherwise to a pharmacy on the prescription  
309 order form under paragraph (1) of this subsection, the pharmacy may dispense a generically  
310 equivalent drug.

311  
312 (d) Inpatient notification exemption. Institutional pharmacies shall be exempt from the labeling  
313 provisions and patient notification requirements of §562.006 and §562.009 of the Act, as  
314 respects drugs distributed pursuant to medication orders.

315  
316  
317 **§309.6 Records**

318  
319 (a) When the pharmacist dispenses a generically equivalent drug pursuant to the Subchapter A,  
320 Chapter 562 of the Act, the following information shall be noted on the original written or hard-  
321 copy of the oral prescription drug order:

322  
323 (1) any substitution instructions communicated orally to the pharmacist by the practitioner or  
324 practitioner's agent or a notation that no substitution instructions were given; and

325  
326 (2) the name and strength of the actual drug product dispensed shall be noted on the original  
327 or hard-copy prescription drug order. The name shall be either:

328  
329 (A) the brand name and strength; or

330  
331 (B) the generic name, strength, and name of the manufacturer or distributor of such generic  
332 drug. (The name of the manufacturer or distributor may be reduced to an abbreviation or initials,  
333 provided the abbreviation or initials are sufficient to identify the manufacturer or distributor. For  
334 combination drug products having no brand name, the principal active ingredients shall be  
335 indicated on the prescription.)

336  
337 (b) If a pharmacist refills a prescription drug order with a generically equivalent product from a  
338 different manufacturer or distributor than previously dispensed, the pharmacist shall record on  
339 the prescription drug order the information required in subsection (a) of this section for the  
340 product dispensed on the refill.

341  
342 (c) If a pharmacy utilizes patient medication records for recording prescription information, the  
343 information required in subsection (a) and (b) of this section shall be recorded on the patient  
344 medication records.

345  
346 (d) The National Drug Code (NDC) of a drug or any other code may be indicated on the  
347 prescription drug order at the discretion of the pharmacist, but such code shall not be used in  
348 place of the requirements of subsections (a) and (b) of this section.

349  
350  
351 **§309.7 Dispensing Responsibilities**

352  
353 (a) The determination of the drug product to be substituted as authorized by the Subchapter A,  
354 Chapter 562 of the Act, is the professional responsibility of the pharmacist, and the pharmacist

355 may not dispense any product that does not meet the requirements of the Subchapter A,  
356 Chapter 562 of the Act. As specified in Chapter 562 of the Act and § 309.2 of this title (relating  
357 to definitions), a generically equivalent product is one that is pharmaceutically equivalent and  
358 therapeutically equivalent to the drug prescribed.

359  
360 (b) Pharmacists shall use as a basis for the determination of generic equivalency as defined in  
361 the Subchapter A, Chapter 562 of the Act, the following:

362  
363 (1) For drugs listed in the publication, pharmacists shall use Approved Drug Products With  
364 Therapeutic Equivalence Evaluations (Orange Book) and current supplements published by the  
365 Federal Food and Drug Administration, within the limitations stipulated in that publication, to  
366 determine generic equivalency. Pharmacists may only substitute products that are rated  
367 therapeutically equivalent in the Orange Book and have an "A" rating. "A" rated drug products  
368 include but are not limited to, those designated AA, AB, AN, AO, AP, or AT in the Orange Book.

369  
370 (2) For drugs not listed in the Orange Book, pharmacists shall use their professional judgment  
371 to determine generic equivalency.

372  
373

#### 374 **§309.8 Advertising of Generic Drugs by Pharmacies**

375

376 Prescription drug advertising comparing generic and brand name drugs is subject to the  
377 §554.054 of the Act and in compliance with federal law.

378