

## RULE ANALYSIS

**Introduction:** THESE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS ADOPTED RULES

**Short Title:** Substitution of Drug Products

**Rule Numbers:** §§309.1, 309.3

**Statutory Authority:** Texas Pharmacy Act, Chapter 551-566 and 568-569, 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;
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act; and
- (3) Section 562.0141 authorizes the Board in consultation with the Texas Medical Board to establish by a rule a list of NTI drugs.

**Purpose:** The amendments, if adopted, establish procedures for practitioners to prohibit substitution based on the manufacturer of the brand or generic product.

**Background:** At the Board's February 2008 meeting, these amendments were presented along with amendments regarding the addition of immunosuppressant and anti-epileptic drugs to the NTI list. The Board directed staff to propose the amendments regarding the NTI list and to present the amendments regarding procedures for practitioners to prohibit substitution at the May 2008 meeting.

**The Board reviewed and voted to propose the amendments during their May 6-7, 2008, meeting. The proposed amendments were published in the June 20, 2008, issue of the *Texas Register* at 33 TexReg 4800.**

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

2 **22 TAC §309.1, §309.3**

3 The Texas State Board of Pharmacy proposes amendments to §309.1, concerning Objective, and  
4 §309.3, concerning Generic Substitution. The amendments, if adopted, establish the procedures  
5 for practitioners to prohibit substitution based on the manufacturer of the brand or generic  
6 product.

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

10 Ms. Dodson has determined that, for each year of the first five-year period the rules will be in  
11 effect, the public benefit anticipated as a result of enforcing the rules will be to provide  
12 procedures for practitioners to prohibit substitution based on the manufacturer of the brand or  
13 generic product. There is no fiscal impact for individuals, small or large businesses or to other  
14 entities which are required to comply with the sections.

15 A public hearing to receive comments on the proposed amendments will be held at 9:00 a.m. on  
16 Tuesday, August 5, 2008, at the Health Professions Council Board Room, William P. Hobby  
17 Building, 333 Guadalupe Street, Tower II, Room 225, Austin, Texas 78701. Persons planning to  
18 present comments to the Board are asked to provide a written copy of their comments prior to the  
19 hearing or bring 20 copies to the hearing. Written comments on the proposed amendments may  
20 be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board  
21 of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, FAX (512) 305-8082.  
22 Comments must be received by 5:00 p.m., July 21, 2008.

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

28 The statutes affected by the amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 -  
29 569, Texas Occupations Code.

30 *§309.1.Objective.*

31 These sections: [~~govern the substitution of lower-priced generically equivalent drug products for~~  
32 ~~certain brand name drug products.~~]

33 (1) govern the substitution of lower-priced generically equivalent drug products for certain brand  
34 name drug products; and

35 (2) establish the procedures for practitioners to prohibit substitution based on the manufacturer of  
36 the brand or generic product.

1 §309.3. *Generic Substitution.*

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

4 ~~[(1) In accordance with Chapter 562 of the Act, a pharmacist may dispense a generically~~  
5 ~~equivalent drug product if:]~~

6 (1) [(A)] the generic product costs the patient less than the prescribed drug product;

7 (2) [(B) ] the patient does not refuse the substitution; and

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

11 ~~[(2) If the practitioner has prohibited substitution through a dispensing directive in compliance~~  
12 ~~with subsection (c) of this section, a pharmacist shall not substitute a generically equivalent drug~~  
13 ~~product unless the pharmacist obtains verbal or written authorization from the practitioner and~~  
14 ~~notes such authorization on the original prescription drug order.]~~

15 (b) (No change.)

16 (c) Dispensing directive.

17 (1) General requirements. The following is applicable to dispensing directives outlines in this  
18 subsection.

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

24 (B) If a practitioner issues a prescription for a generic drug and specifies a particular  
25 manufacturer or that the same manufacturer always be dispensed, the pharmacist may not refill  
26 the prescription with another manufacturer's product without authorization, from the prescribing  
27 practitioner.

28 (C) If the practitioner has prohibited substitution through a dispensing directive in compliance  
29 with this subsection, a pharmacist shall not substitute a generically equivalent drug product  
30 unless the pharmacist obtains verbal or written authorization from the practitioner, notes such  
31 authorization on the original prescription drug order, and notifies the patient in accordance with  
32 §309.4 of this title (relating to Patient Notification).

33 (2) [(4)] Written prescriptions.

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

4 (B) The dispensing directive shall:

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

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

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

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

16 (3) [~~2~~] Verbal Prescriptions.

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

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

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

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

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

32 (4) [~~3~~] Electronic prescription drug orders.

33 (A) To prohibit substitution, the practitioner or practitioner's agent shall note "brand necessary"  
34 or "brand medically necessary" in the electronic prescription drug order.

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

4 (C) To prohibit substitution on an electronic prescription drug order reimbursed through the  
5 medical assistance program specified in 42 C.F.R., §447.331, the practitioner shall fax a copy of  
6 the original prescription drug order which complies with the requirements of a written  
7 prescription drug order specified in paragraph (1) of this subsection within 30 days.

8 (5) [~~(4)~~] Prescriptions issued by out-of-state, Mexican, Canadian, or federal facility practitioners.

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

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

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

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

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

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

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

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

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

30 (III) Such documentation shall be updated yearly.

31 (d) - (e) (No change.)

32 This agency hereby certifies that the proposal has been reviewed by legal counsel and found to  
33 be within the agency's legal authority to adopt.

1 Filed with the Office of the Secretary of State on June 9, 2008.

2 TRD-200802982

3 Gay Dodson, R.Ph.

4 Executive Director/Secretary

5 Texas State Board of Pharmacy

6 Earliest possible date of adoption: July 20, 2008

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

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