

SENATE AMENDMENTS

2nd Printing

By: Zerwas, Davis of Harris, Sheffield,
Thompson of Harris, et al.

H.B. No. 751

A BILL TO BE ENTITLED

1 AN ACT

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

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

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

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

11 (1-a) "Generically equivalent" means a drug that is
12 pharmaceutically equivalent and therapeutically equivalent to the
13 drug prescribed.

14 (1-b) "Interchangeable," in reference to a biological
15 product, has the meaning assigned by Section 351, Public Health
16 Service Act (42 U.S.C. Section 262), or means a biological product
17 that is designated as therapeutically equivalent to another product
18 by the United States Food and Drug Administration in the most recent
19 edition or supplement of the United States Food and Drug
20 Administration's Approved Drug Products with Therapeutic
21 Equivalence Evaluations, also known as the Orange Book.

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

24 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.

ADOPTED

MAY 06 2015

Atty. Gen.
Secretary of the Senate

FLOOR AMENDMENT NO. 1

BY: *L. W. Kelleher*

1 Amend H.B. No. 751 (senate committee printing), in SECTION 5
2 of the bill, in added Section 562.0051(b), Occupations Code (page
3 2, line 17), between "practitioner." and "Otherwise", by inserting
4 "An entry into an electronic records system as described by this
5 subsection is presumed to be sufficient to provide notice to the
6 prescribing practitioner.".

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION

May 7, 2015

TO: Honorable Joe Straus, Speaker of the House, House of Representatives

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: HB751 by Zerwas (Relating to the prescription and pharmaceutical substitution of biological products; amending provisions subject to a criminal penalty.), **As Passed 2nd House**

No significant fiscal implication to the State is anticipated.

The bill would amend the Occupations Code relating to the prescription and pharmaceutical substitution of biological products; amending provisions subject to a criminal penalty. Based on the analysis of the Board of Pharmacy, duties and responsibilities associated with implementing the provisions of the bill could be accomplished by utilizing existing resources.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 515 Board of Pharmacy

LBB Staff: UP, SD, NB, NV, TWh

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION

April 22, 2015

TO: Honorable Charles Schwertner, Chair, Senate Committee on Health & Human Services

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: HB751 by Zerwas (Relating to the prescription and pharmaceutical substitution of biological products; amending provisions subject to a criminal penalty.), **As Engrossed**

No significant fiscal implication to the State is anticipated.

The bill would amend the Occupations Code relating to the prescription and pharmaceutical substitution of biological products; amending provisions subject to a criminal penalty. Based on the analysis of the Board of Pharmacy, duties and responsibilities associated with implementing the provisions of the bill could be accomplished by utilizing existing resources.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 515 Board of Pharmacy

LBB Staff: UP, NB, NV, TWh

**LEGISLATIVE BUDGET BOARD
Austin, Texas**

FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION

March 25, 2015

TO: Honorable Myra Crownover, Chair, House Committee on Public Health

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: HB751 by Zerwas (relating to the prescription and pharmaceutical substitution of biological products; amending provisions subject to a criminal penalty.), **Committee Report 1st House, Substituted**

No significant fiscal implication to the State is anticipated.

The bill would amend the relating to the prescription and pharmaceutical substitution of biological products; amending provisions subject to a criminal penalty. Based on the analysis of the Board of Pharmacy, duties and responsibilities associated with implementing the provisions of the bill could be accomplished by utilizing existing resources.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 515 Board of Pharmacy

LBB Staff: UP, NB, NV, TWh

**LEGISLATIVE BUDGET BOARD
Austin, Texas**

FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION

March 14, 2015

TO: Honorable Myra Crownover, Chair, House Committee on Public Health

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: HB751 by Zerwas (Relating to the prescription and pharmaceutical substitution of biological products.), **As Introduced**

No fiscal implication to the State is anticipated.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 515 Board of Pharmacy

LBB Staff: UP, NB, NV, TWh