CONFERENCE COMMITTEE REPORT FORM

Austin, Texas

May 18, 2015
Date

Honorable Dan Patrick
President of the Senate

Honorable Joe Straus
Speaker of the House of Representatives

Sirs:

We, Your Conference Committee, appointed to adjust the differences between the Senate and the House of Representatives on House Bill 751 have had the same under consideration, and beg to report it back with the recommendation that it do pass in the form and text hereto attached.

Representative John Zerwas, M.D.

Representative Myra Crownover

Representative Sarah Davis

Representative J.D. Sheffield, D.O.

Representative Senfronia Thompson

On the part of the Senate

Senator Lois Kolkhorst

Senator Donna Campbell

Senator Charles Perry

Senator Charles Schwertner, M.D.

Senator Carlos Uresti

On the part of the House

Note to Conference Committee Clerk:

Please type the names of the members of the Conference Committee under the lines provided for signature. Those members desiring to sign the report should sign each of the six copies. Attach a copy of the Conference Committee Report and a Section by Section side by side comparison to each of the six reporting forms. The original and two copies are filed in house of origin of the bill, and three copies in the other house.

CONFERENCE COMMITTEE REPORT

3rd Printing

H.B. No. 751

A BILL TO BE ENTITLED

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

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

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

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

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

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

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

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

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

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

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

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

(c) This section expires September 1, 2019.

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

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

(1) the brand name; or

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

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

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

(2) the date the prescription is dispensed;

(3) the name of the prescribing practitioner;

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

(5) instructions for use;

(6) the quantity dispensed;

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

(8) any other information required by board rule.

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

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

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

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

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

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

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

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

generic equivalents or interchangeable biological products.

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

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

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

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

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

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

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

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

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

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

prescribed; and

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

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

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

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

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

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

Sec. 562.010. RESPONSIBILITY CONCERNING GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT; LIABILITY. (a) A pharmacist who selects a generically equivalent drug or interchangeable biological product to be dispensed under this

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

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

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

Sec. 562.011. RESTRICTION ON SELECTION OF AND CHARGING FOR GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT. (a) A pharmacist may not select a generically equivalent drug or interchangeable biological product unless the generically equivalent drug or interchangeable biological product selected costs the patient less than the prescribed drug or biological product.

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

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

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

this subchapter does not apply to:

(1) an enteric-coated tablet;

(2) a controlled release product;

(3) an injectable suspension, other than an antibiotic;

(4) a suppository containing active ingredients for which systemic absorption is necessary for therapeutic activity; or

(5) a different delivery system for aerosol or nebulizer drugs.

SECTION 13. Section 562.015(a), Occupations Code, is amended to read as follows:

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

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

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

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

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

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

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

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

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

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

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

House Bill 751
Conference Committee Report
Section-by-Section Analysis

HOUSE VERSION	SENATE VERSION (IE)	CONFERENCE
SECTION 1. Section 562.001, Occupations Code, is amended.	SECTION 1. Same as House version.	SECTION 1. Same as House version.
SECTION 2. Section 562.002, Occupations Code, is amended.	SECTION 2. Same as House version.	SECTION 2. Same as House version.
SECTION 3. Section 562.003, Occupations Code, is amended.	SECTION 3. Same as House version.	SECTION 3. Same as House version.
SECTION 4. Section 562.005, Occupations Code, is amended.	SECTION 4. Same as House version.	SECTION 4. Same as House version.
SECTION 5. Subchapter A, Chapter 562, Occupations Code, is amended by adding Section 562.0051 to read as follows: Sec. 562.0051. COMMUNICATION REGARDING CERTAIN DISPENSED BIOLOGICAL PRODUCTS. (a) Not later than the third business day after the date of dispensing a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer or national drug code number. (b) The communication must be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy benefit management system or a pharmacy record, which may include information submitted for the payment of claims, that a pharmacist reasonably concludes is electronically accessible	SECTION 5. Subchapter A, Chapter 562, Occupations Code, is amended by adding Section 562.0051 to read as follows: Sec. 562.0051. COMMUNICATION REGARDING CERTAIN DISPENSED BIOLOGICAL PRODUCTS. (a) Not later than the third business day after the date of dispensing a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer or national drug code number. (b) The communication must be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy benefit management system or a pharmacy record, which may include information submitted for the payment of claims, that a pharmacist reasonably concludes is electronically accessible	SECTION 5. Same as House version.

HOUSE VERSION	SENATE VERSION (IE)	CONFERENCE
by the prescribing practitioner. Otherwise, the pharmacist or the pharmacist's designee shall communicate the biological product dispensed to the prescribing practitioner, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication is not required if: (1) there is no interchangeable biological product approved by the United States Food and Drug Administration for the product prescribed; or (2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription. (c) This section expires September 1, 2019.	by the prescribing practitioner. ***An entry into an electronic records system as described by this subsection is presumed to be sufficient to provide notice to the prescribing practitioner.*** Otherwise, the pharmacist or the pharmacist's designee shall communicate the biological product dispensed to the prescribing practitioner, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication is not required if: [FA1] (1) there is no interchangeable biological product approved by the United States Food and Drug Administration for the product prescribed; or (2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription. (c) This section expires September 1, 2019.	
SECTION 6. Section 562.006, Occupations Code, is amended.	SECTION 6. Same as House version.	SECTION 6. Same as House version.
SECTION 7. Section 562.008, Occupations Code, is amended.	SECTION 7. Same as House version.	SECTION 7. Same as House version.
SECTION 8. The heading to Section 562.009, Occupations Code, is amended.	SECTION 8. Same as House version.	SECTION 8. Same as House version.
SECTION 9. Sections 562.009(a), (b), (c), and (d), Occupations Code, are amended.	SECTION 9. Same as House version.	SECTION 9. Same as House version.

HOUSE VERSION	SENATE VERSION (IE)	CONFERENCE
SECTION 10. Section 562.010, Occupations Code, is amended.	SECTION 10. Same as House version.	SECTION 10. Same as House version.
SECTION 11. Section 562.011, Occupations Code, is amended.	SECTION 11. Same as House version.	SECTION 11. Same as House version.
SECTION 12. Section 562.013, Occupations Code, is amended.	SECTION 12. Same as House version.	SECTION 12. Same as House version.
SECTION 13. Section 562.015(a), Occupations Code, is amended.	SECTION 13. Same as House version.	SECTION 13. Same as House version.
SECTION 14. Subchapter A, Chapter 562, Occupations Code, is amended.	SECTION 14. Same as House version.	SECTION 14. Same as House version.
SECTION 15. (a) Chapter 562, Occupations Code, as amended by this Act, applies only to a prescription issued for a biological product on or after December 1, 2015. A prescription issued for a biological product before December 1, 2015, is governed by the law in effect immediately before that date, and the former law is continued in effect for that purpose. (b) The Texas State Board of Pharmacy shall adopt rules necessary to implement the changes in law made by this Act not later than December 1, 2015.	SECTION 15. Same as House version.	SECTION 15. Same as House version.

HOUSE VERSION	SENATE VERSION (IE)	CONFERENCE
SECTION 16. This Act takes effect September 1, 2015.	SECTION 16. Same as House version.	SECTION 16. Same as House version.

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION

May 20, 2015

TO: Honorable Dan Patrick, Lieutenant Governor, Senate
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.), **Conference Committee Report**

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

Certification of Compliance with
Rule 13, Section 6(b), House Rules of Procedure

Rule 13, Section 6(b), House Rules of Procedure, requires a copy of a conference committee report signed by a majority of each committee of the conference to be furnished to each member of the committee in person or, if unable to deliver in person, by placing a copy in the member's newspaper mailbox at least one hour before the report is furnished to each member of the house under Rule 13, Section 10(a). The paper copies of the report submitted to the chief clerk under Rule 13, Section 10(b), must contain a certificate that the requirement of Rule 13, Section 6(b), has been satisfied, and that certificate must be attached to the copy of the report furnished to each member under Rule 13, Section 10(d). Failure to comply with this requirement is not a sustainable point of order under Rule 13.

I certify that a copy of the conference committee report on HB 751 was furnished to each member of the conference committee in compliance with Rule 13, Section 6(b), House Rules of Procedure, before submission of the paper copies of the report to the chief clerk under Rule 13, Section 10(b), House Rules of Procedure.

John Zerwas
(name)

May 20, 2015
(date)