# BILL ANALYSIS

Senate Research Center

H.B. 751
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Health & Human Services
4/27/2015
Engrossed

## AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

The development and use of biologics, which refers to the class of biopharmaceutical therapies derived from living organisms or organic substances, has led to advancements in the treatment of difficult-to-manage diseases and disorders such as cancer, multiple sclerosis, rheumatoid arthritis, heart disease, HIV and AIDS, chronic renal failure, and Crohn's disease. A biosimilar, or follow-on biologic, is a product marketed after the expiration of a patent on an innovator biologic. Biosimilars have similar properties to existing biological products but are not identical. The federal Public Health Service Act provides for the approval of biosimilars, but a formal regulatory process is still being established by the United States Food and Drug Administration (FDA).

H.B. 751 updates the Texas Pharmacy Practice Act by allowing Texas pharmacists to dispense safe and less expensive biologic medications to patients, by allowing substitution of an FDA approved interchangeable biologic for a prescribed brand name biologic. The pharmacy practice act has specific rules that must be followed to ensure safe generic substitution. Passing H.B. 751 would update these laws to include a similar process to ensure safe biologic substitution. Biosimilars are expected on the market in 2015.

H.B. 751 ensures only FDA approved “interchangeable” biologic products may be substituted without prior prescriber consent. Physicians will retain the authority to use Dispense as Written and ensures patients will be notified of the substitution, in the same way they are notified about a generic substitution.

Because biologic products differ from generics in complexity and are not identical chemical products, H.B. 751 ensures there will be communication between pharmacists and prescribers to ensure medical records reflect which specific product has been dispensed to the patient. This information would be relayed after the prescription is dispensed to alleviate the need for waiting for pre-approval, as current law requires.

Floor amendments adopted in the House of Representatives clarify the communication process between pharmacists and physicians and streamline the process. Specifically, medical records sent to the physician would not need to include information related to payment of claims or other information not related to patient care, and the pharmacist would only need to communicate with the actual prescribing physician and not with a group of physicians. To ensure that pharmacies do not incur unnecessary new costs, the bill allows for pharmacies to use their existing pharmacist benefit management system to communicate with physicians.

H.B. 751 amends current law relating to the prescription and pharmaceutical substitution of biological products, and amends provisions subject to a criminal penalty.

## RULEMAKING AUTHORITY

Rulemaking authority previously granted to the Texas State Board of Pharmacy is modified in SECTION 6 (Section 562.006, Occupations Code) and SECTION 13 (Section 562.015, Occupations Code) of this bill.

**SECTION BY SECTION ANALYSIS**

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

(1) Defines "biological product."

(1-a) Creates this subdivision from existing Subdivision (1) and makes no further change to this subdivision.

(1-b) Defines "interchangeable."

SECTION 2. Amends Section 562.002, Occupations Code, as follows:

Sec. 562.002. LEGISLATIVE INTENT. Provides that 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. Amends Section 562.003, Occupations Code, as follows:

Sec. 562.003. DISCLOSURE OF PRICE; PATIENT'S OPTION. Requires the pharmacist, 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, to 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. Amends Section 562.005, Occupations Code, as follows:

Sec. 562.005. New heading: RECORD OF DISPENSED DRUG OR BIOLOGICAL PRODUCT. Requires a pharmacist to 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. Amends Subchapter A, Chapter 562, Occupations Code, by adding Section 562.0051, as follows:

Sec. 562.0051. COMMUNICATION REGARDING CERTAIN DISPENSED BIOLOGICAL PRODUCTS. (a) Requires the dispensing pharmacist or the pharmacist's designee, not later than the third business day after the date of dispensing a biological product, to 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) Requires that the communication 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. Requires the pharmacist or the pharmacist's designee, otherwise, to 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 (FDA) for the product prescribed; or

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

(c) Provides that this section expires September 1, 2019.

SECTION 6. Amends Section 562.006, Occupations Code, as follows:

Sec. 562.006. LABEL. (a) Requires that the label on the dispensing container, unless otherwise directed by the practitioner, 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) Redesignates existing Subsection (a-1) as Subsection (b). Requires that the label on the dispensing container of a drug or biological product dispensed by a Class A or Class E pharmacy, in addition to the information required by Subsection (a), indicate:

(1)-(3) Makes no change to these subdivisions;

(4) Adds a reference to a biological product and makes no further change to this subdivision;

(5) and (6) Makes no change to these subdivisions;

(7) Adds a reference to a biological product and makes no further change to this subdivision; and

(8) Makes no change to this subdivision.

(c) Redesignates existing Subsection (a-2) as Subsection (c). Changes a reference to Subsection (a-1)(7) to Subsection (b)(7) and makes no further change to this subsection.

(d) Redesignates existing Subsection (a-3) as Subsection (d). Changes a reference to Subsection (a-1) to Subsection (b) and makes no further change to this subsection.

(e) Redesignates existing Subsection (b) as Subsection (e). Requires the pharmacist, if a drug or biological product has been selected other than the one prescribed, to 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) Redesignates existing Subsection (c) as Subsection (f) and makes no further change.

SECTION 7. Amends Section 562.008, Occupations Code, as follows:

Sec. 562.008. New heading: GENERIC EQUIVALENT OR INTERCHANGEABLE BIOLOGICAL PRODUCT AUTHORIZED. (a) Requires the pharmacist, if a practitioner certifies on the prescription form that a specific prescribed brand is medically necessary, to dispense the drug or biological product as written by the practitioner. Requires that the certification be made as required by the dispensing directive adopted under Section 562.015 (Dispensing Directive; Compliance With Federal Law). Provides that 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) Authorizes a pharmacist, except as otherwise provided by this subchapter, 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 to dispense any of the generic equivalents or interchangeable biological products.

SECTION 8. Amends the heading to Section 562.009, Occupations Code, to read as follows:

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

SECTION 9. Amends Sections 562.009(a), (b), (c), and (d), Occupations Code, as follows:

(a) Requires a pharmacist, before delivery of a prescription for a generically equivalent drug or interchangeable biological product, personally, or through the pharmacist's agency or employee, to:

(1) Adds a reference to interchangeable biological product and makes no further change; and

(2) Adds a reference to interchangeable biological product and makes no further change.

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

(1) Makes no change to this subdivision; or

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

(A) Adds a reference to interchangeable biological product and makes no further change; and

(B) Adds a reference to interchangeable biological product and makes no further change.

(c) Provides that 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 the generically equivalent drug or interchangeable biological product and the brand prescribed. Makes nonsubstantive changes.

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

SECTION 10. Amends Section 562.010, Occupations Code, as follows:

Sec. 562.010. New heading: RESPONSIBILITY CONCERNING GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT; LIABILITY. (a) Provides that 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) Adds reference to biological product under this subchapter and makes no further change.

SECTION 11. Amends Section 562.011, Occupations Code, as follows:

Sec. 562.011. New heading: RESTRICTION ON SELECTION OF AND CHARGING FOR GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT. (a) Prohibits a pharmacist from selecting 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) Prohibits a pharmacist from charging 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. Amends Section 562.013, Occupations Code, as follows:

Sec. 562.013. APPLICABILITY OF SUBCHAPTER. Provides that 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)-(5) Makes no change to these subdivisions.

SECTION 13. Amends Section 562.015(a), as follows:

(a) Requires the Texas State Board of Pharmacy (TSBP) to 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. Requires that the rules adopted under this section:

(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), rather than (29 U.S.C. Section 1181 et seq.), and its subsequent amendments;

(3) Makes no change to this subdivision;

(4) be developed to coordinate with 42 C.F.R. Section 447.512 , rather than Section 447.331(c); and

(5) Makes no change to this subdivision.

SECTION 14. Amends Subchapter A, Chapter 562, Occupations Code, by adding Section 562.016, as follows:

Sec. 562.016. LIST OF APPROVED INTERCHANGEABLE BIOLOGICAL PRODUCTS. Requires TSBP to maintain on TSBP's Internet website a link to FDA's list of approved interchangeable biological products.

SECTION 15. (a) Provides that 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. Makes application of this Act prospective to December 1, 2015, in regards to a prescription issued for a biological product.

(b) Requires TSBP to adopt rules necessary to implement the changes in law made by this Act not later than December 1, 2015.

SECTION 16. Effective date: September 1, 2015.