BILL ANALYSIS

C.S.H.B. 751
By: Zerwas
Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

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 U.S. Food and Drug Administration.

Interested parties assert that it would be appropriate for Texas to enact public policy that ensures a physician's and patient's ability to determine whether the most appropriate therapy for the patient is a biologic or a biosimilar. C.S.H.B. 751 seeks to do so by adding statutory provisions relating to the prescription and pharmaceutical substitution of biological products.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

ANALYSIS

C.S.H.B. 751 amends the Occupations Code to apply statutory provisions relating to prescription and substitution requirements for drugs and generically equivalent drugs to the prescription and pharmaceutical substitution of biological products and interchangeable biological products, as defined by the bill, including provisions relating to legislative intent; price disclosures and patient options regarding copayments; records of dispensed drugs; labeling requirements for dispensing containers; requirements for selecting and dispensing generic equivalent drugs and interchangeable biological products; responsibility and liability for selecting generically equivalent drugs and interchangeable biological products; restrictions on selecting and charging for generically equivalent drugs and interchangeable biological products; limits on the applicability of provisions governing prescription and substitution requirements; requirements for adopting rules relating to dispensing directives; and compliance with federal and state laws and regulations.

C.S.H.B. 751 requires a 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 prescribing practitioners the specific product provided to the patient, including the name of the

product and the manufacturer or the national drug code number. The bill requires such communication to be conveyed by making an entry, including information submitted for the payment of claims, into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record that a pharmacist reasonably concludes is electronically accessible by the prescribing practitioner. The bill requires the pharmacist or the pharmacist's designee to otherwise 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 there is no interchangeable biological product approved by the U.S. Food and Drug Administration (FDA) for the product prescribed or if a refill prescription is not changed from the product dispensed on the prior filling of the prescription. The bill's provisions relating to these communication requirements expire September 1, 2019.

C.S.H.B. 751 requires the Texas State Board of Pharmacy to maintain on the board's website a link to the FDA's list of approved interchangeable biological products. The bill applies only to a prescription issued for a biological product on or after December 1, 2015, and requires the Texas State Board of Pharmacy, not later than December 1, 2015, to adopt rules necessary to implement the bill's provisions.

EFFECTIVE DATE

September 1, 2015.

COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 751 may differ from the original in minor or nonsubstantive ways, the following comparison is organized and formatted in a manner that indicates the substantial differences between the introduced and committee substitute versions of the bill.

INTRODUCED	HOUSE COMMITTEE SUBSTITUTE
SECTION 1. Section 562.001, Occupations Code, is amended.	SECTION 1. Same as introduced version.
SECTION 2. Section 562.002, Occupations Code, is amended.	SECTION 2. Same as introduced version.
SECTION 3. Section 562.003, Occupations Code, is amended.	SECTION 3. Same as introduced version.
SECTION 4. Section 562.005, Occupations Code, is amended.	SECTION 4. Same as introduced 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) Within a reasonable time after dispensing a biological product, the dispensing pharmacist or the	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

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.	dispensing pharmacist or the pharmacist's designee shall communicate to prescribing practitioners 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 record that is electronically accessible by the prescribing practitioner. Otherwise, the pharmacist 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:	(b) The communication must be conveyed by making an entry, including information submitted for the payment of claims, into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record 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.	(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 introduced version.
SECTION 7. Section 562.008, Occupations Code, is amended.	SECTION 7. Same as introduced version.
(See SECTION 8 below.)	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 8. Section 562.009, Occupations Code, is amended to read as follows: Sec. 562.009. REQUIREMENTS CONCERNING SELECTION OF	SECTION 9. Sections 562.009(a), (b), (c), and (d), Occupations Code, are amended to read as follows: *(See SECTION 8 above.)*

GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT.

(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-1)~~] In addition to the requirements of Subsection (a), a pharmacist must display, in a prominent place that is in clear public view where prescription drugs or biological products are dispensed, a sign in block letters not less than one inch in height that reads, in both English and Spanish:

"TEXAS LAW REQUIRES A PHARMACIST TO INFORM YOU IF A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT IS AVAILABLE FOR CERTAIN BRAND NAME DRUGS OR PRODUCTS AND TO ASK YOU TO CHOOSE BETWEEN THE GENERIC OR INTERCHANGEABLE BIOLOGICAL PRODUCT AND THE BRAND NAME DRUG OR PRODUCT. YOU HAVE A RIGHT TO ACCEPT OR REFUSE THE GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT."

(c) [~~(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

(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.	chosen either the brand prescribed or the less expensive generically equivalent drug or interchangeable biological product.
(d) [~~(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:	(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	(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.	(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.
(e) [~~(d)~~] If the patient or the patient's agent fails to indicate otherwise to a pharmacy on the prescription order form under Subsection (d) [~~(c)~~], the pharmacy may dispense a generically equivalent drug or interchangeable biological product.	(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.
(f) [~~(e)~~] If the prescription is for an immunosuppressant drug, as defined by Section 562.0141(a)(1), the pharmacist must comply with the provisions of Section 562.0141. This subsection expires if Section 562.0141 expires under the requirements of Section 562.0142.	
SECTION 9. Section 562.010, Occupations Code, is amended.	SECTION 10. Same as introduced version.
SECTION 10. Section 562.011, Occupations Code, is amended.	SECTION 11. Same as introduced version.
SECTION 11. Section 562.013, Occupations Code, is amended.	SECTION 12. Same as introduced version.
SECTION 12. Section 562.015(a), Occupations Code, is amended.	SECTION 13. Same as introduced version.
No equivalent provision.	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 13. (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 introduced version.
SECTION 14. This Act takes effect September 1, 2015.	SECTION 16. Same as introduced version.