BILL ANALYSIS

Senate Research Center

C.S.S.B. 190
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Health & Human Services
2/20/2013
Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Biologics are complex (large) molecules and the term describes the entire class of biopharmaceutical therapies derived from living organisms or organic substances. Biologics have led to great advancements in the treatment of difficult to manage diseases such as cancer, multiple sclerosis, rheumatoid arthritis, heart disease, HIV/AIDS, chronic renal failure, Crohn's disease, and other complicated medical conditions. Biosimilars, or follow-on biologics, are products marketed after the expiration of patents on an innovator biologic. They have similar properties to existing biologic products, but are not identical. As part of the federal healthcare reform legislation, Congress authorized a legal pathway under the Public Health Service Act for approving biosimilars, but a formal regulatory process is still being established by the United States Food and Drug Administration. The most appropriate approach is to enact public policy that preserves the physician's and patient's ability to determine whether the most appropriate therapy for the patient is a biologic or a biosimilar.

C.S.S.B. 190 amends current law relating to the prescription and pharmaceutical substitution of biological products.

RULEMAKING AUTHORITY

Rulemaking authority previously granted to the Texas State Board of Pharmacy (TSBP) is modified in SECTION 5 (Section 562.006, Occupations Code) and SECTION 11 (Section 562.015, Occupations Code) of this bill.

Rulemaking authority is expressly granted to TSBP in SECTION 12 of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 562.001, Occupations Code, by adding Subdivision (4), to define "biological product," "biosimilar," "interchangeable," and "reference product."

SECTION 2. Amends Section 562.002, Occupations Code, to provide that it is the intent of the legislature to save consumers money by allowing the substitution of lower-priced generically equivalent drug products or an interchangeable biosimilar biological product for certain brand name drug or 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 biosimilar biological product to the purchaser.

SECTION 3. Amends Section 562.003, Occupations Code, to require the pharmacist, if the price of a generically equivalent drug or an interchangeable biosimilar 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 product, rather than the drug, 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 (Prescription and Substitution Requirements).

SECTION 5. 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 the brand name or 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 certain information, including 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, and 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 Texas State Board of Pharmacy (TSBP) rule based on standards in the United States Pharmacopeia-National Formulary.

(c) Redesignates existing Subsection (a-2) as Subsection (c). Authorizes the information required by Subsection (b)(7) (relating to certain information that is required to be indicated on the label on the dispensing container of a drug or biological product dispensed by a Class A or Class E pharmacy), rather than (a-1)(7) (relating to certain information that is required to be indicated on the label on the dispensing container of a drug dispensed by a Class A or Class E pharmacy), to be recorded on any label affixed to the dispensing container.

(d) Redesignates existing Subsection (a-3) as Subsection (d). Provides that Subsection (b), rather than Subsection (a-1) (relating to information required to be indicated on the label on the dispensing container of a drug), 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) Redesignates existing Subsection (b) as Subsection (e). Makes conforming changes.

(f) Requires a pharmacist, if the pharmacist dispenses an interchangeable biosimilar biological product to a patient, to notify the prescribing practitioner. Requires that the required notification be transmitted in writing or electronically; identify the name, strength, and manufacturer or distributor of the biological product dispensed to the patient; and be transmitted to the prescribing practitioner not later than the third day after the date the biological product is dispensed.

(g) Redesignates existing Subsection (c) as Subsection (g). Makes no further changes to this subsection.

SECTION 6. Amends Section 562.008, Occupations Code, as follows:

Sec. 562.008. New heading: GENERIC EQUIVALENT OR INTERCHANGEABLE BIOSIMILAR 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 biosimilar biological product unless the substitution is made as provided by this subchapter.

(b) Authorizes 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 biosimilar biological products to dispense any of the generic equivalents or interchangeable biosimilar biological products except as otherwise provided by this subchapter.

SECTION 7. Amends Section 562.009, Occupations Code, as follows:

Sec. 562.009. New heading: REQUIREMENTS CONCERNING SELECTION OF GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT. (a) Requires a pharmacist personally, or through the pharmacist's agent or employee, before delivery of a prescription for a generically equivalent drug or an interchangeable biosimilar biological product, to:

(1) inform the patient or the patient's agent that a less expensive generically equivalent drug or interchangeable biosimilar 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 biosimilar biological products and the brand prescribed.

(b) Redesignates existing Subsection (a-1) as Subsection (b). Requires a pharmacist, in addition to the requirements of Subsection (a), to display a sign, in a prominent place that is in clear public view where prescription drugs are dispensed, meeting certain criteria, in both English and Spanish. Sets forth the required language to be included on the sign.

(c) Redesignates existing Subsection (b) as Subsection (c). Provides that a pharmacy is not required to comply with the provisions of Subsection (a) in certain cases, including if the patient's physician or physician's agent advises the pharmacy that the physician has informed the patient or the patient's agent that a less expensive generically equivalent drug or interchangeable biosimilar biological product is available for the brand prescribed and the patient or the patient's agent has chosen either the brand prescribed or the less expensive generically equivalent drug or interchangeable biosimilar biological product.

(d) Redesignates existing Subsection (c) as Subsection (d). 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 states that if a less expensive generically equivalent drug or interchangeable biosimilar biological product is available for the brand prescribed, the patient or the patient's agent may choose between the generically equivalent drug or interchangeable biosimilar biological product and the brand prescribed; and allows the patient or the patients' agent to indicate the choice between the generically equivalent drug or interchangeable biosimilar biological product and the brand prescribed, rather than to indicate the choice of the generically equivalent drug or the brand prescribed.

(e) Redesignates existing Subsection (d) as Subsection (e). Authorizes a pharmacy, if the patient or the patient's agent fails to indicate otherwise to the pharmacy on the prescription order form under Subsection (d), rather than Subsection (c) (relating to a pharmacy that supplies a prescription by mail being considered to have complied with the provisions of Subsection (a)), to dispense a generically equivalent drug or interchangeable biosimilar biological product.

(f) Redesignates existing Subsection (e) as Subsection (f). Makes no further changes to this subsection.

SECTION 8. Amends Section 562.010, Occupations Code, as follows:

Sec. 562.010. New heading: RESPONSIBILITY CONCERNING GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT; LIABILITY. (a) Provides that a pharmacist who selects a generically equivalent drug or interchangeable biosimilar biological product to be dispensed under this subchapter assumes the same responsibility for selecting the generically equivalent drug or interchangeable biosimilar biological product as the pharmacist does in filling a prescription for a drug prescribed by generic or biological product name.

(b) Provides that 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 9. 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 BIOSIMILAR BIOLOGICAL PRODUCT. (a) Prohibits a pharmacist from selecting a generically equivalent drug or interchangeable biosimilar biological product unless the generically equivalent drug or interchangeable biosimilar 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 biosimilar biological product a professional fee higher than the fee the pharmacist customarily charges for dispensing the brand name drug prescribed.

SECTION 10. Amends Section 562.013, Occupations Code, to provide that drug selection as authorized by this subchapter does not apply to certain pharmaceutical products unless a drug is determined to be generically equivalent or a biological product is determined to be interchangeably biosimilar, to the brand prescribed.

SECTION 11. Amends Subsection (a), Section 562.015, Occupations Code, as follows:

(a) Requires TSBP to adopt rules to provide a dispensing directive to instruct pharmacists on the manner in which to dispense a drug 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 biosimilar biological product for a brand name drug; and

(2)-(5) Makes no changes to these subdivisions.

SECTION 12. Requires TSBP to adopt rules necessary to implement the changes in law made by this Act not later than March 1, 2014.

SECTION 13. Effective date: September 1, 2013.