BILL ANALYSIS

S.B. 190
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Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

The term "biologics" refers to the class of biopharmaceutical therapies derived from living organisms or organic substances. The development and use of biologics have led to advancements in the treatment of many difficult-to-manage diseases. 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 biologic 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 the physician's and patient's ability to determine whether the most appropriate therapy for the patient is a biologic or a biosimilar to the innovator biologic. S.B. 190 seeks to do so by amending statutory provisions relating to the prescription and pharmaceutical substitution of biological products.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTIONS 5, 11, and 12 of this bill.

ANALYSIS

S.B. 190 amends the Occupations Code to apply statutory provisions relating to prescription and substitution requirements for drugs and generically equivalent drugs to the prescription and substitution of biological products and interchangeable biosimilar biological products, including provisions relating to legislative intent; price disclosures; certain record keeping requirements; dispensing container labeling requirements; the requirement that a pharmacist dispense a biological product as written by the practitioner and the authority of a pharmacist to dispense any of the interchangeable biosimilar biological products; requirements concerning the selection of interchangeable biosimilar biological products; a pharmacist's responsibility and liability concerning interchangeable biosimilar biological products; restrictions on the selection of and charging for interchangeable biosimilar biological products; and the applicability of certain provisions relating to drug selection. The bill provides for the meaning of "biological product," "biosimilar," "interchangeable," and "reference product" by reference to the federal Public Health Service Act and establishes that a biological product is not an injectable suspension for the purposes of statutory provisions relating to prescription and substitution requirements of such products.

S.B. 190, in a temporary provision set to expire December 31, 2015, requires a pharmacist to notify the prescribing practitioner if the pharmacist dispenses an interchangeable biosimilar biological product to a patient and requires the notification to be transmitted in writing or electronically; to identify the name, strength, and manufacturer or distributor of the biological product dispensed to the patient; and to be transmitted to the prescribing practitioner not later than the third day after the date the biological product is dispensed.

S.B. 190 requires that the label on the dispensing container of a biological product dispensed by a Class A or Class E pharmacy, if the biological product is dispensed in a container other than the manufacturer's original container, to indicate the date after which the prescription should not be used as determined according to criteria established by Texas State Board of Pharmacy rule based on certain standards. The bill specifies that the board rules required to be adopted by the providing a dispensing directive to pharmacists must require the use of the phrase "brand necessary" or "brand medically necessary" on a prescription form to prohibit the substitution of an interchangeable biosimilar biological product for a brand name drug. The bill requires the board to adopt the rules necessary to implement the bill's provisions not later than March 1, 2014.

EFFECTIVE DATE

September 1, 2013.