BILL ANALYSIS

Senate Research Center
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S.B. 190
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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.

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

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTION 1 (Sections 562.254, 562.255, and 562.263, Occupations Code) and SECTION 2 of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Chapter 562, Occupations Code, by adding Subchapter F, as follows:

SUBCHAPTER F. PRESCRIPTION AND SUBSTITUTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

Sec. 562.251. DEFINITIONS. Defines "biological product," "biosimilar," "interchangeable," and "reference product" in this subchapter.

Sec. 562.252. PRESCRIPTION TRANSMITTED ORALLY BY PRACTITIONER. Requires a pharmacist to whom a prescription for a biological product is transmitted orally to note on the file copy of the prescription the dispensing instructions of the practitioner or the practitioner's agent and retain the prescription for the period specified by law for pharmacy records.

Sec. 562.253. RECORD OF DISPENSED BIOLOGICAL PRODUCT. (a) Requires a pharmacist to record on the prescription form the name, strength, and manufacturer or distributor of a biological product dispensed as authorized by this subchapter.

(b) Provides that a record established under this subchapter is subject to the recordkeeping requirements applicable to pharmacy records.

Sec. 562.254. LABEL. (a) Requires that the label on the dispensing container, unless otherwise directed by the practitioner, indicate the actual biological product dispensed by the brand name or, if there is not a brand name, the actual name of the biological product,

the strength of the biological product, and the name of the manufacturer or distributor of the biological product.

(b) Requires that the label on the dispensing container of a biological product dispensed by a Class A, Class C, Class D, or Class E pharmacy, in addition to the information required by Subsection (a), 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 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 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 the United States Food and Drug Administration (FDA); and

(8) any other information required by Texas State Board of Pharmacy (TSBP) rule.

(c) Authorizes the information required by Subsection (b)(7) to be recorded on any label affixed to the dispensing container.

(d) Sets forth the language required to be placed on the container by the pharmacist if a biological product has been selected other than the one prescribed.

(e) Requires TSBP to 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.

Sec. 562.255. OTHER PRESCRIPTION INFORMATION. Requires TSBP to adopt rules specifying the information a pharmacist must provide to a consumer when dispensing a prescription for a biological product to the consumer for self-administration. Requires that the information be written in plain language, relevant to the prescription, and printed in an easily readable font size.

Sec. 562.256. REFILLS. Requires that a properly authorized prescription refill, except as provided by Section 562.0545 (90-Day Supply and Accelerated Refills), follow the original dispensing instruction unless otherwise indicated by the practitioner or the practitioner's agent.

Sec. 562.257. INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT AUTHORIZED. (a) Prohibits a pharmacy from substituting a biosimilar biological product for a prescribed reference product unless the FDA has determined that the biosimilar biological product is interchangeable with the prescribed reference product for the specified indicated use.

(b) Requires the pharmacist, if a practitioner certifies on the prescription form that a specific prescribed reference product is medically necessary, to dispense the reference product as written by the practitioner. Requires that the certification be made as required by the dispensing directive adopted under Section 562.263.

(c) Authorizes a pharmacist who receives a prescription for a reference product for which there is one or more interchangeable biosimilar biological products, except as otherwise provided by this subchapter, to dispense any of the interchangeable biosimilar biological products for the specified indicated use.

Sec. 562.258. REQUIREMENTS CONCERNING SELECTION OF INTERCHANGEABLE BIOSIMILAR. (a) Requires a pharmacist, before delivery of a prescription for an interchangeable biosimilar biological product, to personally, or through the pharmacist's agent or employee, inform the patient or the patient's agent that a less expensive interchangeable biosimilar biological product is available for the reference product prescribed and ask the patient or the patient's agent to choose between the interchangeable biosimilar biological product and the reference product prescribed.

(b) Provides that 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 interchangeable biosimilar biological product is available for the reference product prescribed; and

(B) the patient or the patient's agent has chosen either the reference product prescribed or the less expensive interchangeable biosimilar biological product.

(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 interchangeable biosimilar biological product is available for the reference product prescribed, the patient or the patient's agent may choose between the interchangeable biosimilar biological product and the reference product prescribed; and

(2) allows the patient or the patient's agent to indicate the choice of the interchangeable biosimilar biological product or the reference product prescribed.

(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 an interchangeable biosimilar biological product.

Sec. 562.259. DISCLOSURE OF PRICE; PATIENT'S OPTION. Requires the pharmacist, if the price of 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 biosimilar biological product at the lower price instead of paying the amount of the copayment.

Sec. 562.260. NOTIFICATION OF SUBSTITUTION. (a) Requires the pharmacist, if a pharmacist dispenses an interchangeable biosimilar biological product to a patient, to notify the prescribing practitioner.

(b) Requires that the notification under Subsection (a) 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.

Sec. 562.261. RESPONSIBILITY CONCERNING BIOSIMILAR BIOLOGICAL PRODUCTS; LIABILITY. (a) Provides that a pharmacist who selects an interchangeable biosimilar biological product to be dispensed under this subchapter assumes the same responsibility for selecting the biosimilar biological product as the pharmacist does in filling a prescription for a reference product.

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

Sec. 562.262. RESTRICTION ON SELECTION OF AND CHARGING FOR BIOSIMILAR BIOLOGICAL PRODUCTS. (a) Prohibits a pharmacist from selecting an interchangeable biosimilar biological product unless the interchangeable product selected costs the patient less than the prescribed reference product.

(b) Prohibits a pharmacist from charging for dispensing an interchangeable biosimilar biological product a professional fee higher than the fee the pharmacist customarily charges for dispensing the reference product prescribed.

Sec. 562.263. DISPENSING DIRECTIVE; COMPLIANCE WITH FEDERAL LAW. Requires TSBP to adopt rules to provide a dispensing directive to instruct pharmacists on the manner in which to dispense a 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 an interchangeable biosimilar biological product for a reference product;

(2) be in a format that protects confidentiality as required by the Health Insurance Portability and Accountability Act of 1996 (29 U.S.C. Section 1181 et seq.); and

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

SECTION 2. Requires TSBP to adopt rules necessary to implement Subchapter F, Chapter 562, Occupations Code, as added by this Act, not later than January 1, 2014.

SECTION 3. (a) Effective date, except as provided by Subsection (b) of this section: September 1, 2013.

(b) Effective date, Subchapter F, Chapter 562, Occupations Code: January 1, 2014.