By: Zerwas H.B. No. 542

A BILL TO BE ENTITLED

AN ACT

relating to the prescription and pharmaceutical substitution of biological products.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Chapter 562, Occupations Code, is amended by adding Subchapter F to read as follows:

SUBCHAPTER F. PRESCRIPTION AND SUBSTITUTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

Sec. 562.251. DEFINITIONS. In this subchapter, "biological product," "biosimilar," "interchangeable," and "reference product" have the meanings assigned by Section 351, Public Health Service Act (42 U.S.C. Section 262).

Sec. 562.252. PRESCRIPTION TRANSMITTED ORALLY BY PRACTITIONER. A pharmacist to whom a prescription for a biological product is transmitted orally shall:

(1) note on the file copy of the prescription the dispensing instructions of the practitioner or the practitioner's agent; and

(2) retain the prescription for the period specified by law for pharmacy records.

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

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

Sec. 562.254. LABEL. (a) Unless otherwise directed by the practitioner, the label on the dispensing container must indicate the actual biological product dispensed by:

(1) the brand name; or

(2) 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) In addition to the information required by Subsection (a), the label on the dispensing container of a biological product dispensed by a Class A, Class C, Class D, or Class E pharmacy must 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; and

(8) any other information required by board rule.

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

(d) If a biological product has been selected other than the one prescribed, the pharmacist shall 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 biological product prescribed.

(e) The board shall 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. The board shall 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. The information must be:

(1) written in plain language;

(2) relevant to the prescription; and

(3) printed in an easily readable font size.

Sec. 562.256. REFILLS. Except as provided by Section 562.0545, a properly authorized prescription refill must 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) A pharmacy may not substitute a biosimilar biological product for a prescribed reference product unless the

United States Food and Drug Administration has determined that the biosimilar biological product is interchangeable with the prescribed reference product for the specified indicated use.

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

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

Sec. 562.258. REQUIREMENTS CONCERNING SELECTION OF INTERCHANGEABLE BIOSIMILAR. (a) Before delivery of a prescription for an interchangeable biosimilar 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 interchangeable biosimilar biological product is available for the reference product prescribed; and

(2) ask the patient or the patient's agent to choose between the interchangeable biosimilar biological product and the reference product 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 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) 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) 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 an interchangeable biosimilar biological product.

Sec. 562.259. DISCLOSURE OF PRICE; PATIENT'S OPTION. 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, the pharmacist shall 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) If a pharmacist dispenses an interchangeable biosimilar biological product to a patient, the pharmacist shall notify the prescribing practitioner.

(b) The notification required under Subsection (a) must:

(1) be transmitted in writing or electronically;

(2) identify the name, strength, and manufacturer or distributor of the biological product dispensed to the patient; and

(3) 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) 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) 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) A pharmacist may not select an interchangeable biosimilar biological product unless the interchangeable product selected costs the patient less than the prescribed reference product.

(b) A pharmacist may not charge 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. The board shall 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. The rules adopted under this section must:

(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. The Texas State Board of Pharmacy shall 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) Except as provided by Subsection (b) of this

section, this Act takes effect September 1, 2013.

(b) Subchapter F, Chapter 562, Occupations Code, as added by this Act, takes effect January 1, 2014.