By: Huffman, Campbell, Nelson S.B. No. 190

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. Section 562.001, Occupations Code, is amended by adding Subdivision (4) to read as follows:

(4) "Biological product," "biosimilar," "interchangeable," and "reference product" have the meanings assigned by Section 351, Public Health Service Act (42 U.S.C. Section 262). For purposes of this subchapter, a biological product is not an injectable suspension.

SECTION 2. Section 562.002, Occupations Code, is amended to read as follows:

Sec. 562.002. LEGISLATIVE INTENT. 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. Section 562.003, Occupations Code, is amended to read as follows:

Sec. 562.003. DISCLOSURE OF PRICE; PATIENT'S OPTION. 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, the pharmacist shall offer the patient the option of paying for the product [~~drug~~] at the lower price instead of paying the amount of the copayment.

SECTION 4. Section 562.005, Occupations Code, is amended to read as follows:

Sec. 562.005. RECORD OF DISPENSED DRUG OR BIOLOGICAL PRODUCT. A pharmacist shall record on the prescription form the name, strength, and manufacturer or distributor of a drug or biological product dispensed as authorized by this subchapter.

SECTION 5. Section 562.006, Occupations Code, is amended to read as follows:

Sec. 562.006. LABEL. (a) Unless otherwise directed by the practitioner, the label on the dispensing container must indicate the actual drug or biological product dispensed, indicated by either:

(1) the brand name; or

(2) 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) [~~(a-1)~~] In addition to the information required by Subsection (a), the label on the dispensing container of a drug or biological product dispensed by a Class A 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 drug or 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 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 board rule based on standards in the United States Pharmacopeia-National Formulary; and

(8) any other information required by board rule.

(c) [~~(a-2)~~] The information required by Subsection (b)(7) [~~(a-1)(7)~~] may be recorded on any label affixed to the dispensing container.

(d) [~~(a-3)~~] Subsection (b) [~~(a-1)~~] 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) [~~(b)~~] If a drug or 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 drug or biological product prescribed.

(f) If a pharmacist dispenses an interchangeable biosimilar biological product to a patient, the pharmacist shall notify the prescribing practitioner. The notification required 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.

(f-1) Subsection (f) and this subsection expire December 31, 2015.

(g) [~~(c)~~] 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.

SECTION 6. Section 562.008, Occupations Code, is amended to read as follows:

Sec. 562.008. GENERIC EQUIVALENT OR INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT AUTHORIZED. (a) If a practitioner certifies on the prescription form that a specific prescribed brand is medically necessary, the pharmacist shall dispense the drug or biological product as written by the practitioner. The certification must be made as required by the dispensing directive adopted under Section 562.015. 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) Except as otherwise provided by this subchapter, 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 may dispense any of the generic equivalents or interchangeable biosimilar biological products.

SECTION 7. Section 562.009, Occupations Code, is amended to read as follows:

Sec. 562.009. REQUIREMENTS CONCERNING SELECTION OF GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT. (a) Before delivery of a prescription for a generically equivalent drug or 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 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 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 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 BIOSIMILAR BIOLOGICAL PRODUCT IS AVAILABLE FOR CERTAIN BRAND NAME DRUGS AND TO ASK YOU TO CHOOSE BETWEEN THE GENERIC OR INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT AND THE BRAND NAME DRUG. YOU HAVE A RIGHT TO ACCEPT OR REFUSE THE GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOSIMILAR 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 biosimilar 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 biosimilar 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:

(1) 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

(2) allows the patient or the patient's agent to indicate the choice between [~~of~~] the generically equivalent drug or interchangeable biosimilar 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 biosimilar 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 8. Section 562.010, Occupations Code, is amended to read as follows:

Sec. 562.010. RESPONSIBILITY CONCERNING GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT; LIABILITY. (a) 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) 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. Section 562.011, Occupations Code, is amended to read as follows:

Sec. 562.011. RESTRICTION ON SELECTION OF AND CHARGING FOR GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT. (a) A pharmacist may not select 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) A pharmacist may not charge 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. Section 562.013, Occupations Code, is amended to read as follows:

Sec. 562.013. APPLICABILITY OF SUBCHAPTER. Unless a drug is determined to be generically equivalent, or a biological product is determined to be interchangeably biosimilar, to the brand prescribed, drug selection as authorized by this subchapter does not apply to:

(1) an enteric-coated tablet;

(2) a controlled release product;

(3) an injectable suspension, other than an

antibiotic;

(4) a suppository containing active ingredients for which systemic absorption is necessary for therapeutic activity; or

(5) a different delivery system for aerosol or nebulizer drugs.

SECTION 11. Subsection (a), Section 562.015, Occupations Code, is amended to read as follows:

(a) The board shall 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. 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 a generically equivalent drug or interchangeable biosimilar biological product for a brand name drug;

(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 its subsequent amendments;

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

(4) be developed to coordinate with 42 C.F.R. Section 447.331(c); and

(5) include an exemption for electronic prescriptions as provided by Subsection (b).

SECTION 12. The Texas State Board of Pharmacy shall adopt rules necessary to implement the changes in law made by this Act not

later than March 1, 2014.

SECTION 13. This Act takes effect September 1, 2013.