By: Kolkhorst S.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. Section 562.001, Occupations Code, is amended by amending Subdivision (1) and adding Subdivisions (1-a) and (1-b) to read as follows:

(1) "Biological product" has the meaning assigned by Section 351, Public Health Service Act (42 U.S.C. Section 262).

(1-a) "Generically equivalent" means a drug that is pharmaceutically equivalent and therapeutically equivalent to the drug prescribed.

(1-b) "Interchangeable," in reference to a biological product, has the meaning assigned by Section 351, Public Health Service Act (42 U.S.C. Section 262), or means a biological product that is designated as therapeutically equivalent to another product by the United States Food and Drug Administration in the most recent edition or supplement of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.

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 for certain brand name drug products and the substitution of interchangeable biological products for certain 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 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 drug or 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 drug or biological product 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. Subchapter A, Chapter 562, Occupations Code, is amended by adding Section 562.0051 to read as follows:

Sec. 562.0051. COMMUNICATION REGARDING CERTAIN DISPENSED BIOLOGICAL PRODUCTS. (a) Within a reasonable time after dispensing a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner the specific product provided to the patient,

including the name of the product and the manufacturer.

(b) The communication must be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record that is electronically accessible by the prescribing practitioner. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescribing practitioner, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication is not required if:

(1) there is no interchangeable biological product approved by the United States Food and Drug Administration for the product prescribed; or

(2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

SECTION 6. 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) [~~(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 7. Section 562.008, Occupations Code, is amended to read as follows:

Sec. 562.008. GENERIC EQUIVALENT OR INTERCHANGEABLE 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 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 biological products may dispense any of the generic equivalents or interchangeable biological products.

SECTION 8. Section 562.009, Occupations Code, is amended to read as follows:

Sec. 562.009. REQUIREMENTS CONCERNING SELECTION OF GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT. (a) Before delivery of a prescription for a generically equivalent

drug or interchangeable 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 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 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 or biological products 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 BIOLOGICAL PRODUCT IS AVAILABLE FOR CERTAIN BRAND NAME DRUGS OR PRODUCTS AND TO ASK YOU TO CHOOSE BETWEEN THE GENERIC OR INTERCHANGEABLE BIOLOGICAL PRODUCT AND THE BRAND NAME DRUG OR PRODUCT. YOU HAVE A RIGHT TO ACCEPT OR REFUSE THE GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE 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 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 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 biological product is available for the brand prescribed, the patient or the patient's agent may choose between the generically equivalent drug or interchangeable 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 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 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 9. Section 562.010, Occupations Code, is amended to read as follows:

Sec. 562.010. RESPONSIBILITY CONCERNING GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT; LIABILITY. (a) A pharmacist who selects a generically equivalent drug or interchangeable biological product to be dispensed under this subchapter assumes the same responsibility for selecting the generically equivalent drug or interchangeable 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 10. 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 BIOLOGICAL PRODUCT. (a) A pharmacist may not select a generically equivalent drug or interchangeable biological product unless the generically equivalent drug or interchangeable 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 biological product a professional fee higher than the fee the pharmacist customarily

charges for dispensing the brand name drug or biological product prescribed.

SECTION 11. 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 to, or a biological product is determined to be interchangeable with, the brand prescribed, drug or biological product 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 12. Section 562.015(a), 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 or 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 a generically equivalent drug or interchangeable biological product for a brand name drug or biological product;

(2) be in a format that protects confidentiality as required by the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) [~~(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 447.512 [~~447.331(c)~~]; and

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

SECTION 13. (a) Chapter 562, Occupations Code, as amended by this Act, applies only to a prescription issued for a biological product on or after December 1, 2015. A prescription issued for a biological product before December 1, 2015, is governed by the law in effect immediately before that date, and the former law is continued in effect for that purpose.

(b) The Texas State Board of Pharmacy shall adopt rules necessary to implement the changes in law made by this Act not later than December 1, 2015.

SECTION 14. This Act takes effect September 1, 2015.