BILL ANALYSIS

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S.B. 542
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AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Biologic drug products are medical products made from a variety of natural sources that are used to prevent, diagnose, and treat disease. Examples include vaccines, blood products related to transfusions, allergy shots, transplant therapies, and tests to screen blood donors for disease. Currently, Texas law does not allow a pharmacist to substitute an interchangeable biologic product for a branded counterpart in the same manner as a generic prescription drug for a more expensive name brand. Allowing them to do so would help to lower drug costs for patients.

Pharmacists are now required to obtain advanced approval from the prescriber before they are allowed to substitute an interchangeable biologic for a brand name biologic. S.B. 542 allows a pharmacist to substitute an interchangeable, FDA-approved biologic for a brand name biologic in a safe and less expensive manner without first seeking approval. A physician will retain the authority to require the drug to be dispensed as written with the same authority as the substitution of a generic prescription drug.

Biologic products differ from generics in complexity and are not identical chemical products. S.B. 542 requires communication between pharmacists and prescribers to ensure medical records reflect which specific product has been dispensed to the patient. This information would be relayed after the prescription is dispensed to alleviate the need for waiting for pre-approval, as current law requires.

S.B. 542 requires a pharmacist or pharmacist's designee to communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer, within a reasonable time following the dispensing of a biological product. The pharmacist shall communicate to the physician by making an entry in an interoperable electronic medical records system, through an electronic prescribing technology, or through a pharmacy record that is electronically accessible by the prescriber. Otherwise, the pharmacist shall communicate the biologic product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means. S.B. 542 does not require the communication when there is no FDA-approved interchangeable biologic for the product prescribed or a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

Other provisions in the bill generally replicate state law pertaining to small molecule products, including the requirements that the patient be aware of the medicine they receive, that physicians retain "dispense as written" authority, and pharmacy records be retained.

As proposed, S.B. 542 amends current law relating to the prescription and pharmaceutical substitution of biological products.

RULEMAKING AUTHORITY

Rulemaking authority previously granted to the Texas State Board of Pharmacy is modified in SECTION 6 (Section 562.006, Occupations Code) and SECTION 12 (Section 562.015, Occupations Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 562.001, Occupations Code, by amending Subdivision (1) and adding Subdivisions (1-a) and (1-b) to define "biological product" and "interchangeable."

SECTION 2. Amends Section 562.002, Occupations Code, as follows:

Sec. 562.002. LEGISLATIVE INTENT. Provides that 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. Amends Section 562.003, Occupations Code, as follows:

Sec. 562.003. DISCLOSURE OF PRICE; PATIENT'S OPTION. Requires the pharmacist, 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, to 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. Amends Section 562.005, Occupations Code, as follows:

Sec. 562.005. New heading: RECORD OF DISPENSED DRUG OR BIOLOGICAL PRODUCT. Requires a pharmacist to 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. Amends Subchapter A, Chapter 562, Occupations Code, by adding Section 562.0051, as follows:

Sec. 562.0051. COMMUNICATION REGARDING CERTAIN DISPENSED BIOLOGICAL PRODUCTS. (a) Requires the dispensing pharmacist or the pharmacist's designee, within a reasonable time after dispensing a biological product, to communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer.

(b) Requires that the communication 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. Requires the pharmacist, otherwise, to 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. Amends Section 562.006, Occupations Code, as follows:

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

(1) Makes no change to this subdivision; 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) Redesignates Subsection (a-1) as Subsection (b). Requires that the label on the dispensing container of a drug or biological product dispensed by a Class A or Class E pharmacy, in addition to the information required by Subsection (a), indicate:

(1)-(3) Makes no change to these subdivisions;

(4) Adds a reference to biological product and makes no further change;

(5) and (6) Makes no change to these subdivisions;

(7) Adds a reference to biological product and makes no further change; and

(8) Makes no change to this subdivision.

(c) Redesignates Subsection (a-2) as Subsection (c). Changes a reference to Subsection (a-1)(7) to Subsection (b)(7) and makes no further change.

(d) Redesignates Subsection (a-3) as Subsection (d). Changes a reference to Subsection (a-1) to Subsection (b) and makes no further change.

(e) Redesignates Subsection (b) as Subsection (e). Provides that 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) Redesignates Subsection (c) as Subsection (f) and makes no further change.

SECTION 7. Amends Section 562.008, Occupations Code, as follows:

Sec. 562.008. New heading: GENERIC EQUIVALENT OR INTERCHANGEABLE BIOLOGICAL PRODUCT AUTHORIZED. (a) Requires the pharmacist, if a practitioner certifies on the prescription form that a specific prescribed brand is medically necessary, to dispense the drug or biological product as written by the practitioner. Requires that the certification be made as required by the dispensing directive adopted under Section 562.015 (Dispensing Directive; Compliance With Federal Law). Provides that 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) Authorizes a pharmacist, except as otherwise provided by this subchapter, 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 to dispense any of the generic equivalents or interchangeable biological products.

SECTION 8. Amends Section 562.009, Occupations Code, as follows:

Sec. 562.009. New heading: REQUIREMENTS CONCERNING SELECTION OF GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT. (a) Requires a pharmacist, before delivery of a prescription for a generically equivalent drug or interchangeable biological product, personally, or through the pharmacist's agency or employee, to:

(1) Adds a reference to interchangeable biological product and makes no further change; and

(2) Adds a reference to interchangeable biological product and makes no further change.

(b) Redesignates Subsection (a-1) as Subsection (b). Requires a pharmacist, in addition to the requirements of Subsection (a), to 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, a certain sign and sets froth the sign and language to be used in the sign.

(c) Redesignates Subsection (b) as Subsection (c). Provides that a pharmacy is not required to comply with the provisions of Subsection (a):

(1) Makes no change to this subdivision; or

(2) if the patient's physician or physician's agent advises the pharmacy that:

(A) Adds a reference to interchangeable biological product and makes no further change; and

(B) Adds a reference to interchangeable biological product and makes no further change.

(d) Redesignates Subsection (c) as Subsection (d). 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 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 the generically equivalent drug or interchangeable biological product and the brand prescribed. Makes nonsubstantive changes.

(e) Redesignates Subsection (d) as Subsection (e). 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 (d), rather than Subsection (c), to dispense a generically equivalent drug or interchangeable biological product.

(f) Redesignates Subsection (e) as Subsection (f) and makes no further change.

SECTION 9. Amends Section 562.010, Occupations Code, as follows:

Sec. 562.010. New heading: RESPONSIBILITY CONCERNING GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT; LIABILITY. (a) Provides that 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) Adds reference to biological product under this subchapter and makes no further change.

SECTION 10. Amends Section 562.011, Occupations Code, as follows:

Sec. 562.011. New heading: RESTRICTION ON SELECTION OF AND CHARGING FOR GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT. (a) Prohibits a pharmacist from selecting 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) Prohibits a pharmacist from charging 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. Amends Section 562.013, Occupations Code, as follows:

Sec. 562.013. APPLICABILITY OF SUBCHAPTER. Provides that 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)-(5) Makes no change to these subdivisions.

SECTION 12. Amends Section 562.015(a), Occupations Code, as follows:

(a) Requires the Texas State Board of Pharmacy (TSBP) to 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. 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 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), rather than (29 U.S.C. Section 1181 et seq.), and its subsequent amendments;

(3) Makes no change to this subdivision;

(4) be developed to coordinate with 42 C.F.R. Section 447.512 , rather than Section 447.331(c); and

(5) Makes no change to this subdivision.

SECTION 13. (a) Provides that 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. Makes application of this Act prospective to December 1, 2015.

(b) Requires TSBP to adopt rules necessary to implement the changes in law made by this Act not later than December 1, 2015.

SECTION 14. Effective date: September 1, 2015.