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H.B. 279
1st Sub. (Buff)

Representative Brad L. Dee proposes the following substitute bill:

PRESCRIPTION NOTIFICATION AMENDMENTS

2015 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Brad L. Dee

Senate Sponsor: _____

LONG TITLE

General Description:

This bill amends provisions related to biosimilar products in the Pharmacy Practice Act.

Highlighted Provisions:

This bill:

- deletes the definition of biosimilar;
- defines interchangeable biological product;
- requires a pharmacist to make an entry into a pharmacy benefit management system when a biological product is dispensed;
- requires a pharmacist to maintain a record when a biological product is dispensed under certain circumstances; and
- amends repealer language.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-605.5, as enacted by Laws of Utah 2013, Chapter 423

63I-2-258, as last amended by Laws of Utah 2013, Chapter 423

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **58-17b-605.5** is amended to read:

58-17b-605.5. Interchangeable biological products.

(1) For the purposes of this section:

(a) "Biological product" [~~is as~~] means the same as that term is defined in 42 U.S.C. Sec. 262[~~;~~].

[~~(b) "biosimilar" is as defined in 42 U.S.C. Sec. 262; and~~]

[~~(c) "interchangeable" is as defined in 42 U.S.C. Sec. 262.~~]

(b) "Interchangeable biological product" means a biological product that the federal Food and Drug Administration:

(i) has:

(A) licensed; and

(B) determined meets the standards for interchangeability pursuant to 42 U.S.C. Sec. 262(k)(4); or

(ii) has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

(2) A pharmacist or pharmacy intern dispensing a prescription order for a specific biological product by brand or proprietary name may substitute [~~a biosimilar~~] an interchangeable biological product for the prescribed biological product only if:

(a) the purchaser specifically requests or consents to the substitute of an interchangeable [~~biosimilar~~] biological product;

[~~(b) the biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;~~]

[~~(c)~~] (b) the interchangeable [~~biosimilar~~] biological product is permitted to move in interstate commerce;

[~~(d)~~] (c) the pharmacist or pharmacy intern counsels the patient on the use and the expected response to the prescribed biological product, whether a substitute or not, and the substitution is not otherwise prohibited by this chapter;

[~~(c)~~] (d) the prescribing practitioner has not prohibited the substitution of an interchangeable [~~biosimilar~~] biological product for the prescribed biological product, as provided in Subsection (6); and

[~~(f)~~] (e) the substitution is not otherwise prohibited by law.

(3) [~~(a)~~] Each out-of-state mail service pharmacy dispensing an interchangeable [~~biosimilar~~] biological product as a substitute for another biological product into this state shall:

(a) notify the patient of the substitution either by telephone or in writing[~~.~~]; and

(b) [~~Each out-of-state mail service pharmacy shall~~] comply with the requirements of this chapter with respect to an interchangeable [~~biosimilar~~] biological product substituted for another biological product, including labeling and record keeping.

(4) Pharmacists or pharmacy interns may not substitute without the prescriber's authorization biological product prescriptions unless the product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product.

(5) A pharmacist or pharmacy intern who dispenses a prescription with an interchangeable [~~biosimilar~~] biological product under this section assumes no greater liability than would be incurred had the pharmacist or pharmacy intern dispensed the prescription with the biological product prescribed.

(6) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of the patient that an interchangeable [~~biosimilar~~] biological product not be substituted for a prescribed biological product, the practitioner may prohibit a substitution either by writing "dispense as written" or by signing in the appropriate space where two lines have been preprinted on a prescription order and captioned "dispense as written" or "substitution permitted."

(b) (i) If the prescription is communicated orally by the prescribing practitioner to the pharmacist or pharmacy intern, the practitioner shall direct the prohibition or substitution.

(ii) The pharmacist or pharmacy intern shall make a written note of the practioner's direction by writing the name of the practitioner and the words "orally by" and the initials of the pharmacist or pharmacy intern written after it.

(7) A pharmacist or pharmacy intern who substitutes an interchangeable [~~biosimilar~~]

biological product for a prescribed biological product shall communicate the substitution to the purchaser. The interchangeable [~~biosimilar~~] biological product container shall be labeled with the name of the interchangeable [~~biosimilar~~] biological product dispensed, and the pharmacist, pharmacy intern, or pharmacy technician shall indicate on the file copy of the prescription both the name of the prescribed biological product and the name of the interchangeable [~~biosimilar~~] biological product dispensed in its place.

[~~(8) (a) A pharmacist or pharmacy intern who substitutes an interchangeable biosimilar product for a prescribed biological product shall:~~]

[~~(i) notify the prescriber in writing, by fax, telephone, or electronic transmission of the substitution, as soon as practicable, but not later than three business days after dispensing the interchangeable biosimilar product in place of the prescribed biological product; and~~]

[~~(ii) include the name and manufacturer of the interchangeable biosimilar product substituted.~~]

[~~(b) This subsection is repealed on May 15, 2015.~~]

(8) (a) Within a reasonable time, which shall not exceed five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall:

(i) make an entry of the specific product provided to a patient, including the name of the product and manufacturer of the product into one of the following pharmacy records electronically accessible to the provider:

(A) an interoperable electronic medical records system;

(B) an electronic prescribing technology; or

(C) a pharmacy benefits management (PBM) system; or

(ii) otherwise communicate to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means the biological product provided to the patient, including the name of the product and manufacturer of the product dispensed.

(b) Entry into an electronic system as described in Subsection (8)(a) is presumed to provide notice to the prescriber.

(9) Notwithstanding the provisions of Subsections (8)(a) and (b), entry shall not be required when:

(a) there is no FDA-approved interchangeable biological product for the product

prescribed; or

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

(10) The board shall maintain a link on its website to the current list of all interchangeable biological products.

Section 2. Section **63I-2-258** is amended to read:

63I-2-258. Repeal dates -- Title 58.

[~~(1) Subsection 58-72-201(1)(b) is repealed July 1, 2014.~~]

[~~(2) Subsection 58-17b-605.5(8) is repealed on May 15, 2015.~~]