interchangeable biosimilar product in the place of a prescribed biological product than would be incurred without the substitution;

▸ sets forth that a prescriber can prohibit the substitution of a biological product with an interchangeable biosimilar product orally or in writing;

▸ establishes requirements for the substitution of a biological product with an interchangeable biosimilar product relating to:

- labeling;
- patient notification; and
- record keeping; and

▸ makes technical changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-102, as last amended by Laws of Utah 2012, Chapters 265 and 320

58-17b-605, as last amended by Laws of Utah 2008, Chapter 205

Ŝ→ 63I-2-258, as last amended by Laws of Utah 2012, Chapters 88 and 369 ←Ŝ

ENACTS:

58-17b-605.5, Utah Code Annotated 1953

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

Section 1. Section **58-17b-102** is amended to read:

58-17b-102. Definitions.

In addition to the definitions in Section 58-1-102, as used in this chapter:

(1) "Administering" means:

(a) the direct application of a prescription drug or device, whether by injection, inhalation, ingestion, or by any other means, to the body of a human patient or research subject by another person; or

(b) the placement by a veterinarian with the owner or caretaker of an animal or group of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other

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 product for a prescribed biological product shall **Ŝ→ communicate the substitution to the purchaser. The interchangeable biosimilar product container shall be labeled with the name of the interchangeable biosimilar 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 product dispensed in its place. [~~:~~**

~~(a) communicate the substitution to the purchaser;~~

~~(b) ensure that the interchangeable product container is labeled with the name and the manufacturer of the interchangeable biosimilar product dispensed; and~~

~~(c) indicate on the file copy of the prescription:~~

~~(i) the name and the manufacturer of the prescribed biological product; and~~

~~(ii) the name and the manufacturer of the interchangeable biosimilar product dispensed in place of the prescribed biological product.~~**] ←Ŝ**

(8) **Ŝ→ (a) ←Ŝ** A pharmacist or pharmacy intern who substitutes an interchangeable biosimilar product for a prescribed biological product shall:

Ŝ→ [~~(a)~~] (i) ←Ŝ notify the prescriber in writing **Ŝ→ , by fax, telephone, or electronic transmission ←Ŝ** 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

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

Ŝ→ (b) This subsection is repealed on Ĥ→ [~~March 31, 2016~~] May 15, 2015 ←Ĥ . ←Ŝ

Ŝ→ [~~(9) The pharmacist or pharmacy intern shall:~~

~~**(a) retain a written record of the substitution for at least five years; and**~~

~~**(b) include the name and manufacturer of the interchangeable product substituted.**~~

~~(10)~~] (9) ←Ŝ A licensed medical practitioner who fails to specify that no substitution is authorized does not constitute evidence of negligence.

Ŝ→ **Section 4. 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-606.5(8) is repealed on Ĥ→ **[~~March 31, 2016.~~]**

May 15, 2015. ←Ĥ ←Ŝ

Legislative Review Note
as of 2-14-13 1:42 PM

Office of Legislative Research and General Counsel