

Superseded 5/12/2015

58-17b-605.5 Interchangeable biosimilar products.

- (1) For the purposes of this section:
 - (a) "biological product" is as 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.
- (2) A pharmacist or pharmacy intern dispensing a prescription order for a specific biological product by brand or proprietary name may substitute a biosimilar product for the prescribed biological product only if:
 - (a) the purchaser specifically requests or consents to the substitute of an interchangeable biosimilar 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) the interchangeable biosimilar product is permitted to move in interstate commerce;
 - (d) 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;
 - (e) the prescribing practitioner has not prohibited the substitution of an interchangeable biosimilar product for the prescribed biological product, as provided in Subsection (6); and
 - (f) the substitution is not otherwise prohibited by law.
- (3)
 - (a) Each out-of-state mail service pharmacy dispensing an interchangeable biosimilar product as a substitute for another biological product into this state shall notify the patient of the substitution either by telephone or in writing.
 - (b) Each out-of-state mail service pharmacy shall comply with the requirements of this chapter with respect to an interchangeable biosimilar 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 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 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 practitioner'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 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.

- (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.