21.0011.02000

Sixty-seventh
Legislative Assembly
of North Dakota

SECOND DRAFT:
Prepared by the Legislative Council staff for the
Health Care Committee
November 2019

Introduced by

A BILL for an Act to amend and reenact section 19-02.1-14.3 of the North Dakota Century Code, relating to prescribing of biosimilar drugs.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Section 19-02.1-14.3 of the North Dakota Century Code is amended and reenacted as follows:

19-02.1-14.3. Biosimilar biological products.

1. In this section:
   a. "Biological product", "biosimilar", "interchangeable", "interchangeable biological product", "license", and "reference product" mean the same as these terms mean under section 351 of the federal Public Health Service Act [42 U.S.C. 262].
   b. "Prescription" means a product that is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)].
2. A pharmacy may not substitute a prescription biosimilar product for a prescribed product ~~only if~~unless each of the following requirements is met:
   a. The biosimilar product has been determined by the United States food and drug administration to be interchangeable with the prescribed product~~;~~.
   b. The prescribing practitioner does not specifically indicate in the practitioner's own handwriting "brand medically necessary" on a written prescription, does not expressly indicate that an oral prescription is to be dispensed as communicated, or has not taken a specific overt action to include the "brand medically necessary" language with an electronically transmitted prescription~~;~~.
   c. The pharmacist or the pharmacist's designee informs the individual receiving the biological product that the biological product may be substituted with a biosimilar

product and that the individual has a right to refuse the biosimilar product selected by the pharmacist and the individual chooses not to refuse~~;~~.

d. ~~The pharmacist notifies the prescribing practitioner orally, in writing, or by electronic transmission within twenty-four hours of the substitution; and~~Within five business days following the dispensing of the biosimilar product, the pharmacist or the pharmacist's designee notifies the prescribing practitioner of the substitution. Notification under this subdivision must include the name of the substitution product and the name of the manufacturer, and may be made using facsimile, telephone, electronic transmission, an entry into an electronic records system, or other prevailing means.

(1) An entry into an electronic records system may be made through:

(a) An interoperable electronic medical records system;

(b) An electronic prescribing technology;

(c) A pharmacy benefit management system; or

(d) A pharmacy record.

(2) An entry into an electronic records system is presumed to provide notice to the prescribing physician.

e. The pharmacy and the prescribing practitioner retain a record of the interchangeable biosimilar substitution for a period of no less than five years.

3. Subsection 2 does not apply to a biologic product refill prescription that is not changed from the interchangeable biosimilar substitution dispensed on the previous filling of the prescription.

4. The board of pharmacy shall maintain on ~~its~~the board's public website a current list, or an internet link to a United States food and drug administration-approved list, of biosimilar biological products determined to be interchangeable under subdivision a of subsection 2.