21.0011.01000

Sixty-seventh
Legislative Assembly
of North Dakota

FIRST DRAFT:
Prepared by the Legislative Council staff for the
Health Care Committee
September 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:
   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 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; and

d. ~~The pharmacist notifies the prescribing practitioner orally, in writing, or by electronic transmission within twenty-four hours of the substitution; and~~

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

3. 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.