Sixty-seventh Legislative Assembly of North Dakota
In Regular Session Commencing Tuesday, January 5, 2021

HOUSE BILL NO. 1033
(Legislative Management)
(Health Care Committee)

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 two 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 interoperable electronic medical record accessible by the prescribing practitioner, or other prevailing means accessible by the prescribing practitioner.

   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.

Speaker of the House	President of the Senate
Chief Clerk of the House	Secretary of the Senate

This certifies that the within bill originated in the House of Representatives of the Sixty-seventh Legislative Assembly of North Dakota and is known on the records of that body as House Bill No. 1033.

House Vote:	Yeas 94	Nays 0	Absent 0
Senate Vote:	Yeas 47	Nays 0	Absent 0

Chief Clerk of the House

Received by the Governor at _____M. on _____, 2021.

Approved at _____M. on _____, 2021.

Governor

Filed in this office this _____day of _____, 2021,

at _____ o'clock _____M.

Secretary of State