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Sixty-third
Legislative Assembly
of North Dakota

SENATE BILL NO. 2190

Introduced by

Senators Dever, Berry, J. Lee

Representatives Damschen, Devlin, Rohr

A BILL for an Act to create and enact a new section to chapter 19-02.1 of the North Dakota Century Code, relating to biosimilar biological products.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 19-02.1 of the North Dakota Century Code is created and enacted as follows:

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 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 substitute a prescription biosimilar product for a prescribed product only if:
   a. The biosimilar product has been determined by the United States food and drug administration to be interchangeable with the prescribed product for the specified indicated use;
   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;

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

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

3. The board of pharmacy shall:

a. Maintain on its 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; and

b. Adopt rules for compliance, under which a pharmacy that violates subsection 2 is subject to a specified civil money penalty.