

Sixty-third
Legislative Assembly
of North Dakota

ENGROSSED SENATE BILL NO. 2190

Introduced by

Senators Dever, Berry, J. Lee

Representatives Damschen, Devlin, Rohr

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

3 **BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

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

6 **Biosimilar biological products.**

7 **1. In this section:**

8 **a. "Biological product", "biosimilar", "interchangeable", "interchangeable biological**
9 **product", "license", and "reference product" mean the same as these terms mean**
10 **under section 351 of the Public Health Service Act [42 U.S.C. 262].**

11 **b. "Prescription" means a product that is subject to section 503(b) of the federal**
12 **Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)].**

13 **2. A pharmacy may substitute a prescription biosimilar product for a prescribed product**
14 **only if:**

15 **a. The biosimilar product has been determined by the United States food and drug**
16 **administration to be interchangeable with the prescribed product;**

17 **b. The prescribing practitioner does not specifically indicate in the practitioner's own**
18 **handwriting "brand medically necessary" on a written prescription, does not**
19 **expressly indicate that an oral prescription is to be dispensed as communicated,**
20 **or has not taken a specific overt action to include the "brand medically**
21 **necessary" language with an electronically transmitted prescription; and**

22 **c. The pharmacist informs the individual receiving the biological product that the**
23 **biological product may be substituted with a biosimilar product and that the**

- 1 individual has a right to refuse the biosimilar product selected by the pharmacist
2 and the individual chooses not to refuse.
- 3 3. The board of pharmacy shall maintain on its public website a current list, or an internet
4 link to a United States food and drug administration-approved list, of biosimilar
5 biological products determined to be interchangeable under subdivision a of
6 subsection 2.