

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 for the specified
17 indicated use;

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

23 c. The pharmacist informs the individual receiving the biological product that the
24 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 d. The pharmacist notifies the prescribing practitioner in writing or via electronic
4 transmission within twenty-four hours of the substitution; and
- 5 e. The pharmacy and the prescribing practitioner retain a written record of the
6 biosimilar substitution for a period of no less than five years.
- 7 3. The board of pharmacy shall:
- 8 a. Maintain on its public website a current list, or an internet link to a United States
9 food and drug administration-approved list, of biosimilar biological products
10 determined to be interchangeable under subdivision a of subsection 2; and
- 11 b. Adopt rules for compliance, under which a pharmacy that violates subsection 2 is
12 subject to a specified civil money penalty.