

Introduced by

1 A BILL for an Act to amend and reenact section 19-02.1-14.3 of the North Dakota Century
2 Code, relating to prescribing of biosimilar drugs.

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

4 **SECTION 1. AMENDMENT.** Section 19-02.1-14.3 of the North Dakota Century Code is
5 amended and reenacted as follows:

6 **19-02.1-14.3. 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 federal 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 not substitute a prescription biosimilar product for a prescribed
14 product ~~only if~~unless:

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;

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; and
3 ~~d. The pharmacist notifies the prescribing practitioner orally, in writing, or by~~
4 ~~electronic transmission within twenty-four hours of the substitution; and~~
5 ~~e. The pharmacy and the prescribing practitioner retain~~retains a record of the
6 interchangeable biosimilar substitution for a period of no less than five years.
7 3. The board of pharmacy shall maintain on ~~its~~the board's public website a current list, or
8 an internet link to a United States food and drug administration-approved list, of
9 biosimilar biological products determined to be interchangeable under subdivision a of
10 subsection 2.