

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 each of the following requirements is met:

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 or the pharmacist's designee informs the individual receiving the  
23 biological product that the biological product may be substituted with a biosimilar

- 1 product and that the individual has a right to refuse the biosimilar product  
2 selected by the pharmacist and the individual chooses not to refuse;\_
- 3 ~~d. The pharmacist notifies the prescribing practitioner orally, in writing, or by~~  
4 ~~electronic transmission within twenty four hours of the substitution; and~~Within five  
5 business days following the dispensing of the biosimilar product, the pharmacist  
6 or the pharmacist's designee notifies the prescribing practitioner of the  
7 substitution. Notification under this subdivision must include the name of the  
8 substitution product and the name of the manufacturer, and may be made using  
9 facsimile, telephone, electronic transmission, an entry into an electronic records  
10 system, or other prevailing means.
- 11 (1) An entry into an electronic records system may be made through:
- 12 (a) An interoperable electronic medical records system;
- 13 (b) An electronic prescribing technology;
- 14 (c) A pharmacy benefit management system; or
- 15 (d) A pharmacy record.
- 16 (2) An entry into an electronic records system is presumed to provide notice to  
17 the prescribing physician.
- 18 e. The pharmacy and the prescribing practitioner retain a record of the  
19 interchangeable biosimilar substitution for a period of no less than five years.
- 20 3. Subsection 2 does not apply to a biologic product refill prescription that is not changed  
21 from the interchangeable biosimilar substitution dispensed on the previous filling of the  
22 prescription.
- 23 4. The board of pharmacy shall maintain on ~~its~~the board's public website a current list, or  
24 an internet link to a United States food and drug administration-approved list, of  
25 biosimilar biological products determined to be interchangeable under subdivision a of  
26 subsection 2.