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SECOND ENGROSSMENT

Sixty-third Legislative Assembly of North Dakota

REENGROSSED 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 and enacted as follows:
- 6 **Biosimilar biological products.**
- 7 1. In this section:

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- 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].
- 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)].
- 13 <u>2. A pharmacy may substitute a prescription biosimilar product for a prescribed product</u>
 14 <u>only if:</u>
 - a. The biosimilar product has been determined by the United States food and drug administration to be interchangeable with the prescribed product:
 - 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

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1			individual has a right to refuse the biosimilar product selected by the pharmacist
2			and the individual chooses not to refuse;
3		<u>d.</u>	The pharmacist notifies the prescribing practitioner orally, in writing, or by
4			electronic transmission within twenty-four hours of the substitution; and
5		<u>e.</u>	The pharmacy and the prescribing practitioner retain a record of the
6			interchangeable biosimilar substitution for a period of no less than five years.
7	<u>3.</u>	The	board of pharmacy shall maintain on its public website a current list, or an internet
8		<u>link</u>	to a United States food and drug administration-approved list, of biosimilar
9		biol	ogical products determined to be interchangeable under subdivision a of
10		sub	section 2.