02/05/21 **REVISOR** SGS/KR 21-02687 as introduced

SENATE STATE OF MINNESOTA NINETY-SECOND SESSION

A bill for an act

S.F. No. 990

(SENATE AUTHORS: NELSON, Klein and Newton)

DATE 02/15/2021 **D-PG** 389 **OFFICIAL STATUS** Introduction and first reading
Referred to Health and Human Services Finance and Policy
Author added Klein 4838

01/31/2022 03/07/2022 5238 Author added Newton

1.1

1.2 1.3 1.4	relating to health; allowing pharmacy and provider choice related to the prescribing and dispensing of biological products; requiring a report; amending Minnesota Statutes 2020, section 151.01, by adding subdivisions; proposing coding for new
1.5	law in Minnesota Statutes, chapter 62W. BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:
	Section 1 162W 07511 ALTEDNATIVE DIOLOCICAL DDODUCTS
1.7	Section 1. [62W.0751] ALTERNATIVE BIOLOGICAL PRODUCTS.
1.8	Subdivision 1. Definitions. (a) For purposes of this section, the following definitions
1.9	have the meanings given them.
1.10	(b) "Biological product" has the meaning provided in section 151.01, subdivision 40.
1.11	(c) "Biosimilar" or "biosimilar product" has the meaning provided in section 151.01,
1.12	subdivision 43.
1.13	(d) "Interchangeable biological product" has the meaning provided in section 151.01,
1.14	subdivision 41.
1.15	(e) "Reference biological product" has the meaning provided in section 151.01,
1.16	subdivision 44.
1.17	Subd. 2. Pharmacy and provider choice related to dispensing reference biological
1.18	products, interchangeable biological products, or biosimilar products. (a) A pharmacy
1.19	benefit manager or health carrier must not require or demonstrate a preference for a pharmacy
1.20	or health care provider to prescribe or dispense any of the following:
1.21	(1) a reference biological product;
1.22	(2) any product that is biosimilar to the reference biological product; or

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<u>(3</u>) any product that is an interchangeable biological product, relative to the reference
biolo	gical product.
<u>(b</u>) If a pharmacy benefit manager or health carrier elects coverage of a product listed
in pai	ragraph (a), clauses (1) to (3), it must also elect equivalent coverage for all of the
orodu	acts listed in paragraph (a), clauses (1) to (3).
<u>(c</u>) Nothing in this section must require switching from a prescribed product listed in
parag	graph (a), clauses (1) to (3), to another product listed in paragraph (a), clauses (1) to
(3), tl	nat has a higher retail price.
<u>(d</u>) This section does not apply to coverage provided through a public health care program
undei	chapter 256B or 256L, or health plan coverage through the State Employee Group
nsur	ance Plan (SEGIP) under chapter 43A.
<u>E</u> :	FFECTIVE DATE. This section is effective January 1, 2022.
Sec	. 2. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to
read:	
<u>S</u> ı	ubd. 43. Biosimilar product. "Biosimilar" or "biosimilar product" means a biological
rodu	act that the United States Food and Drug Administration has:
<u>(1</u>) licensed, and determined to be "biosimilar" under United States Code, title 42, section
262(i	<u>)(2);</u>
<u>(2</u>) determined to be "biosimilar," as set forth in the most recent edition or supplement
of the	e United States Food and Drug Administration publication titled "Lists of Licensed
Biolo	gical Products with Reference Product Exclusivity and Biosimilarity or
Interd	changeability Evaluations"; or
<u>(3</u>) determined to be therapeutically equivalent, as set forth in the most recent edition
or suj	pplement of the United States Food and Drug Administration publication titled
'App	roved Drug Products with Therapeutic Equivalence Evaluations."
<u>E</u> :	FFECTIVE DATE. This section is effective January 1, 2022.
Sec	. 3. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to
read:	
Sı	abd. 44. Reference biological product. "Reference biological product" means the
single	e biological product for which the United States Food and Drug Administration has
appro	oved an initial biological product license application, against which other biological

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products are evaluated for licensure as biosimilar products or interchangeable biological 3.1 products. 3.2

EFFECTIVE DATE. This section is effective January 1, 2022.

Sec. 4. STUDY OF PHARMACY AND PROVIDER CHOICE OF BIOLOGICAL

PRODUCTS.

3.3

3.4

3.5

3.6

The commissioner of health, within the limits of existing resources, shall analyze the effect of Minnesota Statutes, section 62W.0751, on the net price for different payors of 3.7 biological products, interchangeable biological products, and biosimilar products. The 3.8 commissioner of health shall report findings to the chairs and ranking minority members 3.9 of the legislative committees with jurisdiction over health and human services policy and 3.10 finance, and insurance, by December 15, 2023. 3.11

Sec. 4. 3