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State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-SECOND SESSION

H. F. No. 1516

02/25/2021 Authored by Schultz, Bierman and Olson, L.,
The bill was read for the first time and referred to the Committee on Commerce Finance and Policy
03/08/2021 Adoption of Report: Re-referred to the Committee on Health Finance and Policy

1.1 A bill for an act
1.2 relating to health; allowing pharmacy and provider choice related to the prescribing
1.3 and dispensing of biological products; requiring a report; amending Minnesota
1.4 Statutes 2020, section 151.01, by adding subdivisions; proposing coding for new
1.5 law in Minnesota Statutes, chapter 62W.

1.6 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

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

2.1 (3) any product that is an interchangeable biological product, relative to the reference  
 2.2 biological product.

2.3 (b) If a pharmacy benefit manager or health carrier elects coverage of a product listed  
 2.4 in paragraph (a), clauses (1) to (3), it must also elect equivalent coverage for all of the  
 2.5 products listed in paragraph (a), clauses (1) to (3).

2.6 (c) Nothing in this section must require switching from a prescribed product listed in  
 2.7 paragraph (a), clauses (1) to (3), to another product listed in paragraph (a), clauses (1) to  
 2.8 (3), that has a higher retail price.

2.9 (d) This section does not apply to coverage provided through a public health care program  
 2.10 under chapter 256B or 256L, or health plan coverage through the State Employee Group  
 2.11 Insurance Plan (SEGIP) under chapter 43A.

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

2.13 Sec. 2. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to  
 2.14 read:

2.15 Subd. 43. **Biosimilar product.** "Biosimilar" or "biosimilar product" means a biological  
 2.16 product that the United States Food and Drug Administration has:

2.17 (1) licensed, and determined to be "biosimilar" under United States Code, title 42, section  
 2.18 262(i)(2);

2.19 (2) determined to be "biosimilar," as set forth in the most recent edition or supplement  
 2.20 of the United States Food and Drug Administration publication titled "Lists of Licensed  
 2.21 Biological Products with Reference Product Exclusivity and Biosimilarity or  
 2.22 Interchangeability Evaluations"; or

2.23 (3) determined to be therapeutically equivalent, as set forth in the most recent edition  
 2.24 or supplement of the United States Food and Drug Administration publication titled  
 2.25 "Approved Drug Products with Therapeutic Equivalence Evaluations."

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

2.27 Sec. 3. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to  
 2.28 read:

2.29 Subd. 44. **Reference biological product.** "Reference biological product" means the  
 2.30 single biological product for which the United States Food and Drug Administration has  
 2.31 approved an initial biological product license application, against which other biological

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

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

3.4 Sec. 4. **STUDY OF PHARMACY AND PROVIDER CHOICE OF BIOLOGICAL**  
3.5 **PRODUCTS.**

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