State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-FIRST SESSION

H. F. No. 3223

02/13/2020 Authored by Schultz, Hamilton, Liebling, Munson and Bierman
The bill was read for the first time and referred to the Committee on Commerce
02/20/2020 Adoption of Report: Re-referred to the Committee on Health and Human Services Policy
04/14/2020 Adoption of Report: Amended and re-referred to the Health and Human Services Finance Division

A bill for an act

relating to health; allowing pharmacy and provider choice related to the prescribing and dispensing of biological products; requiring a report; amending Minnesota Statutes 2018, section 151.01, by adding subdivisions; proposing coding for new law in Minnesota Statutes, chapter 62W.

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

Section 1. **[62W.0751] ALTERNATIVE BIOLOGICAL PRODUCTS.**

Subdivision 1. **Definitions.** (a) For purposes of this section, the following definitions have the meanings given them.

(b) "Biological product" has the meaning provided in section 151.01, subdivision 40.

(c) "Biosimilar" or "biosimilar product" has the meaning provided in section 151.01, subdivision 42.

(d) "Interchangeable biological product" has the meaning provided in section 151.01, subdivision 41.

(e) "Reference biological product" has the meaning provided in section 151.01, subdivision 43.

Subd. 2. **Pharmacy and provider choice related to dispensing reference biological products, interchangeable biological products, or biosimilar products.** (a) A pharmacy benefit manager or health carrier must not require or demonstrate a preference for a pharmacy or health care provider to prescribe or dispense any of the following:

(1) a reference biological product;

(2) any product that is biosimilar to the reference biological product; or

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

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

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

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

EFFECTIVE DATE. This section is effective January 1, 2021.

Sec. 2. Minnesota Statutes 2018, section 151.01, is amended by adding a subdivision to read:

Subd. 42. **Biosimilar product.** "Biosimilar" or "biosimilar product" means a biological product that the United States Food and Drug Administration has:

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

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

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

EFFECTIVE DATE. This section is effective January 1, 2021.

Sec. 3. Minnesota Statutes 2018, section 151.01, is amended by adding a subdivision to read:

Subd. 43. **Reference biological product.** "Reference biological product" means the single biological product for which the United States Food and Drug Administration has approved an initial biological product license application, against which other biological

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

EFFECTIVE DATE. This section is effective January 1, 2021.

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

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 biological products, interchangeable biological products, and biosimilar products. The commissioner of health shall report findings to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance, and insurance, by December 15, 2022.