

1.1 moves to amend H.F. No. 1516 as follows:

1.2 Delete everything after the enacting clause and insert:

1.3 "Section 1. [62W.0751] ALTERNATIVE BIOLOGICAL PRODUCTS.

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

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

1.7 (c) "Biosimilar" or "biosimilar product" has the meaning provided in section 151.01,
1.8 subdivision 43.

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

1.11 (e) "Reference biological product" has the meaning provided in section 151.01,
1.12 subdivision 44.

1.13 Subd. 2. Pharmacy and provider choice related to dispensing reference biological
1.14 products, interchangeable biological products, or biosimilar products. (a)

1.15 Notwithstanding paragraph (b), a pharmacy benefit manager or health carrier must not
1.16 require or demonstrate a preference for a reference biological product administered to a
1.17 patient by a physician or health care provider or any product that is biosimilar to the reference
1.18 biological product or an interchangeable biological product administered to a patient by a
1.19 physician or health care provider.

1.20 (b) If a pharmacy benefit manager or health carrier elects coverage of a product listed
1.21 in paragraph (a), and there are two or less biosimilar products available relative to the
1.22 reference product, the pharmacy benefit manager or health carrier must elect equivalent

2.1 coverage for all of the products that are biosimilar to the reference biological or
2.2 interchangeable biological products.

2.3 (c) If a pharmacy benefit manager or health carrier elects coverage of a product listed
2.4 in paragraph (a), and there are greater than two biosimilar products available relative to the
2.5 reference product, the pharmacy benefit manager or health carrier must elect preferential
2.6 coverage for all of the products that are biosimilar to the reference biological or
2.7 interchangeable biological products.

2.8 (d) A pharmacy benefit manager or health carrier must not impose limits on access to a
2.9 product required to be covered under paragraph (b) that are more restrictive than limits
2.10 imposed on access to a product listed in paragraph (a), or that otherwise have the same
2.11 effect as giving preferred status to a product listed in paragraph (a) over the product required
2.12 to be covered under paragraph (b).

2.13 (e) This section only applies to new administrations of a reference biological product.
2.14 Nothing in this section requires switching from a prescribed reference biological product
2.15 for a patient on an active course of treatment.

2.16 **EFFECTIVE DATE.** This section is effective January 1, 2023.

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

2.19 Subd. 43. **Biosimilar product.** "Biosimilar" or "interchangeable biologic product" means
2.20 a biological product that the United States Food and Drug Administration has licensed, and
2.21 determined to be "biosimilar" under United States Code, title 42, section 262(i)(2).

2.22 **EFFECTIVE DATE.** This section is effective January 1, 2023.

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

2.25 Subd. 44. **Reference biological product.** "Reference biological product" means the
2.26 single biological product for which the United States Food and Drug Administration has
2.27 approved an initial biological product license application, against which other biological
2.28 products are evaluated for licensure as biosimilar products or interchangeable biological
2.29 products.

2.30 **EFFECTIVE DATE.** This section is effective January 1, 2023.

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

3.3 The commissioner of health, within the limits of existing resources, shall analyze the
3.4 effect of Minnesota Statutes, section 62W.0751, on the net price for different payors of
3.5 biological products, interchangeable biological products, and biosimilar products. The
3.6 commissioner of health shall report findings to the chairs and ranking minority members
3.7 of the legislative committees with jurisdiction over health and human services policy and
3.8 finance, and insurance, by December 15, 2024."

3.9 Amend the title accordingly