Bill Summary

H.F. 1516

As amended by H1516DE4

Subject	Alternative Biological Products
Authors	Schultz
Analyst	Randall Chun
Date	March 23, 2022

Overview

This bill prohibits pharmacy benefit managers (PBMs) and health carriers from requiring or demonstrating a preference for a biological product, and requires that equivalent or preferential coverage be provided for biosimilar products. The bill also requires the commissioner of health to analyze the effect of the bill on the net price for biological products.

Summary

Section	Description
1	**Alternative biological products.** Adds § 62W.0751. **Subd. 1. Definitions.** Defines the following terms: biological product, biosimilar or biosimilar product, interchangeable biological product, and reference biological product. **Subd. 2. Pharmacy and provider choice related to dispensing reference biological products, interchangeable biological products, or biosimilar products.** (a) Prohibits a PBM or health carrier from requiring or demonstrating a preference for a reference biological product administered to a patient by a physician or health care provider or any product that is biosimilar to the reference biological product or an interchangeable biological product. (b) If a PBM or health carrier elects coverage of a product listed in paragraph (a), and there are two or less biosimilar products available relative to the reference product, requires the PBM or health carrier to elect equivalent coverage for all of the products that are biosimilar to the reference biological or interchangeable biological products. (c) If a PBM or health carrier elects coverage of a product listed in paragraph (a), and there are greater than two biosimilar products available relative to the reference product, requires the PBM or health carrier to elect preferential

Section	Description

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

(d) Prohibits a PBM or health carrier from imposing limits on access to a product required to be covered in paragraph (b) that are more restrictive than the limits imposed on a product listed in paragraph (a) or that have the effect of giving preferred status to the product listed in paragraph (a).

(d) States that this section applies only to new administrations of a reference biological product, and that nothing in the section requires a patient on an active course of treatment to switch from a prescribed reference biological product.

Provides a January 1, 2023, effective date.

2 **Biosimilar product.**

Amends § 151.01, by adding subd. 43. Defines "biosimilar" or "interchangeable biological product" as a biological product that the FDA has licensed and determined to be biosimilar.

Provides a January 1, 2023, effective date.

3 **Reference biological product.**

Amends § 151.01, by adding subd. 44. Defines "reference biological product" as the single biological product for which the FDA has approved an initial biological product license application, against which other biological products are evaluated for licensure as biosimilar or interchangeable. Provides a January 1, 2023, effective date.

4 **Study of pharmacy and provider choice of biological products.**

Requires the commissioner of health, within the limits of existing resources, to analyze the effect of section 62W.0751 on the net price for different payors of biological products, interchangeable biological products, and biosimilar products. Requires the commissioner to report to the legislature by December 15, 2024.