# HOUSE RESEARCH

## Bill Summary

**File Number:** H.F. 712 **Date:** March 3, 2017
**Version:** As introduced

**Authors:** Albright and others

**Subject:** Substitution of Biological Products

**Analyst:** Randall Chun



## Overview

This bill expands state law on generic drug substitution to apply to biological products. The bill requires pharmacists to substitute less expensive interchangeable biological products, unless the prescriber requires the prescription to be dispensed as written or the purchaser objects.

**Section**

**1** **Drug.** Amends § 151.01, subd. 5. Modifies the reference to biological products, in a definition of "drug," and excludes blood and blood components.

**2** **Biological product.** Amends § 151.01, by adding subd. 40. States that "biological product" has the meaning provided in United States Code, title 42, section 262 (federal law regulating biological products). This section defines biological product as including a virus, therapeutic serum, toxin, antitoxin, vaccine, allergenic product, protein, and other specified products.

**3** **Interchangeable biological product.** Amends § 151.01, by adding subd. 41. Defines "interchangeable biological product" as a biological product that the U.S. Food and Drug Administration (FDA) has: (1) licensed, and determined to meet federal standards for interchangeability; or (2) determined to be therapeutically equivalent.

**4** **Substitution.** Amends § 156.21. The amendment to subdivision 3 requires a pharmacist, when a biological product is prescribed, to dispense a less expensive interchangeable biological product after disclosing the substitution to the purchaser, unless the purchaser objects or the prescriber has required that the prescription be dispensed as written. Prohibits the pharmacist from substituting a biological product, unless the FDA has determined the substitute is interchangeable with the prescribed biological product.

**Section**

A new subdivision 10 requires a dispensing pharmacist or the pharmacist's designee, within five business days of dispensing a biological product, to communicate to the prescriber the name and manufacturer of the biological product dispensed. Specifies requirements for this communication. Also provides that communication of this information is not required if: (1) there is no FDA approved interchangeable biological product for the product prescribed; or (2) the biological product is a refill and is the same product dispensed on the prior filling.

The amendment to subdivision 4 clarifies that a pharmacist is to substitute the least expensive safely interchangeable drug, and removes reference to brand name or generic drug. (This has the effect of allowing interchangeable biological products to be substituted.)

This section also makes changes in terminology and conforming changes throughout. These change include use of the term "prescription drug order," and adding references to biological products.