Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

ESSB 5594

Brief Description: Concerning biosimilar medicines and interchangeable biological products.

Sponsors: Senate Committee on Health & Long-Term Care (originally sponsored by Senators Harris, Cleveland, Hasegawa and Shewmake).

Brief Summary of Engrossed Substitute Bill

- Authorizes a health carrier or prescription drug utilization management entity to require a patient to try a biosimilar prior to providing coverage for the equivalent branded drug.
- Modifies provisions authorizing the substitution of therapeutically equivalent drugs or interchangeable biological products by pharmacists.

Hearing Date: 3/26/25

Staff: Kim Weidenaar (786-7120).

Background:

Biological Products.
Biological products are regulated by the Food and Drug Administration (FDA) and are used to diagnose, prevent, treat, and cure diseases and medical conditions. There are many types of FDA-approved biological products including therapeutic proteins, monoclonal antibodies, and vaccines. Biological products are more complex than traditional chemical-based drugs because they are manufactured from living organisms and so a replicated biological product will not be identical to the original, reference product and slight variations in manufactured lots of the biological product are normal. When assessing the comparability of biological products, there are two federal FDA classifications.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not part of the legislation nor does it constitute a statement of legislative intent.

Biosimilars are biological products that are highly similar, but not identical, to an already FDA-approved biological product, the original biologic medication, also known as the reference biological product. For the FDA to approve a biosimilar, there must be no differences in the safety and effectiveness of the products. Biosimilars provide the same benefits when treating a disease or condition, are the same strength and dose, and have the same potential side effects.

Interchangeable biological products (interchangeable products) are biosimilars that meet additional FDA requirements. A manufacturer of a proposed interchangeable product must provide additional information to show that an interchangeable product is expected to produce the same clinical result as the reference product in any patient. An interchangeable product may be substituted for the reference product without the involvement of the prescriber.

Regulation of Substitutions.
Federal law allows a product that has been determined by the FDA to be an interchangeable product, to be substituted for the reference product without intervention of the health care provider who prescribed the original product. State law, however, governs the substitution of drugs by pharmacists and requires that every prescription must contain an instruction on whether a therapeutically equivalent generic drug or an interchangeable product may be substituted in its place, unless substitution is permitted under a prior-consent authorization. For written prescriptions, the form must have two signature lines at the bottom of the form labeled "dispense as written" and "substitution permitted" and the prescriber must communicate the substitution instructions by signing the appropriate line. For oral prescriptions, the practitioner must instruct the pharmacist as to whether the drug may be substituted, which must be noted on the file copy of the prescription. If substitution is permitted, and a less expensive alternative for the prescribed biological product is in stock, the pharmacist must substitute the interchangeable product with the original.

Health Carrier Prescription Drug Utilization Management.
Clinical review criteria used to establish a prescription drug utilization management protocol must be evidence-based and updated on a regular basis through review of new evidence, research, and newly developed treatments. When coverage of a prescription drug for the treatment of any medical condition is subject to prescription drug utilization management, the patient and the prescribing practitioner must have access to a clear, readily-accessible, and convenient process to request an exception. A carrier or prescription drug utilization management entity may require a patient to try an AB-rated generic equivalent or a biological product that is an interchangeable product prior to providing coverage for the equivalent branded drug.

State-Procured Qualified Health Plan.
Only health plans certified by the Washington Health Benefit Exchange (Exchange) as qualified health plans (QHPs) may be offered on the Exchange. All QHPs must be offered by licensed carriers and therefore must meet requirements generally applicable to all individual market health plans, including offering the essential health benefits; having their premium rates reviewed and approved by the Insurance Commissioner; and meeting network adequacy

requirements. The Health Care Authority (HCA), in consultation with the Exchange, must contract with at least one health carrier to offer QHPs on the Exchange for plan years beginning in 2021. A health carrier contracting with the HCA must offer at least one bronze, one silver, and one gold QHP in a single county or in multiple counties. The goal of the procurement is to have a choice of QHP offered in every county. The QHPs offered pursuant to an HCA contract must employ utilization management processes that meet national accreditation standards, comply with requirements established by the HCA to address amounts expended on pharmacy benefits including increasing generic utilization and use of evidence-based formularies, and focus on care that has high variation, high cost, or low evidence of clinical effectiveness.

Summary of Bill:

Regulation of Substitutions.
A pharmacist may substitute a therapeutically equivalent drug or interchangeable biological product unless the practitioner indicates the prescription may not be substituted. For oral prescriptions, a pharmacist may substitute a therapeutically equivalent generic drug or interchangeable biological product in its place unless the practitioner or the practitioner's agent instructs the pharmacist not to substitute.

The pharmacist must note the manufacturer of the drug dispensed on the file copy of a written or oral prescription, unless this information is maintained in a separate record that is readily retrievable by the pharmacist.

Provisions requiring every prescription to contain instructions on whether substitution is allowed and written prescription forms to include the two signature lines indicating either "dispense as written" or "substitution permitted" are removed.

Health Carrier Prescription Drug Utilization Management.
Beginning January 1, 2026, a carrier or prescription drug utilization management entity may require a patient to try a biosimilar prior to providing coverage for the equivalent branded drug.

State-Procured Qualified Health Plan.
The state-procured QHPs offered pursuant to an HCA contract must comply with requirements established by the HCA to address amounts expended on pharmacy benefits including increasing generic and biosimilar utilization and use of evidence-based formularies.

Appropriation: None.

Fiscal Note: Available.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.