FINAL BILL REPORT
ESB 5935

C 242 L 15
Synopsis as Enacted

Brief Description: Concerning biological products.

Sponsors: Senators Parlette and Frockt.

Senate Committee on Health Care
House Committee on Health Care & Wellness
House Committee on Appropriations

Background: A biological product, as defined by federal rule, means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product applicable to the prevention, treatment, or cure of a disease or condition of human beings. These are more complex than traditional chemically synthesized drugs. Biological products are manufactured from living organisms by programming cell lines to produce desired therapeutic substances. Examples of biological products include human growth hormone, injectable treatments for arthritis and psoriasis, the Hepatitis B vaccine, and stem cell therapy.

A biosimilar is a biological product that is highly similar to a biological product, with minor differences in clinically inactive components. A biosimilar is considered to be interchangeable with a biological product if it is determined by the Food and Drug Administration that it can be expected to produce the same clinical result as the reference biological product in any given patient and there is no risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the biological product.

The Affordable Care Act amended the Public Health Services Act to create an abbreviated licensure pathway for biosimilar products that are interchangeable with a Food and Drug Administration-licensed biological product. This is similar to the pathway permitted for drug manufactures to substitute generic drugs for brand-name prescription drugs that have been approved under the Food, Drug, and Cosmetic Act. Under this pathway, the Secretary of Health and Human Services may determine a biosimilar to be interchangeable with a biological product if it is determined that the biosimilar is expected to produce the same clinical result as the reference product in any given patient or there is not likely to be a risk to safety or efficacy by switching to the biosimilar. If the biosimilar is interchangeable, a pharmacy may substitute without the intervention of the health care provider.

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

Summary: Every drug prescription form must contain an instruction of whether or not a generic drug or an interchangeable biological product may be substituted. If dispense as written is indicated, an interchangeable biological product may not be substituted. If substitution is permitted, the pharmacist must substitute an interchangeable biological product for the biological product prescribed if the wholesale price of the interchangeable product is less than the wholesale price of the biological product prescribed.

Until August 1, 2020, the pharmacist must notify the prescriber if an interchangeable biological product is being substituted for the drug prescribed. Notice to the practitioner must be made within five days of the substitution and can be accomplished through use of an electronic records system such as an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit management system, or a pharmacy record if the practitioner has access to the electronic medical record system. If electronic medical records are not available, notification may then be made through other methods including facsimile or telephone. Notification is not required for refills or in situations where the pharmacist has communicated with the practitioner before substitution.

The Pharmacy Quality Assurance Commission must maintain a list of interchangeable biological products and all biological products approved as therapeutically equivalent by the federal Food and Drug Administration on its website.

Pharmacists and pharmacies are provided with protection from liability based on the decision to dispense the interchangeable biological product.

Pharmacies must post a sign that interchangeable biological products may be substituted for the drug prescribed by a patient's doctor.

Votes on Final Passage:

Senate	48	1	
House	96	1	(House amended)
Senate	47	1	(Senate concurred)

Effective: July 24, 2015