SENATE BILL REPORT
HB 2251

As of February 28, 2020

Title: An act relating to the expiration date for notification of dispensing an interchangeable biological product.

Brief Description: Concerning the expiration date for notification of dispensing an interchangeable biological product.

Sponsors: Representatives Thai and Cody.

Brief History: Passed House: 2/19/20, 98-0.
Committee Activity: Health & Long Term Care: 2/28/20.

Brief Summary of Bill

- Extends the notification requirement for interchangeable biological products from August 1, 2020 to August 1, 2025.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Staff: LeighBeth Merrick (786-7445)

Background: A biological product is a medication that is made from a living organism or contains components of living organisms such as blood, proteins, or viruses. Examples of biological products include human growth hormone, botox, stem cell therapy, and injectable treatments for arthritis, diabetes, and psoriasis. A biosimilar is a biologic product that is highly similar to the original biological product already approved by the Food and Drug Administration (FDA) with minor differences in clinically inactive components. For the biosimilar product to be classified as interchangeable, the FDA must determine that it can be expected to produce the same clinical result as the original product in any given patient, and there is no risk in terms of safety or diminished efficacy of alternating or switching between the interchangeable biologic product and the biological product.

State law requires every prescription for a biological product to indicate if an interchangeable biological product may be substituted. If substitution is permitted and the patient consents, the pharmacist must substitute the biological product prescribed with an in-stock interchangeable biological product when the wholesale price of the interchangeable product

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is less than the wholesale price of the biological product. The pharmacist must notify the patient if an interchangeable biological product is being substituted for the drug prescribed. Notification must occur at the time of dispensing. Until August 1, 2020, the pharmacist must also notify the prescriber if an interchangeable biological product is being substituted for the drug prescribed. Notice to the prescriber must be made within five days of the substitution and can be accomplished through use of an electronic medical record if the prescriber has access to the record. 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 prescriber before substitution.

Summary of Bill: The requirement for pharmacists to notify prescribers when interchangeable biological products are substituted is extended from August 1, 2020, to August 1, 2025.

Appropriation: None.

Fiscal Note: Not requested.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony: PRO: This is a technical fix that extends the date from 2020 to 2025 which keeps intact the agreement that was reached when the original biosimilar legislation was passed. As these drugs come online, it is logical to extend the notification component of the law.

Persons Testifying: PRO: Bill Clarke, Biotechnology Innovation Organization; Sean Graham, Washington State Medical Association.

Persons Signed In To Testify But Not Testifying: No one.