Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

ESB 5935

Brief Description: Concerning biological products.

Sponsors: Senators Parlette and Frockt.

Brief Summary of Engrossed Bill

- Authorizes a biological product to be substituted in the place of another biological product if the Food and Drug Administration has determined that the substituted biological product is interchangeable with the prescribed biological product.
- Requires, until August 1, 2020, that pharmacists substitute interchangeable biological products if the prescription for the biological product is marked "substitution permitted" and the wholesale price of the interchangeable biological product is less than the wholesale price of the prescribed biological product.
- Requires a pharmacist, within five days of dispensing a biological product, to record the name of the product and the manufacturer in an interoperable electronic medical records system or other electronic prescribing technology that is accessible to the prescribing provider or to communicate the product information directly to the prescribing provider.

Hearing Date: 3/24/15

Staff: Chris Blake (786-7392).

Background:

Biological Products.
Biological drug products replicate natural bodily substances and are often produced in living systems, such as microorganisms or plant or animal cells. Compared to small molecule drugs, which are generally pure chemical substances that can be entirely reproduced, these products are usually larger, more complex, and unlikely to be structurally identical in their production.

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.

Federal law defines "biological products" to include the following items when used for the prevention, treatment, or cure of a disease: a virus, a therapeutic serum, a toxin, an antitoxin, a vaccine, blood, an allergenic product, a protein, or an arsphenamine. Federal law prohibits the introduction of biological products into interstate commerce unless the product has been licensed by the federal Food and Drug Administration (FDA). To receive a license, an applicant must demonstrate that the biological product is safe, pure, and potent and the manufacturing facility maintains those qualities. The law establishes standards for labeling, inspecting manufacturing processes, and recalls of hazardous biological products.

When analyzing biological products for their level of comparability, the FDA assesses the new product against the original, or "reference" product, and determine if the product is either "biosimilar" or "interchangeable." Interchangeability is a higher standard than biosimilarity and requires that the product be expected to produce the same clinical result as the reference product to any given patient. Federal law allows a product that is determined by the FDA to be an interchangeable biological product to be substituted for the reference product without intervention of the health care provider who prescribed the reference product; however, state law governs the substitution of drugs by pharmacists.

Substitution of Drugs.
Drug prescriptions must contain an instruction as to whether or not a therapeutically equivalent generic drug may be substituted, unless a prior-consent authorization allows for substitutions. A prescription is not valid unless the prescribing practitioner has signed whether the prescription must be dispensed as written or if a substitution is permitted.

When filling a prescription under a state-purchased health care program, including Medical Assistance programs, the Public Employee Benefits Board's self-insured program, and Labor and Industries programs, a pharmacist must substitute a preferred drug in the place of a non-preferred drug in a therapeutic class. This requirement does not apply in cases in which the prescribing practitioner has noted on the prescription that the non-preferred drug must be dispensed as written.

Summary of Bill:

"Biological products" are defined as any of the following items when used for the prevention, treatment, or cure of a disease: a virus, a therapeutic serum, a toxin, an antitoxin, a vaccine, blood, an allergenic product, a protein, or an arsphenamine. A biological product is considered to be "interchangeable" if the federal Food and Drug Administration (FDA) has determined that the product either meets safety standards for interchangeability with another biological product or is therapeutically equivalent to another drug product.

Prescriptions for biological products must include instructions on whether or not an interchangeable biological product may be substituted in its place. Until August 1, 2020, pharmacists must substitute an interchangeable biological product for the prescribed biological product if: (1) a prescription is marked "substitution permitted;" and (2) the wholesale price to the pharmacist for the interchangeable biological product is less than the wholesale price for the prescribed product. The mandatory substitution does not apply if the patient or his or her representative requests the prescribed biological product.

Until August 1, 2020, a pharmacist who dispenses a biological product must enter the product name and manufacturer into an interoperable electronic medical record system or a technology that is accessible by the prescribing practitioner within five days. Alternatively, the dispensing pharmacist may communicate the information to the prescribing practitioner by facsimile, telephone, electronic transmission, or other means. The entry and communication provisions do not apply: (1) if there is no interchangeable biological product for the prescribed product; (2) when a refill prescription is the same as the previously dispensed product; or (3) if the pharmacist and the practitioner communicate prior to dispensing and they confirm the product to be dispensed.

When a pharmacist counsels a patient, a dispensing pharmacist must disclose to the patient if he or she has substituted an interchangeable biological product for a prescribed biological product. The disclosure must include the name of the product and the manufacturer of the interchangeable biological product that was dispensed. Pharmacy signage requirements notifying patients of substitutions of equivalent drugs must also reference interchangeable biological products.

Pharmacists assume the same responsibility for selecting an interchangeable biological product as they have when filling that product as prescribed by name. Prescribing practitioners are not liable for a pharmacist's decisions regarding the selection, preparation, or dispensing of an interchangeable biological product.

The Pharmacy Quality Assurance Commission must maintain a link on its website that connects to the federal FDA's most current list of interchangeable biological products.

Appropriation: None.

Fiscal Note: Available.

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