Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

HB 2326

Brief Description: Concerning the prescription of biological products.

Sponsors: Representatives Cody, Schmick, Harris, Morrell, Ross, Manweller, Sullivan, Ryu and Jinkins.

Brief Summary of Bill

- Authorizes biosimilar products to be substituted in the place of a biological product if the United States Food and Drug Administration has determined that the biosimilar product is interchangeable with the biological product.
- Requires pharmacists dispensing biological products to record the name of the product and the manufacturer in an interoperable health records system that is shared with the prescribing provider or to communicate it directly to the prescribing provider.

Hearing Date: 1/20/14

Staff: Chris Blake (786-7392)

Background:

Biological and Biosimilar 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.

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

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by the United States 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.

A "biosimilar product" is defined as an item that is highly similar to a biological reference product and has no clinically meaningful differences with the biological reference product in terms of safety, purity, and potency. A "biological reference product" is a biological product to which another biological product is compared. The FDA considers applications to determine whether a product either meets (1) the definition of a biosimilar or (2) the safety standard of an interchangeable biological product. The FDA's safety standards for interchangeability require that the biological product be determined to be (1) biosimilar to a reference product and (2) expected to produce the same clinical result as the reference product to any given patient. In the case of biological products that are administered to patients in multiple doses, the product must also demonstrate that the safety risks and risks of reduced efficacy when alternating between the biological product and a biological reference product are no different between doses of the same biological reference product.

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 for 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. "Biosimilar products" are items that are highly similar to a biological product and have no clinically meaningful differences with the biological product in terms of safety, purity, and potency.

Prescriptions for biological products must include instructions on whether or not an interchangeable biological product may be substituted in its place. If a pharmacist substitutes a biological product in the place of a different biological product, he or she must record the brand name or non-propriety name of the substitute. The records must be maintained for at least two years.

If the cost of an interchangeable biological product is less than the price of the prescribed product, the pharmacist must substitute the interchangeable biological product unless the patient requests the brand name product.

When a pharmacist dispenses a biological product, he or she must record the name of the product and manufacturer of the product in an interoperable health records system shared with the prescribing practitioner within 10 days. If there is no such health records system in place, the pharmacist must communicate the name of the product to the prescribing practitioner within 10 days. The communication requirement does not apply if there is no interchangeable biological product for the prescribed product or a refill is provided for the product that had been originally dispensed. The Pharmacy Quality Assurance Commission is required to maintain a list of all biological products that the United States Food and Drug Administration has determined to be interchangeable and the associated reference product.

Pharmacists assume the same responsibility for selecting an interchangeable biological product as the pharmacist has 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.

Pharmacy signage requirements notifying patients of substitutions of equivalent drugs must also reference interchangeable biological products. The name of the manufacturer of a drug product must be stated on the drug's label.

Appropriation: None.

Fiscal Note: Not requested.

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