Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

HB 1528

Brief Description: Concerning the prescription of biological products and interchangeable biosimilar products.

Sponsors: Representatives Cody, Harris, Morrell and Ryu.

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.

Hearing Date: 2/22/13

Staff: Chris Blake (786-7392).

Background:

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 nonpreferred drug in a therapeutic class. This requirement does not apply in cases in which the prescribing practitioner has noted on the prescription that the nonpreferred drug must be dispensed as written.

Biological and Biosimilar products.
Federal law prohibits the introduction of biological and biosimilar products into interstate commerce unless the product has been licensed by the United States Food and Drug

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Administration. 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.

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. "Biosimilar products" are defined as 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.

Summary of Bill:

"Biological products" are defined to have the same meaning as in federal law and 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. "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 biosimilar product may be substituted in its place. If a pharmacist substitutes a biosimilar product in the place of a biological product, he or she must record the brand name or nonpropriety name, the strength, and the name of the manufacturer or distributor of the product. The records must be maintained for at least two years.

When filling a prescription covered by a state-purchased health care program, a pharmacist must substitute a preferred biological product in the place of a nonpreferred biological product, unless the prescriber has instructed that the prescription be dispensed as written. Biosimilar products may only 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.

When, a pharmacist dispenses an interchangeable biosimilar product in the place of the prescribed biological product, regardless of whether it is for a state-purchased health care program or not, he or she must notify the patient and the prescriber. The notification to the prescriber must occur within three days of dispensing and must identify the biosimilar product that was dispensed to the patient.

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.