HOUSE BILL REPORT
ESB 5935

As Reported by House Committee On:
Health Care & Wellness
Appropriations

Title: An act relating to biological products.

Brief Description: Concerning biological products.

Sponsors: Senators Parlette and Frockt.

Brief History:
Committee Activity:
Health Care & Wellness: 3/24/15, 3/31/15 [DP];
Appropriations: 4/6/15, 4/7/15 [DPA].

Brief Summary of Engrossed Bill
(As Amended by Committee)

- 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 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 either the name of the product and the manufacturer or the federal Food and Drug Administration's National Drug Code in an interoperable electronic medical records system, a pharmacy benefit management system, an electronic prescribing technology, or a pharmacy record that is accessible to the prescribing provider electronically or to communicate the product information directly to the prescribing provider.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

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.

Majority Report: Do pass. Signed by 14 members: Representatives Cody, Chair; Riccelli, Vice Chair; Schmick, Ranking Minority Member; Harris, Assistant Ranking Minority Member; Caldier, Clibborn, DeBolt, Jinkins, Johnson, Moeller, Robinson, Short, Tharinger and Van De Wege.

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.

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 determines 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.

Staff Summary of Public Testimony:

(In support) There are currently no interchangeable biological products on the market, but it is good to have a law on the books for when that approval finally occurs. This bill is timely because two biological products are likely to be approved this year as interchangeable.

Biological products vary in their effectiveness. The notification requirement is good. Patients have had serious adverse reactions from some biological products. Patients with allergies could be at risk if they do not know which biological products they are receiving. Interchangeable biological products offer more treatment options to patients. This bill allows physicians to prevent substitutions if necessary, requires posting notifications, and encourages communication with patients. Notifications are good because patients talk extensively with their physicians about treatment and should not have a substitution affect that treatment plan.

Physicians support biosimilars legislation, but only if it has a notification process. Physicians need to be comfortable about checking the "Substitution Permitted" box on a prescription and that will only happen if this is recorded in the electronic record. Most biological products will not be provided at a retail pharmacy, but for those that are dispensed through a retail pharmacy, the notification provision will not be an impediment. The notification provisions do not present any additional burdens. This bill protects patients and prescribers by ensuring that they have ready access to dispensing information. Prescribing physicians should be notified of the actual biological product that was dispensed to ensure an accurate patient record.

This bill was created through a large stakeholder process. In drafting this, the controversial sections were left out, except for the substitution and notification sections which expire in 2020.

(In support with concerns) Additional electronic medical record options for notification should be considered. There are insulin products going through the generic pathway and they should not be included in the notification portion of this bill.

(Neutral) Mandatory substitution should be a part of any bill. For achieving cost containment in the biological market over the long term, it may not be a good idea to sunset the mandatory substitution provision.

(With concerns) The sunset provision for the mandatory substitution provision should be removed. The bill should reference the purple book, not the orange book, in the definition of "interchangeable."

Washington should use the Utah notification language because it includes a pharmacy benefit manager notification system that provides another chance for the provider to be able to check what was dispensed. The bill should allow a pharmacy benefit management system as an additional electronically accessible system for the prescriber. The bill should allow for an

exception from notification when biological products are purchased with cash or a cash equivalent. Notification requirements should not be roadblocks.

Section 4 of the bill should be struck or amended to be less cumbersome. Interchangeable biological products go through an extensive review process and are virtually equivalent to their reference product.

(Opposed) The notifications are a way for pharmaceutical companies to set the market. There is no reason for electronic notification. The notification provision is not clinically necessary because the federal Food and Drug Administration protocols will be stringent. Physicians can sign "Dispense as Written" or "Substitution Allowed" and that is sufficient. If there is a substitution allowed, the pharmacist will handle that when counseling the patient. Physician offices can always have access to the information about the dispensed product. The notification requirements could transmit the sense that there is a need for concern even when the federal Food and Drug Administration has determined that the biological product is interchangeable. Biological products should be treated like other generics under current law.

The cost to the patient and the state will be large because notification tends to lead to more prescribing of brand name products. California vetoed the bill because of the cost. There has not been a fiscal note from the Health Care Authority.

Persons Testifying: (In support) Senator Parlette, prime sponsor; Lisa Powell, Global Healthy Living Foundation; Liz Heath, Scleroderma Foundation; Tim Housh; Susie Tracey, Washington State Medical Association; Roman Daniels-Brown, Novartis; Cynthia Laubacher, Express Scripts; and Mary McHale, American Cancer Society and Cancer Action Network.

(In support with concerns) Dave Mastin, Mylan.

(Neutral) Len Sorrin, Premera.

(With concerns) Chris Bandoli, Regence; Amber Ulvenes, Group Health Cooperative; Lis Houchen, National Association of Chain Drug Stores; and Maral Farsi, CVS Health.

(Opposed) Jim Hendrick and Dale Fisher, Walgreens; and Sydney Smith Zvara, Association of Washington Health Care Plans.

Persons Signed In To Testify But Not Testifying: None.

HOUSE COMMITTEE ON APPROPRIATIONS

Majority Report: Do pass as amended. Signed by 23 members: Representatives Hunter, Chair; Ormsby, Vice Chair; Chandler, Ranking Minority Member; Parker, Assistant Ranking Minority Member; Wilcox, Assistant Ranking Minority Member; Buys, Cody, Dent, Dunshee, Fagan, Hansen, Hudgins, S. Hunt, Jinkins, Kagi, Lytton, Pettigrew, Sawyer, Senn, Springer, Stokesbary, Sullivan and Tharinger.

Minority Report: Do not pass. Signed by 5 members: Representatives Haler, G. Hunt, MacEwen, Taylor and Van Werven.

Minority Report: Without recommendation. Signed by 2 members: Representatives Condotta and Magendanz.

Staff: Erik Cornellier (786-7116).

Summary of Recommendation of Committee On Appropriations Compared to Recommendation of Committee On Health Care & Wellness:

The references to the biological products determined by the federal Food and Drug Administration as therapeutically equivalent are removed from the definition of "interchangeable."

The requirement that, as part of the patient counseling requirement, the pharmacist disclose to the patient if an interchangeable biological product is being substituted for the prescribed drug is removed.

The August 1, 2020, expiration of the mandatory substitution of interchangeable biological drug products is removed.

Pharmacists are allowed to provide notice of substitutions through a pharmacy benefit management system. Entering the biological product into an electronic records system is presumed to provide notice to the prescriber that a substitution has been made.

Pharmacists may enter the federal Food and Drug Administration's National Drug Code into an electronic medical records technology as an alternative to entering the product name and manufacturer.

Appropriation: None.

Fiscal Note: Available.

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

Staff Summary of Public Testimony:

(In support) Notification is the heart of the bill. When an interchangeable biologic is dispensed, the physician should be notified to ensure an accurate and enduring medical record. Notification is important in terms of patient care and it is a policy, not fiscal, matter. It is extremely important for a physician to know whether there has been a substitution and what it was. Physicians must have confidence so they feel free to allow substitutions when making prescriptions. It is desirable to have substitutions permitted to generate savings.

This is a well-worked bill with an extensive process with the stakeholders. Physicians and the patient community have sided with it.

Many of the complaints will not come in because it will take time for interchangeable biologics to come into the market.

There will be a large savings to the state when the interchangeable drugs are available and can be substituted at lower prices.

(Opposed) Look at the costs in the fiscal note. Pharmacies will have increased administrative costs for dispensing products to members of Health Care Authority programs. While enrollment in Medicaid and public employee benefits is increasing, the notification requirements will add costs. A fiscal note from Tennessee and a white paper from Emory University show that notification places all of the onus on the pharmacy community.

Nothing in the bill requires the prescriber to put the prescription in the electronic record, so there is no reasonable way to get the information to the prescriber.

Notification requirements are the heart of the fiscal impact. California's Public Employee Retirement System requested that Governor Brown veto a similar bill because of the unnecessary notification requirements which could decrease substitutions. Unnecessary notification provisions create a chilling effect that will prevent substitutions with lower cost drugs. Prescription drug costs are a great concern to many governmental entities and the fastest growing segments of drug costs are specialty drugs and biologics. The notification provision would work against bringing the cost reductions to bear.

This is a solution in search of a problem. There are no interchangeable biologics. There are some biosimilars going through the federal process. There will be interchangeable biologics at some point, but not now. Washington is a state that has a long history of supporting generic utilization, which is at about 90 percent. Washington does not put barriers in front of medicine, yet this bill puts a notice barrier on drugs that do not exist. There is no clinical reason for the notice requirement. It treats biologics differently than generics.

There was a compromise in Utah, and Washington should look at that system.

The sunset in 2020 would stop the savings.

Persons Testifying: (In support) Mary McHale, American Cancer Society-Cancer Action Network; Susie Tracy, Washington State Medical Association; and Trent House, Genontech.

(Opposed) Jim Hedrick, Walgreens; Carrie Tellefson, CVS Health; Chris Bandoli, Regence Blue Shield; and Dave Mastin, Mylon, Inc.

Persons Signed In To Testify But Not Testifying: None.