FINAL BILL REPORT
HB 2251

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Synopsis as Enacted

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

Sponsors: Representatives Thai and Cody.

House Committee on Health Care & Wellness
Senate Committee on Health & Long Term Care

Background:

Biological Products.
The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product applicable to the prevention, treatment, or cure of a disease or condition of human beings. Biological products can be more complex than traditional chemical-based drugs because they are manufactured from living organisms by programming cell lines to produce desired substances. A replicated biological product will therefore not be identical to the reference product. When assessing the comparability of biological products, there are two federal Food and Drug Administration (FDA) classifications:

1. *Biosimilars* are a type of biological product that is compared against a reference biological product and has minor differences in clinically inactive components without any meaningful differences in terms of safety, purity, and potency of the product.
2. *Interchangeable biological products* are a higher standard of product than a biosimilar. These products can be expected to produce the same results in any given patient without compromising safety or efficacy.

Regulation of Substitutions.
Federal law allows a product that has been 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 original product. State law, however, governs the substitution of drugs by pharmacists and requires that every prescription must contain an instruction on whether a therapeutically equivalent generic drug or interchangeable biological product may be substituted in its place, unless substitution is permitted under a prior-consent authorization. If interchangeability has been approved, and a less expensive alternative for

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the prescribed biological product is in stock, the pharmacist must substitute the interchangeable product with the original.

Within five days of dispensing an interchangeable biological product, the dispensing pharmacist or the dispensing pharmacist's designee must notify the patient's practitioner and specify the biological product that has been provided to the patient. The notification must include either the name and manufacturer of the product, or the FDA's national drug code and may either take the form of a record entry in an interoperable health records system, or communication with the practitioner. This notification requirement expires August 1, 2020.

Summary:

The notification requirement for pharmacists substituting interchangeable biological products is extended from August 1, 2020, to August 1, 2025.

Votes on Final Passage:

House	98	0
Senate	49	0

Effective: June 11, 2020