Senate Public Health and Welfare Committee

Senator Patricia H. Vance
Chairman

Room 168 Main Capitol Building
Harrisburg, PA 17120-3031
(717) 787-8524
FAX (717) 772-0576

Amy Powell Bolze, Esq.
Executive Director

Summary
SB 514 PN 464

This legislation amends the Generic Equivalent Drug Law to provide for the substitution of an interchangeable biological product for a brand name biologic.

Background: According to federal law, a biological product is a product replicating natural substances in our bodies and may be made from living cells or tissues. These products are different from conventional drugs because they are not pure chemical substances with a known structure. Due to the fact that they are different and a manufacturer cannot guarantee their version is exactly identical to the original, the US Food and Drug Administration (USFDA) regulates them as biosimilars.

A manufacturer must apply to the USFDA to have their product considered as a biosimilar. A biosimilar is considered to be a product highly similar to the original product with minor differences in clinically inactive components. If approved as a biosimilar, the manufacturer can then apply to have the product be considered an interchangeable biologic. A biologic which is considered interchangeable satisfies USFDA safety standards. An interchangeable biologic may be substituted for a brand name biologic under federal law. The federal government has not yet approved any biosimiliars but is expected to take action on the first application in early March 2015.

Pennsylvania law does not currently provide for the substitution of biosimilars or interchangeable biosimilars. The Generic Equivalent Drug Law only pertains to conventional or small-molecule drugs.

Analysis: Senate Bill 514 will include biological products in the Generic Equivalent Drug Law and will treat them similarly to generics for purposes of pharmacy charges, record keeping, provision of consumer information, pharmacist liability, and notifications required by the Department of Health.

However, the bill will prohibit a pharmacist from substituting an interchangeable biological product for a prescribed biologic unless:

- The USFDA considers the product interchangeable with that which was prescribed.

- The prescriber does not indicate either verbally or in writing that substitution is prohibited.

- The person presenting the prescription receives notification of the substitution in the same manner required for a generic substitution.

The dispensing pharmacist or pharmacist's designee, after dispensing an interchangeable biological product, shall notify the prescriber of the specific product provided to the patient as well as the manufacturer. The notification shall:

  - Occur within a reasonable time, and
  - Transpire through the electronic health record or through electronic prescribing technology accessible by the prescriber

If electronic technology does not exist, the notification shall be made through prevailing means such as facsimile, telephone or other electronic transmission.

Notification is not required if:

- There is no USFDA approved interchangeable biological product; or
- It is a refill prescription where the product is the same product dispensed at the prior filling

This act does not apply to biological products dispensed without a prescription.

Amendment A00206

Deletes language related to additional notification, the five year expiration of the act, the staggered effective date, and reference to the "Orange Book" in the definition of interchangeable biological product. Makes other clarifying changes.

Effective Date
The act shall take effect in 60 days.