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 405 PN 401

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

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 biosimilar. A biosimilar which is considered interchangeable satisfies USFDA safety standards. An interchangeable biosimilar may be substituted for a brand name biologic under federal law. The federal government has not yet approved any biosimiliars.

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.

Senate Bill 405 will include biological products in the Generic Equivalent Drug Law and will prohibit a pharmacist from substituting a biosimilar product for a brand name biologic unless:

- It is considered interchangeable by the USFDA for the indicated use
- The prescriber does not indicate that substitution is prohibited

- The person presenting the prescription provides written consent for the substitution
- The pharmacist notifies the prescriber in writing but no later than 72 hours after dispensing
- A written record of the substitution is retained for no less than 5 years

Amendment A04333–

- Includes biological products approved under a different federal law
- Changes the requirement of consent from the person presenting the prescription to notification by the pharmacist
- Reduces the record keeping requirement to 2 years
- Permits notification to be made verbally, in writing, by fax, email or other electronic transmission and only requires it for the initial substitution
- Deletes the requirement that a biosimilar may only be substituted for the indicated use
- Clarifies that this notification and reporting requirements do not apply to any biological product which may be dispensed without a prescription

Effective Date

This act shall take effect in 60 days.