SENATE APPROPRIATIONS COMMITTEE FISCAL NOTE

BILL NO. Senate Bill 514 **PRINTER NO.** 509

AMOUNT

Indeterminate Savings

FUND

General Fund

DATE INTRODUCED

February 19, 2015

PRIME SPONSOR

Senator Vance

DESCRIPTION AND PURPOSE OF BILL

Senate Bill 514 amends the Generic Equivalent Drug Law to provide for the substitution of an interchangeable biological product for a brand name biologic.

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 the original prescription;
- The prescriber indicates either verbally or in writing that substitution is permitted; and
- 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.

This act shall take effect in 60 days.

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FISCAL IMPACT:

SB 514 will generate savings to the Medicaid program in the Department of Human Services and in the Pennsylvania Employees Benefit Trust Fund program when an interchangeable biological product is substituted for a more expensive prescribed medicine. To the degree that this legislation reduces the practice of substituting an interchangeable biological product, it could reduce those savings.

In March 2015, the Food and Drug Administration approved the first biosimilar product, Zarxio; however, this product is not considered interchangeable. At this time, there are no interchangeable biological products available in the United States market.

In Europe where biosimilars are permitted, it has been demonstrated that the biosimilar drugs are approximately 20% to 30% less than the brand name biologic. However, there are different drug approval processes and pricing differences between prescription drugs in the United States and Europe. These differences may contribute to a different percentage of savings in Pennsylvania.