HOUSE COMMITTEE ON APPROPRIATIONS

FISCAL NOTE

SENATE BILL NO. 514 **PRINTERS NO**. 1970 **PRIME SPONSOR**: Vance

COST / (SAVINGS)

FUND	FY 2015/16	FY 2016/17
General Fund	**See Fiscal Impact**	**See Fiscal Impact**

SUMMARY: Senate Bill 514, Printer's Number 1970, amends the Generic Equivalent Drug Law (Act 259 of 1976) to provide for the substitution of an interchangeable biological product for a brand name biologic. This legislation is effective in 60 days.

ANALYSIS: This bill amends the Generic Equivalent Drug Law by adding interchangeable biological products to the law and creating a new subsection pertaining to biological products. Under this subsection, a pharmacist may substitute a biological product for a prescribed biological product only if:

- It is considered interchangeable by the U.S. Food and Drug Administration;
- The prescriber does not indicate, verbally or in writing on the prescription, that substitution is prohibited;
- The person presenting the prescription receives notification of substitution;
- For the initial substitution, the pharmacist or the pharmacist's designee notifies the prescriber within 72 hours after dispensing (no notice required for refills of the same product)
    - The communication shall be conveyed by making an entry in the electronic health record of the patient, or through an electronic prescribing technology, a pharmacy benefit manager system or pharmacy record that is electronically accessible by prescribers. Entry into one of these electronic systems will be presumed to be notice to the prescriber. If no system is available between the pharmacist and the prescriber, the pharmacist shall communicate using a facsimile, telephone, electronic transmission or other prevailing means.

These requirements do not apply to a biological product which may be dispensed without a prescription.

FISCAL IMPACT: There are no FDA approved interchangeable biological products currently available in the United States. However, when these products do become available, enactment of this legislation will generate savings in the Department of Human Services Medical Assistance program as well as the Pennsylvania Employees Benefit Trust Fund and other health

care programs for Commonwealth employees when an interchangeable biological product is substituted for a more expensive medicine.

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House Appropriations Committee (R)

DATE: June 30, 2016

Estimates are calculated using the best information available. Actual costs and revenue impact incurred may vary from estimates.