

SENATE APPROPRIATIONS COMMITTEE FISCAL NOTE

BILL NO. Senate Bill 405

PRINTER'S NO. 1554

AMOUNT

Indeterminate Savings

FUND

General Fund

DATE INTRODUCED

February 8, 2013

PRIME SPONSOR

Senator Vance

DESCRIPTION AND PURPOSE OF BILL

Senate Bill 405 amends the Generic Equivalent Drug Law to provide for the substitution of an interchangeable biosimilar product for a brand name biologic.

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 receives notification;
- The pharmacist notifies the prescriber verbally, in writing, by fax, email or other electronic transmission and only requires it for the initial substitution but no later than 72 hours after dispensing; and
- A written record of the substitution is retained for no less than 2 years

This notification and reporting requirements do not apply to any biological product which may be dispensed without a prescription.

This act shall take effect in 60 days.

FISCAL IMPACT:

SB 405 will generate savings to the Medicaid program in the Department of Public Welfare and in The Pennsylvania Employees Benefit Trust Fund program when a biosimilar is substituted for a more expensive prescribed medicine.

Currently, the Food and Drug Administration is working on rules for introducing biosimilars. In addition, there are no biosimilar interchangeable drugs available in the United States market.

The Governor's Budget Office noted that as biosimilars come to the market, the Commonwealth would expect that biosimilars would help reduce costs for DPW and PEBTF. Potential savings to the Commonwealth cannot be calculated at this time.