

SENATE APPROPRIATIONS COMMITTEE FISCAL NOTE

BILL NO. Senate Bill 1042

PRINTER'S NO. 1432

AMOUNT

No Significant Fiscal Impact

FUND

General Fund

DATE INTRODUCED

June 24, 2013

PRIME SPONSOR

Senator Vance

HISTORY OF BILL

Referred to PUBLIC HEALTH AND WELFARE, June 24, 2013

Reported as committed, June 25, 2013

First consideration, June 25, 2013

Re-referred to APPROPRIATIONS, June 30, 2013

Re-reported as amended, Oct. 1, 2013

DESCRIPTION AND PURPOSE OF BILL

Senate Bill 1042 amends the Clinical Laboratory Act of 1951 to require all clinical laboratories operating in the Commonwealth to be permitted by the Department of Health and clarifies that prohibited practices are applicable to both in-state and out-of-state licensed laboratories.

The bill aligns recent changes in licensure requirements and provides the Department with the authority to exempt out-of-state labs from PA inspections provided those labs have been licensed or accredited under the federal Clinical Laboratories Improvement Act and the home state if applicable.

Definitions are added to differentiate between specimen collection and acceptance activities by clarifying that specimen collection includes all activities associated with obtaining and processing any material from the human body. This definition will still permit laboratories to pick up specimens to be tested by the laboratory and to operate their own patient collection centers.

Additionally, the bill aligns the Department of Health's laboratory prohibitions with the Department of Public Welfare's rules and regulations that expressly prohibit the placement of laboratory staff, specimen collectors or other laboratory personnel in a provider's office. All laboratories operating in the Commonwealth would further be prohibited from providing payments, regardless of whether such payment is fair market value, or other inducements to a provider in return for specimen collection referrals. Finally, no laboratory would be permitted to rent space from a provider or pay rent for a space located within the provider's office for the purpose of establishing a collection center unless the clinical laboratory and the physician's office are wholly owned and operated by the same entity.

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FISCAL NOTE

Finally, Senate Bill 1042 establishes up to a maximum \$500 per day penalty for failure to comply with the Act. This act shall take effect immediately.

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FISCAL IMPACT:

Senate Bill 1042 will have no significant fiscal impact to the Commonwealth. The Department of Health projects that there may be an increase in costs of \$10,000 for travel because of additional inspections. This amount can be absorbed within existing operating budget.