



Senate Public Health and Welfare Committee

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Summary SB 1042 PN1278

This legislation 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.

Finally, Senate Bill 1042 establishes up to a maximum \$500 per day penalty for failure to comply with the Act.

Effective Date

This act shall take effect immediately.