SENATE APPROPRIATIONS COMMITTEE FISCAL NOTE

BILL NO. Senate Bill 712 **PRINTER NO.** 930

AMOUNT FUND

No Fiscal Impact General Fund

DATE INTRODUCED PRIME SPONSOR

May 26, 2023 Senator Brown

DESCRIPTION

Senate Bill 712 amends the Clinical Laboratory Act regarding advertising for Pennsylvania-licensed labs and adds an exemption for source plasma donation centers.

The bill states that a clinical laboratory certified by the federal government as a clinical lab in Pennsylvania may directly or indirectly advertise or solicit business for diagnostic laboratory testing if all of the following apply:

- For diagnostic testing, the testing is ordered by a health care practitioner licensed in this Commonwealth or another person otherwise authorized by the laws of this Commonwealth to order the test;
- Testing is performed by the clinical laboratory;
- The clinical laboratory is a covered entity or a business associate of a covered entity for the purpose of compliance with the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HI-TECH);
- The clinical laboratory does not make a claim about the reliability and validity
 of the testing that is inconsistent with the testing proficiency standards of the
 federal certification; and
- The clinical laboratory discloses that the diagnostic laboratory test or procedure may or may not be covered by health insurance.

The bill stipulates that the department may prohibit the use of a clinical laboratory's advertisement or solicitation of business for diagnostic laboratory testing or impose a penalty authorized in the act if the department determines any of the following:

- The diagnostic laboratory testing poses a public threat; or
- The diagnostic laboratory testing is not in compliance with this section.

The bill allows a source plasma donation center to collect source plasma through plasmapheresis if the source plasma donation center complies with federal requirements governing the collection of source plasma and operation of a clinical laboratory in a source plasma donation center and clinical laboratory.

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The bill abrogates the regulations of the Health and Safety Code - 28 Pa. Code § 5.73.

This act shall take effect immediately.

FISCAL IMPACT:

Senate Bill 712 will have a no fiscal impact to the Commonwealth.