Department of Legislative Services

Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 1035 (Senator Klausmeier)
Finance

Medical Laboratories - Use or Sale of Data for Research Study and Advertising or Solicitation of Business

This bill prohibits a medical laboratory from using or selling data obtained from the results of a laboratory examination of an individual to another person for use in a research study without the consent of the individual. The bill also authorizes a person to advertise for or solicit business in the State for a medical laboratory, regardless of location, but only if the laboratory meets certain federal requirements, discloses risks associated with each test offered by the laboratory, and provides specific privacy policies to consumers.

Fiscal Summary

State Effect: Although the bill pertains to private-sector activities, any change in enforcement is not expected to materially affect State operations or finances.

Local Effect: None.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary: A person is authorized to advertise for or solicit business in the State for a medical laboratory, regardless of location, only if all products offered by the medical laboratory are accredited in accordance with the federal Clinical Laboratory Improvement Amendments (CLIA) of 1998 [*sic*], and the person advertising or soliciting business for a medical laboratory (1) discloses the risks associated with each test offered by the medical laboratory; (2) provides specific privacy policies to consumers; and (3) complies with the

requirements of the federal Health Insurance Portability and Accountability Act (HIPAA) of 1996.

Current Law/Background: In Maryland, entities must have a Maryland license to perform laboratory tests, as specified in § 17-212 of the Health-General Article. Laboratories are prohibited from advertising or soliciting business from anyone except for physicians, medical laboratories, or other health entities, as specified in § 17-215 of the Health-General Article. A violation of these provisions is a misdemeanor, subject to a maximum fine of $100 for a first offense and $500 for each subsequent conviction for a violation of the same provision. Each day a violation is continued after the first conviction is a subsequent offense.

According to the U.S. Centers for Disease Control and Prevention, CLIA, codified in federal law under 42 U.S.C. § 263a, revised the federal program for certification and oversight of clinical laboratory testing.

CLIA defines a "laboratory" or a "clinical laboratory" as a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

Under CLIA, a person is prohibited from soliciting or accepting materials derived from the human body for laboratory examination or other procedure unless the laboratory has a certificate issued by the Secretary of Health and Human Services that is applicable to the category of examinations or procedures which includes such examination or procedure. A certificate is valid for a maximum of two years. CLIA also establishes requirements for certificates, accreditation, laboratory standards, proficiency testing, inspections, and sanctions.

The Maryland Department of Health's Office of Health Care Quality (OHCQ) is responsible for federal laboratory certification under CLIA, which is required for all clinical laboratory testing sites. According to OHCQ's fiscal 2018 annual report, there are approximately 450 CLIA-certified laboratories in Maryland.

HIPAA required national standards to be developed for the protection of certain health information. The U.S. Department of Health and Human Services issued the HIPAA privacy rule to implement these requirements. The HIPAA privacy rule addresses the use and disclosure of personal health information by organizations subject to the rule, as well as standards for personal privacy rights to help consumers understand and control how their health information is used. Under the HIPAA privacy rule, covered entities (health plans, health care clearinghouses, and health care providers) may not use or disclose protected

health information except either as the privacy rule permits or as an individual authorizes in writing. Covered entities may disclose protected health information without an individual's authorization for such purposes as treatment, payment, health care operations, and public interest activities.

Small Business Effect: Any small businesses that are now able to directly advertise or solicit business in the State for laboratory tests or procedures benefit from the new authorization under the bill. However, any small businesses that sell personal data obtained from the results of a laboratory examination may see a reduction in sales to the extent that a person declines to provide consent for their data to be released for use in a research study.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Maryland Department of Health; U.S. Centers for Disease Control and Prevention; U.S. Department of Health and Human Services; Department of Legislative Services

Fiscal Note History: First Reader - March 28, 2019
sb/jc

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