Department of Legislative Services

Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

House Bill 526 (Delegate Cullison, *et al.*)
Health and Government Operations Rules

Medical Laboratories - Laboratory Tests and Procedures - Advertising

This bill authorizes a person to directly or indirectly advertise for or solicit business in the State for (1) a diagnostic laboratory test or procedure that is ordered by a physician and performed by a medical laboratory certified under federal law, as specified and (2) specified ancestry testing. The Secretary of Health may take legal action to restrict the marketing of a diagnostic laboratory test or procedure under specified circumstances.

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: The bill's authorization is limited to (1) a diagnostic laboratory test or procedure for the purpose of screening, diagnosing, managing, or treating a physical or mental condition or disease and (2) ancestry testing using Y-chromosome mitochondrial DNA or autosomal DNA testing limited to the detection and reporting of genetic evidence of parental lineage and genetic ethnicity. The bill does not apply to germline genetic or genomic testing done in connection with the analysis, diagnosis, or prediction of human diseases.

If a person advertises a diagnostic laboratory test or procedure, the person is a covered entity or the business associate of a covered entity for the purposes of the federal Health Insurance Portability and Accountability Act (HIPAA) of 1996, and the federal Health Information Technology for Economic and Clinical Health (HITECH) Act. The person advertising directly or indirectly for business may not make a claim about the reliability and validity of the test or procedure that is inconsistent with performance as measured under a specified section of federal law (the Clinical Laboratory Improvement Amendment of 1988, better known as CLIA). Additionally, the person must disclose that the diagnostic laboratory test or procedure may or may not be covered by health insurance.

Current Law: 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.

HITECH was enacted as part of the federal American Recovery and Reinvestment Act of 2009, to promote the adoption and meaningful use of health information technology. Subtitle D of HITECH addresses the privacy and security concerns associated with the electronic transmission of health information, in part, through several provisions that strengthen the civil and criminal enforcement of the HIPAA privacy rule.

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.

Additional Information

Prior Introductions: None.

Cross File: SB 495 (Senator Kelley, *et al.*) - Finance.

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 - February 18, 2019
mm/jc Third Reader - April 8, 2019
Revised - Amendment(s) - April 8, 2019

Analysis by: Kathleen P. Kennedy

Direct Inquiries to:
(410) 946-5510
(301) 970-5510