

Department of Legislative Services
Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
First Reader

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

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 a laboratory test or procedure that is ordered by a physician and performed by a medical laboratory certified under specified federal law.

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

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, the Clinical Laboratory Improvement Amendment of 1988 (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.

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; Department of Legislative Services

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md/jc

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