**HB 681**

# Department of Legislative Services

Maryland General Assembly
2018 Session

## FISCAL AND POLICY NOTE
**First Reader**

House Bill 681 (Delegate Parrott, *et al.*)
Health and Government Operations

**Medical Laboratories - Advertising or Solicitation of Business - Repeal of Prohibition**

This bill allows a person to advertise or solicit business in the State for any medical laboratory, regardless of location, from anyone – rather than just a physician, hospital, medical laboratory, clinic, clinical installation, or other medical care facility – by repealing the current prohibition.

## 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, and 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.

**Background:** Repealing the current prohibition could allow any number of types of laboratory testing, including ancestral history testing, genetic risk testing, and general laboratory work, to be provided to Maryland consumers. Direct-to-consumer (DTC) testing is one category of testing that is prevented in Maryland under this ban. DTC testing, and DTC genetic testing in particular, has received significant attention in recent years. Several online services provide DTC genetic testing.

*Federal Oversight of Laboratory Testing*

The U.S. Food and Drug Administration (FDA) regulates medical devices intended for use in humans under the Medical Device Amendments passed by the U.S. Congress in 1976 as an amendment to the Food, Drug, and Cosmetics Act. At that time, the definition of a device applied equally to *in vitro* diagnostic devises (IVDs) manufactured by conventional device manufacturers and those manufactured by laboratories. Historically, FDA has exercised enforcement discretion and generally has not enforced applicable provisions under the Food, Drug, and Cosmetics Act and FDA regulations with respect to laboratory developed tests (LDTs). Instead, FDA has allowed the laboratory community to police itself utilizing laboratory regulatory and accreditation agencies. FDA generally does *not* exercise enforcement discretion for DTC tests regardless of whether they meet the definition of an LDT.

IVDs are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. IVD products are intended for use in the collection, preparation, and examination of specimens taken from the human body. An LDT is an IVD that is intended for clinical use and is designed, manufactured, and used within a single laboratory. FDA does not consider devices to be LDTs if they are designed or manufactured completely, or partly, outside of the laboratory that offers and uses them.

The Centers for Medicare and Medicaid Services (CMS) has also regulated laboratories, under the Clinical Laboratory Improvement Amendments (CLIA) since 1988. CMS governs the accreditation, inspection, and certification process for laboratories. CLIA requirements address the laboratory's testing process (*i.e.*, the ability to perform laboratory testing in an accurate and reliable manner). FDA law assures both the analytical validity (*e.g.*, analytical specificity and sensitivity, accuracy, and precision) and clinical validity of diagnostics tests through its premarket clearance or approval process.

**Small Business Effect:** Small businesses that wish to advertise for or solicit business in the State for a medical laboratory benefit from removal of the current prohibition.

## Additional Information

**Prior Introductions:** HB 1489 of 2017 received a hearing in the House Health and Government Operations Committee, but no further action was taken on the bill. SB 227 of 2014 was withdrawn after a hearing in the Senate Finance Committee.

**Cross File:** None.

**Information Source(s):** Maryland Department of Health; Medical Laboratory Observer; labtestingmatters.org; U.S. Food and Drug Administration; Department of Legislative Services

**Fiscal Note History:** First Reader - March 8, 2018
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