HB 1489

Department of Legislative Services

Maryland General Assembly
2017 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 1489 (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 for those businesses in the State that wish to advertise for or solicit business in the State for a medical laboratory.

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.)

Repealing this prohibition could allow any number of types of laboratory testing, including ancestral history testing, genetic risk testing, and general laboratory work. Direct-to-consumer (DTC) testing is one category of testing that is currently prevented in Maryland under this ban.

Background: DTC genetic testing has received significant attention in recent years. Several online services provide DTC genetic testing, and these services are prohibited by law from serving Maryland consumers.

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 Cosmetic 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. However, 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). 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.

U.S. Food and Drug Administration Warning Letters and Approval for 23andMe

In February 2015, FDA issued a press release announcing that it had authorized 23andMe's Bloom Syndrome carrier DTC genetic test for marketing. The test is used to determine whether a healthy person has a variant in a gene that could lead to their offspring inheriting

the serious disorder. 23andMe, Inc., a California-based DTC genetic testing company, had previously run afoul of both federal and state laws (including in Maryland). Additionally, in October 2015, the company announced that it will again begin providing health information called carrier status, after a two-year hiatus in which the company only provided ancestry information based on genetic data. The carrier status tests will tell people whether they have genetic mutations that could lead to a disease in their offspring. Prior to 2013, the company had marketed a broader personal genome service in the United States but ceased providing direct health information to U.S. consumers (while continuing to provide services in some other countries) after FDA issued a 2013 warning letter.

In November 2015, FDA issued warning letters to three entities – DNA4Life; Interleukin Genetics, Inc.; and DNA-Cardiocheck, Inc. – for marketing genetic tests to consumers under a DTC method without being cleared for use as a "device," as defined in § 201(h) of the Food, Drug, and Cosmetic Act. DNA-Cardiocheck, Inc. markets a test intended to test for DNA markers linked to thrombophia, deep-vein thrombosis, cardiovascular disease, and stroke. DNA4Life markets a test intended to predict how patients will respond to more than 120 of the most commonly prescribed medications. Interleukin Genetics, Inc. markets tests intended to identify individuals with genetic predisposition for increased risk to diabetes and heart attack, osteoarthritis associated conditions, and obesity-related genotype for weight loss.

Additional Information

Prior Introductions: SB 227 of 2014 was withdrawn after a hearing in the Senate Finance Committee.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene; U.S. Food and Drug Administration; *The New York Times*; 23andMe; Department of Legislative Services

Fiscal Note History: First Reader - March 13, 2017
mm/ljm

Analysis by: Kathleen P. Kennedy

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