Department of Legislative Services

Maryland General Assembly
2016 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 1392 (Delegates Parrott and Metzgar)
Health and Government Operations

Medical Laboratories - Direct-to-Consumer Genetic Testing

This bill allows a person to advertise or solicit business in the State for, as well as offer or perform, direct-to-consumer (DTC) genetic testing so long as the laboratory meets specified requirements.

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 that State that wish to advertise for or solicit business in the State for a medical laboratory.

Analysis

Bill Summary: A DTC genetic test is a test that is offered directly to a consumer, instead of being ordered for a consumer through a health care provider. Any laboratory that provides DTC genetic testing must be certified under the federal Clinical Laboratory Improvement Amendments. The consumer who orders the genetic test must be an adult.

The person offering DTC genetic testing must advise each consumer (1) to talk to their health care provider or genetic counselor about the results of the genetic tests; (2) that the results of a genetic test may be used to deny or limit the amount, extent, or kind of long-term care, disability, or life insurance coverage available to the consumer or that insurance providers may charge a higher rate for these types of coverages; and (3) that the

failure to disclose the result of a genetic test on an application for these types of insurance policies could result in the cancellation of the policy or denial of coverage under the policy.

A provider of DTC genetic testing must also provide consumers with information on its policies and procedures relating to security and confidentiality of protected health information and the use of genetic test data in research studies. Finally, a provider must obtain written consent before using or providing another person with the consumer's name or other identifying information for any purpose other than communicating with the consumer about their genetic test.

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, 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.)

This prohibition means that a person cannot provide genetic testing for an individual without a referral from a physician or other medical facility. Several online services provide DTC genetic testing, and these services are prohibited by law from serving Maryland consumers. Such DTC testing services enable a consumer to order testing directly, without a referral.

In 2013, the Department of Health and Mental Hygiene (DHMH) published a review of, and conducted an informal request for public comment regarding, DTC genetic testing; the public comment period was from November 8 to November 26, 2013. DHMH found that DTC lab results were questionable in terms of clinical validity. DHMH received 18 public comments; all but 2 of them were supportive of permitting access to DTC genetic tests. Both a memo from the Maryland medical community and a memo from the Laboratory Advisory Committee expressed concerns and raised questions regarding the accuracy or interpretation of lab results, the potential for self-management based on false positive or negative test results, false advertising, and testing in prenatal settings.

In February 2015, the U.S. Food and Drug Administration (FDA) issued a press release announcing that it had authorized for marketing 23andMe's Bloom Syndrome carrier DTC genetic test, 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. The company had marketed a 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. That letter directed the company to stop selling its product because of failure to obtain marketing clearance or approval to assure their tests were accurate, reliable, and clinically meaningful. In August 2008, DHMH had also sent 23andMe, Inc., a cease and desist letter for violating § 17-215 of the Health-General Article.

Additional Information

Prior Introductions: HB 906 of 2014, a largely similar bill, was withdrawn after a hearing in the House Health and Government Operations Committee.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene, Maryland Insurance Administration, U.S. Food and Drug Administration, Department of Legislative Services

Fiscal Note History: First Reader - March 4, 2016
kb/ljm

Analysis by: Kathleen P. Kennedy

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