Department of Legislative Services

Maryland General Assembly
2014 Session

FISCAL AND POLICY NOTE

Senate Bill 227 (Senator Reilly)
Finance

Health - Medical Laboratories - Advertising for or Soliciting Business - Repeal of Prohibition

This bill allows a person to advertise for or solicit business in the State for any medical laboratory 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 that State that wish to advertise for or solicit business in the State for a medical laboratory.

Analysis

Current Law/Background: The current prohibition means that, for example, a person cannot provide genetic testing for an individual without a referral from a physician or other medical facility. Several online services provide direct-to-consumer (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 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.)

These laws prevent DTC testing. Although the bill allows broad DTC testing, DTC genetic testing is the most publicized and nationally debated type of DTC testing.

The Department of Health and Mental Hygiene (DHMH) recently 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, and all but 2 were supportive of permitting access to DTC genetic tests. However, a memo from the Maryland Medical Community and also a memo from the Laboratory Advisory Committee both expressed concerns that included questions regarding the accuracy of interpretation of lab results, the potential for self-management based on false positive or negative test results, false advertising, and testing in prenatal settings.

23andMe, Inc., is a DTC genetic testing company that has been in the news and also has run up against both federal and State laws. On November 22, 2013, the U.S. Food and Drug Administration (FDA) sent a warning letter to 23andMe, Inc., because it was marketing a Saliva Collection Kit and Personal Genome Service (PGS) without market clearance or approval in violation of the Federal Food, Drug, and Cosmetic Act. In the FDA's warning letter to 23andMe, Inc., the FDA warns that "DTC test results may be used by a patient to self-manage," and that "some of the uses [of the test kits] are particularly concerning, such as assessments for BRCA-related genetic risk and drug responses…because of the potential health consequences that could result from false positive or false negative assessments for high-risk indications such as these." DHMH also sent 23andMe, Inc., a cease and desist letter in August 2008 for violating § 17-215 of Health-General Article.

DHMH's request for public comment revealed that proponents of DTC feel that consumers have the right to access their own genetic information and to make their own decisions. Others wish to do genealogical research. Anne Wojcicki, co-founder of 23andMe, Inc., told *Time Magazine* that she hopes the company "will create a common, standardized resource that has the potential to accelerate drug discovery and bring personalized medicine to the public."

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene, U.S. Food and Drug Administration, Time.com Health and Family (article available at http://healthland.time.com/2012/08/02/23andme-wants-fda-approval-for-personal-dna-testing-what-can-it-reveal/print/), Department of Legislative Services

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