

HOUSE BILL 906

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By: **Delegate Pendergrass**

Introduced and read first time: February 5, 2014

Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Medical Laboratories – Direct-to-Consumer Genetic Testing

FOR the purpose of authorizing a person to advertise for, solicit business in the State for, offer, or perform direct-to-consumer genetic testing only if certain conditions are met; defining certain terms; making conforming changes; and generally relating to medical laboratories and direct-to-consumer genetic testing.

BY repealing and reenacting, with amendments,

Article – Health – General

Section 17-205(a) and 17-215

Annotated Code of Maryland

(2009 Replacement Volume and 2013 Supplement)

BY adding to

Article – Health – General

Section 17-701 and 17-702 to be under the new subtitle “Subtitle 7.
Direct-to-Consumer Genetic Testing”

Annotated Code of Maryland

(2009 Replacement Volume and 2013 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

17-205.

(a) **[A] EXCEPT AS PROVIDED IN § 17-702 OF THIS TITLE**, A person shall hold a license issued by the Secretary before the person may:

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



(1) Offer or perform medical laboratory tests or examinations in this State;

(2) Offer or perform medical laboratory tests or examinations on specimens acquired from health care providers in this State at a medical laboratory located outside this State; or

(3) Represent or service in this State a medical laboratory regardless of the laboratory's location.

17-215.

[A] EXCEPT AS PROVIDED IN § 17-702 OF THIS TITLE, A person may not directly or indirectly advertise for or solicit business in this State for any medical laboratory, regardless of location, from anyone except a physician, hospital, medical laboratory, clinic, clinical installation, or other medical care facility.

SUBTITLE 7. DIRECT-TO-CONSUMER GENETIC TESTING.

17-701.

(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(B) "DIRECT-TO-CONSUMER GENETIC TEST" MEANS A GENETIC TEST THAT IS OFFERED DIRECTLY TO A CONSUMER, INSTEAD OF BEING ORDERED FOR A CONSUMER THROUGH A HEALTH CARE PROVIDER.

(C) "GENETIC TEST" MEANS A LABORATORY TEST OF HUMAN CHROMOSOMES, GENES, OR GENE PRODUCTS THAT IS USED TO IDENTIFY THE PRESENCE OR ABSENCE OF INHERITED OR CONGENITAL ALTERATIONS IN GENETIC MATERIAL THAT ARE ASSOCIATED WITH DISEASE OR ILLNESS.

17-702.

A PERSON MAY ADVERTISE FOR, SOLICIT BUSINESS IN THE STATE FOR, OFFER, OR PERFORM DIRECT-TO-CONSUMER GENETIC TESTING ONLY IF:

(1) THE GENETIC TESTS ARE PERFORMED BY A LABORATORY THAT IS CERTIFIED UNDER THE FEDERAL CLINICAL LABORATORY IMPROVEMENT AMENDMENTS;

(2) THE CONSUMER WHO ORDERS THE GENETIC TEST IS AN ADULT;

(3) THE PERSON ADVISES EACH CONSUMER:

(I) TO TALK TO THE CONSUMER'S HEALTH CARE PROVIDER OR GENETIC COUNSELOR ABOUT THE RESULTS OF THE CONSUMER'S GENETIC TEST;

(II) THAT THE RESULTS OF A GENETIC TEST MAY BE USED TO:

1. DENY OR LIMIT THE AMOUNT, EXTENT, OR KIND OF LONG-TERM CARE INSURANCE COVERAGE OR LIFE INSURANCE COVERAGE AVAILABLE TO THE CONSUMER; OR

2. CHARGE A HIGHER RATE FOR LONG-TERM CARE INSURANCE OR LIFE INSURANCE; AND

(III) THAT FAILURE TO DISCLOSE THE RESULT OF A GENETIC TEST ON AN APPLICATION FOR A LONG-TERM CARE INSURANCE POLICY OR A LIFE INSURANCE POLICY COULD RESULT IN CANCELLATION OF THE POLICY OR DENIAL OF COVERAGE UNDER THE POLICY;

(4) THE PERSON PROVIDES CONSUMERS WITH INFORMATION ON ITS POLICIES AND PROCEDURES FOR:

(I) THE SECURITY AND CONFIDENTIALITY OF PROTECTED HEALTH INFORMATION; AND

(II) THE USE OF GENETIC TEST DATA IN RESEARCH STUDIES; AND

(5) THE PERSON OBTAINS THE WRITTEN CONSENT OF A CONSUMER BEFORE USING OR PROVIDING TO ANOTHER PERSON THE CONSUMER'S NAME OR OTHER IDENTIFYING INFORMATION FOR ANY PURPOSE OTHER THAN TO COMMUNICATE WITH THE CONSUMER ABOUT THE CONSUMER'S GENETIC TEST.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2014.