

HOUSE BILL 1392

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6lr3068

By: **Delegates Parrott and Metzgar**

Introduced and read first time: February 12, 2016

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Medical Laboratories – Direct-to-Consumer Genetic Testing**

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

7 BY repealing and reenacting, with amendments,

8 Article – Health – General

9 Section 17–205(a) and 17–215

10 Annotated Code of Maryland

11 (2015 Replacement Volume)

12 BY adding to

13 Article – Health – General

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

16 Annotated Code of Maryland

17 (2015 Replacement Volume)

18 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

19 That the Laws of Maryland read as follows:

20 **Article – Health – General**

21 17–205.

22 (a) **[A] EXCEPT AS PROVIDED IN § 17–702 OF THIS TITLE**, A person shall hold
23 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 (1) Offer or perform medical laboratory tests or examinations in this State;

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

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

7 17-215.

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

12 **SUBTITLE 7. DIRECT-TO-CONSUMER GENETIC TESTING.**

13 **17-701.**

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

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

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

23 **17-702.**

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

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

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

30 (3) THE PERSON ADVISES EACH CONSUMER:

1 **(I) TO TALK TO THE CONSUMER’S HEALTH CARE PROVIDER OR**
2 **GENETIC COUNSELOR ABOUT THE RESULTS OF THE CONSUMER’S GENETIC TEST;**

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

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

7 **2. CHARGE A HIGHER RATE FOR LONG-TERM CARE**
8 **INSURANCE, DISABILITY INSURANCE, OR LIFE INSURANCE; AND**

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

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

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

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

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

23 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
24 October 1, 2016.