

# SENATE BILL 495

J1, J2

(9lr1192)

## ENROLLED BILL

— Finance/Health and Government Operations —

Introduced by **Senators Kelley, Beidle, Benson, Feldman, Hayes, Klausmeier, and Reilly**

Read and Examined by Proofreaders:

\_\_\_\_\_  
Proofreader.

\_\_\_\_\_  
Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

\_\_\_\_\_ day of \_\_\_\_\_ at \_\_\_\_\_ o'clock, \_\_\_\_\_ M.

\_\_\_\_\_  
President.

### CHAPTER \_\_\_\_\_

1 AN ACT concerning

#### 2 **Medical Laboratories – Laboratory Tests and Procedures – Advertising**

3 FOR the purpose of authorizing a person, subject to certain limitations, to directly or  
4 indirectly advertise for or solicit business in the State for a laboratory test or  
5 procedure ordered by a physician and performed by a medical laboratory certified  
6 under a certain provision of federal law; *requiring a certain person to make a certain*  
7 *disclosure; providing that a certain person is a covered entity or business associate of*  
8 *a covered entity for purposes of certain provisions of federal law; authorizing the*  
9 *Secretary of Health to take a certain legal action under certain circumstances;*  
10 *providing for the application of this Act; making a conforming change; and generally*  
11 relating to medical laboratories.

12 BY repealing and reenacting, with amendments,  
13 Article – Health – General

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#### EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

*Italics indicate opposite chamber/conference committee amendments.*



1 Section 17–215  
 2 Annotated Code of Maryland  
 3 (2015 Replacement Volume and 2018 Supplement)

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

6 **Article – Health – General**

7 17–215.

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

12 (B) (1) (I) **THIS SUBSECTION APPLIES ONLY TO:**

13 **1. A DIAGNOSTIC LABORATORY TEST OR PROCEDURE**  
 14 **FOR THE PURPOSE OF SCREENING, DIAGNOSING, MANAGING, OR TREATING A**  
 15 **PHYSICAL OR MENTAL CONDITION OR DISEASE; AND**

16 **2. ANCESTRY TESTING USING Y-CHROMOSOME**  
 17 **MITOCHONDRIAL DNA OR AUTOSOMAL DNA TESTING LIMITED TO THE DETECTION**  
 18 **AND REPORTING OF GENETIC EVIDENCE ~~OR~~ OF PARENTAL LINEAGE AND GENETIC**  
 19 **ETHNICITY.**

20 (II) **THIS SUBSECTION DOES NOT APPLY TO GERMLINE GENETIC**  
 21 **OR GENOMIC TESTING DONE IN CONNECTION WITH:**

22 **~~1. THE ANALYSIS OR DIAGNOSIS AND CONTROL OF~~**  
 23 **~~HUMAN DISEASES OR MEDICAL CONDITIONS; OR~~**

24 **~~2. THE PREDICTION OF HUMAN DISEASES OR MEDICAL~~**  
 25 **~~CONDITIONS-THE ANALYSIS, DIAGNOSIS, OR PREDICTION OF HUMAN DISEASES.~~**

26 (2) **A SUBJECT TO PARAGRAPH (3) OF THIS SUBSECTION, A PERSON**  
 27 **MAY DIRECTLY OR INDIRECTLY ADVERTISE FOR OR SOLICIT BUSINESS IN THE STATE**  
 28 **FOR A DIAGNOSTIC LABORATORY TEST OR PROCEDURE ORDERED BY A PHYSICIAN**  
 29 **AND PERFORMED BY A MEDICAL LABORATORY CERTIFIED UNDER 42 U.S.C. § 263A.**

30 (3) **A PERSON THAT DIRECTLY OR INDIRECTLY ADVERTISES FOR OR**  
 31 **SOLICITS BUSINESS IN THE STATE FOR A DIAGNOSTIC LABORATORY TEST OR**  
 32 **PROCEDURE UNDER THIS SUBSECTION:**

1                   **(I) ~~MUST BE A COVERED ENTITY UNDER~~ IS A COVERED ENTITY**  
 2 **OR BUSINESS ASSOCIATE OF A COVERED ENTITY FOR PURPOSES OF THE FEDERAL**  
 3 **HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 AND THE**  
 4 **FEDERAL HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL**  
 5 **HEALTH ACT; AND**

6                   **(II) MAY NOT MAKE A CLAIM ABOUT THE RELIABILITY AND**  
 7 **VALIDITY OF THE TEST OR PROCEDURE THAT IS INCONSISTENT WITH THE TEST OR**  
 8 **PROCEDURE’S PERFORMANCE AS MEASURED UNDER 42 U.S.C. § 263A; AND**

9                   **(III) SHALL DISCLOSE THAT THE DIAGNOSTIC LABORATORY TEST**  
 10 **OR PROCEDURE MAY OR MAY NOT BE COVERED BY HEALTH INSURANCE.**

11                   **(4) THE SECRETARY MAY TAKE LEGAL ACTION TO RESTRICT THE**  
 12 **MARKETING OF A DIAGNOSTIC LABORATORY TEST OR PROCEDURE IF THE**  
 13 **SECRETARY DETERMINES THAT:**

14                   **(I) THERE IS A PUBLIC HEALTH THREAT; OR**

15                   **(II) THE DIAGNOSTIC LABORATORY TEST OR PROCEDURE IS**  
 16 **NOT IN COMPLIANCE WITH THE REQUIREMENTS OF THIS SECTION.**

17                   SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
 18                   October 1, 2019.

Approved:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.