

SENATE BILL 495

J1, J2

9lr1192
CF HB 526

By: **Senators Kelley, Beidle, Benson, Feldman, Hayes, Klausmeier, and Reilly**

Introduced and read first time: February 4, 2019

Assigned to: Finance

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 22, 2019

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; authorizing the Secretary of Health to take
7 a certain legal action under certain circumstances; providing for the application of
8 this Act; making a conforming change; and generally relating to medical
9 laboratories.

10 BY repealing and reenacting, with amendments,
11 Article – Health – General
12 Section 17–215
13 Annotated Code of Maryland
14 (2015 Replacement Volume and 2018 Supplement)

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

17 **Article – Health – General**

18 17–215.

19 (A) [A] **EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION**, A person
20 may not directly or indirectly advertise for or solicit business in this State for any medical

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.



1 laboratory, regardless of location, from anyone except a physician, hospital, medical
2 laboratory, clinic, clinical installation, or other medical care facility.

3 (B) (1) (I) THIS SUBSECTION APPLIES ONLY TO:

4 1. A DIAGNOSTIC LABORATORY TEST OR PROCEDURE
5 FOR THE PURPOSE OF SCREENING, DIAGNOSING, MANAGING, OR TREATING A
6 PHYSICAL OR MENTAL CONDITION OR DISEASE; AND

7 2. ANCESTRY TESTING USING Y-CHROMOSOME
8 MITOCHONDRIAL DNA OR AUTOSOMAL DNA TESTING LIMITED TO THE DETECTION
9 AND REPORTING OF GENETIC EVIDENCE OR PARENTAL LINEAGE AND GENETIC
10 ETHNICITY.

11 (II) THIS SUBSECTION DOES NOT APPLY TO GENETIC OR
12 GENOMIC TESTING DONE IN CONNECTION WITH:

13 1. THE ANALYSIS OR DIAGNOSIS AND CONTROL OF
14 HUMAN DISEASES OR MEDICAL CONDITIONS; OR

15 2. THE PREDICTION OF HUMAN DISEASES OR MEDICAL
16 CONDITIONS.

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

21 (3) A PERSON THAT DIRECTLY OR INDIRECTLY ADVERTISES FOR OR
22 SOLICITS BUSINESS IN THE STATE FOR A DIAGNOSTIC LABORATORY TEST OR
23 PROCEDURE UNDER THIS SUBSECTION:

24 (I) MUST BE A COVERED ENTITY UNDER THE FEDERAL HEALTH
25 INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 AND THE FEDERAL
26 HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT;
27 AND

28 (II) MAY NOT MAKE A CLAIM ABOUT THE RELIABILITY AND
29 VALIDITY OF THE TEST OR PROCEDURE THAT IS INCONSISTENT WITH THE TEST OR
30 PROCEDURE'S PERFORMANCE AS MEASURED UNDER 42 U.S.C. § 263A.

31 (4) THE SECRETARY MAY TAKE LEGAL ACTION TO RESTRICT THE
32 MARKETING OF A DIAGNOSTIC LABORATORY TEST OR PROCEDURE IF THE
33 SECRETARY DETERMINES THAT:

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

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

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

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.