

HOUSE BILL 526

J1, J2

9lr1864
CF SB 495

By: **Delegates Cullison, Bagnall, Kelly, Kipke, Krebs, R. Lewis, Metzgar, Morgan, Rosenberg, Sample-Hughes, Szeliga, and K. Young**

Introduced and read first time: February 4, 2019

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 30, 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; requiring a certain person to make a certain
7 disclosure; providing that a certain person is a covered entity or business associate
8 of 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
14 Section 17–215
15 Annotated Code of Maryland
16 (2015 Replacement Volume and 2018 Supplement)

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

19 **Article – Health – General**

20 17–215.

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

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

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

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

13 (II) THIS SUBSECTION DOES NOT APPLY TO GERMLINE GENETIC
14 OR GENOMIC TESTING DONE IN CONNECTION WITH THE ANALYSIS, DIAGNOSIS, OR
15 PREDICTION OF HUMAN DISEASES.

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

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

23 (I) IS A COVERED ENTITY OR BUSINESS ASSOCIATE OF A
24 COVERED ENTITY FOR PURPOSES OF THE FEDERAL HEALTH INSURANCE
25 PORTABILITY AND ACCOUNTABILITY ACT OF 1996 AND THE FEDERAL HEALTH
26 INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT;

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

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

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

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

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

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

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.