

Chapter 413

(Senate Bill 495)

AN ACT concerning

Medical Laboratories – Laboratory Tests and Procedures – Advertising

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

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

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

Article – Health – General

17–215.

(A) [A] **EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION**, 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.

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

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

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

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

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

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

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

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

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

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

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

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

(I) THERE IS A PUBLIC HEALTH THREAT; OR

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

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

Approved by the Governor, May 13, 2019.