

SB0495/287677/1

BY: Finance Committee

AMENDMENTS TO SENATE BILL 495

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in line 3, after “person” insert “, subject to certain limitations,”; and in line 5, after “law;” insert “authorizing the Secretary of Health to take a certain legal action under certain circumstances; providing for the application of this Act;”.

AMENDMENT NO. 2

On page 1, in line 20, after “(B)” insert “**(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 PARENTAL LINEAGE AND GENETIC ETHNICITY.

(II) THIS SUBSECTION DOES NOT APPLY TO 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.

(Over)

(2)”;

in the same line, strike “A” and substitute “SUBJECT TO PARAGRAPH (3) OF THIS SUBSECTION, A”; in line 21, after the first “A” insert “DIAGNOSTIC”; and after line 23, insert:

“(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 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.

(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.”.