

HB0526/146186/1

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL 526
(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 “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;”.

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 OF PARENTAL LINEAGE AND GENETIC ETHNICITY.

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

(2)”;

(Over)

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) 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;

(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.”.