

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1443 Session of 2021

INTRODUCED BY HERSHEY, COX, KLUNK, ROZZI, SNYDER, STEPHENS, ZIMMERMAN AND ROAE, MAY 20, 2021

AS REPORTED FROM COMMITTEE ON HEALTH, HOUSE OF REPRESENTATIVES, AS AMENDED, JUNE 23, 2021

AN ACT

1 Amending the act of September 26, 1951 (P.L.1539, No.389),
2 entitled "An act defining clinical laboratory; regulating the
3 operation of the same; requiring such laboratories to obtain
4 permits, and to be operated under the direct supervision of
5 qualified persons; imposing certain duties upon the
6 Department of Health; and providing penalties," providing for
7 advertisements for laboratory tests.

8 The General Assembly of the Commonwealth of Pennsylvania
9 hereby enacts as follows:

10 Section 1. The act of September 26, 1951 (P.L.1539, No.389),
11 known as The Clinical Laboratory Act, is amended by adding a
12 section to read:

13 Section 13.3. Advertisements for Laboratory Tests.--(a) A
14 clinical laboratory certified under section 353 of the Public
15 Health Service Act (58 Stat. 682, 42 U.S.C. § 263a) or AND a <--
16 clinical laboratory operating under this act may directly or
17 indirectly advertise or solicit business for diagnostic
18 laboratory testing or ancestry testing if all of the following <--
19 apply:

20 (1) The FOR DIAGNOSTIC TESTING, THE testing is ordered by a <--

1 health care practitioner LICENSED IN THIS COMMONWEALTH or <--
2 another person otherwise authorized by the laws of this
3 Commonwealth to order the test.

4 (2) The testing is performed by the clinical laboratory.

5 (3) The clinical laboratory is a covered entity or a
6 business associate of a covered entity for the purpose of
7 compliance with THE Health Insurance Portability and <--
8 Accountability Act of 1996 (Public Law 104-191, 110 Stat. 1936)
9 and the Health Information Technology for Economic and Clinical
10 Health Act (Public Law 111-5, 123 Stat. 226-279 and 467-496).

11 (4) The clinical laboratory does not make a claim about the
12 reliability and validity of the testing that is inconsistent
13 with the testing proficiency standards under section 353 of the
14 Public Health Service Act.

15 (5) THE CLINICAL LABORATORY SHALL DISCLOSE THAT THE <--
16 DIAGNOSTIC LABORATORY TEST OR PROCEDURE MAY OR MAY NOT BE
17 COVERED BY HEALTH INSURANCE.

18 (b) The department may prohibit the use of a clinical
19 laboratory's advertisement or solicitation of business for
20 diagnostic laboratory testing ~~or ancestry testing~~ under <--
21 subsection (a) or impose a penalty authorized under section
22 14(b) if the department determines any of the following:

23 (1) The diagnostic laboratory testing ~~or ancestry testing~~ <--
24 poses a public threat.

25 (2) The diagnostic laboratory testing ~~or ancestry testing~~ is <--
26 not in compliance with this section.

27 (c) As used in this section, the following words and phrases
28 shall have the meanings given to them in this subsection unless
29 the context clearly indicates otherwise:

30 "~~Ancestry testing.~~" Y chromosome mitochondrial DNA or <--

1 ~~autosomal DNA testing for the detection and reporting of genetic~~
2 ~~evidence of parental lineage and generic ethnicity.~~

3 "Business associate." As defined in 45 CFR § 160.103
4 (relating to definitions).

5 "Covered entity." As defined in 45 CFR § 160.103.

6 "Diagnostic laboratory testing." The term includes genetic <--
7 testing or procedures for the purpose of screening, diagnosing,
8 managing or treating a physical or mental condition or disease.

9 THE USE OF SPECIALIZED APPARATUS, EQUIPMENT AND METHODS, FOR THE <--
10 PURPOSE OF SCREENING AND OBTAINING DIAGNOSTIC INFORMATION FROM
11 ANY MATERIAL ORIGINATING FROM THE HUMAN BODY TO AID OR ASCERTAIN
12 A PERSON'S STATE OF HEALTH. THE TERM DOES NOT APPLY TO GERMLINE
13 GENETIC OR GENOMIC TESTING DONE IN CONNECTION WITH THE ANALYSIS,
14 DIAGNOSIS OR PREDICTION OF HUMAN DISEASES.

15 Section 2. All regulations and parts of regulations are
16 abrogated insofar as they are inconsistent with this act.

17 Section 3. This act shall take effect immediately.