
THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1443 Session of
2021

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

REFERRED TO COMMITTEE ON HEALTH, MAY 20, 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 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 testing is ordered by a health care practitioner or

1 another person otherwise authorized by the laws of this
2 Commonwealth to order the test.

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

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

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

14 (b) The department may prohibit the use of a clinical
15 laboratory's advertisement or solicitation of business for
16 diagnostic laboratory testing or ancestry testing under
17 subsection (a) or impose a penalty authorized under section
18 14(b) if the department determines any of the following:

19 (1) The diagnostic laboratory testing or ancestry testing
20 poses a public threat.

21 (2) The diagnostic laboratory testing or ancestry testing is
22 not in compliance with this section.

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

26 "Ancestry testing." Y-chromosome mitochondrial DNA or
27 autosomal DNA testing for the detection and reporting of genetic
28 evidence of parental lineage and generic ethnicity.

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

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

2 "Diagnostic laboratory testing." The term includes genetic
3 testing or procedures for the purpose of screening, diagnosing,
4 managing or treating a physical or mental condition or disease.

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

7 Section 3. This act shall take effect immediately.