

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 712 Session of 2023

INTRODUCED BY BROWN, PENNYCUICK, CULVER, BOSCOLA, DUSH,
BREWSTER, SCHWANK AND J. WARD, MAY 26, 2023

REFERRED TO HEALTH AND HUMAN SERVICES, MAY 26, 2023

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; and abrogating a
8 regulation.

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

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

14 Section 13.3. Advertisements for Laboratory Tests.--(a) A
15 clinical laboratory certified under 42 U.S.C. § 263a (relating
16 to certification of laboratories) and a clinical laboratory
17 operating under this act may directly or indirectly advertise or
18 solicit business for diagnostic laboratory testing if all of the
19 following apply:

20 (1) For diagnostic testing, the testing is ordered by a
21 health care practitioner licensed in this Commonwealth 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 the Health Insurance Portability and
7 Accountability Act of 1996 (Public Law 104-191, 110 Stat. 1936)
8 and the Health Information Technology for Economic and Clinical
9 Health Act (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 42 U.S.C. § 263a.

13 (5) The clinical laboratory discloses that the diagnostic
14 laboratory test or procedure may or may not be covered by health
15 insurance.

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

21 (1) The diagnostic laboratory testing poses a public threat.

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

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

27 "Business associate." As defined in 45 CFR 160.103 (relating
28 to definitions).

29 "Covered entity." As defined in 45 CFR 160.103.

30 "Diagnostic laboratory testing." The term includes genetic

1 testing or procedures for the purpose of screening, diagnosing,
2 managing or treating a physical or mental condition or disease.

3 Section 2. The regulations at 28 Pa. Code § 5.73 are
4 abrogated.

5 Section 3. This act shall take effect immediately.