

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

SENATOR BROOKS, HEALTH AND HUMAN SERVICES, AS AMENDED, JUNE 20, 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," FURTHER <--
7 PROVIDING FOR DEFINITIONS AND FOR EXEMPTIONS AND providing
8 for advertisements for laboratory tests AND FOR SOURCE PLASMA <--
9 DONATION CENTER; and abrogating a regulation.

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

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

15 SECTION 1. SECTION 2 OF THE ACT OF SEPTEMBER 26, 1951 <--
16 (P.L.1539, NO.389), KNOWN AS THE CLINICAL LABORATORY ACT, IS
17 AMENDED BY ADDING DEFINITIONS TO READ:

18 SECTION 2. DEFINITIONS.--THE FOLLOWING WORDS AND PHRASES
19 WHEN USED IN THIS ACT SHALL HAVE THE MEANINGS GIVEN TO THEM IN
20 THIS SECTION UNLESS THE CONTEXT CLEARLY INDICATES OTHERWISE:

21 \* \* \*

1 "PLASMA." THE FLUID PORTION OF HUMAN BLOOD.

2 "PLASMAPHERESIS." A PROCEDURE IN WHICH, DURING A SINGLE  
3 VISIT TO A FACILITY, BLOOD IS REMOVED FROM AN INDIVIDUAL, THE  
4 SOURCE PLASMA IS SEPARATED FROM THE FORMED ELEMENTS AND AT LEAST  
5 THE RED BLOOD CELLS ARE RETURNED TO THE DONOR.

6 "SOURCE PLASMA DONATION CENTER." A FACILITY WHERE PLASMA IS  
7 COLLECTED BY PLASMAPHERESIS AND USED AS SOURCE MATERIAL FOR  
8 FURTHER MANUFACTURING USE. THE TERM SHALL NOT INCLUDE SINGLE-  
9 DONOR PLASMA PRODUCTS INTENDED FOR INTRAVENOUS USE.

10 \* \* \*

11 SECTION 2. SECTION 13 OF THE ACT IS AMENDED TO READ:

12 SECTION 13. EXEMPTIONS.--THIS ACT SHALL NOT INCLUDE NOR  
13 APPLY TO ANY LABORATORY OR LABORATORIES MAINTAINED AND OPERATED  
14 BY THE FEDERAL GOVERNMENT; NOR TO ANY LABORATORY OR LABORATORIES  
15 MAINTAINED AND OPERATED PURELY FOR RESEARCH OR TEACHING  
16 PURPOSES; NOR TO ANY SOURCE PLASMA DONATION CENTER.

17 SECTION 3. THE ACT IS AMENDED BY ADDING SECTIONS TO READ:

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

24 (1) For diagnostic testing, the testing is ordered by a  
25 health care practitioner licensed in this Commonwealth or  
26 another person otherwise authorized by the laws of this  
27 Commonwealth to order the test.

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

29 (3) The clinical laboratory is a covered entity or a  
30 business associate of a covered entity for the purpose of

1 compliance with the Health Insurance Portability and  
2 Accountability Act of 1996 (Public Law 104-191, 110 Stat. 1936)  
3 and the Health Information Technology for Economic and Clinical  
4 Health Act (Public Law 111-5, 123 Stat. 226-279 and 467-496).

5 (4) The clinical laboratory does not make a claim about the  
6 reliability and validity of the testing that is inconsistent  
7 with the testing proficiency standards under 42 U.S.C. § 263a.

8 (5) The clinical laboratory discloses that the diagnostic  
9 laboratory test or procedure may or may not be covered by health  
10 insurance.

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

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

17 (2) The diagnostic laboratory testing is not in compliance  
18 with this section.

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

22 "Business associate." As defined in 45 CFR 160.103 (relating  
23 to definitions).

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

25 "Diagnostic laboratory testing." ~~The term includes genetic~~ <--  
26 ~~testing or procedures for the purpose of screening, diagnosing,~~  
27 ~~managing or treating a physical or mental condition or disease.~~

28 TESTING OR PROCEDURES PERFORMED FOR THE PURPOSE OF SCREENING, <--  
29 DIAGNOSING, PREDISPOSING, MANAGING OR TREATING A PHYSICAL OR  
30 MENTAL CONDITION OR DISEASE. THE TERM SHALL INCLUDE GERMLINE

1 GENETIC AND GENOMIC TESTING.

2 SECTION 13.4. SOURCE PLASMA DONATION CENTER.--

3 NOTWITHSTANDING ANY OTHER LAW, A SOURCE PLASMA DONATION CENTER

4 MAY COLLECT SOURCE PLASMA THROUGH PLASMAPHERESIS IF THE SOURCE

5 PLASMA DONATION CENTER COMPLIES WITH FEDERAL REQUIREMENTS

6 GOVERNING THE COLLECTION OF SOURCE PLASMA AND OPERATION OF A

7 CLINICAL LABORATORY, INCLUDING LAWS GOVERNING DONOR SCREENING

8 AND MONITORING, STAFF QUALIFICATIONS, RESPONSIBILITIES,

9 SUPERVISION AND TRAINING AND DUTIES, IN A SOURCE PLASMA DONATION

10 CENTER AND CLINICAL LABORATORY.

11 Section ~~2~~ 4. The regulations at 28 Pa. Code § 5.73 are <--  
12 abrogated.

13 Section ~~3~~ 5. This act shall take effect immediately. <--