

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1042 Session of 2013

INTRODUCED BY VANCE, KITCHEN, MENSCH, ERICKSON, BAKER, HUTCHINSON, RAFFERTY, TOMLINSON, VULAKOVICH, YUDICHAK, FONTANA, SOLOBAY, FARNESE, SMITH, BLAKE, STACK, WAUGH, WILEY, WARD, FOLMER, McILHINNEY, BROWNE, BRUBAKER AND DINNIMAN, JUNE 24, 2013

SENATOR CORMAN, APPROPRIATIONS, RE-REPORTED AS AMENDED, OCTOBER 1, 2013

AN ACT

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

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

11 Section 1. Section 2 of the act of September 26, 1951
12 (P.L.1539, No.389), known as The Clinical Laboratory Act,
13 amended December 6, 1972 (P.L.1388, No.297), is amended to read:

14 Section 2. Definitions.--The [term] following words and
15 phrases when used in this act shall have the meanings given to
16 them in this section unless the context clearly indicates
17 otherwise:

18 "Accept." The act of receiving specimens that are properly
19 collected, separated, labeled, coded, inputted and packaged for

1 shipment or transport to a clinical laboratory operating in  
2 accordance with the provisions of this act.

3 "Clinical Laboratory." [means any] Any place, establishment  
4 or institution organized and operated primarily for the  
5 performance of all or any bacteriological, biochemical,  
6 microscopical, serological, or parasitological tests by the  
7 practical application of one or more of the fundamental sciences  
8 to material originating from the human body, by the use of  
9 specialized apparatus, equipment and methods, for the purpose of  
10 obtaining scientific data which may be used as an aid to  
11 ascertain the state of health.

12 [The term] "Department." [means the] The Department of  
13 Health[.] of the Commonwealth.

14 "Specimen collection." The instruction, acquisition,  
15 separation, labeling, handling, coding or data entry of any  
16 material originating from the human body for testing to aid or  
17 ascertain a person's state of health.

18 Section 2. Section 11 of the act, amended August 4, 1961  
19 (P.L.920, No.400), is amended to read:

20 Section 11. Inspection.--The department [may at any time  
21 visit, enter, examine and inspect the premises occupied,  
22 maintained and conducted by any laboratory, and may examine all  
23 matters in relation thereto. Periodically the department shall  
24 verify the accuracy of the work of each laboratory using such  
25 means and standards as the department shall specify by rule or  
26 regulation.] shall have the authority to:

27 (1) Investigate the facts submitted in an application for  
28 permit or renewal of a permit by any person to operate a  
29 clinical laboratory in this Commonwealth and conduct inspections <--  
30 as necessary.

1 (2) Promulgate regulations for the criteria and manner to  
2 investigate or inspect a clinical laboratory.

3 (3) Maintain access to and enter upon the premises of a  
4 clinical laboratory to enforce the provisions of this act.

5 (4) Exempt or limit out-of-State clinical laboratories from  
6 the department's inspection process provided the out-of-State  
7 clinical laboratory:

8 (i) is accredited, certified or licensed under the Clinical  
9 Laboratories Improvement Act of 1967 (Public Law 90-174, 81  
10 Stat. 533) and, to the extent applicable, by the state that has  
11 issued a license or permit to operate a clinical laboratory; and

12 (ii) provides proof to the department that the clinical  
13 laboratory applying for a permit or renewal of a permit has met  
14 the requirements for exemption of the inspection process under  
15 this section.

16 Section 3. Sections 13.1 and 14 of the act, amended or added  
17 December 6, 1972 (P.L.1388, No.297), are amended to read:

18 Section 13.1. Unlawful Conduct.--[It shall be unlawful for  
19 any person to solicit, receive, accept, deliver or transmit, by  
20 mail or otherwise, material originating from the human body on  
21 behalf of any person operating a laboratory not in possession of  
22 a permit under this act regardless of whether such laboratory is  
23 located in this Commonwealth. The provisions of this section  
24 shall not apply to transactions with any person operating a  
25 laboratory located in another state, which laboratory has been  
26 issued a license or permit in conformity with the "Clinical  
27 Laboratories Improvement Act of 1967," and related statutes.  
28 Neither shall this section apply to transactions with  
29 laboratories operated in this State which are exempt from the  
30 permit requirements of this act.] (a) Except as provided in

1 section 13, it shall be unlawful for a person or clinical  
2 laboratory regardless of whether the person or clinical  
3 laboratory is located in this Commonwealth or maintains a permit  
4 issued by the department to:

5 (1) Solicit, collect, process, handle, receive, accept,  
6 deliver or transmit, by mail or otherwise, material originating  
7 from the human body on behalf of a person or clinical laboratory  
8 except that this section may not prohibit a clinical laboratory  
9 from referring a specimen to another clinical laboratory issued  
10 a license or permit in conformity with the Clinical Laboratories  
11 Improvement Act of 1967 (Public Law 90-174, 81 Stat. 533) and  
12 related State laws.

13 (2) Pay or receive a commission, bonus, kickback or rebate  
14 or engage in a split-fee arrangement in any form with a health  
15 care provider or other provider, either directly or indirectly,  
16 for patients OR THEIR SPECIMENS referred to a ANY clinical <--  
17 laboratory operating within this Commonwealth OR TESTING A <--  
18 SPECIMEN ACCEPTED OR COLLECTED WITHIN THIS COMMONWEALTH.

19 (3) Lease or rent space, shelves or equipment or other  
20 services within a health care provider's office or other  
21 provider's office including the leasing or renting of space  
22 within a part of a health care provider's office for the purpose  
23 of establishing a collection station.

24 (4) Directly or indirectly provide through employees,  
25 contractors, an independent staffing company, lease agreement or  
26 otherwise, personnel to perform functions or duties in a health  
27 care provider's office, or a part of a health care provider's  
28 office, for any purpose regardless of whether fair market value  
29 is offered or given, including for the collection or handling of  
30 specimens, unless the clinical laboratory and the physician's

1 office are wholly owned and operated by the same entity.

2 (5) Permit the placement of paid or unpaid personnel to  
3 perform services, including but not limited to specimen  
4 collection, processing the specimen or packaging or handling  
5 services or genetic counseling in a health care provider's or  
6 other provider's office regardless of whether fair market value  
7 is offered or given.

8 (b) This section does not preclude a clinical laboratory  
9 from owning or investing in a building in which space is leased  
10 or rented for adequate and fair consideration to health care  
11 providers or other providers.

12 Section 14. Penalty.--(a) Any person operating a clinical  
13 laboratory without first having obtained a permit from the  
14 [Department of Health] department or violating the provisions of  
15 section 13.1 of the act shall, upon conviction thereof, be  
16 sentenced to pay a fine not exceeding five hundred dollars  
17 (\$500) or to imprisonment not exceeding one (1) year, or both.

18 (b) ~~The~~ IN ADDITION TO ANY OTHER PENALTY THAT MAY BE IMPOSED <--  
19 BY THE DEPARTMENT, THE department may assess a civil penalty of  
20 up to five hundred dollars (\$500) per day on a person or  
21 clinical laboratory that engages in any of the following:

22 (1) Violates the provisions of this act or the department's  
23 regulations.

24 (2) Operates a clinical laboratory within this Commonwealth  
25 without a permit from the department.

26 (3) Performs testing without a permit from the department on  
27 any specimen accepted or collected within this Commonwealth.

28 (c) Moneys received from civil penalties imposed by the  
29 department on a person or clinical laboratory shall be paid into  
30 the State Treasury and shall be credited to the general

1 government appropriations of the department for administering  
2 and enforcing the provisions of this act.

3 Section 4. This act shall take effect immediately.