
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 AND SMITH, JUNE 24, 2013

REFERRED TO PUBLIC HEALTH AND WELFARE, JUNE 24, 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
20 shipment or transport to a clinical laboratory operating in

1 accordance with the provisions of this act.

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

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

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

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

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

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

30 (2) Promulgate regulations for the criteria and manner to

1 investigate or inspect a clinical laboratory.

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

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

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

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

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

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

30 section 13, it shall be unlawful for a person or clinical

1 laboratory regardless of whether the person or clinical
2 laboratory is located in this Commonwealth or maintains a permit
3 issued by the department to:

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

12 (2) Pay or receive a commission, bonus, kickback or rebate
13 or engage in a split-fee arrangement in any form with a health
14 care provider or other provider, either directly or indirectly,
15 for patients referred to a clinical laboratory operating within
16 this Commonwealth.

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

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

30 (5) Permit the placement of paid or unpaid personnel to

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

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

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

16 (b) The department may assess a civil penalty of up to five
17 hundred dollars (\$500) per day on a person or clinical
18 laboratory that engages in any of the following:

19 (1) Violates the provisions of this act or the department's
20 regulations.

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

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

25 (c) Moneys received from civil penalties imposed by the
26 department on a person or clinical laboratory shall be paid into
27 the State Treasury and shall be credited to the general
28 government appropriations of the department for administering
29 and enforcing the provisions of this act.

30 Section 4. This act shall take effect immediately.