

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

AS AMENDED ON SECOND CONSIDERATION, HOUSE OF REPRESENTATIVES,
NOVEMBER 18, 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

1 collected, separated, labeled, coded, inputted and packaged for
2 shipment or transport to a clinical laboratory operating in
3 accordance with the provisions of this act.

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

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

15 "HEALTH CARE PRACTITIONER." AS DEFINED IN SECTION 103 OF THE <--
16 ACT OF JULY 19, 1979 (P.L.130, NO.48), KNOWN AS THE "HEALTH CARE
17 FACILITIES ACT."

18 "HEALTH CARE PROVIDER." AS DEFINED IN SECTION 103 OF THE ACT
19 OF JULY 19, 1979 (P.L.130, NO.48), KNOWN AS THE "HEALTH CARE
20 FACILITIES ACT."

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

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

27 Section 11. Inspection.--The department [may at any time
28 visit, enter, examine and inspect the premises occupied,
29 maintained and conducted by any laboratory, and may examine all
30 matters in relation thereto. Periodically the department shall

1 verify the accuracy of the work of each laboratory using such
2 means and standards as the department shall specify by rule or
3 regulation.] shall have the authority to:

4 (1) Investigate the facts submitted in an application for
5 permit or renewal of a permit by any person to operate a
6 clinical laboratory and conduct inspections as necessary.

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

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

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

14 (i) ~~is accredited, certified or licensed under the Clinical~~ <--
15 ~~Laboratories Improvement Act of 1967 (Public Law 90 174, 81~~
16 ~~Stat. 533) CERTIFIED OR ACCREDITED UNDER SECTION 353 OF THE~~ <--
17 PUBLIC HEALTH SERVICE ACT (58 STAT. 682, 42 U.S.C. § 263A) and,
18 to the extent applicable, by the state that has issued a license
19 or permit to operate a clinical laboratory; and

20 (ii) provides proof to the department that the clinical
21 laboratory applying for a permit or renewal of a permit has met
22 the requirements for exemption of the inspection process under
23 this section.

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

26 Section 13.1. Unlawful Conduct.--[It shall be unlawful for
27 any person to solicit, receive, accept, deliver or transmit, by
28 mail or otherwise, material originating from the human body on
29 behalf of any person operating a laboratory not in possession of
30 a permit under this act regardless of whether such laboratory is

1 located in this Commonwealth. The provisions of this section
2 shall not apply to transactions with any person operating a
3 laboratory located in another state, which laboratory has been
4 issued a license or permit in conformity with the "Clinical
5 Laboratories Improvement Act of 1967," and related statutes.
6 Neither shall this section apply to transactions with
7 laboratories operated in this State which are exempt from the
8 permit requirements of this act.] (a) Except as provided in
9 section 13, it shall be unlawful for a person or clinical
10 laboratory regardless of whether the person or clinical
11 laboratory is located in this Commonwealth or maintains a permit <--
12 issued by the department to:
13 (1) Solicit, collect, process, handle, receive, accept,
14 deliver or transmit, by mail or otherwise, material originating
15 from the human body on behalf of a person or clinical laboratory
16 except that this section may not prohibit a clinical laboratory
17 from referring a specimen to another clinical laboratory issued
18 a license or permit in conformity with the Clinical Laboratories
19 Improvement Act of 1967 (Public Law 90-174, 81 Stat. 533) and
20 related State laws. TO SOLICIT, COLLECT, PROCESS, HANDLE, <--
21 RECEIVE, ACCEPT, DELIVER OR TRANSMIT, BY MAIL OR OTHERWISE,
22 MATERIAL ORIGINATING FROM THE HUMAN BODY ON BEHALF OF A PERSON
23 OR CLINICAL LABORATORY NOT IN POSSESSION OF A PERMIT UNDER THIS
24 ACT, EXCEPT THAT THIS SECTION MAY NOT PROHIBIT A CLINICAL
25 LABORATORY HOLDING A PERMIT FROM THE DEPARTMENT FROM REFERRING A
26 SPECIMEN TO ANOTHER CLINICAL LABORATORY HOLDING A PERMIT FROM
27 THE DEPARTMENT OR TO A CLINICAL LABORATORY ISSUED A CERTIFICATE
28 OR ACCREDITATION IN CONFORMITY WITH SECTION 353 OF THE PUBLIC
29 HEALTH SERVICE ACT (58 STAT. 682, 42 U.S.C. § 263A) AND RELATED
30 STATE LAWS.

(B) IT SHALL BE UNLAWFUL FOR A PERSON OR CLINICAL LABORATORY
REGARDLESS OF WHETHER THE PERSON OR CLINICAL LABORATORY IS
LOCATED IN THIS COMMONWEALTH OR MAINTAINS A PERMIT ISSUED BY THE
DEPARTMENT TO:

~~(2)~~ (1) Pay or receive a commission, bonus, kickback or <--
rebate or engage in a split-fee arrangement in any form with a
health care provider or ~~other provider~~ HEALTH CARE PRACTITIONER, <--
either directly or indirectly, for patients or their specimens
referred to any clinical laboratory operating within this
Commonwealth or testing a specimen accepted or collected within
this Commonwealth.

~~(3)~~ (2) Lease or rent space, shelves or equipment or other <--
services within a health care provider's office or ~~other~~ <--
~~provider's~~ HEALTH CARE PRACTITIONER'S office including the
leasing or renting of space within a part of a health care
provider's OR HEALTH CARE PRACTITIONER'S office for the purpose <--
of establishing a collection station.

~~(4)~~ (3) Directly or indirectly provide through employees, <--
contractors, an independent staffing company, lease agreement or
otherwise, personnel to perform functions or duties in a health
care provider's office, or a part of a health care provider's <--
~~office~~ OR HEALTH CARE PRACTITIONER'S OFFICE, for any purpose
regardless of whether fair market value is offered or given,
including for the collection or handling of specimens, unless
the clinical laboratory and the ~~physician's~~ HEALTH CARE <--
PROVIDER'S office OR HEALTH CARE PRACTITIONER'S OFFICE are <--
wholly owned and operated by the same entity.

~~(5)~~ (4) Permit the placement of paid or unpaid personnel to <--
perform services, including but not limited to specimen
collection, processing the specimen or packaging or handling

1 services or genetic counseling in a health care provider's or
2 ~~other provider's~~ OR HEALTH CARE PRACTITIONER'S office regardless <--
3 of whether fair market value is offered or given.

4 ~~(b)~~ (C) This section does not preclude a clinical laboratory <--
5 from owning or investing in a building in which space is leased
6 or rented for adequate and fair consideration to health care
7 providers or ~~other providers~~ HEALTH CARE PRACTITIONERS. <--

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

14 (b) In addition to any other penalty that may be imposed by
15 the department, the department may assess a civil penalty of up
16 to five hundred dollars (\$500) per day on a person or clinical
17 laboratory that engages in any of the following:

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

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

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

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

29 Section 4. This act shall take effect immediately.