

CLINICAL LABORATORY ACT, THE
Act of Sep. 26, 1951, P.L. 1539, No. 389
AN ACT

Cl. 35

Defining clinical laboratory; regulating the operation of the same; requiring such laboratories to obtain permits, and to be operated under the direct supervision of qualified persons; imposing certain duties upon the Department of Health; and providing penalties. (Title amended Dec. 6, 1972, P.L.1388, No.297)

Whereas, the health and lives of the citizens of this Commonwealth are endangered by incompetent supervision of clinical laboratory tests; and

Whereas, a due regard for public health and preservation of human life demands that none but scientists competent and properly qualified by sufficient training in the fundamental sciences and experienced in their applications in the clinical laboratory shall be permitted to supervise the work of such laboratories.

(Preamble amended Dec. 6, 1972, P.L.1388, No.297)

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

Section 1. Short Title.--This act shall be known and may be cited as "The Clinical Laboratory Act."

(1 amended Dec. 6, 1972, P.L.1388, No.297)

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

"Accept." The act of receiving specimens that are properly collected, separated, labeled, coded, inputted and packaged for shipment or transport to a clinical laboratory operating in accordance with the provisions of this act.

"Clinical Laboratory." Any place, establishment or institution organized and operated primarily for the performance of all or any bacteriological, biochemical, microscopical, serological, or parasitological tests by the practical

application of one or more of the fundamental sciences to material originating from the human body, by the use of specialized apparatus, equipment and methods, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health.

"Department." The Department of Health of the Commonwealth.

"Health Care Practitioner." As defined in section 103 of the act of July 19, 1979 (P.L.130, No.48), known as the "Health Care Facilities Act."

"Health Care Provider." As defined in section 103 of the act of July 19, 1979 (P.L.130, No.48), known as the "Health Care Facilities Act."

"Plasma." The fluid portion of human blood. (Def. added Apr. 15, 2024, P.L.22, No.6)

"Plasmapheresis." A procedure in which, during a single visit to a facility, blood is removed from an individual, the source plasma is separated from the formed elements and at least the red blood cells are returned to the donor. (Def. added Apr. 15, 2024, P.L.22, No.6)

"Source plasma donation center." A facility where plasma is collected by plasmapheresis and used as a source material for further manufacturing use. The term does not include single donor plasma products intended for intravenous use. (Def. added Apr. 15, 2024, P.L.22, No.6)

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

(2 amended Dec. 18, 2013, P.L.1232, No.122)

Section 3. Limitations.--A clinical laboratory shall be under the direct and personal supervision of:

1. A holder of a doctor of science degree or its equivalent in the basic sciences, including professional degrees in public health, medicine, osteopathy, pharmacy, dentistry and veterinary medicine, from a college or university recognized by the National Committee of Regional Accrediting Agencies or the Department of Education, in chemistry, biology or microbiology, and who has had two years of experience in a laboratory acceptable to the department.

2. The holder of a master of science degree or its equivalent in the basic sciences from a college or university recognized by the National Committee of Regional Accrediting Agencies or the Department of Education, in chemistry, biology or microbiology, and who has had a minimum of four years' experience in a laboratory acceptable to the department.

3. The holder of a bachelor of science degree or its equivalent in the basic sciences from a college or university recognized by the National Committee of Regional Accrediting Agencies or the Department of Education, in chemistry, biology or microbiology, and who has had a minimum of five years' experience in laboratory work in a laboratory acceptable to the department.

4. From and after July 1, 1973, no clinical laboratory shall be under the direction and personal supervision of any person who does not meet the qualifications set forth in clause 2 of this section, and from and after July 1, 1974, no clinical laboratory shall be under the direction and personal supervision of any person who does not meet the requirements of clause 1 of this section: Provided, however, That this clause shall apply only to those laboratories for which an application for a permit is made on or after the dates herein specified: And provided further, That this provision shall apply only to those clinical

laboratories required to have a permit pursuant to the provisions of this act.

5. The foregoing limitations shall not apply to those persons operating a clinical laboratory prior to the effective date of this act.

(3 amended Dec. 6, 1972, P.L.1388, No.297)

Section 3.1. Advisory Committee.--An advisory committee shall be established for the purpose of advising the secretary in matters relating to administration of the act. There shall be seven members, each of whom is experienced in the clinical laboratory field. At least one member shall be qualified in the discipline of anatomic pathology and one in clinical pathology and licensed to practice medicine in the Commonwealth or eligible for licensure, one shall be qualified in the field of clinical chemistry, and one shall be qualified in the field of clinical microbiology. Members of the committee shall be appointed by the secretary.

(3.1 added Dec. 6, 1972, P.L.1388, No.297)

Section 4. Application for Permit.--All persons now operating or hereafter desiring to operate an analytical-biochemical-biological laboratory shall make written application to the department for a permit to operate, which application shall be accompanied by a fee of twenty-five dollars (\$25), payable to the department, and shall be retained by the department.

Compiler's Note: Section 6(a) of Act 48 of 1981, which provided for the fixing of fees charged by administrative agencies, provided that section 4 is repealed insofar as it establishes a set fee for any activity inconsistent with the fees set forth in Act 48.

Section 5. Contents of Application.--The application shall contain at least the following:

(a) The name and address of the persons owning the place, establishment or institution in which the analytical-biochemical-biological laboratory is to be or is operated.

(b) The name and address of the persons operating or to operate such laboratory.

(c) The name and address of the qualified person under whose direct and personal supervision such laboratory is to be or is operated.

(d) The kind and nature of the laboratory work to be or is being done.

(e) The description of the building, its location, facilities, equipment, apparatus and appliances to be furnished or used in the operation of such laboratory.

(f) Such additional information as the department may require by any rule or regulation.

The facts as set forth in the application shall be duly sworn to or affirmed by one of the owners of such laboratory.

Section 6. Revocation of Permit.--(a) Permits shall become void upon change of director and also upon the removal of the laboratory to other quarters. A new permit may be issued without charge when the department has passed upon the qualifications of the new director or upon the adequacy of the new quarters and equipment.

(b) A permit may be revoked at any time for failure to maintain proper standards of accuracy, for unethical practice or for unethical advertising, or for any other cause deemed adequate by the department.

Section 7. Investigation by Department.--Upon the filing of any application for a permit or for renewal, the department shall investigate the facts set forth in the application.

Section 8. Issuance of Permit.--If the department finds the statements contained in the application are true, the said department shall issue a permit.

Section 9. Contents and Signing of Permit.--The permits shall contain at least the following:

(a) The name and address of the laboratory and of its owner.

(b) The name and address of the person charged with the operation of the laboratory.

(c) The name of the qualified person under whose supervision the laboratory is operated.

(d) All permits shall be signed or counter-signed by the Secretary of Health.

Section 10. Statement of Grounds for Denial of Permits.--If the department does not, within six months after the filing of the application, issue a permit, it shall state the grounds and reasons for its refusal, in writing, furnishing a copy to the applicant.

Section 11. Inspection.--The department shall have the authority to:

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

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

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

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

(i) is certified or accredited under section 353 of the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 263a) and, to the extent applicable, by the state that has issued a license or permit to operate a clinical laboratory; and

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

(11 amended Dec. 18, 2013, P.L.1232, No.122)

Section 11.1. Rules and Regulations.--The Department of Health shall have the power, and its duty shall be, to adopt rules and regulations for the proper enforcement of this act with regard to the following:

(1) Contents of application;

(2) Adequacy of laboratory quarters and equipment;

(3) Means and standards of accuracy of laboratory procedures;

(4) Definition of unethical practice and unethical advertising;

(5) Any other matters it may deem advisable for the protection of the public and for carrying out the provisions and purposes of this act.

(11.1 added Aug. 4, 1961, P.L.920, No.400)

Section 12. Hearings and Appeals.--If an application for a permit is denied, as provided in section ten hereof, the applicant may request and be entitled to a hearing before the Secretary of Health, if such request was made within thirty days after the permit was denied. A permit issued under the provisions of this act may be revoked or suspended by the department for cause: Provided, That the permittee is permitted

to be heard by the department, either personally, by counsel, or both: And provided further, That a written copy of the causes be furnished him, by registered mail, ten days in advance of the date set for hearing. Said notice shall fix the time and place for said hearing, which shall not be more than thirty days from the date of the mailing of said notice.

Any person who shall be aggrieved by any action of the department under this act or by any rule or regulation promulgated by the department shall have the right to file a complaint with the Secretary of Health and to have a hearing thereon before the Secretary of Health. Such hearing shall be conducted and the decision of the Secretary of Health on the issue involved shall be rendered in accordance with the provisions of the Administrative Agency Law and its amendments, approved June fourth, one thousand nine hundred forty-five (Pamphlet Laws 1388), relating to adjudication procedure.

(12 repealed in part Apr. 28, 1978, P.L.202, No.53)

Section 13. Exemptions.--This act shall not include nor apply to:

(1) Any laboratory or laboratories maintained and operated by the Federal government.

(2) Any laboratory or laboratories maintained and operated purely for research or teaching purposes.

(3) Any source plasma donation center that performs only hematocrit and total protein donor eligibility tests.

(13 amended Apr. 15, 2024, P.L.22, No.6)

Section 13.1. Unlawful Conduct.--(a) Except as provided in section 13, it shall be unlawful for a person or clinical laboratory regardless of whether the person or clinical laboratory is located in this Commonwealth to solicit, collect, process, handle, receive, accept, deliver or transmit, by mail or otherwise, material originating from the human body on behalf of a person or clinical laboratory not in possession of a permit under this act, except that this section may not prohibit a clinical laboratory holding a permit from the department from referring a specimen to another clinical laboratory holding a permit from the department or to a clinical laboratory issued a certificate or accreditation in conformity with section 353 of the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 263a) and related 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:

(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 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.

(2) Lease or rent space, shelves or equipment or other services within a health care provider's office or 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.

(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 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 health care provider's office or health care practitioner's office are wholly owned and operated by the same entity.

(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 services or genetic counseling, in a health care provider's or health care practitioner's office regardless of whether fair market value is offered or given.

(c) This section does not preclude a clinical laboratory from owning or investing in a building in which space is leased or rented for adequate and fair consideration to health care providers or health care practitioners.

(13.1 amended Dec. 18, 2013, P.L.1232, No.122)

Section 13.2. Glomerular Filtration Rate Testing.--The director of a clinical laboratory licensed in this Commonwealth shall provide that when the laboratory tests a specimen to determine the serum creatinine level for a patient age 18 or older, the laboratory shall also calculate the patient's estimated glomerular filtration rate at no additional charge. The laboratory shall include the patient's estimated glomerular filtration rate with its report to the health care professional. Clinical laboratories in health care facilities shall report the estimated glomerular filtration rate based on a protocol developed by the laboratory in consultation with either or both its medical staff or clinical departments. A laboratory shall only be required to calculate and report a patient's estimated glomerular filtration rate if information necessary for the calculation to be considered medically appropriate and valid for the patient has been made available to the laboratory by the health care professional. This section shall not apply to clinical trials and research. Clinical laboratories that do not have information systems capable of providing estimated glomerular filtration rates on an automated basis shall have two years to comply with this section.

(13.2 added Nov. 9, 2006, P.L.1354, No.144)

Compiler's Note: Section 2 of Act 144 of 2006, which added section 13.2. provided that, in recognition of the constantly evolving nature of medicine and technology, section 2 shall expire on July 1, 2010. The reference to section 2 probably should have been to section 13.2.

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

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

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

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

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

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

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

(14 amended Dec. 18, 2013, P.L.1232, No.122)

Section 15. Interpretation of Act.--The provisions of this act are severable and if any of its provisions shall be held unconstitutional, the decision of the court shall not affect or impair any of the remaining provisions of this act. It is hereby declared to be the legislative intent that this act would have been adopted had such unconstitutional provisions not been included herein.

Section 16. Effective Date.--This act shall become effective on the first day of January, one thousand nine hundred fifty-two.