

No. 335

AN ACT

SB 1103

Defining blood banks, serum exchanges, blood bank depositories; blood fractionization and blood products operation; regulating the operations of same; requiring such organizations to obtain licenses to engage in these activities; requiring minimal standards of operation and qualifications of supervising personnel; imposing certain duties upon the Department of Health; establishing a blood bank advisory committee and providing penalties.

WHEREAS, A small number of incompetent operations of blood banks, and improper transfusion of blood or injection of blood products could endanger the health and lives of the citizens of the Commonwealth; and

WHEREAS, Properly qualified persons of scientific background are required for adequate supervision of all phases of blood banking, transfusion, blood fractionization, and associated activities in order to protect the health and lives of the public; and

WHEREAS, Adequate facilities, equipment, and procedures are vital to the safe operation of blood banks and related activities.

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 “Pennsylvania Blood Bank Act.”

Section 2. Declaration of Public Policy.—The public policy of this Commonwealth is to safeguard the health and well-being of the citizens of this State with reference to the use of blood and blood products in the treatment of many human diseases, as well as its use in the treatment of injuries resulting from casualties or disasters. Use of blood and blood products in this manner has increased to such proportions that, in the public interest, there is need for establishing Statewide minimum standards for the control and licensing of the activities of blood banks. It is declared that the purpose of this act is to provide for the better protection of public health (i) through the development, establishment, and enforcement of standards to establish, equip, maintain and conduct a suitable program to collect, process, store and distribute whole human blood, and the various human blood derivatives prepared from single units of whole blood by the licensing of blood banks, (ii) by providing qualifications for the personnel of such blood banks and (iii) by insuring that the procedures performed by blood banks are performed with a high degree of scientific and professional competency. This act shall be liberally construed to carry out these objects and purposes.

Section 3. Definitions.—As used in this act:

(1) “Act” means this act and any rule or regulation adopted hereunder.

(2) "Person" means any natural person, partnership, association, corporation, institution, agency, or other similar type entity.

(3) "Blood bank" means any place, organization, institution or establishment that is operated wholly or in part for the purpose of obtaining, storing, processing, preparing for transfusing, or selling human blood or parts or fractions of single blood units or products derived from single blood units, whether such procedures are done for direct therapeutic use or for storage for future use of such products, and whether a place, organization, institution, or establishment is operated on a charitable, commercial, or nonprofit basis.

(4) "Department" means the Department of Health of the Commonwealth of Pennsylvania.

(5) "Secretary" means the Secretary of the Department of Health of the Commonwealth of Pennsylvania.

(6) "Blood product" means any part or fraction of single units of whole human blood, or any material derived from single units of such blood which is subsequently administered to human subjects.

(7) "Collection" means the obtaining of blood by the bleeding of donors by a phlebotomy or plasmapheresis.

(8) "Processing" means the standards governing the technical procedures required to prepare and identify the blood as to its suitability for transfusing, including the performance of tests to screen out any communicable diseases.

(9) "Storage" means the holding of blood in connection with collection or processing prior to the distribution of transfusion.

(10) "Distribution" means the removal of blood from a blood bank to any other location for processing or storage for the purpose of providing the blood for therapeutic or prophylactic purposes.

(11) "Licensee" means a person holding a license under the provisions of this act.

(12) "Screening of donors" means the evaluation of prospective donors by the blood bank to determine the acceptability of the donor's past medical history, present state of health and indicated laboratory studies.

Section 4. Facilities.—The premises and equipment used by any blood bank shall meet minimal requirements determined by the secretary. This shall include storage provisions, temperature controls, laboratory testing and controls for the proper examination and evaluation of blood and blood products, conditions of obtaining and administering blood and blood products, and safety factors such as construction, and preservation of sterile operating procedures where essential.

Section 5. Records.—(a) All records and files shall be maintained in a standardized manner designated by the department. The department will make every effort to insure that they do not require duplicate records of blood banks. Coordination shall be made with existing programs requiring records.

(b) The department shall establish a central registry of blood donors who have a history of hepatitis or have tested positive for Australian antigen.

(c) A copy of the blood donor registry shall be sent to every blood bank within two months of their licensing and each blood bank shall be notified periodically to update this list, at least once a year.

Section 6. Direction and Supervision.—A blood bank must be under the direction of a qualified person who has specific experience in the field of blood bank operations, hematology and immunohematology.

Any procedures involving the service of transfusing or injecting of blood or blood products into humans must be under the supervision of a medical director who has experience and/or training which is acceptable to the department. The medical director may also serve as the director of the blood bank if qualifications are suitable. Anytime blood is being obtained from a human donor, a physician must be available who is licensed to practice medicine in the Commonwealth of Pennsylvania.

Section 7. Application for Licenses.—All persons now operating or hereafter desiring to operate a blood bank shall make written application to the department for a license to operate, which application shall be accompanied by a fee. For a blood bank participating in a voluntary inspection program outlined in section 13, the fee shall be fifty dollars (\$50) per year. For all blood banks not participating in a voluntary inspection program approved by the department the fee shall be two hundred dollars (\$200). A separate fee shall be charged for each permanent blood bank location.

Section 8. Contents of Application.—The application shall contain at least the following:

- (1) The name and location of the blood bank.
- (2) Name and address of the person owning the blood bank.
- (3) Name and address of the person operating the blood bank.
- (4) Education and experience of all persons having directoral, supervisory, or technical duties in the blood bank.
- (5) Description of physical facilities, location, equipment, sources of materials, and methods of storage and distribution of products.
- (6) Description of all technical procedures in the routine operations for which license is to be issued.
- (7) Such additional information as the department may require by rule and regulation.

A standard form shall be established by the department for the application.

Section 9. Investigation by the Department.—Upon filing of application for license, the department shall investigate all facts set forth in the application.

Section 10. Inspection.—The department shall inspect the premises

and facilities of all applicants before issuance of license, and at any subsequent time deemed necessary, such inspection to include all matters pertaining to the operation of the blood bank as defined by this act.

No notice shall be given to the blood banks prior to inspections that follow the initial licensing inspection. All blood banks shall be inspected at least annually by the department. This annual inspection can be waived by the department when the blood bank is complying with section 13 of this act.

Section 11. Licensing.—(a) No person shall hereafter operate or conduct a blood bank in this Commonwealth unless duly licensed by the secretary under the provisions of this act. The license required by this act shall be in addition to any other license or permit required by any local board of health or other body exercising the powers of such a board in this Commonwealth.

(b) The department shall issue a license to the applicant to operate a blood bank to provide the service and program described in the application if the department is satisfied that the applicant has complied with the provisions of this act and the rules and regulations adopted by the department pursuant to this act. Any person who has conducted or maintained a blood bank prior to the effective date of this act may, until action has been taken on such application by the department, continue in operation if applications are made for a license within one hundred eighty days after the effective date of this act.

(c) A license shall expire one year after the date of issuance unless renewed. Licenses may be renewed in the same manner and subject to the same conditions as the issuance of the original license and upon payment of a renewal application fee.

(d) If any major change in the program or services, including the discontinuance of substantial services of the blood bank are made, the changes shall be registered with the department within thirty days.

(e) Each blood bank must have a license. A single license must be obtained for each location of a blood bank even though several blood banks or locations may be supervised by the same director. A license shall be valid only in the hands of the person to whom it is issued and shall not be a subject of sale, assignment, or transfer, voluntary or involuntary, nor shall a license be valid for any premises other than that for which issued. However, a new license may be secured for a new location, or owner prior to the actual change, provided that the contemplated change is in compliance with the provisions of this act and the rules and regulations adopted by the department pursuant to this act.

Section 12. Contents and Signing of License.—The license shall contain at least the following:

- (1) Name and address of the blood bank.
- (2) Name and address of owner.
- (3) Name and address of the person responsible for operation of blood bank.

(4) Any specific limitations of permit as may be determined by rule and regulation.

(5) Signature of the secretary.

Any person maintaining a blood bank shall display in a prominent place in his establishment the current license issued to him by the department.

Section 13. Performance and Evaluation.—Each blood bank shall meet one or more of the following requirements once each year:

(1) Hold a currently valid Federal license to operate a blood bank and meet any additional requirements determined by the department.

(2) Participate in and be accredited under an evaluation program as conducted by agencies, approved by the department, providing the results of such evaluation are on file with the department, and meet any additional requirements determined by the department.

(3) Participate in an evaluation by the department according to provision to be established by rule and regulation.

Section 14. Rules and Regulations.—The department shall with the advice of the Blood Bank Advisory Committee establish rules and regulations for the standards and specific requirements for operation of blood banks including, but not limited to:

(1) Facilities.

(2) Proficiency evaluation of testing procedures.

(3) Standards for collection, processing, storage, distribution and proper conduct of the blood transfusion service of blood and blood products.

(4) The identification and screening of donors.

(5) Qualifications for director of and personnel employed in a blood bank.

(6) Restrictions upon the use of blood donors.

(7) A system of identifying the donor of the blood and blood donated at all times including after the blood has been administered to the recipient.

(8) The department shall set guidelines for the location of blood banks in order to avoid areas of high risk where there are high levels of hepatitis or other diseases transferred by blood transfusions.

(9) Help communities establish a system for determining the inventory of blood in all blood banks and the coordination of the distribution of blood and blood products for the purpose of reducing wastage.

(10) The department shall help communities establish and develop volunteer blood donor programs. This will include advice and assistance in public education and the organizational structure of these programs.

(11) The department shall establish standards for blood shipped into the Commonwealth, which is collected outside the State.

(12) The department shall make a major effort to insure that its rules

and regulations governing blood banks are coordinated with and do not conflict with existing State or Federal laws.

Section 15. Statement of Grounds for Denial of License.—If the department does not, within six months after filing of the application, issue a license, it shall state the grounds and reason for its refusal, in writing, with a copy to the applicant.

Section 16. Hearings and Appeals.—If an applicant is refused a license, as provided in section 15 of this act, the applicant may request and receive a hearing before the secretary, if such request is made within thirty days after receiving notice of denial.

Section 17. Revocation of License.—Any license issued in accordance with the provisions of this act may be suspended or revoked by the department for a violation of any of the provisions of this act or of the rules and regulations adopted by the department pursuant to this act. Before the department suspends or revokes a license, it shall provide written notification to the licensee or applicant. Such notification shall specify the reason for revocation or suspension, and indicate a time and place for a hearing on the matter, to be held within thirty days of notification. Any person aggrieved by the action of the department in refusing to renew a license, or by suspension or revocation of license, or by any other action of the department may appeal from such action in writing to the Commonwealth Court. No such appeal shall act as supersedeas except on special allowance of the court before which the appeal is pending.

The department shall have the power and authority and it shall be its duty to enter and inspect, with no prior notice, any blood bank and to make such investigations of the premises and the books and records as is reasonably necessary to carry out the provisions of this act and the regulations adopted pursuant to this act.

Section 18. Injunction.—(a) Whenever the department shall have refused to grant or renew a license, or shall have revoked or suspended a license required under this act to operate or conduct a blood bank, or shall have ordered the person to refrain from conduct violating the rules and regulations of the department and the person deeming himself aggrieved by such refusal or revocation or order shall have appealed the action of the department, the court may during pendency of such appeal, issue a restraining order or injunction upon proof that the operation of the private institution or its failure to comply with the order of the department is dangerous to the public health.

(b) Should a person, who is refused a license or the renewal of a license to operate or conduct a blood bank or whose license to operate or conduct a blood bank is revoked or who has been ordered to refrain from conduct or activity which violates the rules and regulations of the department, fail to appeal or should such appeal be decided finally favorably to the department, then the court shall issue a permanent injunction upon proof that the person is operating or conducting a blood bank without a license

as required by law, or has continued to violate the rules and regulations of the department.

(c) An action authorized under the provisions of this section shall be instituted in the court of common pleas in the county where the alleged unauthorized activity is committed.

(d) Appeals from any final decision of a court of common pleas to the Superior or Supreme Court shall be as in similar cases.

(e) No bond shall be required of and no costs shall be taxed against the department on account of any such action.

(f) The provisions of this section shall be construed as supplementary to all other provisions dealing with the same subject matter. No action brought under the provisions of this section shall prevent the prosecution or institution of any civil or criminal action otherwise provided by law for violation of any law providing for licensing or departmental rules or regulations promulgated thereunder.

Section 19. Exemptions.—This act shall not include or apply to any blood bank operated by the Federal Government, or any blood bank operated purely for research or teaching purposes: Provided, That the blood and blood products are not injected into humans. Nor shall it include any commercial establishment which obtains and processes blood and blood products which are never transfused or injected into humans.

Section 20. Community, State, and Interstate Coordination.—The department shall investigate with the advice of the Blood Bank Advisory Committee the feasibility of (i) a community-wide, (ii) Statewide and (iii) an interstate system for inventory coordination and control of blood and blood products. If practical, the State shall put into effect such an inventory system. This system will be developed, as far as practical, in the stages mentioned above. The blood banks, physicians, consumer groups, hospitals and the public in each community shall be encouraged and permitted to meaningfully participate in the planning of the community-wide coordination systems. No blood bank shall be forced to accept blood or blood products from another blood bank.

Section 21. Advisory Committee.—A committee known as “The Blood Bank Advisory Committee” shall be established by the secretary for the purpose of advising the secretary on matters relating to the administration of this act. This committee shall consist of seven persons, four who are experienced in the operation of blood banks. At least three shall be currently engaged as a director of a blood bank and one shall be a qualified blood bank medical technologist. Three shall be from the general public.

Section 22. Penalty.—Any person operating a blood bank without first obtaining a license from the department or operating a blood bank after suspension or revocation of license has become effective shall, upon conviction thereof, be sentenced to pay a fine of one thousand dollars (\$1,000). Each day’s violation shall constitute a separate offense.

Section 23. Appropriation.—An amount of twenty-five thousand dollars (\$25,000) is appropriated for costs of administration of the provisions of this act.

Section 24. Effective Date.—This act shall take effect in ninety days.

APPROVED—The 6th day of December, A. D. 1972.

MILTON J. SHAPP

The foregoing is a true and correct copy of Act of the General Assembly No. 335.

A handwritten signature in black ink, reading "C. McLaughlin Tucker". The signature is written in a cursive style with a large, prominent initial "C".

Secretary of the Commonwealth.