
THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL
No. 1103 Session of
1971

INTRODUCED BY HILL, MESSINGER, OESTERLING, MCCREESH, FRAME,
DWYER AND GOOD, OCTOBER 12, 1971

REFERRED TO PUBLIC HEALTH AND WELFARE, OCTOBER 12, 1971

AN ACT

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

9 WHEREAS, A small number of incompetent operations of blood
10 banks, and improper transfusion of blood or injection of blood
11 products endangers the health and lives of the citizens of the
12 Commonwealth; and

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

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

21 The General Assembly of the Commonwealth of Pennsylvania

1 hereby enacts as follows:

2 Section 1. Short Title.--This act shall be known and may be
3 cited as the "Pennsylvania Blood Bank Act."

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

24 Section 3. Definitions.--As used in this act:

25 (1) "Act" means this act and any rule or regulation adopted
26 hereunder.

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

30 (3) "Blood bank" means any place, organization, institution

1 or establishment that is operated wholly or in part for the
2 purpose of obtaining, storing, processing, preparing for
3 transfusing, or selling human blood or parts or fractions of
4 blood or products derived from blood, whether such procedures
5 are done for direct therapeutic use or for storage for future
6 use of such products, and whether a place, organization,
7 institution, or establishment is operated on a charitable,
8 commercial, or nonprofit basis.

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

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

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

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

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

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

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

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

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

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

13 Section 5. Records.--All records and files shall be
14 maintained in a standardized manner designated by the
15 department.

16 Section 6. Direction and Supervision.--A blood bank must be
17 under the direction of an individual who holds a doctoral degree
18 in the biological or medical sciences, and who has specific
19 experience in the field of blood bank operations and related
20 subjects. Such experience must be acceptable to the department.

21 Any procedures involving the service of injecting of blood or
22 blood products into humans must be under the supervision of a
23 medical director who is a physician licensed to practice in the
24 Commonwealth of Pennsylvania or an osteopathic physician
25 licensed to practice in the Commonwealth of Pennsylvania, and
26 who has had specific experience in blood bank operations and
27 related subjects which is acceptable to the department. The
28 medical director may also serve as the director of the blood
29 bank. Anytime blood is being obtained from a human donor, a
30 physician must be available who is licensed to practice medicine

1 in the Commonwealth of Pennsylvania.

2 Section 7. Application for Licenses.--All persons now
3 operating or hereafter desiring to operate a blood bank shall
4 make written application to the department for a license to
5 operate, which application shall be accompanied by a fee set by
6 the department, the estimated total income of said fees shall
7 cover the costs of administering this act. This fee shall be
8 payable to the department and shall be retained by the
9 department to be used only for the administration of this act.
10 The fees shall be prorated as equitably as possible by the
11 department. Two of the factors that shall be taken into
12 consideration by the department in the prorating of the fees
13 include:

14 (1) The fee shall vary in direct relationship to the
15 department's cost of inspecting each blood bank; and

16 (2) The fee shall vary in direct relationship to the number
17 of units of blood handled by the blood bank each year. If a
18 blood bank is participating in one of the voluntary inspections
19 listed in section 13, the fee shall be lower than if the
20 department conducts the entire inspection, other factors being
21 equal.

22 Section 8. Contents of Application.--The application shall
23 contain at least the following:

24 (1) The name and location of the blood bank.

25 (2) Name and address of the person owning the blood bank.

26 (3) Name and address of the person operating the blood bank.

27 (4) Education and experience of all persons having
28 directoral, supervisory, or technical duties in the blood bank.

29 (5) Description of physical facilities, location, equipment,
30 sources of materials, and methods of storage and distribution of

1 products.

2 (6) Description of all technical procedures in the routine
3 operations for which license is to be issued.

4 (7) Such additional information as the department may
5 require by rule and regulation.

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

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

11 Section 10. Inspection.--The department shall inspect the
12 premises and facilities of all applicants before issuance of
13 license, and at any subsequent time deemed necessary, such
14 inspection to include all matters pertaining to the operation of
15 the blood bank as defined by this act.

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

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

28 (b) The department shall issue a license to the applicant to
29 operate a blood bank to provide the service and program
30 described in the application if the department is satisfied that

1 the applicant has complied with the provisions of this act and
2 the rules and regulations adopted by the department pursuant to
3 this act. Any person who has conducted or maintained a blood
4 bank prior to the effective date of this act may, until action
5 has been taken on such application by the department, continue
6 in operation if applications are made for a license within one
7 hundred eighty days after the effective date of this act.

8 (c) A license shall expire one year after the date of
9 issuance unless renewed. Licenses may be renewed in the same
10 manner and subject to the same conditions as the issuance of the
11 original license and upon payment of a renewal application fee
12 which shall be set by the department to cover the costs of
13 administering this act. This fee shall be payable to the
14 department and shall be retained by the department for the
15 administration of this act.

16 (d) If any change in the program or services, including the
17 discontinuance of any of the services of the blood bank, the
18 changes shall be registered with the department within thirty
19 days on forms prescribed by the department as an amendment to
20 the original application.

21 (e) A separate license must be obtained for each location.
22 This does not include mobile donor stations which are under the
23 direct supervision of a licensed blood bank. A license shall be
24 valid only in the hands of the person to whom it is issued and
25 shall not be a subject of sale, assignment, or transfer,
26 voluntary or involuntary, nor shall a license be valid for any
27 premises other than that for which issued. However, a new
28 license may be secured for a new location, or owner prior to the
29 actual change, provided that the contemplated change is in
30 compliance with the provisions of this act and the rules and

1 regulations adopted by the department pursuant to this act.

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

4 (1) Name and address of the blood bank.

5 (2) Name and address of owner.

6 (3) Name and address of the person responsible for operation
7 of blood bank.

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

10 (5) Signature of the secretary.

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

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

17 (1) Hold a currently valid license to operate a blood bank
18 issued by the National Institutes of Health of the United States
19 Public Health Service, and meet any additional requirements
20 determined by the department.

21 (2) Participate in and be accredited under an evaluation
22 program as conducted by the American Association of Blood Banks
23 or similar agency, if approved by the department, providing the
24 results of such evaluation are on file with the department, and
25 meet any additional standards determined by the department.

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

28 Section 14. Rules and Regulations.--The department shall
29 establish rules and regulations for the standards and specific
30 requirements for operation of blood banks including, but not

1 limited to:

2 (1) Facilities.

3 (2) Proficiency evaluation of testing procedures.

4 (3) Standards for collection, processing, storage, and
5 distribution of blood and blood products.

6 (4) The identification and screening of donors.

7 (5) Qualifications for personnel employed in a blood bank.

8 (6) Restrictions upon the use of blood donors.

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

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

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

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

26 Section 17. Revocation of License.--Any license issued in
27 accordance with the provisions of this act may be suspended or
28 revoked by the department for a violation of any of the
29 provisions of this act or of the rules and regulations adopted
30 by the department pursuant to this act. Before the department

1 suspends or revokes a license, it shall provide written
2 notification to the licensee or applicant. Such notification
3 shall specify the reason for revocation or suspension, and
4 indicate a time and place for a hearing on the matter, to be
5 held within thirty days of notification. Any person aggrieved by
6 the action of the department in refusing to renew a license, or
7 by suspension or revocation of license, or by any other action
8 of the department may appeal from such action in writing to the
9 Commonwealth Court. No such appeal shall act as supersedeas
10 except on special allowance of the court before which the appeal
11 is pending.

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

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

30 (b) Should a person, who is refused a license or the renewal

1 of a license to operate or conduct a blood bank or whose license
2 to operate or conduct a blood bank is revoked or who has been
3 ordered to refrain from conduct or activity which violates the
4 rules and regulations of the department, fail to appeal or
5 should such appeal be decided finally favorably to the
6 department, then the court shall issue a permanent injunction
7 upon proof that the person is operating or conducting a blood
8 bank without a license as required by law, or has continued to
9 violate the rules and regulations of the department.

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

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

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

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

25 Section 19. Exemptions.--This act shall not include or apply
26 to any blood bank operated by the Federal Government, or any
27 blood bank operated purely for research or teaching purposes,
28 provided the blood and blood products are not injected for
29 therapeutic purposes, or to any commercial establishment which
30 obtains and processes blood solely for uses other than direct

1 transfusion or injection, nor for preparation of blood products
2 for human therapeutic use.

3 Section 20. Community, State, and Interstate Coordination.--

4 The department shall investigate the feasibility of (i) a
5 community-wide, (ii) Statewide and (iii) an interstate system
6 for inventory coordination and control of blood and blood
7 products. If practical, the State shall put into effect such an
8 inventory system. This system will be developed, as far as
9 practical, in the stages mentioned above. The blood banks in
10 each community shall be encouraged and permitted to meaningfully
11 participate in the planning of the community-wide coordination
12 systems. No blood bank shall be forced to accept blood or blood
13 products from another blood bank.

14 Section 21. Advisory Committee.--A committee known as "The
15 Blood Bank Advisory Committee" shall be established by the
16 secretary for the purpose of advising the secretary on matters
17 relating to the administration of this act. This committee shall
18 consist of five persons who are experienced in the direction and
19 operation of blood banks. At least three shall be currently
20 engaged as medical directors of blood banks.

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

27 Section 23. Appropriation.--An amount of ten thousand
28 dollars (\$10,000) is appropriated for initial costs of
29 administration of the provisions of this act.

30 Section 24. Effective Date.--This act shall take effect in

1 ninety days.