

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1103 Session of
1971INTRODUCED BY HILL, MESSINGER, OESTERLING, MCCREESH, FRAME,
DWYER AND GOOD, OCTOBER 12, 1971SENATOR COPPERSMITH, PUBLIC HEALTH AND WELFARE, AS AMENDED,
SEPTEMBER 11, 1972

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~~ COULD ENDANGER the health and lives of the <—
12 citizens of the 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.

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

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

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

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

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

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

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

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

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

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

17 (7) "Collection" means the obtaining of blood by the
18 bleeding of donors by a phlebotomy or ~~plasmapheresis~~. <—
19 PLASMAPHERESIS. <—

20 (8) "Processing" means the ~~technical~~ standards GOVERNING THE <—
21 TECHNICAL PROCEDURES required to prepare and identify the blood
22 as to its suitability for transfusing, including the performance
23 of tests to screen out any communicable diseases.

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

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

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

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

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

15 Section 5. Records.--(A) All records and files shall be <—
16 maintained in a standardized manner designated by the
17 department. THE DEPARTMENT WILL MAKE EVERY EFFORT TO INSURE THAT <—
18 THEY DO NOT REQUIRE DUPLICATE RECORDS OF BLOOD BANKS.
19 COORDINATION SHALL BE MADE WITH EXISTING PROGRAMS REQUIRING
20 RECORDS.

21 (B) THE DEPARTMENT SHALL ESTABLISH A CENTRAL REGISTRY OF
22 BLOOD DONORS WHO HAVE A HISTORY OF HEPATITIS OR HAVE TESTED
23 POSITIVE FOR AUSTRALIAN ANTIGEN.

24 (C) A COPY OF THE BLOOD DONOR REGISTRY SHALL BE SENT TO
25 EVERY BLOOD BANK WITHIN TWO MONTHS OF THEIR LICENSING AND EACH
26 BLOOD BANK SHALL BE NOTIFIED PERIODICALLY TO UPDATE THIS LIST,
27 AT LEAST ONCE A YEAR.

28 Section 6. Direction and Supervision.--A blood bank must be
29 under the direction of ~~an individual who holds a doctoral degree~~ <—
30 ~~in the biological or medical sciences, and~~ A QUALIFIED PERSON <—

1 who has specific experience in the field of blood bank
2 operations, ~~and related subjects. Such experience must be~~ <—
3 ~~acceptable to the department.~~ HEMATOLOGY AND IMMUNOHEMATOLOGY. <—

4 Any procedures involving the service of TRANSFUSING OR <—
5 injecting of blood or blood products into humans must be under
6 the supervision of a medical director ~~who is a physician~~ <—
7 ~~licensed to practice in the Commonwealth of Pennsylvania or an~~
8 ~~osteopathic physician licensed to practice in the Commonwealth~~
9 ~~of Pennsylvania, and who has had specific experience in blood~~
10 ~~bank operations and related subjects~~ WHO HAS EXPERIENCE AND/OR <—
11 TRAINING which is acceptable to the department. The medical
12 director may also serve as the director of the blood bank IF <—
13 QUALIFICATIONS ARE SUITABLE. Anytime blood is being obtained
14 from a human donor, a physician must be available who is
15 licensed to practice medicine in the Commonwealth of
16 Pennsylvania.

17 Section 7. Application for Licenses.--All persons now
18 operating or hereafter desiring to operate a blood bank shall
19 make written application to the department for a license to
20 operate, which application shall be accompanied by a fee. ~~set by~~ <—
21 ~~the department, the estimated total income of said fees shall~~
22 ~~cover the costs of administering this act. This fee shall be~~
23 ~~payable to the department and shall be retained by the~~
24 ~~department to be used only for the administration of this act.~~
25 ~~The fees shall be prorated as equitably as possible by the~~
26 ~~department. Two of the factors that shall be taken into~~
27 ~~consideration by the department in the prorating of the fees~~
28 ~~include:~~

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

1 ~~(2) The fee shall vary in direct relationship to the number~~
2 ~~of units of blood handled by the blood bank each year. If a~~
3 ~~blood bank is participating in one of the voluntary inspections~~
4 ~~listed in section 13, the fee shall be lower than if the~~
5 ~~department conducts the entire inspection, other factors being~~
6 ~~equal.~~ FOR A BLOOD BANK PARTICIPATING IN A VOLUNTARY INSPECTION <—
7 PROGRAM OUTLINED IN SECTION 13, THE FEE SHALL BE FIFTY DOLLARS
8 (\$50) PER YEAR. FOR ALL BLOOD BANKS NOT PARTICIPATING IN A
9 VOLUNTARY INSPECTION PROGRAM APPROVED BY THE DEPARTMENT THE FEE
10 SHALL BE TWO HUNDRED DOLLARS (\$200). A SEPARATE FEE SHALL BE
11 CHARGED FOR EACH PERMANENT BLOOD BANK LOCATION.

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

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

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

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

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

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

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

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

28 (c) A license shall expire one year after the date of
29 issuance unless renewed. Licenses may be renewed in the same
30 manner and subject to the same conditions as the issuance of the

1 original license and upon payment of a renewal application fee.
2 ~~which shall be set by the department to cover the costs of~~ <—
3 ~~administering this act. This fee shall be payable to the~~
4 ~~department and shall be retained by the department for the~~
5 ~~administration of this act.~~

6 (d) If any MAJOR change in the program or services, <—
7 including the discontinuance of ~~any of the~~ SUBSTANTIAL services <—
8 of the blood bank ARE MADE, the changes shall be registered with <—
9 the department within thirty days. ~~on forms prescribed by the~~ <—
10 ~~department as an amendment to the original application.~~

11 (e) EACH BLOOD BANK MUST HAVE A LICENSE. A ~~separate~~ SINGLE <—
12 license must be obtained for each location OF A BLOOD BANK EVEN <—
13 THOUGH SEVERAL BLOOD BANKS OR LOCATIONS MAY BE SUPERVISED BY THE
14 SAME DIRECTOR. ~~This does not include mobile donor stations which~~ <—
15 ~~are under the direct supervision of a licensed blood bank.~~ A
16 license shall be valid only in the hands of the person to whom
17 it is issued and shall not be a subject of sale, assignment, or
18 transfer, voluntary or involuntary, nor shall a license be valid
19 for any premises other than that for which issued. However, a
20 new license may be secured for a new location, or owner prior to
21 the actual change, provided that the contemplated change is in
22 compliance with the provisions of this act and the rules and
23 regulations adopted by the department pursuant to this act.

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

- 26 (1) Name and address of the blood bank.
27 (2) Name and address of owner.
28 (3) Name and address of the person responsible for operation
29 of blood bank.
30 (4) Any specific limitations of permit as may be determined

1 by rule and regulation.

2 (5) Signature of the secretary.

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

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

9 (1) Hold a currently valid FEDERAL license to operate a <—
10 blood bank ~~issued by the National Institutes of Health of the~~ <—
11 ~~United States Public Health Service,~~ and meet any additional
12 requirements determined by the department.

13 (2) Participate in and be accredited under an evaluation
14 program as conducted by ~~the American Association of Blood Banks~~ <—
15 ~~or similar agency,~~ if AGENCIES, approved by the department, <—
16 providing the results of such evaluation are on file with the
17 department, and meet any additional ~~standards~~ REQUIREMENTS <—
18 determined by the department.

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

21 Section 14. Rules and Regulations.--The department shall
22 WITH THE ADVICE OF THE BLOOD BANK ADVISORY COMMITTEE establish <—
23 rules and regulations for the standards and specific
24 requirements for operation of blood banks including, but not
25 limited to:

26 (1) Facilities.

27 (2) Proficiency evaluation of testing procedures.

28 (3) Standards for collection, processing, storage, and <—
29 distribution AND PROPER CONDUCT OF THE BLOOD TRANSFUSION SERVICE <—
30 of blood and blood products.

1 (4) The identification and screening of donors.

2 (5) Qualifications for DIRECTOR OF AND personnel employed in <—
3 a blood bank.

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

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

8 (8) THE DEPARTMENT SHALL SET GUIDELINES FOR THE LOCATION OF <—
9 BLOOD BANKS IN ORDER TO AVOID AREAS OF HIGH RISK WHERE THERE ARE
10 HIGH LEVELS OF HEPATITIS OR OTHER DISEASES TRANSFERRED BY BLOOD
11 TRANSFUSIONS.

12 ~~(8)~~ (9) Help communities establish a system for determining <—
13 the inventory of blood in all blood banks and the coordination
14 of the distribution of blood and blood products for the purpose
15 of reducing wastage.

16 (10) THE DEPARTMENT SHALL HELP COMMUNITIES ESTABLISH AND <—
17 DEVELOP VOLUNTEER BLOOD DONOR PROGRAMS. THIS WILL INCLUDE ADVICE
18 AND ASSISTANCE IN PUBLIC EDUCATION AND THE ORGANIZATIONAL
19 STRUCTURE OF THESE PROGRAMS.

20 (11) THE DEPARTMENT SHALL ESTABLISH STANDARDS FOR BLOOD
21 SHIPPED INTO THE COMMONWEALTH, WHICH IS COLLECTED OUTSIDE THE
22 STATE.

23 (12) THE DEPARTMENT SHALL MAKE A MAJOR EFFORT TO INSURE THAT
24 ITS RULES AND REGULATIONS GOVERNING BLOOD BANKS ARE COORDINATED
25 WITH AND DO NOT CONFLICT WITH EXISTING STATE OR FEDERAL LAWS.

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

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

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

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

28 Section 18. Injunction.--(a) Whenever the department shall
29 have refused to grant or renew a license, or shall have revoked
30 or suspended a license required under this act to operate or

1 conduct a blood bank, or shall have ordered the person to
2 refrain from conduct violating the rules and regulations of the
3 department and the person deeming himself aggrieved by such
4 refusal or revocation or order shall have appealed the action of
5 the department, the court may during pendency of such appeal,
6 issue a restraining order or injunction upon proof that the
7 operation of the private institution or its failure to comply
8 with the order of the department is dangerous to the public
9 health.

10 (b) Should a person, who is refused a license or the renewal
11 of a license to operate or conduct a blood bank or whose license
12 to operate or conduct a blood bank is revoked or who has been
13 ordered to refrain from conduct or activity which violates the
14 rules and regulations of the department, fail to appeal or
15 should such appeal be decided finally favorably to the
16 department, then the court shall issue a permanent injunction
17 upon proof that the person is operating or conducting a blood
18 bank without a license as required by law, or has continued to
19 violate the rules and regulations of the department.

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

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

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

28 (f) The provisions of this section shall be construed as
29 supplementary to all other provisions dealing with the same
30 subject matter. No action brought under the provisions of this

1 section shall prevent the prosecution or institution of any
2 civil or criminal action otherwise provided by law for violation
3 of any law providing for licensing or departmental rules or
4 regulations promulgated thereunder.

5 Section 19. Exemptions.--This act shall not include or apply
6 to any blood bank operated by the Federal Government, or any
7 blood bank operated purely for research or teaching purposes:

8 ~~provided the blood and blood products are not injected for~~ <—
9 ~~therapeutic purposes, or to any commercial establishment which~~

10 ~~obtains and processes blood solely for uses other than direct~~
11 ~~transfusion or injection, nor for preparation of blood products~~

12 ~~for human therapeutic use.~~ PROVIDED, THAT THE BLOOD AND BLOOD <—

13 PRODUCTS ARE NOT INJECTED INTO HUMANS. NOR SHALL IT INCLUDE ANY
14 COMMERCIAL ESTABLISHMENT WHICH OBTAINS AND PROCESSES BLOOD AND
15 BLOOD PRODUCTS WHICH ARE NEVER TRANSFUSED OR INJECTED INTO
16 HUMANS.

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

18 The department shall investigate WITH THE ADVICE OF THE BLOOD <—
19 BANK ADVISORY COMMITTEE the feasibility of (i) a community-wide,

20 (ii) Statewide and (iii) an interstate system for inventory
21 coordination and control of blood and blood products. If

22 practical, the State shall put into effect such an inventory
23 system. This system will be developed, as far as practical, in

24 the stages mentioned above. The blood banks, PHYSICIANS, <—
25 CONSUMER GROUPS, HOSPITALS AND THE PUBLIC in each community

26 shall be encouraged and permitted to meaningfully participate in
27 the planning of the community-wide coordination systems. No
28 blood bank shall be forced to accept blood or blood products
29 from another blood bank.

30 Section 21. Advisory Committee.--A committee known as "The

1 Blood Bank Advisory Committee" shall be established by the
2 secretary for the purpose of advising the secretary on matters
3 relating to the administration of this act. This committee shall
4 consist of ~~five~~ SEVEN persons, FOUR who are experience in the <—
5 ~~direction and~~ operation of blood banks. At least three shall be <—
6 currently engaged as ~~medical directors of blood banks.~~ A <—
7 DIRECTOR OF A BLOOD BANK AND ONE SHALL BE A QUALIFIED BLOOD BANK
8 MEDICAL TECHNOLOGIST. THREE SHALL BE FROM THE GENERAL PUBLIC.

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

15 Section 23. Appropriation.--An amount of ~~ten thousand~~ <—
16 ~~dollars (\$10,000)~~ TWENTY-FIVE THOUSAND DOLLARS (\$25,000) is <—
17 appropriated for ~~initial~~ costs of administration of the <—
18 provisions of this act.

19 Section 24. Effective Date.--This act shall take effect in
20 ninety days.