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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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# SENATE BILL

## No. 1103

Session of  
1971

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

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AS AMENDED ON SECOND CONSIDERATION, HOUSE OF REPRESENTATIVES,  
OCTOBER 4, 1972

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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 could endanger the health and lives of the citizens of  
12 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 PREPARED FROM SINGLE UNITS     <—  
20 OF WHOLE BLOOD by the licensing of blood banks, (ii) by  
21 providing qualifications for the personnel of such blood banks  
22 and (iii) by insuring that the procedures performed by blood  
23 banks are performed with a high degree of scientific and  
24 professional competency. This act shall be liberally construed  
25 to carry out these objects and purposes.

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

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

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

1 type entity.

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

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

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

15 (6) "Blood product" means any part or fraction of SINGLE <—  
16 UNITS OF whole human blood, or any material derived from SINGLE <—  
17 UNITS OF such blood which is subsequently administered to human  
18 subjects.

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

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

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

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

1 purposes.

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

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

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

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

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

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

29 Section 6. Direction and Supervision.--A blood bank must be  
30 under the direction of a qualified person who has specific

1 experience in the field of blood bank operations, hematology and  
2 immunohematology.

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

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

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

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

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

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

1       (2) Name and address of owner.

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

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

6       (5) Signature of the secretary.

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

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

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

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

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

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

28      (1) Facilities.

29      (2) Proficiency evaluation of testing procedures.

30      (3) Standards for collection, processing, storage,

1 distribution and proper conduct of the blood transfusion service  
2 of blood and blood products.

3 (4) The identification and screening of donors.

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

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

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

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

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

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

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

25 (12) The department shall make a major effort to insure that  
26 its rules and regulations governing blood banks are coordinated  
27 with and do not conflict with existing State or Federal laws.

28 Section 15. Statement of Grounds for Denial of License.--If  
29 the department does not, within six months after filing of the  
30 application, issue a license, it shall state the grounds and

1 reason for its refusal, in writing, with a copy to the  
2 applicant.

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

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

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

30 Section 18. Injunction.--(a) Whenever the department shall

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

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

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

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

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

30 (f) The provisions of this section shall be construed as

1 supplementary to all other provisions dealing with the same  
2 subject matter. No action brought under the provisions of this  
3 section shall prevent the prosecution or institution of any  
4 civil or criminal action otherwise provided by law for violation  
5 of any law providing for licensing or departmental rules or  
6 regulations promulgated thereunder.

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

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

27 Section 21. Advisory Committee.--A committee known as "The  
28 Blood Bank Advisory Committee" shall be established by the  
29 secretary for the purpose of advising the secretary on matters  
30 relating to the administration of this act. This committee shall

1 consist of seven persons, four who are experienced in the  
2 operation of blood banks. At least three shall be currently  
3 engaged as a director of a blood bank and one shall be a  
4 qualified blood bank medical technologist. Three shall be from  
5 the general public.

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

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

15 Section 24. Effective Date.--This act shall take effect in  
16 ninety days.