CHAPTER 30. BLOOD BANKS

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Authority

The provisions of this Chapter 30 issued under section 14 of the Pennsylvania Blood Bank Act (35 P. S. § 6514), unless otherwise noted.

Source

The provisions of this Chapter 30 adopted May 13, 1977, 7 Pa.B. 1277, unless otherwise noted.

Cross References

This chapter cited in 28 Pa. Code § 125.2 (relating to blood transfusion).

GENERAL PROVISIONS

§ 30.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Act—The Pennsylvania Blood Bank Act (35 P. S. §§ 6501—6523).

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

Blood product—Any part or fraction of single units of whole human blood, including pools of such single units, or any material derived from single units, including pools of such single units, of such blood which is subsequently prepared for the purpose of administration to human subjects.

Collection—The obtaining of human blood by the bleeding of donors by a phlebotomy or plasmapheresis.

Department—The Department of Health of the Commonwealth.

Distribution—The removal of blood and blood products from a blood bank to any other location for processing or storage for the purpose of providing the blood for diagnostic, therapeutic, or prophylactic purposes.

Licensee—A person holding a license under the provisions of the act and this chapter.

Person—Any natural person, partnership, association, corporation, institution, agency, or other similar entity.

Processing—The standard technical procedures used to prepare blood and blood products, methods of identification, tests for suitability for intended purpose, and performance of tests for communicable diseases.

Screening of donors—The evaluation of prospective donors by the blood bank to determine the acceptability of the donor by evaluating his past medical history, his present state of health, and laboratory studies.

Secretary—The Secretary of the Department.

Storage—The holding of blood and blood products for subsequent distribution and use.

§ 30.2. Applicability and exemptions.

(a) Except as otherwise provided, this chapter applies to all blood banks operating in this Commonwealth.

(b) The provisions of this chapter shall not apply to blood banks operated by the Federal government, nor to any blood bank operated purely for research and

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teaching purposes, provided blood or blood products from such research or teaching are not injected into humans.

LICENSING, FEES AND INSPECTIONS

§ 30.10. Licensing.

(a) Any person operating a blood bank in this Commonwealth shall be required to obtain a license in accordance with the provisions of this chapter.

(b) A license is valid for 1 year after issuance and shall be renewed on an annual basis.

(c) A blood bank participating in an inspection and evaluation program other than that of the Department shall be required to remit a fee of $50 per annum, payable to the Department. For all blood banks participating in the inspection and evaluation program of the Department, the fee shall be $200 per annum. A separate fee shall be charged for each permanent blood bank location.

(d) The application for license shall contain the following information:

(1) Name and location of blood bank.

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

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

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

(5) Description of physical facilities and equipment.

(6) Sources of materials and methods of storage and distribution of products.

(7) Description of technical procedures.

(8) Current blood bank licenses, approvals and certifications.

(e) Applications shall be made on forms provided by the Department.

§ 30.11. Inspection and evaluation of blood banks.

(a) At least once each year, the blood bank will be inspected and evaluated by a representative of the Department.

(b) The Department may accept the inspection and evaluation of a private or Federal agency. The record of the inspection and evaluation must be made available in its entirety to the Department.

(c) The Department may inspect the blood bank at any time other than at routine annual inspections.

§ 30.20. Personnel.

(a) *Required staff.* Each blood bank shall have a blood bank director, medical director, and supervisor. The medical director may also serve as the blood bank director and supervisor.

(b) *Qualifications of medical director.* The medical director must be a physician, licensed to practice in this Commonwealth, with at least 4 years full time postdoctoral clinical laboratory training which includes blood banking and related subjects acceptable to the Department or certified in blood banking by the American Board of Pathology.

(c) *Qualifications of a blood bank director.* A person may not be a director of a blood bank unless the person conforms with one of the following requirements:

(1) The person shall hold a doctoral degree in medicine, osteopathy, or one of the biological sciences, and shall have at least 2 years full time postdoctoral training and experience in blood bank operations and related subjects, acceptable to the Department.

(2) The person shall hold an M.A. or M.S. degree from an accredited institution with a major in medical technology or one of the biological sciences or Blood Bank certificates SBB (ASCP), and shall have at least 4 years' experience in blood bank operations and related subjects, acceptable to the Department.

(3) The person shall hold a baccalaureate degree in medical technology or one of the biological sciences and shall have at least 6 years' experience in blood bank operations and related subjects, acceptable to the Department.

(d) *Qualifications of a blood bank supervisor.* A person may not act as a supervisor of a blood bank unless the person conforms with one of the following requirements:

(1) The person shall hold a master's degree in medical technology or one of the biological sciences or Blood Bank certification SBB (ASCP), and shall have at least 2 years' experience and training in blood bank operations, acceptable to the Department.

(2) The person shall hold a baccalaureate degree in medical technology or one of the biological sciences and shall have at least 3 years' experience and training in blood bank operations, acceptable to the Department.

(3) The person shall be a certified technician MLT (ASCP) or MLT (AMT), a nurse registered to practice in this Commonwealth, or an individual who has received a passing grade in the HEW proficiency examination, and shall have at least 4 years' experience and training in blood bank operations, acceptable to the Department.

(e) *Technical personnel.* Technical personnel employed in a blood bank shall meet education and experience requirements consistent with the duties assigned specifically by the supervisor. In selection of technical employes, recognition shall be given to categories of medical laboratory personnel acceptable to the Department.

(f) *Prior employment.* Any individual employed in a blood bank as a director, medical director, supervisor, medical technologist or technician prior to the effective date of this chapter, may continue to act in the capacity and may not be required to meet subsections (b)—(d).

§ 30.21. Responsibilities of directors and supervisor.

(a) The medical director shall be responsible for determining and establishing policies and procedures governing all phases of blood banking. The licensee is obliged to demonstrate that the medical director spends sufficient time on the premises to fulfill the requirements of this section.

(b) The blood bank director shall be responsible, under the direction of the medical director, for implementing policies and procedures governing all phases of blood banking.

(c) The supervisor shall be responsible, under the direction of the medical director and blood bank director, for application of policies and procedures governing all phases of blood banking. Depending upon the size and complexity of the establishment, there may be more than one level of technical and nursing supervisors.

(d) Any procedures involving the service of transfusing or injecting of blood products into humans must be under the supervision of the medical director.

(e) The supervisor must be present during the normal working hours of the blood bank, including mobile units.

(f) The medical director or properly qualified designee must be available for consultation at all times outside of regular working hours.

(g) Any time blood is being obtained from a human donor, a physician who is licensed to practice medicine in this Commonwealth shall be available within ten to 15 minutes so as to be able to handle emergencies which may arise.

§ 30.30. Identification and screening of donors.

Selection for donor criteria shall at least be equivalent to all current Federal regulations and shall include the following:

(1) Donors must be identified by name, age, sex and address. There shall be a numerical system to positively identify and relate the donor, donor record, blood container and pilot tubes in each step from donor to recipient and including preparation of components.

(2) Donors shall be between the ages of 17 through 65. Donors between ages of 17 and 18 must have a written consent signed by a parent or guardian. Donors, after their 66th birthday, who meet all other criteria for acceptability may be accepted at the discretion of the medical director if they have obtained written consent from a physician within 2 weeks before the date of donation or if the medical director contacts the attending physician and secures concurrence.

(3) Intervals between donations of a full unit of blood shall be eight weeks except for autologous transfusion, and the interval between donations by plasmapheresis shall be at least 48 hours.

(4) Donors must be examined at the time of donation, and at least the following physical criteria must be within medically accepted limits for blood

donors: temperature, blood pressure, and pulse. There must be no sign of acute disease or history of disease that will affect the normal use of blood. Any history of chronic disease shall disqualify the donor, unless specific approval is obtained from the donor and the medical director of the blood bank. Final acceptance of a donor is the responsibility of the medical director.

(5) Donors must weigh at least 110 pounds if they are to give a full donation of 480 milliliters. Donors weighing less than 110 pounds may be bled less than full amounts, when required, under the direct supervision of the medical director.

(6) All donors must be within normal limits of hemoglobin or hematocrit. Blood group and Rh type shall be determined and recorded for each donation. Blood group and Rh type determinations are not required for plasmapheresis donors.

(7) Donors shall be free from infectious diseases known to be transmissible by blood insofar as can be determined by usual examinations.

(i) *Viral hepatitis.* Donors with a history of viral hepatitis as well as those who, within 6 months, have had close contact with an individual having the disease, shall be excluded. A donor shall be excluded permanently if his was the only unit of blood, blood component, or derivative administered to a patient who, within 6 months, developed post-transfusion hepatitis and who received no other icterogenic blood fractions or his blood has ever been known to contain Hepatitis B Antigen (HBsAg). When hepatitis has developed after transfusion of blood, blood components, or derivatives from more than one donor, those donors who have not previously been suspected of hepatitis need not be rejected as future donors of whole blood; exclusion of other donors should be evaluated individually by the blood bank physician. The possible presence of the agent or viral hepatitis in donors cannot at present be detected with certainty by any available means, including history, physical examination, and laboratory tests, including a test for presence of HBsAg.

(ii) *Malaria.* Travelers who have been in areas considered endemic for malaria by the Malaria Program, Center for Disease Control, United States Department of Health, Education and Welfare, may be accepted as regular blood donors 6 months after return to the nonendemic area, provided they have been free of symptoms and have not taken antimalarial drugs in the interim. Prospective donors who have had malaria shall be deferred for 3 years either after becoming asymptomatic or after cessation of therapy, whichever is later. Prospective donors who have taken antimalaria prophylaxis or who have been military personnel in an endemic area shall be deferred for 3 years after cessation of therapy or after departure from the area if they have been asymptomatic in the interim. Immigrants or visitors from endemic areas may be accepted as blood donors three years after departure from the area if they have been asymptomatic in the interim. Donations to be

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used for the preparation of plasma, plasma components or fractions devoid of intact red blood cells are exempted from the restrictions set forth in this clause.

(iii) *Syphilis and hepatitis.* Donors must be nonreactive to standard serologic tests for syphilis and negative to (HBsAg) hepatitis antigen by acceptable systems of detection. If such tests are determined to be reactive or positive after blood has been obtained, the blood shall not be administered to humans. Source plasma obtained by plasmapheresis, intended for further manufacturing, may be utilized even if reactive to a standard serologic test for syphilis.

(8) Donors, other than plasmapheresis donors, shall be excluded if dental surgery has been performed within the past 72 hours.

(9) Known pregnancy shall exclude a donor. A donor shall be excluded for 6 weeks postpartum.

(10) Donors shall not give blood within 24 hours after immunization with inactivated vaccines or immunizing agents including prophylactic rabies and within 2 weeks after receiving live immunizing agents. Persons immunized for Rubella shall be acceptable as donors 2 months after receiving the last injection.

(11) Donors with a history of recent drug therapy shall be evaluated by a physician. Exceptions to this paragraph include ingestion of vitamins or oral contraceptives.

(12) Evidence of narcotic or alcoholic habituation or intoxication shall exclude a donor.

(13) Donors shall be excluded for a period of 6 months after receiving blood or blood components.

(14) The skin of the donor must be free of lesion at the site of phlebotomy.

(15) Donors with active tuberculosis shall be excluded.

§ 30.31. Collection, processing, storage and distribution of blood products.

(a) The containers shall be pyrogen-free, sterile and free of foreign material and shall contain sufficient anticoagulant for the quantity of blood to be collected.

(b) Only anticoagulants which meet standards of Federal regulations shall be used, in the amounts necessary to give optimal proportion of blood to anticoagulant.

(c) Both donor and future recipient shall be protected by proper preparation of the site of the venipuncture. Preparation of the skin shall provide maximum assurance of an aseptic procedure and a sterile product. Care shall be taken to prevent contamination of the phlebotomy needle and the phlebotomy site.

(d) All instruments used in the bleeding and processing of blood shall be sterile and dry prior to use.

(e) Pilot samples shall be attached to the container and identified by a numerical system to relate directly to the donor or to the container.

(f) Specific instructions and appropriate materials for the handling and treatment of adverse donor reactions shall be readily available to all personnel in the blood bank.

(g) Blood shall be stored at temperatures between 1° and 6°C with avoidance of fluctuations of more than 2°C. The temperature of blood during shipment should be maintained between 1°C and 10°C.

(h) All equipment used in processing blood and blood products shall be in optimal working condition, checked, and calibrated. Maintenance and control data shall be recorded and available for inspection by the Department.

(i) The refrigerator in which blood is stored shall contain only blood and blood components. It shall be provided with a fan for circulating air or be of such capacity and design to ensure adequate circulation of air.

(j) Expiration rules shall be as follows:

(1) The expiration date for ACD or CPD whole blood (human) and red blood cells (human) shall be 21 days from date of collection. Expiration date for heparinized blood shall be 48 hours after collection provided the product is collected in a closed system and remains in the same bleeding container. If the seal is broken, blood must be transfused within 24 hours.

(2) The expiration date for platelet concentrate, room temperature storage, shall be 72 hours from time of collection, with storage at temperatures between 20° and 24°C.

(3) The expiration date for fresh frozen plasma and cryoprecipitate is 12 months from donation of original pint of blood, with storage at -18°C or lower.

(4) The expiration date for frozen blood cells is 3 years from the date of donation, stored at -65°C or colder. After reconstitution, expiration date is within 24 hours, stored at temperatures between 1° and 6°C.

(5) The expiration date for single donor plasma (human) is 6 weeks, stored at temperatures between 1° and 6°C. These expiration dates are in effect until modified by Federal Regulations. Reference should be made to 21 CFR Part 640.

(k) Before issuing blood from the blood bank, all data on the label shall be carefully checked and ascertained to be clear and legible.

(l) All procedures for the preparation of blood products shall meet standards acceptable to the Department. Complete protocols for these procedures shall be submitted to the Department at the time of license application or when any protocol is modified and when any amendment to the license is requested.

§ 30.32. Quality control and proficiency evaluation of testing procedures.

(a) The blood bank shall participate in a continuing proficiency testing program for blood bank laboratory procedures. Private agency programs, or those provided by governmental agencies, shall be used, together with any additional

requirements stipulated by the Department. All proficiency evaluation programs will be approved by the Department.

(b) A continuing internal program of quality control shall be maintained by each blood bank to include reagents, equipment, records, and personnel.

(c) All laboratory procedures used in a blood bank shall meet or exceed the standards of The Clinical Laboratory Act of 1951 (35 P. S. §§ 2151—2164), and regulations promulgated pursuant thereto, and shall be in compliance with applicable Federal regulations.

PHYSICAL FACILITIES AND RECORDS

§ 30.40. Facilities.

The premises and equipment used by any blood bank shall meet the following minimum requirements:

(1) Provide adequate space for the following:

(i) Private and accurate examinations of individuals to determine their suitability as blood donors.

(ii) The withdrawal of blood from donors with minimal risk of contamination and equipment unrelated to blood collection.

(iii) The storage of blood or blood components pending completion of tests.

(iv) The quarantine storage of blood or blood components in a designated location pending repetition of those tests that initially gave questionable serological results.

(v) The storage of finished products prior to distribution.

(vi) The quarantine storage, handling, and disposition of products and reagents not suitable for use.

(vii) The orderly collection, processing, compatibility testing, storage and distribution of blood and blood components to prevent contamination.

(viii) The adequate and proper performance of all steps in plasmapheresis and leukapheresis procedures.

(ix) The orderly conduction of all packaging, labeling and other finishing operations.

(x) Provide adequate lighting, ventilation and screening of open windows and doors.

(2) Refrigeration equipment and facilities shall be provided to accommodate all blood, blood products and reagents. Refrigeration equipment shall be supplied with automatic temperature recording and alarm mechanisms where required. Temperature controls shall be within the limits of current Federal regulation for storage of blood and blood products.

(3) Fire prevention and other safety factors shall meet the requirements of applicable building codes and ordinances.

§ 30.41. Records.

All licensed blood banks shall maintain records which are adequate to identify all data pertinent to donors, handling and testing of units of blood, disposition of blood from the blood bank, and related information. Records should enable tracing of all units from donor bleeding to final disposition. The records shall include the following:

(1) Donor history, physical examination, any reactions, and results of laboratory tests, including a test for hepatitis-associated antigen. Authorization for bleeding and identification of person taking history and performing the phlebotomy must also be included.

(2) Results of all tests performed on each unit of blood.

(3) Requests for transfusion of blood or blood products, including the full name of the recipient, hospital identification number, sex, amount of blood product required, and the name of the requesting physician.

(4) Disposition of all blood not used for transfusion, including persons or organizations receiving such material, dates, and amounts of the material.

(5) Disposition of all units of blood which are found to contain hepatitis-associated antigen or other contaminants.

(6) Record of transfusions.

(7) Records of adverse reactions to transfusions and subsequent investigations.

§ 30.42. Registry of hepatitis cases.

(a) All licensed blood banks shall submit the following information on or before the 15th day of each month to the Bureau of Laboratories of the Department.

(1) Identification of all donors whose blood indicates, by a test approved by the Department, the presence of (HBsAg) hepatitis antigen. The identification shall include the name, address and age of donor, and date and place of bleeding and testing.

(2) Names of all donors whose blood was transfused into a recipient who subsequently developed hepatitis. Any related information requested by the Department shall also be supplied. Suitable forms for this purpose will be furnished by the Department.

(b) The Bureau of Laboratories will distribute, at least annually, to each licensed blood bank a list of donors whose blood has been found positive in an accepted test for hepatitis-associated antigen.

COMPLIANCE WITH FEDERAL LAW

§ 30.50. Plasmapheresis laboratories.

Plasmapheresis laboratories shall be in compliance with all requirements of the applicable Federal Food and Drug Administration Regulations.

§ 30.51. Manufacture of blood products.

Persons and organizations engaged in the preparation of blood fractions or products for subsequent distribution shall show evidence of compliance with all requirements of the United States Public Health Service and applicable Federal and state regulations. Appropriate records of manufacturing procedures shall be provided to the Department upon request.

§ 30.52. Compliance with other laws.

Blood banks licensed under this chapter shall be required to comply with all pertinent laws and regulations administered by the Federal Food and Drug Administration and any other Federal agency which regulates blood banks and transfusion services, and with The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780-144), and regulations issued thereunder.

PROCEDURE

§ 30.60. Hearings and appeals.

If a license is denied or revoked, the applicant or holder of such license shall be entitled to the rights of notification hearings and appeals provided for in section 17 of the Pennsylvania Blood Bank Act (35 P. S. § 6517), and the Administrative Agency Law (71 P. S. §§ 1710.1—1710.51) (Repealed), and all the regulations promulgated pursuant to them. The notification provided by section 17 of the Pennsylvania Blood Bank Act shall constitute an order to show cause within the meaning of 1 Pa. Code § 35.14 (relating to orders to show cause).

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