

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 135.000: USE OF BLOOD, BLOOD COMPONENTS, AND DERIVATIVES FOR THE PURPOSE OF TRANSFUSION

Section

- 135.001: Purpose
- 135.002: Authority
- 135.003: Citation
- 135.010: Scope
- 135.020: Definitions

Enforcement

- 135.100: Licensure and Approval
- 135.110: Inspections and Statements of Deficiency
- 135.120: Reports
- 135.130: Proficiency Testing Requirements
- 135.140: Denial or Revocation of License or Approval

General Requirements

- 135.200: Requirements
- 135.210: Personnel, Qualifications, and Training
- 135.220: Special Donor Screening Protection Requirements
- 135.230: Contaminated Materials
- 135.240: Significant Reactions
- 135.250: Donor Immunization and Hyperimmunization
- 135.260: Waiver of Requirements Imposed on Blood Banks and Transfusion Services

Transfusion Practices

- 135.400: Personnel, Qualifications, and Training
- 135.410: Transfusion Outside of a Licensed Hospital

135.001: Purpose

105 CMR 135.000 seeks to ensure the quality and safety of human blood transfusion.

135.002: Authority

105 CMR 135.000 is adopted under the authority of M.G.L. c. 111, §§ 3, 51 through 56, and 184B.

135.003: Citation

105 CMR 135.000 shall be known and may be cited as 105 CMR 135.000: *Use of Blood, Blood Components, and Derivatives for the Purpose of Transfusion*. The short form of citation is Massachusetts Blood Banking Regulations, 105 CMR 135.000.

135.010: Scope

105 CMR 135.000 applies to every blood bank and transfusion service operated in the Commonwealth in both hospital and non-hospital settings.

135.020: Definitions

Blood Bank means a facility equipped and staffed to procure, draw, process, store and/or dispense human whole blood and/or its components and/or derivatives.

Blood Bank Director is a physician with training and experience in blood bank techniques who has the responsibility and authority for all medical and technical policies and procedures of a blood bank and/or transfusion service, and for supportive services that relate to the safety of patients and donors.

105 CMR: DEPARTMENT OF PUBLIC HEALTH

135.020: continued

Component means a product removed from whole blood by physical procedures.

Department means the Massachusetts Department of Public Health.

Derivative means a product removed from whole blood by chemical procedures.

Physician means a doctor of medicine or doctor of osteopathy registered by the Board of Registration in Medicine under M.G.L. c. 112, § 2.

Transfusion means the administration of whole blood or any of its components and/or derivatives to humans.

Transfusion Service means a service within a hospital designed, equipped, and staffed to dispense and/or administer whole blood and/or its components and/or derivatives by transfusion to humans.

135.100: Licensure and Approval

Every blood bank in the Commonwealth shall operate in accordance with 105 CMR 135.000 and either be part of a hospital under the provisions of M.G.L. c. 111, § 51 or if outside of a hospital, approved by the Department.

135.110: Inspections and Statements of Deficiency

(A) All blood banks and transfusion services subject to 105 CMR 135.000 will be inspected by the Department to assess their compliance with 105 CMR 135.000. As evidence of such compliance, the Department will accept the American Association of Blood Banks (AABB) or the College of American Pathologists (CAP) accreditation; provided, however, that AABB or CAP, or both, if inspected by both, provide to the Department all statements of deficiencies and certification of compliance with requirement for accreditation. The Department retains the right to request a plan of correction and perform inspections as it deems necessary.

(B) Upon inspection, the Department will send a deficiency statement to notify the blood bank or transfusion service of any violation of 105 CMR 135.000. The blood bank or transfusion service shall submit to the Department a written plan of correction for each violation within ten working days of receipt of the deficiency statement. The Department will notify the blood bank or transfusion service about whether the plan is acceptable or not.

(C) The Department will issue a letter of approval to any blood bank or transfusion service found to be in compliance with 105 CMR 135.000 which is not part of a hospital subject to licensure by the Department.

135.120: Reports

Blood banks and transfusion services subject to 105 CMR 135.000 shall report to the Department not later than the tenth of each month, on Departmental forms, on their activities in the preceding month. The reportable activities will be specified on the forms provided by the Department.

135.130: Proficiency Testing Requirements

(A) Every blood bank subject to 105 CMR 135.000 shall participate successfully in the Comprehensive Blood Bank Series J of the College of American Pathologists (CAP) or an equivalent program approved by the Department. The extent to which a blood bank participates will be determined by the procedures performed by that blood bank. A blood bank must be enrolled in such a program to the extent necessary to cover all testing which it uses for diagnosis or treatment. Every blood bank that performs infectious disease testing on donor blood for the purpose of approving blood for transfusion purposes shall successfully

105 CMR: DEPARTMENT OF PUBLIC HEALTH

135.130: continued

participate in the AABB-CAP Viral Markers Series W or an equivalent program approved by the Department.

(B) The Department shall set standards for successful participation that all blood banks and transfusion services shall meet.

(C) Any blood bank or transfusion service subject to 105 CMR 135.000 which fails to meet any standard for successful participation specified by the Department will be required to submit such information as required by the Department.

(D)(1) The Department may provide additional proficiency testing samples to a blood bank or transfusion service.

(2) Any proficiency testing samples provided by the Department shall meet the same criteria as samples used by the proficiency testing programs approved by the Department.

135.140: Denial or Revocation of License or Approval

(A) Non-compliance with any of 105 CMR 135.000 may result in denial, suspension or revocation of the license of the hospital of which the blood bank or transfusion service is a part or in the imposition of any other sanction which may be imposed on such a hospital under 105 CMR 130.000.

(B) Non-compliance with any applicable provisions of 105 CMR 135.000 by a blood bank or transfusion service subject to M.G.L. c. 111, § 184B which is not part of a hospital subject to Department licensure may result in denial, suspension or revocation of any approval.

(C) Non-compliance with any applicable provisions of 105 CMR 135.000 by a transfusion service which is a part of an out-of-hospital service subject to Department licensure under M.G.L. c.111, § 51A may result in denial or revocation of the license of the out-of-hospital service or temporary or permanent withdrawal of the right of the out-of-hospital service to operate a transfusion service.

135.200 Requirements

All blood banks and transfusion services shall comply with the most recent AABB edition of "Standards for Blood Banks and Transfusion Services". In addition, for the purpose of applying 105 CMR 135.000, all AABB Standards which incorporate the word "should" will be taken to mean "shall" except upon written authorization by the blood bank director for good cause. The blood bank or transfusion service shall document the rationale for all such authorizations. The blood bank's or transfusion service's procedure manual may serve as an acceptable form of authorization.

135.210: Personnel, Qualifications, and Training

(A) Any change in the position of blood bank director shall be reported to the Department within 30 days.

(B) Blood donor screening and venipuncture procedures shall be performed only by suitably qualified individuals who have received appropriate training. The blood bank shall maintain records documenting the training of such qualified individuals. Ongoing continuing education and retraining shall be provided if applicable or as needed. Training must be provided by experienced health professionals with experience in clinical detection, measurement and analysis appropriate to the donor screener's responsibilities. The training programs must include at a minimum:

- (1) a thorough training on content and application of pertinent screening protocols;
- (2) a thorough training on venipuncture blood collection and processing procedures;

135.210: continued

- (3) a thorough training on worker and patient safety including emergency procedures required to aid a distressed donor;
- (4) a means for testing employee technique and proficiency in performing assigned duties and responsibilities. Such assessments shall be made by the blood bank director (or his/her designee) on an annual basis and shall make personal inspections of the donor centers to insure suitable handling of donors and to instruct employees.

135.220: Special Donor Screening Protection Requirements

The blood bank, in addition to using established donor screening criteria to protect donors from ill effects of blood donation, shall:

- (A) define pertinent screening parameters and/or test levels which may indicate or contribute to a disease state;
- (B) inform the donor of all significant findings including disease risk(s) and, as necessary, provide medical counselling and/or referral.

The blood bank may establish a tier system in responding to degrees of disease risk(s). It is not necessary for the defined action parameters/levels to correspond to the ranges resulting in donor deferral.

135.230: Contaminated Materials

All infectious or physically dangerous medical waste, including blood saturated materials and sharps, must be stored and disposed of in accordance with the requirements set forth in 105 CMR 480.000 of the State Sanitary Code, Chapter VIII.

135.240: Significant Reactions

- (A) All fatal transfusion reactions shall be reported to the Bureau of Biologics of the FDA and to the Department.
- (B) All fatal donor reactions shall be reported to the Department.

135.250: Donor Immunization and Hyperimmunization

- (A) Every immunization or hyperimmunization program undertaken to enhance the usefulness of the recipient's plasma for subsequent donation as whole blood or plasma shall be supervised and approved by an institutional review board established and conducted in the manner specified in 21 C.F.R. Part 312 concerning supervision of new drugs for investigational use.
- (B) The selection and scheduling of the injection of the antigen, and the evaluation of each donor's clinical response, shall be by a qualified physician.
- (C) Antigens used in such programs shall be either a product licensed under Section 351 of the Public Health Service Act, 42 U.S.C. § 262, for such purpose or one specifically approved by the Director, Bureau of Biologics, FDA.
- (D) If there is no suitable licensed antigen, a full description of the antigen to be used should be provided to the institutional review board established pursuant to 105 CMR 135.250(A), which should be convinced of the safety of the antigen preparation and be assured that the donor will not be harmed as a result of the procedure. All antigens should be sterile, or when viable antigens are used should be free of all other infectious agents, as determined by appropriate test before use.

105 CMR: DEPARTMENT OF PUBLIC HEALTH

135.250: continued

(E) Schedules for administration of antigen, criteria for acceptability of plasma, and anticipated results with suitable standards by the assay to be used shall be made available to the institutional review board established pursuant to 105 CMR 135.250(A) before the procedure is begun.

(F) All records concerning the antigen, the laboratory characteristics of the plasma donor, and the immunization schedule shall be retained by the blood bank for a least five years after the donor retires from the program.

(G) The selection and administration of human erythrocytes as antigens should be subject to the following additional safeguards:

(1) The erythrocyte donor must meet all the requirements intended for the safety of the recipient that apply to whole blood donors for transfusion.

(2) Aliquots of large quantities of freeze-preserved erythrocytes from donors whose blood is considered to carry a minimal risk of transfusion-transmitted diseases should be used when possible.

(H) The institutional review board established pursuant to 105 CMR 135.250(A) shall satisfy itself that all appropriate steps have been taken to minimize the likelihood that the cells to be used as antigen will transmit transfusion-transmitted diseases to the potential plasma donor or will result in the production of additional blood group antibodies.

(I) Immunized women who are to be subject to further immunization should be at least two years past menopause or have been permanently sterilized.

135.260: Waiver of Requirements Imposed on Blood Banks and Transfusion Services

(A) The Commissioner may waive the applicability to a particular blood bank or transfusion service of one or more of the requirements imposed on that blood bank or transfusion service by 105 CMR 135.000 if the Commissioner finds that:

(1) compliance would cause undue hardship; and

(2) the blood bank or transfusion service is in substantial compliance with the spirit of the requirement; and

(3) the blood bank's or transfusion service's non-compliance does not adversely affect the quality of the blood bank.

(B) The blood bank or transfusion service shall provide to the Commissioner or his/her designee written documentation supporting its request for a waiver.

135.400: Personnel, Qualifications, and Training

A transfusion shall be performed only by:

(A) A physician; or

(B) A registered nurse, registered by the Board of Registration in Nursing under M.G.L. c. 112, § 74, who is specially trained for this duty, provided that a physician shall be available within 15 minutes to respond to any adverse reaction to the transfusion by the recipient.

(C) Other personnel, approved by the health care facility, who are specially trained for this duty, provided that a physician shall be available within 15 minutes to respond to any adverse reaction to the transfusion by the recipient.

135.410: Transfusion Outside of a Licensed Hospital

(A) No transfusion shall be performed outside of a transfusion service within a licensed hospital unless the blood products are obtained through an agreement with a blood bank governed by 105 CMR 135.000 and are administered in one of the following circumstances:

- (1) In an out-patient kidney dialysis facility licensed under 105 CMR 145.000 for dialysis-related purposes.
- (2) In dialysis-related treatment of a home dialysis patient, providing there is documentation that the dialysis helper has been adequately trained in transfusion practices and precautions.
- (3) In the home treatment of hemophilia.
- (4) In other unusual circumstances, to protect patient health or safety, as deemed necessary by a blood bank director, providing that:
 - (a) the blood bank director reviews and approves the procedures being used to accomplish the transfusion; and
 - (b) the physician ordering the transfusion is responsible for the administration of the blood or blood product to the patient.
- (5) In a health care facility or service setting (other than a hospital) licensed by the Department, under agreement with a blood bank and if authorized by the relevant health care facility or service setting licensure regulations.

(B) The transport and transfusion of blood or blood products in accordance with 106 CMR 135.410(A) shall be performed in accordance with 105 CMR 135.000 and if, in addition, informed consent is obtained from the patient.

REGULATORY AUTHORITY

105 CMR 135.000: M.G.L. c. 111, §§ 3, 51 through 56 and 184B.