

Note: These provisions are excerpted from 10 NYCRR, Subpart 58-2, as it relates to Ambulance Transfusion Services. Consult Part 58 for a comprehensive text of regulations applicable to transfusion services.

<http://w3.health.state.ny.us/dbspace/NYCRR10.nsf/56cf2e25d626f9f785256538006c3ed7/8525652c00680c3e8525653000617fd5?OpenDocument&Highlight=0,58>

Section 58-2.1 Definitions. As used in this Subpart:

(a) *Blood bank* means a facility for the collection, processing, storage or distribution of human blood, human blood components or derivatives, or the performance of reinfusion procedures. A blood bank shall employ a qualified director for administrative purposes and, if blood collection is performed, a qualified medical director.

(d) *Blood components* means those preparations separated from a single donation of whole blood, or collected by apheresis, intended for direct use in transfusion, including but not limited to plasma, fresh frozen plasma, plasma frozen within 24 hours after phlebotomy (FP24), red blood cells, washed red blood cells, leukocyte-reduced red blood cells, platelets, granulocytes, and cryoprecipitate, but does not include lymphocytes collected from a donor of hematopoietic progenitor cells, as defined in Subpart 58-5.

(e) *Derivatives* means those preparations separated from plasma derived from multiple donors, including but not limited to albumin, immune globulin, plasma protein fraction and clotting factor concentrates.

(f) *Blood products* means whole blood, blood components or derivatives.

(l) *Limited transfusion service* means a facility, home care services agency, physician's office, or other entity which administers blood or blood components, and may temporarily store blood or blood components, and distribute them within its own organization, but relies on a blood bank holding a permit in blood services-transfusion to perform laboratory tests required under section 58-2.17 of this Subpart.

(n) *Transfusion service* means a service that issues blood, or blood components for administration into a person, but does not include a limited transfusion service or an ambulance transfusion service.

(ae) *Ambulance transfusion service* means an ambulance service certified by the department that administers blood components during transport from one hospital to another hospital.

58-2.6 Collection and handling of blood for subsequent allogeneic or autogeneic transfusion.

(m) Except for blood recovered intraoperatively or postoperatively, or collected for use in a reinfusion procedure, all blood intended for transfusion shall upon collection become the responsibility of the blood collection service. Disposition of blood collected by phlebotomy shall be at the discretion of the director of the collection service until the blood is transferred to a transfusion service, at which time its disposition shall be at the discretion of the director of transfusion services. The director of the blood bank shall ensure that during any transport blood is packed and handled appropriately and only by authorized individuals. No directed or

autogeneic blood unit or component shall be transported to a transfusion service unless the director of the receiving transfusion service or his/her designee has authorized such transport. A transfusion service which has granted standing authorization for receipt of blood shall be given specific notice prior to each shipment. Disposition of blood recovered intraoperatively or postoperatively shall be at the discretion of the intraoperative or postoperative blood collection service, unless the blood is transferred to the hospital blood bank for storage, at which time its disposition shall be at the discretion of the director of transfusion services. Blood banks shall not release blood or blood components intended for transfusion to any site or entity in New York State not holding a department permit as a collection service or transfusion service, or approved by the department as a limited transfusion service or an ambulance transfusion service.

58-2.8 Standard operating procedures.

(c) The standard operating procedure manual shall include written policies and procedures regarding the following, for activities performed at the site:

- (1) use and maintenance of blood warming devices;
- (2) type of infusion sets and filters for all components;
- (3) issuance of components, which must include visual inspection prior to issuance;
- (4) type of personnel authorized to issue components;
- (5) for collecting facilities, obtaining blood or components from other institutions during emergency situations;
- (6) all transfusion-related testing, prenatal testing, and neonatal testing;
- (7) prompt evaluation of reported transfusion reactions and other adverse events; and
- (8) emergency release of uncrossmatched blood, which must include compatibility testing performed after release;
- (9) method validation requirements;
- (10) professional qualifications of personnel who may collect blood specimens for pretransfusion testing;
- (11) specimen and labeling requirements for pretransfusion samples;
- (12) release of blood and blood components to limited transfusion services and ambulance transfusion services; and
- (13) administration of blood components, including prevention of transfusion reactions.

58-2.9 Issuance of blood, blood components and derivatives.

(c) Blood, blood components and derivatives shall be issued only if ordered by a licensed physician or other person authorized by law. Recipients shall receive whole blood of the same ABO group or compatible red blood cells. Rh-negative recipients shall receive RhD-negative blood except for reasonable exempting circumstances as determined by the director of transfusion services. Rh-positive recipients may receive RhD-positive or RhD-negative whole blood or red blood cells. In an emergency, appropriately documented in the records, blood may be released for transfusion prior to the completion of compatibility tests. Any transfusion service which issues blood components for transfusion by a limited transfusion service or ambulance transfusion service shall perform the required tests on its own premises.

(n) Blood components issued to an ambulance transfusion service shall be transported in a leak-resistant, crush-resistant and puncture-resistant container that has been validated to maintain the appropriate temperature for the anticipated duration of transport and has a label indicating the intended receiving hospital's blood bank.

58-2.12. Records to be kept when blood, blood components or derivatives are issued for allogeneic or autogeneic transfusion.

(a) For blood and blood components, records of the following information, as applicable, shall be kept in the blood bank and made available to the department for inspection:

- (1) source;
- (2) unit identification code upon receipt and, if different, upon issuance;
- (3) unit ABO and Rh groups;
- (4) expiration date;
- (5) results of all pretransfusion testing;
- (6) disposition of the unit, including remote storage location, if any, and intended recipient's name or, if the name is unknown, identification code;
- (7) identification of the station code or person taking possession of the unit;
- (8) documentation of visual inspection;
- (9) date and time of issuance; and

(10) results of all tests associated with the investigation of all transfusion reactions, with the conclusions reached and the report signed, or approved by electronic equivalent, by the director of the blood bank or a qualified physician designated by the director of the blood bank.

(b) For coagulation factor concentrates, logbook records of the following information shall be kept and made available to the department for inspection:

- (1) manufacturer;

- (2) lot number;
- (3) expiration date;
- (4) disposition, including recipient's name if administered; and
- (5) date of issue.

(c) For all derivatives, records associated with the investigation of all reactions, with the conclusions reached and the report signed, or approved by electronic equivalent, by the director of the blood bank or a qualified physician designated by the director of the blood bank, shall be kept and made available to the department for inspection.

(d) These recordkeeping requirements shall also apply to blood components issued to limited transfusion services and to blood components issued to ambulance transfusion services.

58-2.16 Required standards for transfusions.

(a) Transfusion services. Every institution which performs transfusions or supplies blood to a limited transfusion service or ambulance transfusion service shall designate a physician who is a member of the staff as director of transfusion services. Such physician must be licensed and currently registered in New York State. The premises, equipment, procedure manuals, records, and all blood, blood components and derivatives shall be available for inspection by the department.

(1) It shall be the responsibility of the chief executive officer or other person in charge of each institution and of the director of transfusion services to determine that:

(i) the rules and regulations of the Council on Human Blood and Transfusion Services and the Administrative Rules and Regulations of the department and related requirements are complied with;

(ii) attending and other staff members and nurses are properly instructed regarding all required procedures;

(iii) records required by the aforesaid rules and regulations are maintained;

(iv) serious unexpected reactions and incidents involving blood components that have been issued by the transfusion service are reported to the department's Wadsworth Center, with sufficient detail to facilitate evaluation and investigation, within seven calendar days of the reaction or incident, or its discovery and, if required, to federal authorities; and

(v) a written policy exists regarding use of blood components negative for cytomegalovirus antibody, irradiated components, leukocyte-reduced components and other specialty components. Such a policy shall include recommended indications for component use and a protocol for component processing and issuance. There shall also be a written policy on recommended indications for transfusion of whole blood, fresh frozen plasma and platelets.

(2) The institution shall report annually to the department the name(s) of the physician(s) in charge of the transfusion service.

(3) If blood components are issued to a limited transfusion service or an ambulance transfusion service, the director of transfusion services of the issuing facility and the director of the limited transfusion service or ambulance transfusion service performing the transfusion shall ensure compliance with all requirements of this Part.

(b) Each institution that performs transfusions or supplies blood to a limited transfusion service and/or an ambulance transfusion service shall have a transfusion committee that meets at least quarterly. The committee shall:

(1) be composed of at least five members;

(2) include members with expertise in clinical medicine in/or transfusion medicine and who are qualified to review the appropriateness and technical aspects of a transfusion; and

(3) review all or a representative sample of transfusions of all categories of blood and blood products issued by the facility for administration at any location, including all intraoperative and postoperative recovery procedures.

(c) Each institution, through its transfusion committee, shall establish guidelines for reservation (compatibility or crossmatching) of blood for each elective surgical procedure which has been performed there more than five times in the preceding calendar year and shall set the maximum number of hours that crossmatched blood will be held on reserve.

(d) Whole blood, red blood cells, plasma, or other components and derivatives shall be prepared and administered by methods generally accepted by the F.D.A. or American Association of Blood Banks and/or by other methods approved by the department as in conformance with generally accepted laboratory principles. No medications except physiologic saline for intravenous use shall be added to, mixed with, or administered in the same line with a blood component unless approved for this use by F.D.A. and there is documentation available to show that the addition is safe and does not adversely affect the blood component. A filter meeting F.D.A. requirements shall be incorporated into the intravenous administration set to be used for blood or blood component transfusions.

(e) In a health care setting, the person initiating transfusion of blood or blood components shall be a:

(1) physician;

(2) registered nurse;

(3) physician assistant;

(4) nurse practitioner;

(5) board-certified cardiovascular perfusionist (intraoperatively); or

(6) licensed practical nurse who has completed a transfusion training program meeting criteria specified by the department by the New York State Education

Department, when supervised by a registered nurse, physician assistant, or a physician who is immediately available on-site.

(f) In a healthcare setting, following comparison of the unit's label with all accompanying information, the person initiating transfusion of a blood component shall, at the patient's side, immediately prior to initiating the transfusion, positively identify the recipient and the blood component to be transfused, using the patient's name and a unique numerical or alphanumeric identifier. One additional person authorized to initiate transfusion, and who is not a licensed practical nurse if the person initiating the transfusion is a licensed practical nurse, shall also so identify the recipient and the blood component, unless another procedure to ensure accurate identification is used, in which case a single identification shall be sufficient. Each identification procedure shall be documented in writing by each participant. Two persons authorized to initiate blood transfusions shall be immediately available during a blood component transfusion and for 30 minutes afterward, except for transfusion of a patient enrolled in a chronic transfusion program who has no history of adverse reactions. A blood component recipient's vital signs shall be serially recorded, in accordance with written policies and procedures. If the person recording the vital signs is a licensed practical nurse, all measurements outside of established parameters shall be reported to a registered nurse, physician, physician assistant, or nurse practitioner for assessment and action. Such notification shall be documented.

(g) For transfusions outside a health care setting, including those in a patient's home, but not including those in an ambulance, the person initiating the transfusion and monitoring the patient shall be a physician, registered nurse, physician assistant, or nurse practitioner. Following comparison of the blood product label with all accompanying information, this person shall, at the patient's side, immediately prior to initiating the transfusion, positively identify the recipient and the blood product to be transfused or infused, using the patient's name and a unique numerical or alphanumeric identifier. Each such identification procedure shall be documented in writing. A person authorized to monitor transfusions and another competent adult, other than the recipient, shall be immediately available at all times during a transfusion. Both persons shall be available for 30 minutes afterwards, except for transfusions of patients enrolled in a chronic transfusion program who have no history of adverse reactions. The recipient's vital signs shall be monitored and documented, in accordance with written policies and procedures.

(h) Transfusions during transport between hospitals may be administered only by a registered nurse, nurse practitioner, physician assistant, physician, or emergency medical technician certified at the critical care or paramedic level, provided such emergency medical technician has received training in blood administration in accordance with requirements established by the department and is performing these services as part of an ambulance transfusion service approved by the department. Blood components to be issued to an ambulance transfusion service must be ordered by a health care provider caring for the patient using a standard order form approved by the department. The transfusion service issuing the blood components shall be made aware that the blood is intended for possible administration during transport between hospitals and shall be informed of the destination hospital. Blood components intended for possible administration during transport shall be packed in a suitable container validated to maintain the appropriate temperature for the anticipated duration of transport. Prior to departure, the identification of the patient and of any blood components to be transported for possible administration during transport shall be verified in accordance with subdivision (f) of this section. In addition, a registered nurse, physician assistant, nurse practitioner, or physician shall verify, at the patient's side, the identification of the patient and all blood units, with the qualified person who will be caring for the patient during transport.

(i) Every facility or limited transfusion service performing transfusions shall provide 24-hour-a-day post-transfusion patient coverage by telephone as necessary.

(j) Each institution, through its transfusion committee, shall develop and implement procedures to encourage the use of autogeneic blood whenever medically indicated. These procedures shall include a mechanism for informing staff physicians of the risks and benefits of autogeneic blood and the options for autogeneic blood transfusion available at the institution, including, but not limited to, inoperative blood recovery, isovolemic hemodilution and presurgical deposit, as applicable. These procedures shall also include a mechanism to encourage physicians to inform their patients of such options whenever medically indicated.

(k) If blood is warmed prior to transfusion, the warming system shall be equipped with a visible thermometer and an alarm to ensure that the blood is not warmed above the temperature specified by the director of the blood bank, in conformance with the system manufacturer's instructions. Blood warmer temperature shall be monitored and recorded on each day of use, and such records shall be available for inspection for at least five years. Maintenance and operation of blood warmers must conform to the manufacturer's instructions.

58-2.20 Ambulance Transfusion Services.

(a) No person shall own or operate an ambulance transfusion service in New York State unless approved by the Department. An inspection may be conducted prior to departmental approval. Ambulance transfusion services shall comply with the provisions of this Part governing transfusions in general.

(b) Ambulance transfusion services shall have a written agreement with all hospitals issuing blood components to the ambulance transfusion service for possible administration during transport to another hospital, except in cases when no ground or air, as needed, ambulance transfusion service with an agreement in place is available. The agreement shall be subject to the prior approval of the department. The agreement shall:

(1) specify the division of responsibilities for ensuring compliance with the provisions of this Subpart;

(2) include a statement that ambulance transfusion service personnel will have adequately completed training in administering blood components according to a curriculum approved by the department; and

(3) include the written approval of the issuing facility's director of transfusion services and the director of the ambulance transfusion service.

(c) A qualified licensed physician shall provide general supervision of ambulance transfusion service personnel continuing and/or initiating transfusions and shall be responsible for ensuring that such personnel have adequate training and experience.

(d) Any order for a transfusion to be continued and/or initiated in an ambulance shall be documented on an order form approved by the department, and shall specify:

(1) the blood component(s) to be transfused;

(2) the number of units to be transfused;

(3) the rate of infusion;

(4) any special instructions; and

(5) any actions, including transfusion of additional units, to be taken based on circumstances that may arise.

(e) Every transfusion administered in an ambulance shall be documented on a transfusion record approved by the department. Such documentation must include:

(1) date of the transfusion;

(2) name of the person who performed the transfusion and who attended the recipient during the transfusion.

(3) for each unit:

(i) blood component transfused;

(ii) unit identification code;

(iii) unit ABO and Rh groups; and

(iv) start time and completion time.

(f) Any adverse reaction shall be documented on a prehospital care report. Such documentation shall include a description of the adverse reaction and actions taken in response.

(g) Any ambulance in which a transfusion is performed by an ambulance transfusion service shall maintain an inventory of isotonic saline and any supplies needed for blood administration and for monitoring transfusion recipients, and have a means to communicate with medical control. All medications, equipment, and supplies necessary for the management of adverse reactions shall be immediately available. Medical waste disposal must be undertaken, in collaboration with receiving hospital, using containers and procedures found acceptable to the department pursuant to Part 70 of this Title.

58-2.24 Disposal of untransfused and expired blood units.

Units deemed unsuitable for transfusion, those not transfused for any reason, and those designated for disposal for any reason, shall be disposed of by an appropriate method in accordance with all applicable regulations and requirements. All expired blood components shall be transferred to a separate storage location within 24 hours of expiration. All such components shall be destroyed, discarded, or removed for non-transfusion purposes within 72 hours of expiration, or returned to the collection facility within one week of expiration.