

Plasmapheresis Centers and Blood Collection Facilities

19a-36-A47. Plasmapheresis centers and blood collection facilities: Definitions

For the purposes of sections 19a-36-A47 to 19a-36-A55 inclusive, the following definitions shall apply:

- (a) "Advisory Committee on Plasmapheresis and Blood Banking" means a group of consultants, appointed by the state commissioner of health and serving in a voluntary capacity, to advise the department of health on matters relating to the regulation of plasmapheresis and blood banking. Two of the consultants shall be physicians licensed to practice in Connecticut who are in charge of blood banking facilities in hospitals licensed in accordance with sections 19a-A490 to 19a-A503 of the general statutes; one shall be a physician licensed to practice in Connecticut who is associated with or employed by a plasmapheresis or blood banking center which is not a part of a licensed hospital; one shall be a physician who is licensed to practice in Connecticut, is board-certified in clinical pathology, and is the director of a hospital laboratory registered and approved in accordance with sections 19a-36-A25 to 19a-36-A35 and section 19-4-1 of the public health code; and one shall be a licensed physician who is not associated with a plasmapheresis center or blood banking facility. The commissioner of health, if he deems it necessary, may appoint additional consultants to this advisory committee.
- (b) "Department" means the state department of health.
- (c) "Director" means the person designated by the registrant to be responsible for the daily technical and scientific operations of the plasmapheresis center or blood banking facility including the choice and application of methods, daily technical and scientific operations, donor selection and care, phlebotomies, and reintroduction of red cells as appropriate.
- (d) "Center" means any area where plasmapheresis, plateletpheresis or blood banking operations are conducted.
- (e) "Plasmapheresis Center" means any area where blood is removed from a human being to obtain plasma, its components, or the non-erythrocytic formed elements with subsequent reinfusion of the red cells into the donor.
- (f) "Blood Collection Facility" means any area where blood is removed from a human being for the purpose of administering said blood or any of its components, to any human being.
- (g) "Owner" means any individual, firm, partnership, association, corporation, the State of Connecticut, or any municipality or other subdivision thereof, or any other entity whether organized for profit or not.
- (h) "Registrant" means the person in whose name the registration is granted. The registrant shall be the owner, if the center is owned by a single individual, or a responsible officer or representative when the center is owned by a group, partnership, firm, corporation, or governmental agency.
- (i) "Specimen" means material derived from a human being or body.
- (j) "Donor" means any person, whether for profit or not, who submits to plasmapheresis or allows a unit of blood more or less to be taken from his or her body for the purpose of transfusion or preparation of blood derivatives or components.
- (k) "Unit" means 450 milliliters of blood more or less.
- (l) "Transfusion" means the intravenous administration of whole blood, packed red blood cells, plasma, and other blood components, fractions, or derivatives to a human being. (Effective October 25, 1989.)

19a-36-A48. Registration of a plasmapheresis center and/or blood collection facility

- (a) The owner or duly designated registrant shall apply to the department for registration of the center or renewal thereof on forms provided for that purpose by the department. No procedures shall be performed therein until the registrant has been notified by the

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- department that registration is in effect. No such procedures shall be performed after registration has expired or has been suspended or revoked as provided herein until such registration is renewed or reinstated.
- (b) In applying for registration, the applicant shall set forth the name and location of the center, a complete statement of its ownership, the name and qualifications of the director, the procedures for which registration is sought and such other information as to quarters, facilities, personnel and proposed operations as the department may require. In the application for registration or renewal thereof, the registrant and director shall agree to abide by all general statutes, regulations and administrative directives pursuant thereto.
 - (c) Prior to registration, the owner shall cause the quarters, facilities and records of the center to be made available for inspection upon request of a representative of the department and shall cooperate with such representative by furnishing information in any pertinent investigation or inspection. The commissioner or his designee shall inspect each center at least once every twelve months unless the commissioner elects to accept an inspection report from the American Association of Blood Banks in lieu of one annual departmental inspection during any two year period. For the purpose of this subsection, representatives of the department shall have the right of entry into the premises of the center at any time during the hours of operation.
 - (d) The duration of each registration shall be set at the discretion of the department but no longer than two years from its effective date. The terms of registration or renewal thereof may restrict the scope of operations or establish a time limit for the owner to carry out recommendations based upon inspection or investigation. In all cases, application for renewal of registration shall be made as follows:
 - (1) within thirty calendar days prior to the expiration of the registration then current;
 - (2) before any change in ownership or change in director is made;
 - (3) prior to any major expansion or alteration in quarters in an existing location; and
 - (4) prior to removal of the center to new quarters. Registration or renewal thereof shall not be effective until the registrant is so notified.
 - (e) A Connecticut registration number will be assigned to the center by the department upon initial registration.
 - (f) A mobile or temporary blood collection facility shall not require registration provided that the person or organization conducting said facility is otherwise registered in this state in accordance with these regulations.
 - (g) Additional blood collection facilities shall not require separate registration provided that the person or organization conducting such facilities is otherwise registered in accordance with these regulations and has filed with the department a list of all permanent locations.
(Effective October 25, 1989.)

19a-36-A49. Denial, suspension or revocation of registration

- (a) Registration of a center shall be denied, revoked, suspended, limited, or renewal thereof denied for knowingly:
 - (1) making false statements of material information on an application for registration or renewal thereof or any other documents required by the department;
 - (2) permitting unauthorized persons to perform any medical or technical procedure such as but not necessarily limited to: plasmapheresis, phlebotomies, and medical history interviews;
 - (3) demonstrating incompetence in the performance of any procedure;
 - (4) performing a procedure for which registration has not been granted;
 - (5) lending the use of the name of the registered center or its personnel to an unregistered center;
 - (6) operating a program of mobile or permanently fixed collection stations without prior written approval from the department; and
 - (7) operating the center in a manner which is deemed prejudicial to the public health.

19a-36-A50. Qualifications of director

- (b) At the discretion of the commissioner of health, the registrant may be directed by written notice to appear not less than ten days after receipt of such notice at a hearing before said commissioner or his agent to show cause why registration should not be denied, suspended, or revoked. When in the judgment of the commissioner of health, conditions so warrant, suspension of the registration may be invoked without prior hearing if the continued operation is prejudicial to the public health. Revocation of a suspended registration will become effective within thirty days after suspension unless otherwise ordered by the commissioner of health. Prior to revocation, the registrant may request a hearing before the commissioner of health or his agent to petition for reconsideration stating upon what grounds such petition is based.
(Effective October 25, 1989.)

19a-36-A50. Qualifications of director

No person shall be the director of a center unless said person is a physician licensed to practice in Connecticut who is board-certified in clinical pathology or blood banking by the American Board of Pathology, or has received a minimum of one year of specialized training in blood banking, or has equivalent experience and training acceptable to the department.
(Effective October 25, 1989.)

19a-36-A51. Responsibilities of registrant and director

- (a) The registrant shall be responsible to ensure that the center is at all times under the direction of a director acceptable to the department as set forth in section 19a-36-A50. Whenever the designated director is to be on leave from his duties for more than thirty calendar days, the registrant shall so notify the department in advance in writing and shall designate, subject to departmental approval, an interim director of the center. The registrant shall notify the department in advance whenever the designated director is about to sever connection with the center.
- (b) The registrant and director shall, if different persons, be jointly and severally responsible for the operation of the center in compliance with sections 19a-36-A47 to 19a-36-A55 inclusive, and with any other pertinent regulatory and statutory requirements.
- (c) The director shall be responsible for the proper performance of all procedures including phlebotomies, plasmapheresis and all procedures performed by subordinates. He shall be responsible for the continuous application of quality control procedures to the work in accordance with recommendations and directives of the department.
- (d) Except for illness, vacation, or other justifiable leave, the director shall be present and in active direction of the center during at least one-half of its normal working hours each week. When the total normal working hours of a center exceed thirty hours weekly, a total of fifteen working hours shall satisfy the requirements of this subsection.
(Effective October 25, 1989.)

19a-36-A52. Minimum standards for operation of centers

- (a) The center shall be operated in compliance with all applicable laws, ordinances, and regulations and with all administrative directives pursuant thereto that shall be issued by the department.
- (b) Quarters in which any procedures are performed or specimens collected shall be kept free from filth, excessive dirt or other objectionable conditions, shall be adequately lighted and ventilated, shall be of adequate size and arrangement for the proper conduct of the work and shall be free from unnecessary safety hazards.
- (c) Equipment shall be adequate and in good order at all times as considered necessary for the proper handling of procedures for which registration may be granted.
- (d) All persons engaged in the performance of any procedures in the center shall be qualified to do the work in the opinion of the director subject to appraisal by the state department of health.

19a-36-A53. Standards for plasmapheresis and blood collection

- (e) No misrepresentation of the scope of the procedures performed by the center, or of the qualifications or special abilities of persons associated with the center, shall be permitted.
- (f) No person shall be subjected to plasmapheresis except when a physician licensed to practice in Connecticut is on the premises.
(Effective October 25, 1989.)

19a-36-A53. Standards for plasmapheresis and blood collection

The department shall, upon recommendation of the Advisory Committee, establish such standards as it deems necessary for the performance of plasmapheresis and phlebotomies. Such standards shall include but may not be limited to: donor selection requirements, blood container and pilot tube identification, donor arm preparation, phlebotomy, collection of blood, plasmapheresis, availability of equipment in the event of donor reaction, processing requirements for donor blood, space and ventilation requirements, and equipment maintenance.

(Effective October 25, 1989.)

19a-36-A54. Maintenance of records and reports

- (a) The medical history and a written record of weight, blood pressure, hemoglobin level (or acceptable alternate test), temperature, pulse, and such other tests as shall be required shall be maintained for a minimum of one year.
- (b) Prior to plasmapheresis, each center shall require positive identification of the donor.
(Effective October 25, 1989.)

19a-36-A55. Laboratory tests

Such laboratory tests as deemed necessary in any standards as may be established pursuant to section 19a-36-A53 shall be performed in a laboratory approved in accordance with section 19a-36-A33.

(Effective October 25, 1989.)