State of Connecticut

Department of Public Health

Regulation Concerning

Blood Collection Facilities

The Regulations of Connecticut State Agencies are amended by adding sections 19a-36-F1 to 19a-36-F6 as follows:

(NEW) Sec. 19a-36-F1. Definitions

As used in this section, and sections 19a-36-F2 to 19a-36-F6, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Accreditation organization" means an entity that sets and evaluates quality and performance standards for blood collection facilities, including through on-site assessment.
(2) "Adverse event" means an event related to donation, and classified according to nationally recognized classifications, that has a negative effect on donor health or safety.
(3) "Apheresis" has the same meaning as provided in section 2 of Public Act 24-7.
(4) "Blood" means a product that is a fluid containing dissolved and suspended elements which was collected from the vascular system of a human.
(5) "Blood collection facility" has the same meaning as provided in section 19a-490(t) of the Connecticut General Statutes.
(6) "Blood component" means a product containing a part of blood separated by physical or mechanical means.
(7) "Business entity" has the same meaning as provided in section 19a-565(a) of the Connecticut General Statutes.
(8) "Centers for Disease Control" or "CDC" means the Centers for Disease Control and Prevention.
(9) "Certification in CPR" means training and certification in cardiopulmonary resuscitation by the American Heart Association, the American Red Cross, the American Safety and Health Institute or an organization that uses guidelines for cardiopulmonary resuscitation and emergency cardiovascular care published by the American Heart Association and the International Liaison Committee on Resuscitation.
(10) "Clinical laboratory" has the same meaning as provided in section 19a-490(h) of the Connecticut General Statutes.
(11) "CLIA" means the regulations adopted pursuant to the Clinical Laboratory Improvement Amendments of 1988, set forth in 42 CFR 493, as amended from time to time.
(12) "CLIA certificate" means a certificate of compliance or accreditation as defined in 42 CFR 493.2.
(13) "Commissioner" means the Commissioner of Public Health or the commissioner's designee.
(14) "Department" means the Department of Public Health.
(15) "Director" means a person designated by a licensee to be responsible for the daily technical and administrative operations of a blood collection facility, including oversight of all other personnel.
(16) "Donor" has the same meaning as provided in section 19a-918 of the Connecticut General Statutes.

(17)"Licensee" means a holder of a blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies.
(18)"Physician substitute" means an advanced practice registered nurse licensed pursuant to chapter 378 of the Connecticut General Statutes, a physician assistant licensed pursuant to chapter 370 of the Connecticut General Statutes, or a registered nurse licensed pursuant to chapter 378 of the Connecticut General Statutes.
(19)"Plasmapheresis" has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.
(20) "Reference laboratory" means a laboratory that receives and performs tests on blood or blood components collected by a blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies.
(21) "Responsible physician" means an individual who has the qualifications provided in 21 CFR 630.5, as amended from time to time, and unless serving as director, reports to the director.
(22)"Source plasma" has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.
(23)"Source plasma donation center" has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.
(24)"Storage" means the holding of blood or blood components related to collection thereof.
(25)"Trained person" has the same meaning as provided in 21 CFR 630.3, as amended from time to time.

(NEW) Sec. 19a-36-F2. Licensure Procedures

(a) No person or business entity shall establish, conduct, operate or maintain a blood collection facility unless such person or business entity holds a license issued by the department in accordance with this section. Such person or entity shall secure the applicable CLIA certificate, or a CLIA certificate of waiver if applicable, required to establish, conduct, operate or maintain such facility.
(b) A source plasma donation center shall not be required to obtain a blood collection facility license pursuant to this section if such center is not performing the function of a blood collection facility as provided in section 19a-490(t) of the Connecticut General Statutes.
(c) A hospital licensed under chapter 368v of the Connecticut General Statutes shall not be required to obtain a license as a blood collection facility for blood component collection activities that take place on the hospital campus, as defined in section 19a-508c of the Connecticut General Statutes.
(d) Approval for licensure as a blood collection facility pursuant to this section shall exempt such facility that collects and sells for secondary use any single donor products, including blood components that do not meet the definition of source plasma, from requirements for additional licensure as a source plasma donation center.
(e) Approval for licensure as a blood collection facility pursuant to this section shall exempt such facility that conducts solely waived tests and has a current CLIA certificate of waiver from requirements for licensure as a clinical laboratory. A licensed clinical laboratory requires separate licensure as a blood collection facility to conduct those functions provided in section 19a-490(t) of the Connecticut General Statutes.

(f) A mobile or temporary blood collection facility shall not require additional licensure provided that the person or business entity operating said facility is otherwise licensed in this state as a blood collection facility in accordance with this section.

(g) Application for initial or renewal licensure.

(1) Application for initial or renewal licensure shall be made by the applicant in a form and manner prescribed by the department. No blood collection shall be conducted until the applicant has been notified by the department that the license is approved and in effect. No blood collection shall be conducted after the expiration of a license or if a license has been suspended, denied or revoked.

(2) Each application for initial or renewal licensure shall include, but not be limited to, the following:

(A) Name and address of the facility;

(B) Statement of ownership and operation, including name and address of the applicant or licensee, and name and address of legal operating entity, parent organization, or both, as applicable;

(C) Name, address and qualifications of the blood collection facility director;

(D) Business identification number issued by the Secretary of the State;

(E) Certificates of malpractice and public liability insurance;

(F) Current CLIA certificate or CLIA certificate of waiver;

(G) A list of proposed services offered;

(H) A list of reference laboratories to be used;

(I) Policies and procedures required under section 19a-36-F3 of the Regulations of Connecticut State Agencies;

(J) A roster of qualified personnel to be employed or under contract to meet the personnel requirements under section 19a-36-F5 of the Regulations of Connecticut State Agencies;

(K) The initial licensure or renewal fee provided in section 19a-565(f) of the Connecticut General Statutes; and

(L) Such additional information as the department may require.

(3) Inspection.

(A) Upon determination that the application materials are complete, the department shall notify the applicant of inspection. The applicant shall make the premises, facilities, equipment, policies and procedures required under section 19a-36-F3 of the Regulations of Connecticut State Agencies and records available for department inspection upon request of the department and shall make personnel available for interviews.

(B) The commissioner may, in the commissioner's discretion, waive inspection upon renewal of a license issued under this section, if the commissioner elects to accept a favorable and timely accreditation assessment report conducted by an accreditation organization. In the event of any corrective action plan under such accreditation, the department shall review such plan and evidence of remediation and may require completion of the implementation of the plan before a license will be granted.

(4) Issuance or renewal of license.

(A) The department may issue a license or renew a license to operate a blood collection facility if the commissioner determines following inspection that the facility is in compliance with the statutes and regulations pertaining to its licensure.

(B) The commissioner shall issue a license to the blood collection facility in the name of the applicant. The license shall not be transferable or assignable.

(C) A licensee operating a blood collection facility licensed pursuant to this section with more than one permanent location shall require a separate license for each permanent location.

(D) The licensee shall post the license in a conspicuous location at each location of the blood collection facility.

(E) A license issued under this section shall be renewed biennially. Applications for renewal shall be submitted to the department not later than four months prior to the expiration of the current license.

(h) Denial of a license. The commissioner may, in the commissioner's discretion, deny an initial or renewal application for licensure for any of the following reasons:

(1) The applicant or licensee has failed to comply with applicable federal, state or local laws;

(2) Failure of the blood collection facility to permit department inspection of the premises upon request of the department;

(3) If licensure would pose a threat to the health, safety or well-being of the public; or

(4) There is a material misstatement of fact on the application.

(i) Change in ownership. Any change in ownership of a blood collection facility licensed pursuant to this section shall be made in compliance with section 19a-493 of the Connecticut General Statutes.

(j) Change in facilities. Any blood collection facility licensed pursuant to this section proposing an expansion or alteration of its facility shall notify the department at least thirty days prior to enacting any such expansions or alterations.

(k) Change or absence of director. Any blood collection facility licensed pursuant to this section proposing a change in director shall notify the department at least thirty days prior to such change. In the event of an unplanned change in director, or the absence of a director for a period more than thirty days, the licensee shall notify the department in writing within twenty-four hours of the date the licensee receives notice of the unplanned change or absence greater than thirty days. In the event of an unplanned change or absence greater than thirty days the licensee may designate an interim director who meets the qualifications set forth in section 19a-36-F5(c)(3) of the Regulations of Connecticut State Agencies for a period of up to six weeks.

(l) Waiver.

(1) The commissioner may waive provisions of sections 19a-36-F2 to 19a-36-F6, inclusive, of the Regulations of Connecticut State Agencies as provided in section 19a-495 of the Connecticut General Statutes.

(2) The licensee requesting a waiver shall do so in a form and manner prescribed by the commissioner. Such request shall include:

(A) The specific regulations for which the waiver is requested;

(B) Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the blood collection facility upon enforcement of the regulations;
(C) The specific relief requested;
(D) Any documentation that supports the request for waiver; and
(E) Alternative policies and procedures proposed.

(3) In determining whether to grant or deny a waiver, the commissioner may consider:
(A) The impact of a waiver on services provided; and
(B) Alternative policies or procedures proposed by the blood collection facility.

(4) The commissioner may request additional information before determining whether to grant or deny the request for a waiver.

(NEW) Sec. 19a-36-F3. Minimum standards for operation

(a) Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall comply with applicable federal, state and local laws.

(b) Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall comply with the requirements of 21 CFR 607.7, as amended from time to time, and all requirements for donor eligibility, blood donation including apheresis, and donor notification in 21 CFR 630 and 21 CFR 640, as amended from time to time.

(c) All reference laboratories utilized by a blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall hold a CLIA certificate or state license or both, as applicable, and shall comply with the requirements of 21 CFR 607.7, as amended from time to time.

(d) Policies and procedures setting forth minimum standards of operation shall be provided to the department for review upon initial or renewal application and on request. Such policies and procedures shall be available to facility personnel for use in areas where procedures are performed. Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall develop and implement such policies and procedures in writing to include, but not be limited to, the following:

(1) Policies and procedures for donors, including but not limited to:
(A) Donor education including donation process and donation risks;
(B) Donor consent in language that is clear and accessible;
(C) Donor care including privacy, confidentiality, response to adverse events, and the provision of emergency care;
(D) Donor eligibility including health assessment and donation limits;
(E) Post-procedure instructions for donors including potential adverse events;
(F) Donor notification in the event of abnormal findings and test results;
(G) Procedures for donors to file complaints with a blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies; and

(H) Procedures for donors to file complaints with the department regarding a blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies.

(2) Documentation and recordkeeping, including confidentiality and retention of donor records.

(3) Staffing, including educational and training requirements, including, but not limited to:

(A) A defined training program to verify the qualifications and ability of all trained persons in accordance with section 19a-36-F5(c)(5) of the Regulations of Connecticut State Agencies;

(B) Policies to identify ongoing training and education needs for personnel who perform activities affecting the quality of blood and blood components and the health and safety of donors;

(C) Records of personnel qualifications and training shall be kept verifying the qualifications of personnel, and to document ongoing training and continuing education of personnel;

(D) Establishment and maintenance of minimum staffing levels; and

(E) Staffing plans to ensure that personnel cross-trained in blood collection, specific to the equipment and facility, are available to maintain safe staffing levels in the event of a personnel or donor emergency and to maintain minimum staffing levels established pursuant to subparagraph (D) of this subdivision.

(4) Emergency preparedness including an emergency communications plan to include notification of the director. If the facility operates temporary or mobile locations, the emergency plan shall include such locations.

(5) Medical contingency planning.

(6) Data collection and reporting in accordance with the requirements of section 19a-36-F6 of the Regulations of Connecticut State Agencies.

(7) Quality assurance and infection control in compliance with all federal and state regulatory requirements, including but not limited to:

(A) Quality assurance and process improvement procedures including the competency of personnel, and periodic documented review to assess the effectiveness of such quality assurance and process improvement procedures.

(B) Equipment policies and procedures to ensure appropriate calibration, maintenance and monitoring for health and safety.

(C) Handling and discarding of blood and blood components to meet standards of practice governing safe disposal, including a written procedure for documented review prior to the release and final labeling of blood or blood components.

(D) Labeling.

(E) Contamination. Policies and procedures to prevent contamination and ensure aseptic methods of collection of blood, in accord with CDC standards for infection prevention and control that apply in healthcare settings and which shall include

but not be limited to changing gloves between donors when conducting phlebotomy procedures.

(F) Errors and adverse events. Policies and procedures regarding errors and adverse events shall include a list of potential adverse events and plan for response to such events. Such policies and procedures shall ensure the identification, assessment, investigation, documentation, and monitoring of deviations from, or of failure to meet, specified requirements, including adverse donor reactions. The investigation shall, when applicable, include an assessment of the effect of the deviation or failure on donor eligibility and donor and patient safety. The responsibility for review and authority for the disposition of nonconforming blood, blood components, tissue, derivatives, critical materials, and services shall be defined. Adverse events shall be reported in accordance with section 19a-36-F6 of the Regulations of Connecticut State Agencies and in accordance with federal requirements.

(8) Facilities and equipment.

(A) The management, operation, personnel, equipment, sanitation and maintenance of the facility shall be such as to ensure the health, comfort and safety of donors, staff and the public at all times.

(B) Facilities, physical environment, and equipment shall be maintained to provide safe and acceptable standards for handling of human blood and blood components. Blood collection facilities shall maintain at a minimum a pre-donation waiting area, a private donor screening area for confidential donor examinations and questioning, a donor recovery area, lavatory facilities on the same floor, clean and convenient handwashing facilities for personnel, and the proper equipment for conducting testing and apheresis, and for the immediate storage and labeling of blood and blood components until such blood and blood components are tested and qualified as suitable for labeling. The facility shall be designed and constructed to ensure accessibility and confidentiality in accordance with state and federal law.

(C) Any areas of the facility where procedures are performed or blood or blood components are collected shall be kept clean, adequately lighted and ventilated, and shall be of adequate size to ensure the health and safety of donors and staff.

(D) Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall maintain appropriate facilities and equipment for record keeping in accordance with these regulations.

(E) Equipment shall be adequate and in good order at all times as considered necessary for the proper handling of work for which licensure may be granted. Equipment shall be validated for installation, operation and performance, maintained and repaired, and qualified for its intended use according to the manufacturer's written instructions, and monitored for compliance with requirements according to a documented schedule. Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall maintain, at a minimum, emergency equipment for resuscitation and defibrillation.

(e) Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall maintain written documentation that each person employed is fully trained in the policies and procedures setting forth minimum standards of operation as required pursuant to this section.

(NEW) Sec. 19a-36-F4. Examinations and laboratory tests

(a) Blood collection facilities licensed pursuant to this section shall conduct all donor testing at a duly licensed clinical laboratory.
(b) Blood and blood components collected shall be tested according to the requirements of 21 CFR 610.40 and 21 CFR 640.5, as amended from time to time.
(c) All donor eligibility testing conducted at a reference laboratory shall be conducted by personnel licensed as required in the state where testing occurs.

(NEW) Sec. 19a-36-F5. Personnel requirements and qualifications

(a) A blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall ensure a minimum of two members of the personnel with current certification in CPR are on-site for every ten donors present, and a minimum of one member of the personnel with current certification in CPR is on-site if fewer than ten donors are present. No blood shall be drawn or collected, including through apheresis, unless personnel so certified in CPR and trained in emergency response protocols to donor adverse events is present on-site.
(b) The licensee shall be responsible for ensuring an adequate number of suitably qualified personnel is available during all hours of operation to ensure the health and safety of donors and staff.
(c) The licensee shall be responsible for obtaining a qualified director and qualified technical staff as follows:
    (1) The licensee shall ensure that a qualified director supervises operations of the blood collection facility and shall ensure the performance of all said director's duties set forth in this section at all times unless such responsibility is delegated pursuant to this section. If so required under the licensee's current CLIA certificate the licensee shall also be responsible for ensuring that supervision of testing is designated to a qualified laboratory director at all times. The roles of director and laboratory director may be performed by the same person if duly

qualified for both roles. If the director will be absent for thirty days or more, the licensee shall report such absence to the department in writing in accordance with section 19a-36-F2(k).

(2) Qualifications and responsibilities of a laboratory director.

(A) If so required under the licensee's current CLIA certificate, the licensee shall designate a laboratory director. The laboratory director shall meet the qualification standards for directors of clinical laboratories in accordance with CLIA requirements.

(B) The laboratory director shall be responsible for ensuring compliance with the requirements of 42 CFR 493, as amended from time to time.

(3) Qualifications and responsibilities of a director.

(A) The director of the blood collection facility shall be a physician licensed to practice in Connecticut with a minimum of one year of specialized clinical experience which shall include blood banking, blood collection, or pathology, or may be a responsible physician. The director and the licensee shall be responsible for the facility's compliance with all applicable state and federal statutes and regulations.

(B) The director shall be responsible for ensuring compliance with all procedures and policies required under Section 19a-36-F3 of the Regulations of Connecticut State Agencies.

(C) The director shall not individually serve as director of more licensed blood collection facilities than permitted by applicable CLIA requirements. If the director serves as director of any blood collection facility located out of the state, the director shall notify the department thereof.

(D) The director shall be responsible for the following:

(i) Oversight of the blood collection facility personnel's in-service training to ensure personnel acquire and maintain the required skills and knowledge for their responsibilities; and

(ii) All personnel's adherence to established policies and procedures.

(E) The director may delegate his or her responsibilities for administering the licensed activities of the blood collection facility to a responsible physician or to a physician substitute. The director may delegate the specific activities with the corresponding levels of medical supervision to a trained person in accordance with the medical supervision requirements of 21 CFR 630.5, as amended from time to time. If the director delegates any responsibilities or activities, the director shall be responsible for the proper performance of all such delegated responsibilities or activities.

(4) The director shall be on-site during hours of operation except when the director has delegated his or her responsibilities pursuant to this section, and when a responsible physician, physician substitute, or trained person is permitted under 21 CFR 630.5, as amended from time to time, to be on-site without a director.

(5) Responsibilities of a physician substitute and responsible physician. A responsible physician or physician substitute shall be responsible for the following, as delegated by the director:

(A) Ensuring the health and safety of donors and the performance of apheresis, as applicable, during all hours of operation;

(B) Oversight of the clinical training of all trained persons, however a physician substitute shall only be responsible for the oversight of clinical training for either a less experienced physician substitute or a person with a lower level of professional credentials;

(C) Assurance that each trained person has completed the training program and has demonstrated competency in all technical and theoretical areas; and

(D) The performance of all responsibilities delegated to them by the director.

(6) Qualification, responsibilities, and training of a trained person.

(A) The minimum qualification for each trained person conducting donor screening, blood collection and apheresis activities, as applicable, shall be a high school diploma or equivalent and documented experience and proficiency of skills and knowledge specific to the equipment and facility. Training shall include but not limited to the following:

(i) Venipuncture;

(ii) Specimen collection and labeling;

(iii) Emergency response; and

(iv) Apheresis, as applicable.

(B) Trained persons shall work under the direction of the director, or a responsible physician or physician substitute to whom the director has delegated responsibility, during all hours of operation of a blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies.

(d) A blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall ensure sufficient personnel are cross-trained in blood collection specific to the equipment and facility to maintain safe staffing levels in the event of staff or donor emergency pursuant to the minimum standards for operation in section 19a-36-F3(d)(3)(E) of the Regulations of Connecticut State Agencies.

(NEW) Sec. 19a-36-F6. Record and reporting requirements

(a) Records. Donor records shall be maintained in accordance with applicable federal and state law including in accordance with 21 CFR 606.160 and 21 CFR 640.72, as amended from time to time. Blood collection facilities shall comply with the requirements of Section 36a-701b of the Connecticut General Statutes.

(b) Confidentiality. Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall comply with the requirements of section 36a-701b of the Connecticut General Statutes, and with all applicable federal and state laws regarding the confidentiality, privacy and security of donor records and personal information including health information.

(c) Adverse events. Records of donor reactions occurring on-site at the blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies, or reported to the facility after the donor has left the facility, shall be kept in a manner that complies with the requirements of 21 CFR 640.72, as amended from time to time.

(d) Reporting. Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall comply with all requirements in 21 CFR 640.73, as amended from time to time, governing reporting of adverse events. Fatalities confirmed to be caused by blood donation shall be reported to the department, and to the FDA in accordance with 21 CFR 606.170(b), as amended from time to time.

(e) Reportable diseases. Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall comply with the reporting requirements under section 19a-215 of the Connecticut General Statutes.

(f) If an error or accident occurs and any blood or blood component not suitable for any use is released for use, immediate effort shall be made to locate and destroy all such blood or blood components. All actions taken to address an error or accident shall be documented in writing.

Statutory Authority

The statutory authority for proposed sections 19a-36-F1 to 19a-36-F6, inclusive, of the Regulations of Connecticut State Agencies is section 19a-565(b) of the Connecticut General Statutes, as amended by Public Act 24-7.

Statement of Purpose

The purpose of these proposed regulations is to establish standards to exempt blood collection facilities, as defined in revised section 19a-490 of the Connecticut General Statutes, from the requirements of licensure as clinical laboratories. The proposed regulations, once adopted as final regulation, would replace current policies and procedures establishing standards for such blood collection facilities to secure licensure by the department under a separate licensure category, as provided in revised section 19a-565 of the Connecticut General Statutes.

The proposed regulations establish standards for the licensure of blood collection facilities in Connecticut. Proposed section 19a-36-F2 establishes licensure procedures, including inspection, renewal, waiver, and disciplinary provisions. Section 19a-36-F3 sets minimum standards of operation to be established and implemented as policies and procedures at a licensed blood collection facility to ensure health and safety, in accord with applicable law. Section 19a-36-F4 sets standards for donor testing and examination. Section 19a-36-F5 sets standards for the required personnel categories and their respective training, qualifications and competencies. Section 19a-36-F6 establishes record and reporting requirements for donor records, reportable diseases, errors and adverse reactions.

Separate proposed regulations establish standards for the licensure of source plasma donation centers to meet the requirements of section 19a-565 of the Connecticut General Statutes and repeal sections 19a-36-A47 to 19a-36-A55, inclusive, of the Regulations of Connecticut State Agencies, which previously have governed plasmapheresis as a registration within the clinical laboratory licensure category.