Connecticut Department of Public Health

Policies and Procedures Regarding

Blood Collection Facilities

In accordance with Section 19a-565 of the Connecticut General Statutes as amended by Public Act 24-7, and until such time regulations are adopted, the Commissioner of Public Health shall implement the following policies and procedures as regulation.

Section 1. 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:

(1) "Accreditation organization" means an entity that sets and evaluates quality and performance standards for blood collection facilities, as such facilities are defined in these regulations, including through onsite assessment.
(2) "Adverse events" means events related to donation, and classified according to nationally recognized classifications, that have a negative effect on donor health or safety.
(3) "Apheresis" a process by which blood is drawn from a donor and separated into its components, one or more of which is retained with the remainder returned by transfusion to the donor.
(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 and Prevention" or "CDC" means the United States Centers for Disease Control and Prevention.
(9) "Clinical laboratory" has the same meaning as provided in section 19a-490(h) of the Connecticut General Statutes.
(10) "Clinical Laboratory Improvement Amendments" or "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.
(11) "CLIA certificate" means a certificate of compliance or accreditation as defined in 42 CFR 493.2.
(12) "Commissioner" means the Commissioner of the Department of Public Health or the commissioner's designee.
(13) "Department" means the Connecticut Department of Public Health.

(14)“Director” means the person designated by the licensee to be responsible for the daily technical and administrative operations of the blood collection facility.
(15)“Distribution” means the transfer of blood or blood components to any location for processing, storage, or any other purpose.
(16)“Donor” means a person who donates blood or blood components for therapeutic use or for further manufacturing use, or who presents as a potential candidate for such donation.
(17)“Food and Drug Administration” or “FDA” means the federal Food and Drug Administration.
(18)“Licensee” means a blood collection facility licensed pursuant to this section.
(19)"Moderate complexity tests" means laboratory tests categorized as moderate complexity in accordance with CLIA, 42 CFR 493.5, as amended from time to time.
(20)“Physician substitute” means an advanced practice registered nurse (APRN) licensed pursuant to Chapter 378 of the Connecticut General Statutes, a physician assistant licensed pursuant to Chapter 370, or a registered nurse licensed pursuant to Chapter 378 of the Connecticut General Statutes.
(21)“Plasmapheresis” has the same meaning as provided in Section 19a-490(u) of the Connecticut General Statutes.
(22)“Reference laboratory” means a laboratory that receives and performs tests on blood or blood components collected by a facility licensed pursuant to this section.
(23) “Responsible physician” has the same meaning as provided in 21 CFR 630.03, as amended from time to time.
(24)“Source plasma” has the same meaning as provided in Section 19a-490(u) of the Connecticut General Statutes.
(25)“Source plasma donation center” has the same meaning as provided in Section 19a-490(u) of the Connecticut General Statutes.
(26)“Storage” means the holding of blood or blood components related to collection thereof.
(27)“Trained person” means an individual, including a physician substitute, who is adequately instructed and qualified to perform specified functions pertaining to apheresis under the direction of the responsible physician.

(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 facility holds a license issued by the department in accordance with these policies and procedures. Such person or entity shall secure the applicable CLIA certificate, including CLIA certificate of waiver if applicable, required to establish, conduct, operate or maintain such center and shall present to the department satisfactory evidence that such person or entity has retained the services of personnel qualified pursuant to these regulations to conduct blood collection.
(b) A source plasma donation center as defined in Section 19a-490(u) of the Connecticut General Statutes and licensed pursuant to the Regulations of Connecticut State Agencies shall not be required to obtain a blood collection facility license pursuant to these policies and procedures 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 386v 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 under Section 19a-565(b) of the Connecticut General Statutes.

(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 under Section 19a-565(b) 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 these policies and procedures.

(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, except at a blood collection facility as defined in Section 19a-36-A47 of the Regulations of Connecticut State Agencies registered with the department before October 1, 2023. No blood collection shall be conducted upon the expiration of licensure or if the license has been suspended, denied or revoked.

(2) Application for the grant of initial licensure or licensure renewal 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 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 State;

(E) Certificates of malpractice and public liability insurance;

(F) Current CLIA certificate;

(G) A list of proposed services offered;

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

(I) Policies and procedures for the minimum standards of operation required under Section 19a-36-F3 of these policies and procedures;

(J) A roster of qualified personnel under Section 19a-36-F2(a) above;

(K) The licensing 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 these policies and procedures and make 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 and renewal of license.

(A) The department may issue a license or renewal of a license to operate a blood collection facility if the commissioner determines following inspection that the facility complies with the statutes and regulations pertaining to its licensure, including compliance with these policies and procedures.

(B) The commissioner shall issue a license to the blood collection facility in the name of the owner of the blood collection facility, business entity or parent organization appearing on the application. 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 by the end of the twentieth month of the current license.

(5) Denial, suspension or revocation of licensure.

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

(i) The licensee has failed to comply with applicable federal, state and local laws;

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

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

(B) A license issued under this section may be revoked or suspended in accordance with chapter 54, or subject to any other disciplinary action specified in Section 19a-17 of the Connecticut General Statutes if the licensed blood collection facility has engaged in fraudulent practices, fee-splitting inducements or bribes including, but not limited to, violations of any provision of Section 19a-565 of the Connecticut General Statues, violations of section 9 of Public Act 23-31 as per section (g) of that section, or violations of these policies and

procedures, or if licensure would pose a threat to the health, safety and well-being of the public.

(h) Change in ownership. Any change in ownership of an entity licensed pursuant to this section shall be made in compliance with Section 19a-493 of the Connecticut General Statutes.

(i) Change in facilities. Any entity 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 changes, expansions or alterations.

(j) Change or absence of director. Any entity licensed pursuant to these policies and procedures 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 greater than thirty days, the licensee shall notify the department within twenty-four hours of the unplanned change or absence greater than thirty days, and the licensee may designate an interim director who meets the qualifications set forth in Section 19a-36-F5(c)(3) of these policies and procedures for a period of up to six weeks.

(k) Waiver.

(1) The commissioner may waive provisions of these policies and procedures as provided in section 19a-495 of the Connecticut General Statutes if the commissioner determines that such waiver would not endanger the health, safety or welfare of any donor. The commissioner may impose conditions upon granting the waiver that assure the health, safety and welfare of donors, and may revoke the waiver upon a finding that the health, safety, or welfare of any donor has been jeopardized.

(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 or policies and procedures 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 or policies and procedures;

(C) The specific relief requested;

(D) Any documentation that supports the request for waiver; and

(E) Alternative policies and procedures proposed.

(3) In consideration of any request for 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 reserves the right to request additional information before processing the request for waiver.

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

(a) Blood collection facilities licensed pursuant to this section shall comply with applicable federal, state and local laws.

(b) Blood collection facilities licensed pursuant to this section 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 section 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 this section shall hold a federal 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 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 these regulations 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 under these policies and procedures; and

(H) Procedures for donors to file complaints with the department regarding a blood collection facility licensed under these policies and procedures.

(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 ability of all trained persons in accordance with Section 19a-36-E5 of these regulations;

(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 staff, and to document ongoing training and continuing education of staff;

(D) Each facility licensed pursuant to this section shall establish and maintain minimum staffing levels; and

(E) Staffing plans to ensure that cross-trained staff are available to maintain minimum levels as established in subdivision (D) above if there is a staffing or donor emergency.

(4) Emergency preparedness including an emergency communications plan to include notification of the medical 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-F7.
(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, which shall conform with the most recent FDA standards.
    (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. Such policies and procedures shall ensure the capture, 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 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 these policies and procedures and in accordance with federal requirements.
(8) Facilities and equipment.
    (A) The management, operation, personnel, equipment, facilities, 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, environment, and equipment shall be provided to maintain safe and acceptable standards for handling of human blood and blood components. Blood collection facilities shall consist of at least 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 the collections 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 these policies and procedures shall maintain appropriate facilities and equipment for record keeping in accordance with this section.

(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 this section shall maintain, at a minimum, emergency equipment for resuscitation and defibrillation.

(F) Blood collection facilities licensed pursuant to these policies and procedures shall ensure their facilities comply with applicable federal, state and local laws.

(e) Blood collection facilities shall maintain written documentation that each staff 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 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 these policies and procedures shall ensure a minimum of two personnel with current CPR certification is onsite for every ten donors present, with a minimum of one personnel with current CPR certification onsite for less than ten donors. No blood shall be drawn or collected, including through apheresis, unless personnel so certified in CPR and trained in donor emergency response protocols are present onsite.

(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 blood collection facility director and qualified technical staff as follows:

(1) The licensee shall be responsible for ensuring that a qualified director supervises operations of the blood collection facility and the performance of all said director's duties set forth in this section at all times unless 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(j) of these policies and procedures.

(2) Qualifications and responsibilities of 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.

(3) Qualifications and responsibilities of blood collection facility director.

(A) The director of the blood collection facility shall be a responsible physician as defined in Section 19a-36-F1 of these policies and procedures. The director and the licensee shall be responsible for the facility's compliance with the rules set forth in these policies and procedures, and all applicable state and federal statutes and regulations.

(B) The director shall be responsible for ensuring compliance with all procedures and policies as required under Section 19a-36-F6 of these policies and procedures.

(C) The director shall not individually serve as director of more than five licensed blood collection facilities including those located out of state. If the director serves as director of any facility located outside of Connecticut, 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 properly qualified and trained responsible physician, or to a physician substitute who shall meet the qualifications of subdivision (4) of this section. 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, the director shall be responsible for the proper performance of all such delegated duties.

(F) The director shall be on site during hours of operation except when the director has delegated his or her responsibilities pursuant to this section. Notwithstanding the foregoing, the director, a responsible physician or a physician substitute shall be on site as required under 21 CFR 630.5, as amended from time to time.

(4) Qualification and responsibilities of a physician substitute.

(A) A physician substitute may be a registered nurse, advance practice registered nurse, or physician assistant as defined for the purposes of this section.

(B) The responsible physician or physician substitute shall be responsible for the following:

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

(ii) Coordination of the technical training of all trained persons;

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

(iv) The performance of all duties delegated to them by the director.

(5) Qualification and responsibilities of trained persons.

(A) Trained persons include phlebotomists, plasmapheresis technicians, or other persons duly qualified under this section.

(B) 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 processing;

(iii) Emergency response; and

(iv) Plasmapheresis, as applicable.

(6) A blood collection facility licensed under this section shall ensure sufficient staff are cross-trained in blood collection specific to the equipment and facility to maintain staffing levels in the event of staff or donor emergency pursuant to the minimum standards for operation in Section 19a-36-F3(e)(3)(E) of these policies and procedures.

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

(a) Records. Donor records shall be maintained in accordance with applicable federal and state law and in accordance with the federal requirements in 21CFR 606.160 and 21 CFR 640.72, as amended from time to time.

(a) Confidentiality. Blood collection facilities licensed under this section 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.

(b) Adverse reactions. Records of donor reactions occurring onsite at the blood collection facility licensed pursuant to this section, 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.

(c) Reporting. Blood collection facilities licensed under this section shall comply with all requirements in 21 CFR 640.73, as amended from time to time, governing reporting of adverse reactions. 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).

(d) Reportable diseases. Blood collection facilities licensed under this section shall comply with the reporting requirements under section 19a-215 of the Connecticut General Statutes.

(e) 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 components. All actions taken to address an error or accident shall be documented in writing.

Sec. 2. Sections 19a-36-A47 to 19a-36- A55, inclusive, of the Regulations of Connecticut State Agencies are repealed.

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.

Effective upon posting on eRegulations.