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Regulation of the

Department of Public Health

Concerning

Source Plasma Donation Centers

Regulations adopted after July 1, 2013, become effective upon posting to the Connecticut eRegulations System, or at a later date if specified within the regulation.

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EFFECTIVE DATE

March 19, 2025

Approved by the Attorney General on

January 17, 2025

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February 25, 2025

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March 11, 2025

Form ICM-ECOPY (NEW 6/2015)
State of Connecticut
Secretary of the State



IMPORTANT NOTICE FOR CONNECTICUT STATE AGENCIES
This form should be used only for regulations first noticed *on and after March 23, 2015*.

Electronic Copy Certification Statement

(Submitted in accordance with the provisions of section 4-172 of the Connecticut General Statutes)

Regulation of the
Department of Public Health
Concerning
Source Plasma Donation Centers

Approved by the Legislative Regulation Review Committee: **February 25, 2025**

eRegulations System Tracking Number: **PR2023-039**

I hereby certify that the electronic copy of the above-referenced regulation submitted herewith to the Secretary of the State is a true and accurate copy of the regulation approved in accordance with sections 4-169 and 4-170 of the *Connecticut General Statutes*.

And I further certify that in accordance with the approval of Legislative Regulation Review Committee, all required technical corrections, page substitutions and deletions, if any, have been incorporated into said regulation.

In testimony whereof, I have hereunto
set my hand on **March 10, 2025**.

A handwritten signature in black ink, appearing to read "Manisha Juthani", written over a horizontal line.

Manisha Juthani, MD

Commissioner

Department of Public Health

State of Connecticut
Department of Public Health
Regulation Concerning
Source Plasma Donation Centers

Section 1. The Regulations of Connecticut State Agencies are amended by adding sections 19a-36-E1 to 19a-36-E6 as follows:

(NEW) Sec. 19a-36-E1. Definitions

As used in this section, and sections 19a-36-E2 to 19a-36-E6, inclusive, of the Regulations of Connecticut State Agencies:

- (1) “Accreditation organization” means an entity that sets and evaluates quality and performance standards for source plasma donation centers, 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) “Blood” means a product that is a fluid containing dissolved and suspended elements which was collected from the vascular system of a human.
- (4) “Blood collection facility” has the same meaning as provided in section 19a-490(t) of the Connecticut General Statutes.
- (5) “Business entity” has the same meaning as provided in section 19a-565(a) of the Connecticut General Statutes.
- (6) “Centers for Disease Control” or “CDC” means the Centers for Disease Control and Prevention.
- (7) “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.
- (8) “Clinical laboratory” has the same meaning as provided in section 19a-490(h) of the Connecticut General Statutes.
- (9) “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.
- (10) “CLIA certificate” means a certificate of compliance or accreditation as defined in 42 CFR 493.2, as amended from time to time.
- (11) “Commissioner” means the Commissioner of Public Health or the commissioner’s designee.
- (12) “Department” means the Department of Public Health.
- (13) “Director” means a person designated by a licensee to be responsible for the daily technical and administrative operations of a source plasma donation center, including oversight of all other personnel.
- (14) “Donor” has the same meaning as provided in Section 19a-918 of the Connecticut General Statutes.

- (15) “Licensee” means a holder of source plasma donation center license issued pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies.
- (16) “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.
- (17) “Plasmapheresis” has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.
- (18) “Reference laboratory” means a laboratory that receives and performs tests on blood or blood components collected by a source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies.
- (19) “Responsible physician” means an individual who has the qualifications provided in 21 CFR 630.3, as amended from time to time, and, unless serving as director, reports to the director.
- (20) “Source plasma” has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.
- (21) “Source plasma donation center” has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.
- (22) “Storage” means the holding of blood or blood components related to collection thereof.
- (23) “Trained person” has the same meaning as provided in 21 CFR 630.3, as amended from time to time.

(NEW) Sec. 19a-36-E2. Licensure Procedures

- (a) No person or business entity shall establish, conduct, operate or maintain a source plasma donation center unless such person or business entity holds a license issued by the department in accordance with section 19a-36-E2 of the Regulations of Connecticut State Agencies. No source plasma donation center shall operate without the applicable CLIA certificate. Applicants may apply for a CLIA certificate concurrently with their application for a license as a source plasma donation center. Prior to issuance of such license, the applicant shall secure the applicable CLIA certificate required to establish, conduct, operate or maintain such center.
- (b) A source plasma donation center licensed pursuant to this section that conducts only those functions described in section 19a-490(u) of the Connecticut General Statutes shall be exempt from requirements for licensure as a clinical laboratory under section 19a-565(b) of the Connecticut General Statutes. Licensed clinical laboratories require separate licensure as a source plasma donation center to conduct those functions described in section 19a-490(u) of the Connecticut General Statutes.
- (c) 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 plasmapheresis shall be conducted until the applicant has been notified by the department that the license is approved and in effect. No plasmapheresis shall be conducted after the expiration of licensure 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 center;
 - (B) Statement of ownership and operation, including name and address of the applicant or licensee;
 - (C) Name, address and qualifications of the source plasma donation center director;
 - (D) Business identification number issued by the Secretary of the State;
 - (E) Certificates of malpractice and public liability insurance;
 - (F) Current CLIA certificate, as applicable;
 - (G) A list of reference laboratories to be used;
 - (H) Policies and procedures required as described in section 19a-36-E3 of the Regulations of Connecticut State Agencies;
 - (I) A roster of qualified personnel to be employed or under contract to meet the personnel requirements as described in section 19a-36-E5 of the Regulations of Connecticut State Agencies;
 - (J) Training curricula and documentation of training provided by the applicant to personnel, including training completed and in progress, as applicable;
 - (K) The licensure or renewal licensure fees 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-E3 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 this section if the commissioner elects to accept a favorable and timely on-site assessment report conducted by an accreditation organization. In the event of any corrective action plan issued by such accreditation organization, 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 the source plasma donation center if the department determines following inspection that the source plasma donation center is in compliance with the statutes and regulations pertaining to its licensure.
 - (B) The commissioner shall issue a license to the source plasma donation center in the name of the applicant. The license shall not be transferable or assignable.
 - (C) The licensee shall post the license in a conspicuous location at the source plasma donation center.
 - (D) 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.

- (d) Denial of a license. The department may deny an initial or renewal application for a license 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 source plasma donation center to permit department inspection of the premises or access to the center's records 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.
- (e) Change in ownership. Any change in ownership of a source plasma donation center licensed pursuant to this section shall be made in compliance with section 19a-493 of the Connecticut General Statutes.
- (f) Change in facilities. Any source plasma donation center 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.
- (g) Change or absence of director. Any source plasma donation center 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 of more than thirty days, the licensee shall notify the department in writing within twenty-four hours of the date the licensee receives notice of such 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-E5(c)(3) of the Regulations of Connecticut State Agencies for a period of up to six weeks.
- (h) Waiver.
 - (1) The commissioner may waive provisions of sections 19a-36-E2 to 19a-36-E6, 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 source plasma donation center 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 any request for a waiver, the commissioner may consider:
 - (A) The impact of a waiver on services provided; and
 - (B) Alternative policies or procedures proposed by the source plasma donation center.
 - (4) The commissioner may request additional information before determining whether to grant or deny a request for a waiver.

(NEW) Sec. 19a-36-E3. Minimum standards for operation

- (a) Source plasma donation centers licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall comply with applicable federal, state and local laws.
- (b) Source plasma donation centers licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall at minimum comply with all requirements for donor eligibility and screening, blood donation, and donor notification in section 21 CFR 630, as amended from time to time.
- (c) Source plasma donation centers licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall comply with all requirements for source plasma in 21 CFR 640.60 to 21 CFR 640.76, inclusive, 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. Source plasma donation centers licensed pursuant to section 19a-36-E2 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 or test results;
 - (G) Procedures for donors to file complaints with a source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies; and
 - (H) Procedures for donors to file complaints with the department regarding a source plasma donation center licensed pursuant to section 19a-36-E2 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-E5(c)(7) 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 conducting plasmapheresis specific to the device, 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.
 - (5) Medical contingency planning.
 - (6) Data collection and reporting in accordance with the requirements of section 19a-36-E6 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 plans for responding 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-E6 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. Source plasma donation centers 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 plasmapheresis, and for the immediate labeling and storage of blood and blood components until such blood and blood components are tested. 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 lit and ventilated, and shall be of adequate size to ensure the health and safety of donors and staff.
- (D) Source plasma donation centers licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall maintain appropriate facilities and equipment for record keeping in accordance with section 19a-36-E6 of the Regulations of Connecticut State Agencies.
- (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. Source plasma donation centers licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall maintain, at a minimum, emergency equipment for resuscitation and defibrillation.

- (e) Source plasma donation centers 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-E4. Examinations and laboratory tests

- (a) Source plasma donation centers licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall only perform donor eligibility tests. The performance of any other laboratory testing shall require a clinical laboratory license effective pursuant to section 19a-36-D21 of the Regulations of Connecticut State Agencies.
- (b) Blood and blood components collected shall be tested according to the requirements of 21 CFR 610.40, as amended from time to time. If the source plasma donation center refers specimens to a reference laboratory located in the state of Connecticut, the reference laboratory shall have a clinical laboratory license effective pursuant to 19a-36-D21 of the Regulations of Connecticut State Agencies. Reference laboratories located outside of the state of Connecticut shall comply with applicable state and federal licensing requirements.
- (c) All donor eligibility testing shall be conducted by personnel licensed and authorized as required in the state where testing occurs.
- (d) Source plasma donation centers licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall meet the requirements of 42 CFR 493, Subpart H, as amended from time to time, regarding enrollment in an approved proficiency testing program under the source plasma donation center's CLIA certificate for each non-waived donor eligibility test conducted.
- (e) If proficiency testing is required by federal regulation, records of such testing, including results and interpretations, shall be maintained for two years.
- (f) All reference laboratories utilized by a source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall hold a federal certificate or license, or state license, or both, as applicable.

(NEW) Sec. 19a-36-E5. Personnel requirements and qualifications

- (a) A source plasma donation center licensed pursuant to section 19a-36-E2 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 plasmapheresis, unless personnel so certified in CPR and trained in emergency response protocols for 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 source plasma donation center 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 ensure 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-E2(h) of the Regulations of Connecticut State Agencies.
 - (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 performing tests categorized as moderate complexity 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 shall be a physician licensed to practice in Connecticut, and shall have one of the following qualifications:
 - (i) A minimum of one year of specialized clinical experience which shall include blood banking, blood collection, or pathology; or
 - (ii) Qualification as a responsible physician.
 - (B) The director shall be responsible for ensuring compliance with the requirements for plasmapheresis set forth in 21 CFR 630 and 21 CFR 640, as amended from time to time.
 - (C) The director shall be responsible for ensuring compliance with all procedures and policies required under section 19a-36-E3 of the Regulations of Connecticut State Agencies.
 - (D) The director shall not individually serve as director of more than five licensed source plasma donation centers including any source plasma donation center located out of state. If the director serves as director of any source plasma donation center located out of the state, the director shall notify the department thereof.
 - (E) The director shall be responsible for ensuring the source plasma donation center personnel's in-service training delivers the required skills and knowledge to safely conduct donor and plasmapheresis services, and shall be responsible for all personnel's adherence to established policies and procedures.
 - (F) The director may delegate his or her responsibilities for administering the licensed activities of the source plasma donation center 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 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.
 - (G) The director shall be on-site during hours of operation except when the director has delegated his or her responsibilities, pursuant to this section, to a responsible physician,

physician substitute, or trained person, and when a responsible physician, physician substitute or a trained person is permitted under 21 CFR 630.5, as amended from time to time, to be on-site without a director.

- (4) Responsibilities of a physician substitute and a 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 plasmapheresis during all hours of operation;
 - (B) Oversight of the clinical training of all trained persons, except that a physician substitute shall only be responsible for the oversight of clinical training for 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 clinical and theoretical areas; and
 - (D) The performance of all responsibilities delegated to them by the director.
- (5) Qualifications and responsibilities of a center manager.
 - (A) The director shall remain responsible for quality and compliance in all technical operations, but may delegate administrative duties related to the daily operation of a source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies to a center manager.
 - (B) The minimum qualification for each center manager conducting such administrative duties shall be an associate's degree and two years documented management experience at a source plasma donation center or equivalent facility. Such equivalent facility may include any institution, as defined in section 19a-490 of the Connecticut General Statutes, or any facility requiring a CLIA certificate.
- (6) Qualifications, responsibilities, training and supervision of a trained person.
 - (A) The department shall review training curricula and documentation of training provided by the licensee upon application. Training shall be documented and shall include direct observations. All training related to the use of plasmapheresis devices shall include documentation of education and ability specific to the device and in accord with federal requirements.
 - (B) The minimum qualification for each trained person conducting donor screening and conducting plasmapheresis shall be a high school diploma or equivalent and documented experience and proficiency of skills and knowledge specific to the device, equipment and facility. Training shall include but not be limited to the following:
 - (iii) Venipuncture;
 - (iv) Specimen processing;
 - (v) Emergency response; and
 - (vi) Plasmapheresis.
 - (C) Trained persons shall work under the direction of the director, a responsible physician, physician substitute, or a trained person as permitted under 21 CFR 630.5, as amended from time to time, to whom the director has delegated responsibility, during all hours of operation of a source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies.

- (7) A source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall ensure sufficient personnel are cross-trained in conducting plasmapheresis specific to the device, equipment and facility to maintain safe staffing levels in the event of personnel or donor emergency pursuant to the minimum standards for operation in section 19a-36-E3(d)(3)(E) of the Regulations of Connecticut State Agencies.

(NEW) Sec. 19a-36-E6. Records, data collection and reporting requirements

- (a) Records. Donor records shall be maintained in accordance with applicable federal and state law, including 21 CFR 606.160 and 21 CFR 640.72, as amended from time to time. Quality control records of total protein determinations shall be maintained to ensure that no donor shall donate source plasma if the total protein determination is outside normal limits.
- (b) Confidentiality. Source plasma donation centers licensed pursuant to section 19a-36-E2 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 source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies, or reported to the center 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. Severe reactions that require the provision of medical attention and fatal reactions shall be reported to the department within twenty-four hours.
- (d) Reporting. Source plasma donation centers licensed pursuant to section 19a-36-E2 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. Source plasma donation centers licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall submit annual reports to the department of all donor complaints filed including documentation of the complaint resolution.
- (e) Reportable diseases. Source plasma donation centers licensed pursuant to section 19a-36-E2 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 or source plasma not suitable for any or the intended use is released for use, immediate effort shall be made to locate and destroy all such blood or blood components or source plasma. 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.

Sec. 3. Section 19a-36-A1 of the Regulations of Connecticut State Agencies is amended to read as follows:

As used in Sections 19a-36-A1 to [19a-36-A55] 19a-36-A46 of the Regulations of Connecticut State Agencies:

[(a)] (1) “Authorized agent” means an individual designated by a local director of health to act for him or her in the performance of any of his or her duties.

[(b)] (2) “Carrier” means an infected person or animal who, without any apparent symptoms of communicable disease, harbors a specific infectious agent and may serve as a source of infection for humans. The state of harboring a specific infectious agent may occur in an individual with an infection that is inapparent throughout its course (asymptomatic carrier), or in an individual during the incubation period, convalescence, and post-convalescence of a clinically recognizable disease (incubatory carrier and convalescent carrier). The carrier state may be of short duration (transient carrier) or long duration (chronic carrier).

[(c)] (3) “Case” means a person or animal who exhibits evidence of disease.

[(d)] (4) “Cleaning” means the process of removal of organic matter conducive to growth or maintenance of infectivity of infectious agents by scrubbing and washing as with hot water and soap.

[(e)] (5) “Commissioner” means the state commissioner of health services.

[(f)] (6) “Communicable disease” means a disease or condition, the infectious agent of which may pass or be carried directly or indirectly, from the body of one person or animal to the body of another person or animal.

[(g)] (7) “Communicable period” means any time period during which a specific infectious agent may be transferred directly or indirectly from an infected person or animal to another human or animal.

[(h)] (8) “Contact” means a person or animal known to have had association with an infected person or animal in such a manner as to have been exposed to a particular communicable disease.

[(i)] (9) “Contamination” means the presence of undesirable substance or material which may contain an infectious agent on external body surfaces (e.g., skin), articles of apparel, inanimate surfaces or in food or beverages.

[(j)] (10) “Cultures” mean growths of an infectious agent propagated on selected living or artificial media.

[(k)] (11) “Date of onset” means the day, month and year on which the case or suspected case experienced the first sign or symptoms of the disease.

[(l)] (12) “Department” means the Connecticut Department of Health Services.

[(m)] (13) “Disinfection” means a directly applied chemical or physical process by which the disease producing powers of infectious agents are destroyed. (1) “Concurrent disinfection” means the immediate disinfection and disposal of body discharges, and the immediate disinfection or destruction of all infected or presumably infected materials. (2) “Terminal disinfection” means the process of rendering the personal clothing and immediate physical environment of a patient free from the probability of conveying an infectious agent to others after removal of the patient or at a time when the patient is no longer a source of infection.

[(n)] (14) “Epidemic” means the occurrence of cases of illness clearly in excess of normal expectancy over a specific time period in a community, geographic region, building or institution. The number of cases indicating an epidemic may vary according to the causative agent, size and type of population exposed, previous experience with the disease, and time and place of occurrence. An outbreak of disease is an epidemic.

[(o)] (15) “Epidemiologic investigation” means an inquiry into the incidence, distribution and source of disease to determine its cause, means of prevention, and efficacy of control measures.

[(p)] (16) “Foodborne outbreaks” means illness in two or more individuals acquired through the ingestion of common-source food or water contaminated with chemicals, infectious agents or their toxic products. Foodborne outbreaks include, but are not limited to, illness due to heavy metal intoxications, staphylococcal food poisoning, botulism, salmonellosis, shigellosis, Clostridium perfringens intoxication and hepatitis A.

[(q)] (17) “Foodhandler” means a person who prepares, processes, or otherwise handles food or beverages for people other than members of his or her immediate household.

[(r)] (18) “Health care facility” means any hospital, long term care facility, home health care agency, clinic or other institution licensed under Chapter 368v of the Connecticut General Statutes and also facilities operated and maintained by any state agency for the care or treatment of mentally ill persons or persons with mental retardation or substance abuse problems.

[(s)] (19) “Health care provider” means a person who has direct or supervisory responsibility for the delivery of health care or medical services. This shall include but not be limited to: licensed physicians, nurse practitioners, physician assistants, nurses, dentists, medical examiners, and administrators, superintendents and managers of health care facilities.

[(t)] (20) “Incubation period” means the time interval between exposure to a disease organism and the appearance of the first symptoms of the resulting disease.

[(u)] (21) “Infection” means the entry and multiplication of an infectious agent in the body of a person or animal with or without clinical symptoms.

[(v)] (22) “Infectious agent” means a microorganism capable of producing infection with or without disease.

[(w)] (23) “Isolation” means the use of special precautions during the period of communicability to prevent transmission of an infectious agent. Such special precautions may include: physical separation of infected persons or animals from others, or precautions such as blood precautions that do not necessarily result in physical separation of individuals.

[(x)] (24) “Laboratory” means any facility licensed, or approved by the department in accordance with section 19a-30 of the Connecticut General Statutes.

[(y)] (25) “Local director of health” means and includes the city, town, borough or district director of health and any person legally authorized to act for the local director of health.

[(z)] (26) “Medical information” means the recorded health information on an individual who has a reportable disease or who has symptoms of illness in the setting of an outbreak. This information includes

details of a medical history, physical examination, any laboratory test, diagnosis, treatment, outcome and the description and sources of suspected causative agents for such disease or illness.

[(aa)] (27) “Nosocomial infection” means infections that develop within a hospital or other health care facility or are produced by microorganisms acquired while in a hospital or health care facility.

[(bb)] (28) “Outbreak.” See “epidemic.”

[(cc)] (29) “Quarantine” means the formal limitation of freedom of movement of persons or animals exposed to, or suffering from a reportable disease for a period of time not longer than either the longest incubation period or the longest communicable period of the disease, in order to prevent spread of the infectious agent of that disease.

[(dd)] (30) “Reportable disease” means a communicable disease, disease outbreak, or other condition of public health significance required to be reported to the department and local health directors.

[(ee)] (31) “Reportable laboratory finding” means a laboratory result suggesting the presence of a communicable disease or other condition of public health significance required to be reported to the department and local health directors.

[(ff)] (32) “State epidemiologist” means the person designated by the Commissioner as the person in charge of communicable disease control for the state.

[(gg)] (33) “Surveillance” means the continuing scrutiny of all aspects of occurrence and spread of a disease relating to effective control of that disease, which may include but not be limited to the collection and evaluation of: morbidity and mortality reports; laboratory reports of significant findings; special reports of field investigations of epidemics and individual cases; data concerning the availability, use, and untoward side effects of the substances used in disease control, such as rabies vaccine; and information regarding immunity levels in segments of the population.

[(hh)] (34) “Suspected case” means a person or animal suspected of having a particular disease in the temporary or permanent absence of definitive clinical or laboratory evidence.

[(ii)] (35) “Other condition of public health significance” means a non-communicable disease caused by a common source or prevalent exposure such as pesticide poisoning, silicosis or lead poisoning.

Statutory Authority

The statutory authority for proposed sections 19a-36-E1 to 19a-36-E6, 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 source plasma donation centers, 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 source plasma donation centers to seek licensure by the department under a separate licensure category, as provided in revised section 19a-565 of the Connecticut General Statutes.

Section 1 of these proposed regulations establishes standards for the licensure of source plasma donation centers in Connecticut. Proposed section 19a-36-E2 establishes licensure procedures, including inspection, renewal, waiver, and disciplinary provisions. Section 19a-36-E3 sets minimum standards of operation to be established and implemented as policies and procedures at a licensed source plasma donation center to ensure health and safety, in accord with applicable law. Section 19a-36-E4 sets standards for testing and examination, and specifies that source plasma donation centers licensed pursuant to this section are exempt from clinical laboratory licensure requirements. Section 19a-36-E5 sets standards for the required personnel categories and their respective training, qualifications and competencies. Section 19a-36-E6 establishes record and reporting requirements for donor records, reportable diseases, errors and adverse reactions.

Section 2 repeals 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.

Separate proposed regulations establish standards for the licensure of blood collection facilities to meet the requirements of section 19a-565 of the Connecticut General Statutes.

IMPORTANT NOTICE FOR CONNECTICUT STATE AGENCIES

This form is to be used for proposed permanent and technical amendment regulations only and must be completed in full.

AGENCY CERTIFICATION**Department of Public Health**

Proposed Regulation Concerning

Source Plasma Donation Centers

eRegulations System Tracking Number PR2023-039

I hereby certify the following:

(1) The above-referenced **regulation** is proposed pursuant to the following statutory authority or authorities: **Sections 19a-495(c) and 19a-565(b) of the Connecticut General Statutes.**

For technical amendment regulations proposed without a comment period, complete #2 below, then skip to #8.

(2) As permitted by Section 4-168(h) of the *Connecticut General Statutes*, the agency elected to proceed without prior notice or hearing and posted the text of the proposed technical amendment regulation on eRegulations System website on _____.

For all other non-emergency proposed regulations, complete #3 - #7 below, then complete #8)

(3) The agency posted notice of intent with a specified comment period of not less than 30 days to the eRegulations System website on **January 2, 2024.**

(4) *(Complete one)* No public hearing held or was required to be held. **OR** One or more public hearings were held on: **January 25, 2024**

(5) The agency posted notice of decision to move forward with the proposed regulation to the eRegulations System website on **September 25, 2024.**

(6) *(Complete one)* No comments were received. **OR** Comments were received and the agency posted the statements specified in subdivisions (1) and (2) of CGS Section 4-168(e) to the eRegulations System website on **September 25, 2024**

(7) The final wording of the proposed regulation was posted to the eRegulations System website on **January 15, 2025.**

(8) Subsequent to approval for legal sufficiency by the Attorney General and approval by the Legislative Regulation Review Committee, **the final regulation shall be effective**

(Check one and complete as applicable)

When posted to the eRegulations System website by the Secretary of the State.

OR On _____

(Date must be a specific calendar date not less than 11 days after submission to the Secretary of the State)


SIGNED

*(Head of Board, Agency or Commission,
or duly authorized deputy)*

Commissioner

OFFICIAL TITLE

1-15-2025

DATE

**OFFICE OF THE ATTORNEY GENERAL
REGULATION CERTIFICATION**

Agency: Department of Public Health

REGULATION NUMBER: PR2023-039

This Regulation is hereby APPROVED by the Attorney General as to legal sufficiency in accordance with Connecticut General Statutes § 4-169.

DATE: 1/17/2025

Signed: _____



Sean Kehoe

Associate Attorney General

Chief of the Division of Government Affairs

Duly Authorized

The Connecticut General Assembly

Legislative Regulation Review Committee

Senator Sujata Gadkar-Wilcox
Senate Chair



Representative Christie Carpino
House Chair

Official Record of Committee Action

February 25, 2025

Agency: Department of Public Health
Description: Source Plasma Donation Centers
LRRC Regulation Number: 2024-029A
eRegulation Tracking Number: PR2023-039

The above-referenced regulation has been

Approved with Technical Corrections

by the Legislative Regulation Review Committee in accordance
with CGS Section 4-170.

Catherine M. Thomas
Committee Administrator



State of Connecticut
Office of the Secretary of the State

Confirmation of Electronic Submission

Re: Regulation of the Department of Public Health concerning Source Plasma
Donation Centers
eRegulations System Tracking Number PR2023-039
Legislative Regulation Review Committee Docket Number 2024-029A

The above-referenced regulation was electronically submitted to the Office of the Secretary of the State in accordance with Connecticut General Statutes Section 4-172 on March 11, 2025.

Said regulation is assigned Secretary of the State File Number 6429.

The effective date of this regulation is March 19, 2025.

A handwritten signature in blue ink, appearing to read "Stephanie Thomas".

Stephanie Thomas
Secretary of the State
March 19, 2025

By:

/s/ Christopher R. Drake
Christopher R. Drake
Director, Business Services
Division