

**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.

*Regulations of Connecticut State Agencies*

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(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.

(Effective March 19, 2025)