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.

(Effective March 19, 2025)