

Pursuant to the authority vested in the Commissioner of Health by sections 571 and 575-a of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to be effective upon publication of a Notice of Adoption in the State Register, to read as follows:

A new subpart 58-4 is added to Title 10, to read as follows:

#### SUBPART 58-4 SOURCE PLASMA DONATION CENTERS

58-4.1 Definitions.

(a) *Source plasma* is defined as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use. This definition excludes single donor plasma products intended for intravenous use (i.e., transfusion).

(b) *Source plasma donation center* means a facility where source plasma is collected by plasmapheresis, and total protein and hematocrit testing is performed on prospective donors. Source plasma donation center does not include collection of single source donor plasma intended for intravenous use (i.e., transfusion).

(c) *Responsible physician* means an individual who is:

- (1) Licensed and registered to practice medicine by the New York State Education Department;

- (2) In good standing with the New York State Education Department and the Office of Medical Professional Conduct of the New York State Department of Health;
  - (3) Adequately trained and qualified to direct and control personnel and relevant procedures concerning the determination of donor eligibility; collection of blood and blood components; the immunization of a donor; and the return of red blood cells or other blood components to the donor during collection of blood component(s) by apheresis; and
  - (4) Designated by the collection establishment to perform the activities described in paragraph (c)(3) of this section.
- (d) *Physician substitute* means a trained and qualified person(s) who is:
- (1) Currently licensed and registered as a health care worker by the New York State Education Department;
  - (2) Currently certified in cardiopulmonary resuscitation; and
  - (3) Trained and authorized under State law, and/or local law when applicable, to perform the specified functions under the direction of the responsible physician.
- (e) *Laboratory director* means an individual who meets the qualifications listed under the Code of Federal Regulations including, Title 42, Part 493, Section 1405.

58-4.2 Registration of source plasma donation centers.

(a) Each source plasma donation center must apply for registration on forms provided by the Department, which shall include: the necessary demographic information of the source plasma donation center; current license and registration of the responsible physician overseeing collection activities; name, address and credentials of the laboratory director; name and address of the owner of the donation center; and other such information as the department may require.

(b) A source plasma donation center registration shall not be issued unless the responsible physician meets all criteria in section 58-4.1(c) of this Subpart, the laboratory director meets the requirements in section 58-4.1(e) of this Subpart, the registration fees have been paid and the registration application is complete.

(c) The source plasma donation center registration shall be valid for a period of two years from the date of issuance and may be renewed for successive two-year periods thereafter. The original application and each renewal application shall be accompanied by a registration fee of six hundred dollars. A renewal application must be received at least sixty (60) days prior to registration expiration.

(d) Source plasma donation centers shall only perform hematocrit and total protein donor eligibility tests. Any other clinical laboratory testing shall require a clinical laboratory permit pursuant to Section 574 of the Public Health Law.

(e) The responsible physician and laboratory director shall be jointly responsible for ensuring compliance with this Subpart. The responsible physician shall be responsible for ensuring compliance with the Code of Federal Regulations, Title 21, Parts 630 and 640. The laboratory director will be responsible for ensuring compliance with the Code of

Federal Regulations, Title 42, Part 493.

(f) Source plasma donation centers shall notify the Department no later than sixty (60) calendar days after any change in the responsible physician, laboratory director, owner, or location. Failure to provide proper notice pursuant to this subdivision may result in the revocation of the source plasma donation center's registration.

#### 58-4.3 Incorporation by Reference.

The provisions of the Code of Federal Regulations which have been incorporated by reference in this Subpart have been filed in the Office of the Secretary of State of the State of New York, the publication so filed being the booklet entitled: Code of Federal Regulations, Title 21, Parts 630 and 640, revised as of May 22, 2015 and April 1, 2016, respectively, and Title 42, Part 493, revised as of August 10, 2022, published by the Office of the Federal Register, National Archives and Records Administration and Code of Federal Regulations. The regulations incorporated by reference may be examined at the Records Access Office, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237 or can be directly obtained from the Superintendent of Documents, US Government Printing Office, Washington, D.C. 20402.

#### 58-4.4 Enforcement.

(a) Registration under this Subpart may be denied, suspended, revoked or annulled by the department upon a determination that a registrant:

(1) failed to comply with the requirements of this Subpart;

(2) provided services that constitute an unwarranted risk to human health;

(3) intentionally provided any false or misleading information to the Department relating to registration or performing donor eligibility and collection procedures; or

(4) has demonstrated incompetence or shown consistent errors in the performance of donor eligibility or collection procedures.

(b) A registration shall not be suspended or revoked without a hearing. However, a registration may be temporarily suspended without a hearing for a period not to exceed thirty (30) days upon notice to the registrant following a finding by the Department that the public health, safety or welfare is in imminent danger.

(c) Source plasma donation centers shall provide the Department with immediate access to all registered facilities during reported operating hours, equipment, records, and personnel, as required by the Department to determine compliance with this Subpart and compliance with federal requirements in the Code of Federal Regulations, including Title 21, Parts 630 and 640 and Title 42, Part 493.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Public Health Law (PHL) § 571 defines source plasma donation centers as entities separate and apart from blood banks. PHL § 575-a sets forth the allowable activities performed at source plasma donation centers and authorizes the Commissioner of the Department of Health to promulgate regulations establishing a registration process for such entities.

### **Legislative Objectives:**

The legislative objective of PHL § 575-a is to separate source plasma donation centers as a regulatory entity distinct from blood banks, authorize collection of source plasma at source plasma donation centers that comply with federal law, and create a streamlined registration process for these facilities.

### **Needs and Benefits:**

Source plasma collection through donation is the first step in manufacturing plasma protein therapies to treat diseases, including creation of clotting factor products for individuals with bleeding disorders, autoimmune disorders, and other conditions. It is a completely separate process from blood and blood component collection for transfusion purposes.

The proposed regulations are needed to ensure source plasma donation centers in New York State operate in a safe manner and in compliance with federal standards. The regulations accomplish this by requiring source plasma donation centers to register

with the Department of Health (Department) and be subject to periodic inspections. These requirements will positively impact entities seeking to operate source plasma collection facilities by harmonizing the federal and state requirements. In addition, by establishing source plasma donation centers as a regulatory entity distinct from blood banks, such entities are relieved of the burden of ensuring the director of the facility holds a certificate of qualification, obtaining a blood bank permit, and employing individuals who hold appropriate licensure from the State Education Department to perform the federally mandated total protein and hematocrit testing.

**Costs:**

**Costs to Regulated Parties:**

Source plasma donation centers will be subject to a biennial registration fee of \$600. There will be no additional cost to the regulated party for the assessment of compliance by on-site inspection.

**Costs to the Department, State and Local Governments:**

A new regulatory program will be needed to oversee source plasma donation centers. The Department anticipates hiring two (2) full-time employees to administer the registration process and perform biennial inspections to ensure compliance with both state and federal requirements. The anticipated start-up costs are approximately \$140,000 and the estimated annual operating costs are approximately \$200,000.

Local governments are not expected to incur any costs as a result of this regulation.

**Local Government Mandates:**

The proposed regulations do not impose new mandates on any county, city, town or village government; or school, fire or other special district.

**Paperwork:**

The proposed regulations will require the generation of new forms to facilitate the registration of source plasma donation centers. In addition, source plasma donation centers will be required to maintain the same documentation consistent with federal regulations, to include but not be limited to, personnel credentials, donor demographics and medical history, testing results for donor eligibility, and disposition of all donations.

**Duplication:**

Source plasma donation centers are subject to the Code of Federal Regulations, Title 21, Parts 630 (Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing) and 640 (Additional Standard for Human Blood and Blood Products), and Title 42, Part 493 (Laboratory Requirements). The Department has applied and been approved for an exemption from the federal government for the laboratory requirements (42 CFR 493) continuously since 1995, granting the Department the authority as the primary accrediting body for clinical laboratories operating in New York. Consequently, there is no duplication with regard to



status of source plasma donation centers as clinical laboratories performing total protein and hematocrit testing.

**Alternatives:**

One alternative to the proposed regulations would be to not adopt regulations and allow source plasma donation centers to operate in New York without registering with the Department. However, this alternative was not considered a viable option since requiring source plasma donation centers to register will provide the Department better oversight of these facilities within New York and ensure that such facilities are meeting minimum health and safety requirements.

**Federal Standards:**

Source plasma donation centers are subject to the Code of Federal Regulations, Title 21, Parts 630 (Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing) and 640 (Additional Standard for Human Blood and Blood Products), and Title 42, Part 493 (Laboratory Requirements).

**Compliance Schedule:**

Recent amendments to the Public Health Law, carving out source plasma donation centers from the definition of a blood bank, went into effect on June 19, 2022. Prior to June 19, 2022, these facilities needed to be permitted as a blood bank. Source plasma donation centers currently operating under the authority of a blood bank will have the option of continuing their permit or registering under the regulation. Any facility

currently operating a source plasma donation center or seeking to operate a new source plasma donation center, that does not hold a blood bank permit, will be required to register with the Department once the regulations are in effect. The regulations will be effective upon publication of the Notice of Adoption in the New York State Register.

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## **STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

## **STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not being submitted because the amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no other compliance costs imposed on public or private entities in rural areas as a result of the amendments.

**STATEMENT IN LIEU OF  
JOB IMPACT STATEMENT**

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.