



PA 24-7—sSB 368

Public Health Committee

AN ACT CONCERNING SOURCE PLASMA DONATION CENTERS

SUMMARY: Existing law requires the Department of Public Health (DPH) to adopt regulations to implement new licensure categories, established by PA 23-31, for source plasma donation centers and blood collection facilities.

This act eliminates prior law's requirement that the regulations require a registered nurse or advanced practice registered nurse to be on-site during these facilities' operating hours. It also requires the regulations to allow "responsible physicians" (see BACKGROUND) to be directors of these facilities. (In doing so, it aligns with federal regulations.)

Under the act, the commissioner must update DPH policies and procedures by October 1, 2024, to include the act's requirements. By law, these policies and procedures are valid until final regulations are adopted. (DPH issued initial policies and procedures for these centers and facilities to implement PA 23-31's requirements in October 2023, and proposed regulations for public comment in January 2024.)

Additionally, the act exempts someone who performs apheresis on a healthy donor to collect blood or its components from needing a nursing license. Under the act, a person may do this regardless of existing health care institution and nursing laws, so long as they follow federal and state regulations.

Under the act, "apheresis" is a process that removes blood from a person and separates its components (e.g., white blood cells, plasma, red blood cells, and platelets), of which some is kept, and the rest is returned to the donor. A "donor" is a person who donates blood or its components for therapeutic or manufacturing use or presents as a potential candidate for this donation.

EFFECTIVE DATE: Upon passage

BACKGROUND

Blood Collection Facilities and Source Plasma Donation Centers

By law, a "blood collection facility" is a facility that performs blood component collection activities where blood is removed from a person to administer the blood, or its components, to any person. It excludes facilities that perform these activities to collect source plasma or perform testing that requires a clinical laboratory license.

A "source plasma donation center" is a facility where source plasma is collected by plasmapheresis, which is a procedure that removes blood from a donor, separates the plasma, and then returns the red blood cells to the donor at the time of donation. "Source plasma" is the liquid part of human blood collected by plasmapheresis for

O L R P U B L I C A C T S U M M A R Y

use as a source material for further manufacturing use. It does not include single donor plasma products for intravenous use (CGS § 19a-490).

Responsible Physicians

Under federal regulation, a “responsible physician” is someone who is (1) licensed to practice medicine in the jurisdiction where the facility is located; (2) adequately trained and qualified to direct staff and relevant procedures (e.g., donor eligibility, blood collection, and apheresis); and (3) designated by a source plasma center or blood collection facility to perform these activities (21 C.F.R. § 630.3).