
OLR Bill Analysis

sSB 368 (File 300, as amended by Senate "A")*

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 for source plasma donation centers and blood collection facilities established by PA 23-31.

This bill eliminates current 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 bill, the commissioner must update DPH policies and procedures by October 1, 2024, to include the bill'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 bill exempts someone who performs apheresis on a healthy donor to collect blood or its components from needing a nursing license. 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 bill, "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.

*Senate Amendment “A” replaces the underlying bill and (1) allows responsible physicians to direct the facilities and (2) makes a minor change to the definition of “apheresis.” It also eliminates the requirement that DPH amend its regulations to have the same requirements as federal law and regulation on source plasma center staff supervision, training, and duties.

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 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).

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute

Yea 37 Nay 0 (03/20/2024)