OLR Bill Analysis sSB 368

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 (1) allow source plasma donation centers to designate licensed physicians as directors of these centers and (2) have the same requirements in federal law and regulation on source plasma donation center staff supervision, training, and duties.

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 for transfusion 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

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to the donor by transfusion. 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

Source Plasma Donation Centers

By law, 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).

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute Yea 37 Nay 0 (03/20/2024)