



Senate

General Assembly

File No. 300

February Session, 2024

Substitute Senate Bill No. 368

Senate, April 8, 2024

The Committee on Public Health reported through SEN. ANWAR of the 3rd Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING SOURCE PLASMA DONATION CENTERS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. Subsection (b) of section 19a-565 of the 2024 supplement to
2 the general statutes is repealed and the following is substituted in lieu
3 thereof (*Effective from passage*):

4 (b) The Department of Public Health shall adopt regulations, in
5 accordance with the provisions of chapter 54, governing clinical
6 laboratories, blood collection facilities and source plasma donation
7 centers. Such regulations shall establish reasonable standards for
8 entities exempt from licensure as a clinical laboratory, operations and
9 facilities, personnel qualifications and certification, levels of acceptable
10 proficiency in testing programs approved by the department, the
11 collection, acceptance and suitability of specimens for analysis and such
12 other pertinent laboratory functions, including the establishment of
13 advisory committees, as may be necessary to ensure public health and
14 safety. Such regulations shall (1) allow source plasma donation centers
15 to designate physicians, licensed pursuant to chapter 370, as directors of

16 such facilities, and (2) for source plasma donation centers, have the same
 17 requirements as set forth in federal laws and regulations governing
 18 source plasma donation center staff supervision, training and duties,
 19 and shall not include a requirement that a registered nurse or advanced
 20 practice registered nurse licensed under chapter 378 be onsite during
 21 the hours of operation of a blood collection facility or source plasma
 22 donation center. On or before October 1, 2023, the [Commissioner of
 23 Public Health] commissioner shall implement policies and procedures
 24 necessary to administer the provisions of this section while in the
 25 process of adopting such policies and procedures as regulations,
 26 provided the department posts such policies and procedures on the
 27 eRegulations System prior to adopting them. On or before October 1,
 28 2024, the commissioner shall update the department's policies and
 29 procedures to include policies and procedures consistent with the
 30 provisions of subdivisions (1) and (2) of this subsection. Policies and
 31 procedures implemented pursuant to this section shall be valid until
 32 final regulations are adopted in accordance with the provisions of
 33 chapter 54.

34 Sec. 2. (NEW) (*Effective from passage*) Notwithstanding any provision
 35 of chapter 368v or 378 of the general statutes, a person performing
 36 apheresis on a healthy donor for the purpose of collecting blood or
 37 blood components for transfusion need not be licensed pursuant to
 38 chapter 378 of the general statutes, provided such person performs such
 39 procedure in accordance with federal and state regulations. For the
 40 purposes of this section, (1) "apheresis" means a process by which blood
 41 is drawn from a donor and separated into its components, one or more
 42 of which is retained, with the remainder returned by transfusion to the
 43 donor, and (2) "donor" means a person who (A) donates blood or blood
 44 components for therapeutic use or further manufacturing use, or (B)
 45 presents as a potential candidate for such donation.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>from passage</i>	19a-565(b)

Sec. 2	<i>from passage</i>	New section
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PH *Joint Favorable Subst.*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note**State Impact:** None**Municipal Impact:** None**Explanation**

The bill makes various changes to statutes concerning source plasma donation centers and blood collection facilities that are not anticipated to result in a fiscal impact to the state or municipalities.

The Out Years**State Impact:** None**Municipal Impact:** None

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 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)