



Substitute Senate Bill No. 368

Public Act No. 24-7

AN ACT CONCERNING SOURCE PLASMA DONATION CENTERS.

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

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 Subsection (b) of section 19a-565 of the 2024 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(b) The Department of Public Health shall adopt regulations, in accordance with the provisions of chapter 54, governing clinical laboratories, blood collection facilities and source plasma donation centers. Such regulations shall establish reasonable standards for entities exempt from licensure as a clinical laboratory, operations and facilities, personnel qualifications and certification, levels of acceptable proficiency in testing programs approved by the department, the collection, acceptance and suitability of specimens for analysis and such other pertinent laboratory functions, including the establishment of advisory committees, as may be necessary to ensure public health and safety. Such regulations shall [include a requirement that a registered nurse or advanced practice registered nurse licensed under chapter 378 be onsite during the hours of operation of a blood collection facility or source plasma donation center] provide that a responsible physician, as defined in 21 CFR 630.3, as amended from time to time, may serve as the director of a blood collection facility or source plasma donation

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center. On or before October 1, 2023, the Commissioner of Public Health shall implement policies and procedures necessary to administer the provisions of this section while in the process of adopting such policies and procedures as regulations, provided the department posts such policies and procedures on the eRegulations System prior to adopting them. On or before October 1, 2024, the commissioner shall update the department's policies and procedures to include policies and procedures consistent with the provisions of this subsection. Policies and procedures implemented pursuant to this section shall be valid until final regulations are adopted in accordance with the provisions of chapter 54.

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

Approved May 9, 2024