



General Assembly

February Session, 2024

Raised Bill No. 368

LCO No. 2698



Referred to Committee on PUBLIC HEALTH

Introduced by:
(PH)

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2 the general statutes is repealed and the following is substituted in lieu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.

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

Statement of Purpose:

To require the Commissioner of Public Health to (1) adopt regulations allowing source plasma donation centers to (A) designate physicians as directors of such centers, and (B) collect source plasma through plasmapheresis, provided such centers comply with federal laws and regulations governing source plasma collection; and (2) update the department's policies and procedures concerning source plasma donation centers.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]