

**Proposed Substitute
Bill No. 368**

February Session, 2024

LCO No. 3231

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2 the general statutes is repealed and the following is substituted in lieu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