



General Assembly

Amendment

February Session, 2024

LCO No. 4550



Offered by:

SEN. ANWAR, 3rd Dist.
REP. MCCARTHY VAHEY, 133rd Dist.
SEN. SOMERS, 18th Dist.
REP. KLARIDES-DITRIA, 105th Dist.

To: Subst. Senate Bill No. 368

File No. 300

Cal. No. 217

"AN ACT CONCERNING SOURCE PLASMA DONATION CENTERS."

1 Strike everything after the enacting clause and substitute the
2 following in lieu thereof:

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4 to the general statutes is repealed and the following is substituted in lieu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

6 (b) The Department of Public Health shall adopt regulations, in
7 accordance with the provisions of chapter 54, governing clinical
8 laboratories, blood collection facilities and source plasma donation
9 centers. Such regulations shall establish reasonable standards for
10 entities exempt from licensure as a clinical laboratory, operations and
11 facilities, personnel qualifications and certification, levels of acceptable
12 proficiency in testing programs approved by the department, the

13 collection, acceptance and suitability of specimens for analysis and such
14 other pertinent laboratory functions, including the establishment of
15 advisory committees, as may be necessary to ensure public health and
16 safety. Such regulations shall [include a requirement that a registered
17 nurse or advanced practice registered nurse licensed under chapter 378
18 be onsite during the hours of operation of a blood collection facility or
19 source plasma donation center] provide that a responsible physician, as
20 defined in 21 CFR 630.3, as amended from time to time, may serve as
21 the director of a blood collection facility or source plasma donation
22 center. On or before October 1, 2023, the Commissioner of Public Health
23 shall implement policies and procedures necessary to administer the
24 provisions of this section while in the process of adopting such policies
25 and procedures as regulations, provided the department posts such
26 policies and procedures on the eRegulations System prior to adopting
27 them. On or before October 1, 2024, the commissioner shall update the
28 department's policies and procedures to include policies and
29 procedures consistent with the provisions of this subsection. Policies
30 and procedures implemented pursuant to this section shall be valid
31 until final regulations are adopted in accordance with the provisions of
32 chapter 54.

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