

Date of Hearing: May 21, 2025

ASSEMBLY COMMITTEE ON APPROPRIATIONS

Buffy Wicks, Chair

AB 725 (Solache) – As Amended May 1, 2025

Policy Committee: Health

Vote: 16 - 0

Urgency: No

State Mandated Local Program: Yes

Reimbursable: No

SUMMARY:

This bill requires the California Department of Public Health (CDPH) establish a licensing and enforcement program for source plasma donation centers, with a licensing application fee amount sufficient to cover the reasonable costs of administering licensing and enforcement of plasma donation centers. The bill also requires the operator of a source plasma donation center to obtain a license from CDPH.

Specifically, this bill:

- 1) Sets minimum elements for the source plasma donation center license and requires CDPH to state grounds and reasons for refusal to approve of a license application within 60 days of the filing of the application.
- 2) Establishes various requirements for a plasma donation center, including criteria for personnel who may perform skin puncture and venipuncture, the types of tests the plasma donation center may run, and supervision by a licensed physician, among other provisions.
- 3) Allows a plasma donation center to offer payment to a donor, and makes various requirements relating to plasma donation, including requirements for identification of the donor, notifying the donor of various tests and risks, and requiring a registered nurse to conduct donor screening.
- 4) Authorizes CDPH to engage in specified activities, such as unannounced inspections, copying records, and taking photographs, to secure compliance with the provisions of this bill. Requires CDPH suspend or revoke a license for violations, as specified, and provides that a local prosecutor may prosecute a violation of the provisions of this bill.

For a more detailed enumeration of this bill's provisions, please refer to the Assembly Health Committee Analysis.

FISCAL EFFECT:

CDPH estimates costs of \$3.7 million for each of fiscal years (FY) 2027-28 and 2028-29 and \$2.53 million for FY 2029-30 and ongoing to implement the provisions of the bill. These costs include eight full-time equivalents (FTEs), promulgating regulations, and creating an information technology (IT) platform to set up the new Source Plasma Donation Centers facility license program (Clinical Laboratory Improvement Fund).

Costs include the Project Approval Lifecycle (PAL) planning process, which CDPH estimates will require approximately \$5.72 million and 17 months to complete. After the PAL process, CDPH states it will need two more years to implement the IT system.

While the bill specifies the licensing application fee will be in an amount sufficient to cover the reasonable costs of administering the licensing program, CDPH would incur significant costs before licensing fees could be collected.

CDPH recommends the implementation date be extended to January 1, 2029, as the system will not be operational until then.

COMMENTS:

- 1) **Purpose.** This bill is sponsored by Plasma Protein Therapeutics Association. According to the author:

The regulatory framework surrounding source plasma donation centers has not been updated since the 1990s despite significant advancement in donation methods. As a result, regulations no longer reflect current technology, creating unnecessary burdens in the way of patient care. These outdated laws restrict the availability of source plasma, which is necessary for producing plasma-derived therapies. These therapies are essential for treating hundreds of thousands of people with rare and severe health conditions and are vital in critical-care settings.

AB 725 aims to streamline the licensing process for source plasma donation centers and update current law to reflect current practice.

- 2) **Background. Plasma.** Plasma is the largest component of blood, making up about 55% of its content. Plasma carries water, salts, and enzymes, as well as antibodies, clotting factors, and the proteins albumin and fibrinogen. The main role of plasma is to take nutrients, hormones, and proteins to the parts of the body that need it. Plasma also carries all parts of the blood through the circulatory system.

Therapeutic Uses of Plasma. Plasma can be separated and concentrated into various products. These products are then used as treatments for people suffering from immune deficiencies, burns, shock, trauma, and other medical emergencies. According to the sponsors, the use of medicine made from plasma is expected to increase due to a growing number of diagnoses, easier access to care, and improved coverage of medicines. Use of plasma-derived therapies to treat primary immune deficiencies increased in the U.S. by 67% from 2014 to 2020.

Regulation of Source Plasma Donation Centers. CDPH's Laboratory Field Services Biologics Program is responsible for licensing and investigation of community blood banks and collection centers, hospital blood banks, blood and blood components collection centers, cord blood banks and collection entities, and plasma collection centers. Source plasma donation centers are regulated as plasma collection centers. A source plasma collection center operates under a blood bank license and a clinical laboratory license, both valid for one year.

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