SENATE COMMITTEE ON HEALTH
Senator Akilah Weber Pierson, Chair

BILL NO: AB 2009
AUTHOR: Chen and Solache
VERSION: April 23, 2026
HEARING DATE: June 24, 2026
CONSULTANT: Reyes Diaz

SUBJECT: Blood banks and plasma centers

SUMMARY: Makes various updates in licensing provisions for plasma centers (PCs), including excluding PCs from blood bank licensing laws; eliminating requirements pertaining to blood transfusion principles and practices; modernizing the requirements for acceptable identification to be a plasma donor; allowing for other licensed health professionals to do pre-donor screenings; and, allowing for the continuity of PC operation when there are personnel changes.

Existing law:
1) Prohibits a person from engaging in the production of human whole blood or human whole blood derivatives unless the person is licensed by the California Department of Public Health (CDPH), and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with standards for all licensed blood banks (including PCs) and blood transfusion services in the state set by the American Association of Blood Banks and specified state regulations. [HSC §1602.5]

2) Requires blood to be processed into plasma only in blood banks adequately staffed and equipped for that purpose. Requires the individual directly in charge of plasma processing to be a licensed physician or an individual sufficiently trained in laboratory procedures relating to blood banking and plasma processing and whose qualifications have been approved by CDPH. Permits the staff to include other trained persons necessary for the proper operation of plasma processing. [17 CCR §1011]

3) Permits a person to perform a total protein test using a digital refractometer in a licensed PC, if CDPH, as part of its routine, fee-supported inspection of the licensed PC, including its review of personnel reports for licensed and unlicensed personnel and job descriptions of all center positions for a licensed plasma collection center, determines that specific conditions, such as education, training, and supervision, are met. [BPC §1246.7]

4) Requires each blood bank or PC to require as identification either a driver's license or other photographic identification issued by the Department of Motor Vehicles (DMV) from all donors of human whole blood or blood components who receive payment in return for the donation of that blood or blood components. [HSC §1603.2(a)]

5) Requires establishments that receive human whole blood and human whole blood derivatives specified by regulation and are not subject to licensure provisions for human whole blood, human whole blood derivatives, and other biologics, to be considered as blood bank depositories. Laboratory tests and other procedures with respect to the preparation of blood for transfusion are the sole responsibility of the blood bank depository. [HSC §1605]

6) Requires blood bank and PC licenses to be automatically revoked when there is a change of address, ownership, or person in charge of biologics production. Permits a new license to be secured for the new location, owner, or person in charge prior to the actual change if the contemplated change is in compliance with all the provisions of relevant existing law. [HSC §1615]

This bill:

1) Makes various updates to laws governing the operation of PCs and related licensing provisions that:
   a) Specify that "source plasma donation centers" are not blood bank depositories. Defines "source plasma donation centers" as a facility, other than a licensed blood bank, where source plasma is collected by plasmapheresis;
   b) Expands the forms of identification blood banks and PCs are required to obtain from all donors of human whole blood or blood components who receive payment for the donation to include identification issued by another state, federal agency, or tribal government. Permits CDPH to notify PCs of the acceptable forms of donor identification by means of a provider bulletin or notice, policy letter, or other similar instructions without taking regulatory action; and,
   c) Deletes the requirement that a PC license be automatically revoked upon a change in the person in charge of the PC. Requires a PC, if the person in charge of biologics production disassociates with it, to provide written notification to CDPH within 24 hours of the date of the disassociation and to submit, within 30 days, an amendment to the application designating a new person in charge.

2) Prohibits a licensee from operating without the supervision of a duly appointed person in charge of biologics production. If a new person in charge of biologics production is required, a qualified backup person in charge of biologics production, who has been approved for another center, including a center affiliated with the same or a different licensee, is required to assume immediate oversight of operations. This oversight is required to continue pending submission of the amendment designating the new person in charge of biologics production to, and approval by, CDPH.

3) Permits a licensee, if a person in charge of biologics production disassociates themselves with a licensed facility, to designate an interim person in charge for up to 30 calendar days if both of the following conditions are met:
   a) The interim designee satisfies the qualifications to be the person in charge of biologics production; and,
   b) Written notice is provided to CDPH of the interim designee's relevant information, qualifications, and anticipated duration of service.

4) Requires a license to be revoked if a replacement person in charge of biologics production is not designated within 30 days. Permits CDPH to provide an additional 30-day extension for good cause.

5) Permits a licensed PC's supervising physician to establish protocols for authorizing other licensed health care professionals acting within their scope of practice to perform donor screenings, predonation health screenings, and donor suitability assessments.

6) Permits a licensed PC's supervising physician to delegate to other licensed health care professionals the performance of health services duties that are both of the following:

a) Within the scope of practice of the licensed health care professional, as defined under that person's respective licensing act; and,
b) Performed under the supervision and protocols established by the supervising physician, consistent with facility policies and applicable federal requirements.

7) Specifies that 6) above does not expand the scope of practice of any licensed health care professional or limit the authority of CDPH to regulate PCs.

8) Adds to the list of conditions under which a person may perform a total protein test using a digital refractometer that the licensed PC's supervising physician or licensed clinical laboratory director has sufficient proficiency and knowledge with the use and supervision of digital refractometers in performing total protein tests. If the PC only performs services related to plasma collection, CDPH is prohibited from imposing additional unrelated experiential requirements for supervisors of PCs, including transfusion principles and transfusion practices.

FISCAL EFFECT: According to the Assembly Appropriations Committee, this bill results in costs of an unknown amount, potentially in the low- to mid-hundreds of thousands of dollars if CDPH needs to promulgate regulations and make changes to survey practices and instructions (Clinical Laboratory Improvement Fund). If CDPH does not require regulations, the costs would likely be lower.

PRIOR VOTES:

Assembly Floor:	77 - 0
Assembly Appropriations Committee:	15 - 0
Assembly Health Committee:	16 - 0

COMMENTS:

1) *Author's statement.* According to the author, California prides itself on being a leader in innovation and health care, but outdated laws are holding us back. This bill will improve our ability to collect source plasma efficiently and better meet the needs of patients who depend on these therapies every day. California is one of only ten states in the nation that does not collect enough plasma to meet the needs of its residents, forcing reliance on long, out-of-state supply chains for essential medicines. This bill brings California's policies into alignment with modern medical practice without compromising safety.

2) *Author's stated need for updates.* In background information provided by the author's office, it is stated that California currently applies a mix of laws written for other entities (blood banks for transfusion, clinical labs, etc.) to govern PCs. Some of these laws are from a time when source plasma donation was a manual process. The plasma donation process has been automated since the 1990s. As a result of these antiquated rules and regulations, California lags far behind other states when it comes to plasma donation. Even though California is the most populous state and the fourth largest economy in the world, California ranks 39th in the country in terms of per capita plasma donation. In fact, California only collects 80% of the plasma needed to meet the needs of its residents.

3) *Whole blood vs. plasma donation.* According to the Red Cross website, whole blood is simply the blood that flows through one's veins. It contains red cells, white cells, and

platelets, suspended in plasma. Whole blood is the most flexible type of donation and can be transfused in its original form, or used to help multiple people when separated into its specific components of red cells, plasma, and platelets. Every day, donations help save the lives of children and adults fighting to survive cancer, blood disorders, traumatic injuries, and more. During a plasma-only donation, blood is drawn from one arm and sent through a machine that collects plasma and returns red cells and platelets back to the donor, along with some saline. It takes only a few minutes longer than donating blood but can have a profound impact. Type AB plasma is the only universal type and can be given to patients of any blood type. Only 4% of the population has type AB blood. Plasma products are used by burn, trauma, and cancer patients.

4) *Prior legislation.* AB 725 (Solache of 2025) would have authorized a person to operate a source plasma donation center for the purpose of collecting source plasma upon the operator obtaining a license from CDPH. *AB 725 was held on the Assembly Appropriations Committee suspense file.*

   AB 392 (Nazarian, Chapter 429, Statutes of 2022) extends indefinitely the authorization for licensed PCs to utilize personnel, including unlicensed personnel, to perform a total protein test using a digital refractometer.

5) *Support.* The Plasma Protein Therapeutics Association, as sponsor, and other supporters state that this bill would modernize California's laws that regulate PCs, where human plasma is donated for the purpose of manufacturing plasma-derived therapies (PDTs). There are currently more than 60 PCs in the Golden State, providing between 3,000 and 6,000 high-paying jobs and injecting more than $300 million into local economies. Enactment of this bill would facilitate additional development of plasma collection in our state and, in doing so, ensure that the patients who depend on PDTs have reliable access to these lifesaving therapies.

6) *Need for consistent terminology.* This bill uses various terms to describe plasma centers, such as "source plasma donation center," "licensed plasma center," and "plasma center." As the sponsor of this bill indicated they and the author are still awaiting technical assistance from CDPH, the author may wish to address this inconsistency as the bill moves forward.

SUPPORT AND OPPOSITION:

Support: Plasma Protein Therapeutics Association (sponsor)
Bay Area Cancer Connections
Biocom
Bleeding Disorders Council of California
California Chronic Care Coalition
California Life Sciences Association
Center for Inherited Blood Disorders
Grifols, Inc.
Hereditary Angioedema Association
International Foundation for Autoimmune & Autoinflammatory Arthritis
Liver Coalition of San Diego
Neuropathy Action Foundation
Patient Advocates United in San Diego County
Plasminogen Deficiency Foundation
Takeda Pharmaceuticals America

Oppose: None received

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