
THIRD READING

Bill No: AB 2009
Author: Chen (R) and Solache (D), et al.
Amended: 8/13/26 in Senate
Vote: 21

SENATE HEALTH COMMITTEE: 11-0, 6/24/26

AYES: Weber Pierson, Valladares, Caballero, Durazo, Gonzalez, Grove,
Menjivar, Padilla, Pérez, Rubio, Smallwood-Cuevas

SENATE APPROPRIATIONS COMMITTEE: 7-0, 8/13/26

AYES: Cervantes, Seyarto, Cabaldon, Dahle, Grayson, Richardson, Wahab

ASSEMBLY FLOOR: 77-0, 5/26/26 - See last page for vote

SUBJECT: Blood banks and plasma centers

SOURCE: Plasma Protein Therapeutics Association

DIGEST: This bill 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 photographic 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 or ownership changes.

ANALYSIS:

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. [Health and Safety Code (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 California Code of Regulations (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. [Business and Professions Code (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 photographic 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, posting on CDPH’s website, 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 medical director.
- 3) Requires a license to be automatically revoked when there is a change of address, ownership, or the 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 of the contemplated change is in compliance with all the provisions of this bill’s provisions and regulations.
- 4) Prohibits CDPH from automatically revoking a PC’s license when there is a change of the person in charge of biologics production if: (1) The owner or the owner’s representative provides written notification of the change to CDPH within five days of the change that includes the name of the previous person in charge of biologics and their date of departure, the name and qualifications of the interim designee and anticipated duration of service, and the signature of the owner or owner’s representative; and (2) the licensee submits, within 30 days of

the change, the application for a new person in charge of biologics production pursuant to this bill's provisions.

- 5) Permits a licensed PC's medical director to establish protocols for authorizing other licensed health care professionals, as approved by CDPH, acting within their scope of practice to perform donor screenings, predonation health screenings, and donor suitability assessments.
- 6) Permits a licensed PC's medical director 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 approved by CDPH and as defined under that person's respective licensing act; and,
 - b) Performed under the supervision and protocols established by the medical director, consistent with facility policies and applicable state and 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 medical 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 medical directors of PCs, including transfusion principles and transfusion practices.
- 9) Requires PCs and their auxiliaries to be under the direction of a medical director or person in charge of biologics production who is both a licensed physician and has a minimum of three months of experience or training in PC methods and meets other applicable state and federal requirements.

Background

According to the author of this bill:

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.

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.

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.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: Yes

According to the Senate Appropriations Committee, unknown costs, potentially tens of thousands, for the California Department of Public Health (CDPH) for state administration (Clinical Laboratory Improvement Fund).

SUPPORT: (Verified 8/13/26)

Plasma Protein Therapeutics Association (source)
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

OPPOSITION: (Verified 8/13/26)

None received

ARGUMENTS IN 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.

ASSEMBLY FLOOR: 77-0, 5/26/26

AYES: Addis, Aguiar-Curry, Ahrens, Alanis, Alvarez, Arambula, Ávila Fariás, Bains, Bauer-Kahan, Bennett, Berman, Boerner, Bonta, Bryan, Calderon, Caloza, Carrillo, Castillo, Chen, Connolly, Davies, DeMaio, Dixon, Elhawary, Ellis, Flora, Fong, Gabriel, Gallagher, Garcia, Gipson, Jeff Gonzalez, Mark González, Hadwick, Haney, Harabedian, Hart, Hoover, Irwin, Jackson, Johnson, Kalra, Krell, Lackey, Lowenthal, Macedo, McKinnor, Nguyen, Ortega, Pacheco, Papan, Patel, Patterson, Pellerin, Petrie-Norris, Quirk-Silva, Ramos, Ransom, Michelle Rodriguez, Rogers, Blanca Rubio, Sanchez, Schiavo, Schultz, Sharp-Collins, Solache, Soria, Stefani, Ta, Tangipa, Valencia, Wallis, Ward, Wicks, Wilson, Zbur, Rivas

NO VOTE RECORDED: Lee, Muratsuchi, Celeste Rodriguez

Prepared by: Reyes Diaz / HEALTH / (916) 651-4111
8/17/26 10:47:34

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