CONCURRENCE IN SENATE AMENDMENTS
AB 2009 (Chen and Solache)
As Amended August 13, 2026
Majority vote

SUMMARY

Adds identification (ID) issued by another state, federal agency, or tribal government to the list additional acceptable ID a source plasma donation center is authorized to accept. Prohibits the Department of Public Health (DPH) from automatically revoking the plasma collection center's license when there is a change of the person in charge of biologics production if the owner or the owner's representative provides written notification of the change to DPH within 5 days of the change, as specified, and the licensee submits, within 30 days of the change, the application for a new person in charge of biologics production. Prohibits a licensee from operating without the supervision of a medical director.

Senate Amendments
Require plasma centers and their auxiliaries to be under the direction of a medical director or person in charge of biologics production who meets specified qualifications, including being a physician and surgeon and having a minimum of 3 months of experience or training in plasma center methods.

COMMENTS

Plasma is the liquid part of the blood that carries proteins, hormones and nutrients to the cells. Source plasma is collected by a method called plasmapheresis, through a method which involves drawing a donor′s blood and passing it through a machine that separates the plasma from other blood components (such red blood cells, white blood cells and platelets), and then returning these other blood components to the donor, while the plasma is collected and stored for medical use.

Source plasma is used for further manufacturing into medicines, such as treatments to address hemophilia, other bleeding disorders, certain immunodeficiencies, and shock and burns, among other conditions. According to the Plasma Protein Therapeutics Association (PPTA), the sponsor of this bill, there are currently more than 60 plasma donation centers in the state.

Plasma center regulations. Current law provides for automatic revocation of a biologics license when there is a change in ownership due to the health consequences of improper processing or handling of the blood or blood products. Any change in the licensed individual providing the oversight renders the license invalid. If DPH has concerns about the facility or its operations, the director and owners of the plasma collection center are responsible for addressing them and DPH must have knowledge of the individuals on file.

Donor Screenings. State and federal law require a physician to examine and certify that a donor is in good health within no more than one week prior to the initial plasmapheresis and requires a donor to have a physician examination by a licensed physician and surgeon at least once a year. This bill authorizes a licensed plasma collection center′s supervising physician and surgeon 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.

Distinction from Blood Bank Depositories. This bill specifies that plasma centers are not blood bank depositories. The author and sponsors state that there is a mix of statutes and regulations designed primarily for blood donation centers, resulting in inconsistent rules for plasma collection centers, and that this bill clarifies plasma centers are not blood bank depositories for the purposes of California′s biologics licensing laws. DPH states that plasma centers are not considered blood bank depositories currently. Blood bank depositories are designated as transfusion services and plasma collected in a plasma center does not qualify because it is collected from paid donors, which is prohibited for blood bank depositories under existing law. Licensees must follow the laws applicable to their relevant activities that are defined in state law. Plasma collected in plasma centers is not permitted for use in direct patient transfusion, therefore, DPH does not enforce the quality requirement for the storage and distribution of the collected material in plasma centers.

According to the Author
California prides itself on being a leader in innovation and health care, but outdated laws are holding us back. The author states that 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. The author concludes that this bill brings California′s policies into alignment with modern medical practice, without compromising safety.

Arguments in Support
PPTA is the sponsor of this bill and states that there have been reports that patients in need of plasma derived therapies (PDTs) medicines occasionally experience obstacles in accessing their therapies and that an expert panel of clinicians concluded it is imperative that the regulatory environment be improved to promote increased plasma donation. PPTA states that California is one of approximately a dozen states that requires source plasma centers to obtain a license, and the only state that requires two licenses, the biologics license (which includes a requirement for 6 months of blood bank experience) and a clinical laboratory license. PPTA continues that the existing regulatory framework is redundant, burdensome, and inappropriate for source plasma collection. PPTA **s**tates that because of these regulations, California lags far behind other states when it comes to plasma donation, ranking 39th in the country in terms of per capita plasma donation. PPTA states that other states have modified their regulatory landscape to increase investment, such as New York and Connecticut which have created unique licenses for source plasma donation centers recently and Pennsylvania exempted plasma donation centers from their clinical laboratory laws in 2024. PPTA states that this bill would reduce administrative burdens, eliminate inappropriate staffing requirements, and facilitate plasma collection in California, all while assuring the safety of donors and patients.

Arguments in Opposition
None on file.

FISCAL COMMENTS

According to the Senate Appropriations Committee, unknown costs, potentially tens of thousands, for DPH for state administration (Clinical Laboratory Improvement Fund).

VOTES:

ASM HEALTH: 16-0-0
YES: Bonta, Chen, Addis, Aguiar-Curry, Ahrens, Caloza, Carrillo, Mark González, Johnson, Patel, Patterson, Rogers, Sanchez, Schiavo, Sharp-Collins, Stefani

ASM APPROPRIATIONS: 15-0-0
YES: Wicks, Hoover, Aguiar-Curry, Calderon, Caloza, Dixon, Fong, Mark González, Krell, Pacheco, Pellerin, Sharp-Collins, Solache, Ta, Tangipa

ASSEMBLY FLOOR: 77-0-3
YES: Addis, Aguiar-Curry, Ahrens, Alanis, Alvarez, Arambula, Ávila Farías, 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
ABS, ABST OR NV: Lee, Muratsuchi, Celeste Rodriguez

UPDATED

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