

ASSEMBLY THIRD READING
AB 2009 (Chen and Solache)
As Amended April 23, 2026
Majority vote

SUMMARY

Adds identification (ID) issued by another state, federal agency or tribal government to the list of additional acceptable IDs a source plasma donation center is authorized to accept. Prohibits the State Department of Public Health (DPH) from imposing unrelated experiential requirements on supervisors of plasma donation centers, including transfusion principles and transfusion practices. Authorizes the plasma donation center's supervising physician and surgeon to delegate licensed health care professionals acting within their scope of practice to perform donor screenings, predonation health screenings, and donor suitability assessments. Changes the existing requirement for a license to be automatically revoked when there is a change of the person in charge of biologics production and establishes a new process to provide a licensee with time to submit an amendment to DPH designating a new person in charge of biologics production, as specified.

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 as 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.

How would this bill change how source plasma centers are regulated?

- 1) *Timelines for automatic revocation.* Current law is strict, providing 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, it is the director and owners of the plasma collection center who are responsible for addressing them and DPH must have knowledge of the individuals on file.

This bill allows a source plasma donation center licensee to notify DPH within 24 hours of the disassociation and gives the center a 30-day deadline to file an amendment of the existing license designating the new person in charge of biologics production. This bill also allows the source plasma donation center to appoint an interim designee that has been approved for another center. Under this bill, if the source plasma donation center fails to designate a new medical director within 30 days, the license is to be automatically revoked, with an authorization for DPH to provide a 30-day extension.

- 2) *Experiential Requirements.* State regulations require blood banks to be under the direction of a physician and surgeon duly licensed by the State of California, and who is required to have a minimum of six months experience in blood bank methods, transfusion principles, and transfusion practices, satisfactory to DPH.

State regulations define a blood bank as "a medical facility designed, equipped, and staffed to procure, to process, to store, or to distribute human whole blood or blood derivatives for transfusion purposes." PPTA contends that despite the fact that source plasma donation centers do not meet the definition of a blood bank (in that they do not collect whole blood or blood derivatives for transfusion purposes), they are currently being held to the experience requirements found in state regulations.

This bill prohibits DPH from imposing unrelated experiential requirements on source plasma donation centers, including transfusion principles and transfusion practices.

- 3) *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. The intent of this provision is to address staffing shortages associated with the shortage of healthcare professionals. Federal law authorizes responsible physicians to delegate activities related to determining the eligibility of a donor and documenting assessments related to that determination, except in specified circumstances relating to donors with certain blood pressure or pulse measurements outside specified limits and for certain more frequent donations.
- 4) *Donor ID.* Current law requires plasma centers to require as ID either a photographic driver's license or other photographic ID that is 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 the blood or blood components. This bill adds ID issued by another state, federal agency or tribal government to the list of acceptable ID a blood bank or plasma center is authorized to accept. In expanding the types of acceptable ID, the anticipated impact is a larger pool of donors.
- 5) *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, so this bill clarifies 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, so 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

The Plasma Protein Therapeutics Association (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 states 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 Assembly Committee on Appropriations, costs of an unknown amount, potentially in the low- to mid-hundreds of thousands of dollars if DPH needs to promulgate regulations and make changes to survey practices and instructions (Clinical Laboratory Improvement Fund). If DPH does not require regulations, the costs would likely be lower.

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

UPDATED

VERSION: April 23, 2026

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