

Date of Hearing: April 21, 2026

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2009 (Chen) – As Introduced February 17, 2026

SUBJECT: Blood banks and plasma centers.

SUMMARY: Exempts source plasma centers that hold biologics licenses from clinical laboratory licensure if they only perform digital protein refractometer tests. 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 State Department of Public Health (DPH) from imposing unrelated experiential requirements on supervisors of plasma donation centers. 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. Specifically, **this bill:**

- 1) Defines a “source plasma donation center” to mean a facility, other than a licensed blood bank, where source plasma is collected by plasmapheresis (a procedure in which blood is removed from a donor and plasma is separated from other blood components, further described in the Background below).
- 2) Specifies source plasma donation centers are not blood bank depositories.

Clinical Licensure

- 3) Exempts a source plasma donation center that holds a biologics license and is performing only a digital protein refractometer test (and no other test of moderate or high complexity classification under the federal Clinical Laboratory Improvement Amendments of 1988 or “CLIA”) from a clinical laboratory license.

Donor ID

- 4) 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.
- 5) Authorizes DPH to notify collection centers of the acceptable forms of ID by means of a provider bulletin or notice, policy letter or another similar instructions without taking regulatory action.

Experiential Requirements

- 6) Adds to the list of requirements for a person to perform a total protein test using a digital protein refractometer in 9) below that the licensed plasma collection center’s supervising physician and surgeon or licensed clinical laboratory director has sufficient proficiency and knowledge with the use and supervision of digital refractometers in performing total protein

tests. Prohibits DPH from imposing additional unrelated experiential requirements for supervisors of plasma donation centers (including, but not limited to, those required for the supervision of blood banks) if the plasma collection center only performs services related to plasma collection.

Donor Screenings

- 7) 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.
- 8) Authorizes a licensed plasma collection center's supervising physician and surgeon 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 and surgeon, consistent with facility policies and applicable federal requirements.
- 9) Specifies that this bill does not expand the scope of practice of any licensed health care professional or limit the authority of DPH to regulate source plasma collection facilities.

Operational Changes

- 10) 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 follows:
 - a) Requires, if a person in charge of biologics production disassociates with the licensed facility, the licensee to provide written notification to DPH within 24 hours of the date of the disassociation;
 - b) Gives the licensee a period of 45 days to submit an amendment to the application designating a new person in charge of biologics production;
 - c) Prohibits the licensee from operating without the supervision of a duly appointed person in charge of biologics production;
 - d) Requires 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) to assume immediate oversight of operations if a new person in charge of biologics production is required. Requires this oversight to continue pending submission of the amendment designating the new person in charge of biologics production to, and approval by, DPH;
 - e) Authorizes a licensee to designate an interim person in charge of biologics production for a period not to exceed 45 calendar days if a person in charge of biologics production

disassociates themselves with a licensed facility, if both of the following conditions are met:

- i) The interim designee otherwise satisfies the qualifications to be the person in charge of biologics production; and,
 - ii) Written notice is provided to DPH of the interim designee's relevant information, qualifications, and anticipated duration of service;
- f) Requires the license to be revoked if a replacement person in charge of biologics production is not designated within 45 days. Authorizes DPH to provide an additional 45-day extension for good cause.

EXISTING LAW:

State Law

- 1) Establishes the biologics license which is required for persons engaging in the production of biologics (which includes human whole blood and whole blood derivatives offered for sale or distribution for the treatment of disease) requires the application for licenses to contain at least the following:
 - a) The name and address of the person owning the place, establishment, or institution in which biologics production is planned;
 - b) The name and address of the person to be in charge of biologics production;
 - c) The types of biologics to be produced;
 - d) A full description of the building, its location, facilities, equipment, and apparatus to be used in biologics production;
 - e) The name and address of each blood collection center operated by the applicant and whether the applicant operates any mobile units; and,
 - f) Any additional information as DPH may require. [Health and Safety Code (HSC) § 1602.5; HSC § 1613]
- 2) Specifies in regulation that blood banks and their auxiliaries are required 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. [Title 17, California Code of Regulations (CCR) § 998]
- 3) Specifies in regulation that blood is required 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 and surgeon or an individual sufficiently trained in laboratory procedures relating to blood banking and plasma processing and whose qualifications have been approved by DPH. Authorizes the staff of a plasma center to include other trained persons necessary for the proper operation of plasma processing. [17 CCR § 1011]

- 4) Establishes in regulation requirements for plasmapheresis, including an examination that the donor is in good health by a duly licensed physician and surgeon and a determination of the donor's total protein (in the blood). [17 CCR § 1025]
- 5) Requires a license to be automatically revoked when there is a change of address, ownership, or person in charge of biologics production. Authorizes 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 regulations pertaining thereto. [HSC § 1615]
- 6) Requires blood banks or 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), as specified, 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]
- 7) Defines a "blood bank depository" to mean any place other than a blood bank where human whole blood and human whole blood derivatives specified by regulation are stored and held for transfusion. States that such blood bank depositories are clinical laboratories, as specified. [HSC § 1600.3]
- 8) Requires in regulation a laboratory or clinical laboratory receiving biological specimens to operate under a clinical laboratory license and with a current federal CLIA certificate. [22 CCR § 51211.2]
- 9) Specifies that a person is authorized to perform a total protein test using a digital protein refractometer if DPH determines that specified conditions are met, including specified education, training requirements, and supervision requirements. [Business and Professions Code § 1246.7]
- 10) Requires in regulation a laboratory or clinical laboratory receiving biological specimens to operate under a clinical laboratory license and a current federal CLIA certificate. [22 CCR § 51211.2]

Federal Law

- 1) Establishes the current good manufacturing practice requirements for the collection, processing, compatibility testing, storage, distribution of blood and blood components, as provided. [Title 21, Code of Federal Regulations (CFR) § 606]
- 2) Establishes minimum criteria for each donation of blood and blood components, for the following:
 - a) Determining the eligibility of a donor of blood and blood components;
 - b) Determining the suitability of the donation of blood and blood components; and
 - c) Notifying a donor who is deferred from donation. [Title 21, CFR § 630]
- 3) Specifies that the responsible physician is authorized to delegate the determination of the eligibility of a donor and documenting assessments relate to that donor (except in specified circumstances) as well as other activities to a trained person who is adequately trained and

experienced to do so and to recognize and respond to the adverse responses associated with blood collection procedures.

- 4) Establishes requirements for the collection of blood for source plasma, including processing, manufacturing responsibility, records, reporting, and the modification of source plasma. [21 CFR § 640, *et seq.*]
- 5) Establishes the minimum current good manufacturing practice requirements for the preparation of drug products for administration to humans or animals. [21 CFR § 211]
- 6) Establishes CLIA which includes federal standards applicable to all United States facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease, as provided. [Title 42, United States Code § 263a]
- 7) Establishes in regulation the conditions laboratories are required to meet to be certified to perform testing under CLIA. [42 CFR § 493, *et seq.*]
- 8) Establishes requirements for the federal biologics license application. Requires a supplement (to the license application) to be submitted for any change in the product, production process, quality controls, equipment, facilities, or responsible personnel that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product within 30 days. [21 CFR § 601]

FISCAL EFFECT: Unknown. This bill has not been analyzed by a fiscal committee.

COMMENTS:

- 1) **PURPOSE OF THIS BILL.** 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.
- 2) **BACKGROUND.** 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.

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

- i) 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 45-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 45 days, the license is to be automatically revoked, with an authorization for DPH to provide a 45-day extension.

- ii) 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, but does not specify what those requirements are.

- iii) CLIA.** Under the federal CLIA law, labs that perform tests on human specimens must be certified by the Centers for Medicare and Medicaid Services. The requirements for CLIA certification vary depending on the complexity of the laboratory tests performed. The three complexities are waived, moderate, and high complexity. In general, the more complicated the test, the more stringent the requirements under CLIA.

Under California law, all laboratory tests classified under CLIA must be performed by personnel specified in statute under the overall operation and administration of a laboratory director, with limited exceptions.

- iv) Addressing Dual Licensure.** Plasma collection centers must have a license from DPH for the production of biologics, a clinical laboratory license from DPH, and a federal CLIA certificate.

Plasma centers are required to hold a clinical laboratory license because they use a digital refractometer to measure a donor's total protein. Digital refractometers are laboratory instruments that measure how lights bends, or refracts, as it passes through a liquid sample. This bending is directly related to the concentration of dissolved substances within that liquid. For the purpose of total protein measurements, refractometers offer a rapid method to assess protein levels in blood samples.

The author and sponsors contend that although this device is classified by the federal Food and Drug Administration (FDA) as a "moderate complexity test," it is simple to use, requires no independent judgment, and is not used to diagnose or treat disease, thus requiring a state clinical laboratory license is therefore unnecessary and duplicative.

According to DPH, total protein testing is required by state and federal law and is performed prior to plasma donation to ensure donor safety and verify blood quality by screening for underlying health issues like liver/kidney disease, malnutrition, or infection. Tests or examinations intended to assess the health of an individual are considered a clinical laboratory test under state and federal law. The FDA considers the total protein refractometer a "moderate complexity" device under CLIA. Facilities are required to obtain a clinical laboratory license from DPH to perform moderate complexity tests.

- v) **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.
- vi) **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 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.
- vii) **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.

- 3) 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.
- 4) PREVIOUS LEGISLATION.**
- a) AB 725 (Solache) of 2025 would have authorized a person to operate a source plasma donation center for the purpose of collecting source plasma, as defined. Would have authorized a source plasma donation center to offer payment to a donor of money or other valuable consideration. Would have required the operator of a source plasma donation center to obtain a license from DPH as specified. Would have authorized DPH to regulate source plasma donation centers, including to inspect the property or records of the center and to suspend or revoke a license for violation of specified law or regulation. Would have authorized DPH to promulgate any regulations it deems necessary to implement the bill's provisions. AB 725 was held on the Assembly Appropriations suspense file.
 - b) AB 392 (Nazarian), Chapter 429, Statutes of 2022 extends indefinitely the authorization for licensed plasma collection centers to utilize personnel, including unlicensed personnel, to perform a total protein test using a digital refractometer.
- 5) POLICY COMMENTS.** The bill prohibits DPH from imposing “unrelated experiential requirements on source plasma donation centers (including, but not limited to, those required for the supervision of blood banks) if the plasma collection center only performs services related to plasma collection, but does not specify what these “unrelated experiential requirements” are. The author and sponsors highlight that these requirements refer to the requirement for blood bank directors to have six months of blood bank experience as well as

experience in transfusion related practices. As this bill moves forward, the author is encouraged to work with DPH on amendments that strike the appropriate balance between ensuring that the licensed blood bank's supervising physician and surgeon has the appropriate level of experience for the role that they perform within a source plasma donation center.

6) AMENDMENTS.

- a) **Experiential Requirements.** Given that transfusion does not occur within source plasma donation centers, the Committee may wish to amend this bill to specify that the unrelated experiential requirements include training on transfusion principles and transfusion practices.
- b) **Timeline for License Amendments for Changes of the Person in Charge.** Federal law as described in 8) of Existing Law requires facilities to provide a supplement to their biologics license application for specific types of changes, including responsible personnel, within 30 days. For better alignment with federal law, the Committee may wish to amend this bill to give the licensee a period of 30 days to submit an amendment to the application designating a new person in charge of biologics production prior to license revocation and make conforming changes for the amount of time the interim designee can serve and authorize DPH to give a 30-day extension for good cause.
- c) **Clinical Laboratory Licensure.** Given that total protein testing is used in source plasma donation centers to assess the health and safety of an individual and is considered a clinical laboratory test under state and federal law, the Committee may wish to amend this bill to remove the exemption for clinical laboratory licensure and make a related conforming change.

REGISTERED SUPPORT / OPPOSITION:

Support

Plasma Protein Therapeutics Association (sponsor)
 AiArthritis
 Bay Area Cancer Connections
 Biocom
 Bleeding Disorders Council of California
 California Life Sciences Association
 Center for Inherited Blood Disorders (CIBD)
 Grifols, INC.
 Hereditary Angioedema Association (HAEA)
 Liver Coalition of San Diego
 Neuropathy Action Foundation
 Patient Advocates United in San Diego County
 Plasminogen Deficiency Foundation
 Takeda Pharmaceuticals America

Opposition

None on file

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