

Date of Hearing: May 6, 2026

ASSEMBLY COMMITTEE ON APPROPRIATIONS

Buffy Wicks, Chair

AB 2009 (Chen) – As Amended April 23, 2026

Policy Committee: Health

Vote: 16 - 0

Urgency: No

State Mandated Local Program: Yes

Reimbursable: No

**SUMMARY:**

This bill makes various changes to statutes governing the operation of source plasma donation centers.

The changes include distinguishing a plasma donation center from a blood bank repository, authorizing a plasma donation center's supervising physician to delegate specified activities to other licensed health care professionals, establishing a process to provide a licensee with time to designate an interim person in charge of biologics production, and adding types of identification accepted. Specifically, this bill:

- 1) Adds identification issued by another state, federal agency, or tribal government to the list of acceptable identification a blood bank or plasma center is authorized to accept.
- 2) Authorizes the California Department of Public Health (CDPH) to notify plasma collection centers of the acceptable forms of identification by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.
- 3) Requires a plasma collection center's supervising physician or clinical laboratory director have sufficient proficiency and knowledge with the use and supervision of digital refractometers in performing total protein tests, if a person performs a total protein test using a digital protein refractometer.
- 4) Prohibits CDPH from imposing unrelated experiential requirements for supervisors of plasma donation centers if the plasma collection center performs only plasma collection.
- 5) Authorizes a licensed plasma collection center's supervising physician to establish protocols for authorizing other licensed professionals acting within their scope of practice to perform donor screenings, pre-donation health screenings, and donor suitability assessments.
- 6) Authorizes a licensed plasma collection center's supervising physician to delegate to other licensed health care professionals the performance of health services duties that are within the scope of practice of the licensed health care professional and performed under the supervision and protocols established by the supervising physician.
- 7) 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 instead establishes a new process to provide a licensee with time to submit to CDPH an amendment designating a new person in charge of biologics production, as follows:

- a) Requires a licensee to provide written notification to CDPH within 24 hours if a person in charge of biologics production disassociates with the facility.
- b) Allows a licensee a period of 30 days to submit an amendment to the application designating a new person in charge of biologics production.
- c) Prohibits a 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, CDPH.
- e) Authorizes a licensee to designate an interim person in charge of biologics production for a period not to exceed 30 calendar days if a person in charge of biologics production disassociates themselves with a licensed facility and the interim designee otherwise satisfies the qualifications to be the person in charge of biologics production; and the facility notifies CDPH of the interim designee's relevant information, qualifications, and anticipated duration of service.
- f) Requires CDPH to revoke a license if the facility does not designate a replacement person in charge of biologics production within 30 days.
- g) Authorizes CDPH to provide an additional 30-day extension for good cause.

**FISCAL EFFECT:**

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.

**COMMENTS:**

- 1) **Purpose.** This bill is sponsored by Plasma Protein Therapeutics Association. According to the author:

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) **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, 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.

- 3) **Prior Legislation.** AB 725 (Solache), of the current legislative session, took a different approach in attempting to address plasma collection centers. AB 725 would have authorized CDPH to regulate source plasma donation centers, including inspecting the property or records of the center and suspending or revoking a license for violation of a law or regulation. AB 725 was held on this committee's suspense file.

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