Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 725 (Solache) – As Introduced February 18, 2025

**SUBJECT**: Source plasma donation.

**SUMMARY**: Authorizes a person to operate a source plasma donation center for the purpose of collecting source plasma, as defined. Authorizes a source plasma donation center to offer payment to a donor of money or other valuable consideration. Requires the operator of a source plasma donation center to obtain a license from the State Department of Public Health (DPH), as specified. Authorizes 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. Authorizes DPH to promulgate any regulations it deems necessary to implement the bill's provisions. Specifically, **this bill**:

**Donations**

1) Authorizes, notwithstanding any other provision of law, a person to operate a source plasma donation center for the purpose of collecting source plasma if they are licensed under this bill and the source plasma is collected in accordance with this bill.

2) Exempts a source plasma donation center that is licensed pursuant to this bill is exempt from licensure as described in existing law 3) below.

3) Authorizes a source plasma donation center to offer payment to a donor of money or any other valuable consideration that can be converted to money by the recipient in return for the donation of source plasma.

4) Requires a source plasma donation center to require a donor of source plasma who receives payment in exchange for the donation of source plasma to provide photographic driver's license or other photographic identification that is issued by the Department of Motor Vehicles, or other acceptable identification issued by any other state or federal government agency, or tribal government, as specified in regulation.

5) Requires, before a donor donates source plasma for the first time, a source plasma donation center to do all of the following:

    a) Require the donor to complete a donor history questionnaire recognized by the United States Food and Drug Administration;

    b) Advise the donor of the risks and hazards of plasmapheresis and obtain informed consent from the donor;

    c) Notify the donor in writing and obtain a written statement confirming the notification that each donation will be tested for evidence of relevant transfusion-transmitted infections;

    d) Notify the donor in writing that the test results may result in the donor being deferred from future donations and being placed on the National Donor Deferral Registry; and,

e) Require a registered nurse to conduct a donor screening examination of the donor.

6) Requires a source plasma donation center to prominently display at each of its donation sites a notice that provides the addresses and telephone numbers of sites, within the proximate area of the source plasma donation center, where anonymous HIV antibody testing provided pursuant to existing law may be administered without charge.

7) Prohibits, notwithstanding any other provision of law, civil liability or criminal sanction from being imposed for disclosure of test results to a local health officer if the disclosure is necessary to locate and notify a plasma donor of a reactive result to HIV antibody testing if reasonable efforts by the source plasma donation center to locate the donor have failed.

8) Requires, upon completion of the local health officer's efforts to locate and notify a source plasma donor of a reactive result to HIV antibody testing, all records obtained from the source plasma donation center pursuant to this subdivision, or maintained pursuant to this subdivision, including, but not limited to, any individual identifying information or test results, to be expunged by the local health officer.

9) Prohibits, notwithstanding existing law 8) below, or any other provision of law, any public entity or any private source plasma donation center from being liable for an inadvertent, accidental, or otherwise unintentional disclosure of the results of an HIV test.

10) Provides that a "public entity" includes, but is not limited to, any publicly owned or operated source plasma donation center, local health officer, and DPH.

11) Prohibits DPH or any source plasma donation center, including a source plasma donation center owned or operated by a public entity or a local health officer, from being held liable for any damage resulting from the disclosure of test results obtained pursuant to 6) above.

12) Provides that the procurement, processing, distribution, or use of source plasma is the provision of a service by a person, firm, or corporation rather than a sale of source plasma.

**Administration of Source Plasma Donation Centers**

13) Authorizes, notwithstanding any other law, personnel who are explicitly authorized by the source plasma donation center and who meet the education, training, and competency standards of the source plasma donation center to obtain a predonation health history and perform predonation screening, including nondiagnostic general health assessments for which blood collection is performed by skin puncture.

14) Requires when unlicensed personnel perform the duties described in 13) above, the review of work required by federal regulations described in 27) and 28) of existing law below to be performed by a staff member who is a licensed health care professional.

15) Requires, notwithstanding any other law, a licensed clinical laboratory bioanalyst, a licensed clinical laboratory technologist, a registered clinical laboratory technologist trainee, a licensed vocational nurse, a registered nurse, a blood donor phlebotomist, as defined by the American Association of Blood Banks, or a source plasma donor phlebotomist may perform skin puncture and venipuncture for the purposes of collecting human source plasma.

16) Requires the actions described in 13) and 15) above to be performed under both of the following conditions:

    a) In a source plasma donation center licensed pursuant to this chapter and according to standard operating procedures approved by the United States Food and Drug Administration.

    b) Under the general supervision of a licensed physician and surgeon. Requires the licensing and registration to be pursuant to the Business and Professions Code.

    c) Authorizes, notwithstanding 14) above, source plasma to be collected at a source plasma donation center when a physician or surgeon is not physically present on the premises. Authorizes the physician and surgeon to delegate the general supervision duties to a registered nurse, but requires the physician and surgeon to remain responsible for ensuring that all those duties and responsibilities are properly performed.

17) Requires a source plasma donation center to have a medical director.

18) Requires, notwithstanding any other provision of law, the medical director to meet the definition in 47) b) below and be designated in the source plasma donation center license as the medical director.

19) Authorizes, notwithstanding any other provision of law, a source plasma donation center to employ a person to perform total protein tests using a digital refractometer pursuant to 19) of existing law below.

20) Exempts, notwithstanding any other provision of law, a source plasma donation center performing only a total protein test using a digital total protein refractometer classified as a moderate complexity test and performing no other test of a moderate or high complexity classification under the Clinical Laboratory Improvement Amendments in 29) of existing law below from licensure as a clinical laboratory.

21) Authorizes, notwithstanding any other provision of law, a person who has attained the age of 18 to consent to the donation of their source plasma and to the penetration of tissue necessary to accomplish a source plasma donation, and a licensed source plasma donation center may accept the donation and compensate the donor for the donation pursuant to 3) above.

22) Provides this bill does not repeal or in any manner affect any provision of the Business and Professions Code (BPC) relating to the practice of medicine.

**Licenses**

23) Requires DPH develop a form for the application for a source plasma donation center license issued pursuant to this chapter. Requires the form to contain, at a minimum, all of the following:

    a) The name and address of the person owning the place, establishment, or institution in which source plasma donation or production is planned;

    b) The name and address of the medical director who will be in charge of the production of source plasma;

c) A full description of the building, its location, facilities, equipment, and apparatus to be used in source plasma production;

d) The name and address of each source plasma donation center operated by the applicant within this state; and,

e) Any additional information as DPH may require by regulation.

24) Requires, if DPH does not, within 60 days after the filing of the application, issue a license, DPH to state the specific grounds and reasons for its refusal in writing and serve a copy upon the applicant. Requires, if DPH does not issue its written refusal of the application for the license within this period, the application to be deemed approved and a license issued following expiration of the 60-day application review period. Authorizes the notice of refusal to be served by registered mail addressed to the applicant at their last known address.

25) Provides that a license is subject to revocation of the license if there is a change of address, ownership, or the person in charge of source plasma production.

26) Authorizes a licensee to request an amendment of an existing license for a change of medical director of the source plasma donation center if the request is submitted within 30 days of the change of address, ownership, or the person in charge and the proposed change is in compliance with all the provisions of this chapter.

27) Requires, in the event the medical director of a source plasma donation center disassociates from the licensed source plasma donation center, the licensee to, within 24 hours of the date of the disassociation, notify DPH in writing of the disassociation.

28) Requires the licensee replace the medical director within 45 days.

29) Requires, in order to replace the medical director, the licensee to file an application for amendment of the existing license in the manner prescribed by DPH designating the new medical director.

30) Requires, upon failure of the licensee to submit an application to DPH naming the new medical director within 45 days of the disassociation date of the former medical director, the license for the source plasma donation center to be automatically revoked.

31) Authorizes a new license to be secured for a new location, owner, or person in charge prior to the actual change if the contemplated change is in compliance with all the provisions of this chapter and relevant regulations.

32) Authorizes license to be denied for any reason applicable to the revocation and suspension of licenses.

33) Requires proceedings for the denial of a license or a license amendment to be conducted in accordance with 7) of existing law below.

34) Requires each application for a license, a license amendment, or a license renewal pursuant to this chapter to be accompanied by a fee determined by the director in regulation and in an amount sufficient to cover the reasonable cost of administering this chapter, but not to exceed those costs, as specified pursuant to Section 1633.4.

35) Requires DPH to receive and account for all moneys received pursuant to this chapter and deposit them with the State Treasurer for deposit in the Clinical Laboratory Improvement Fund established pursuant to 14) of existing law below.

36) Requires all funds received pursuant to this chapter to, be expended to administer this chapter, upon appropriation by the Legislature.

37) Requires each license issued under this chapter to expire 24 months from the date of its issuance. Application for renewal of license accompanied by the fee to be filed with DPH not less than 10 days prior to its expiration. Requires failure to make a timely renewal to result in expiration of the license.

38) Clarifies that source plasma collection centers are not blood bank depositories pursuant to 15) of existing law below.

**Enforcement**

39) Requires DPH to implement the provisions of this bill.

40) Authorizes, in order to carry out this chapter, a duly authorized representative of the DPH to do any of the following:

    a) Enter or inspect on an announced or unannounced basis any building, premise, equipment, materials, records, or information at any reasonable time to secure compliance with, or prevent a violation of, this bill or the regulations adopted pursuant to this bill.

    b) Inspect, photograph, or copy any records, reports, test results, test specimens, or other information related to the requirements of this chapter or the regulations adopted pursuant to this chapter.

    c) Secure any sample, photograph, or other evidence from any building or premise for the purpose of enforcing this chapter or the regulations adopted pursuant to this bill.

41) Requires a license to be suspended or revoked by DPH for the violation of any provision of this bill, or of any rule or regulation made by DPH adopted pursuant to this chapter. The proceedings shall be conducted in accordance with 7) of existing law below.

42) Authorizes a district or city attorney to prosecute a violation of this chapter upon evidence of a violation within their respective jurisdictions submitted by DPH.

43) States the intent of the Legislature that this chapter does not conflict with the Sherman Food, Drug, and Cosmetic Law. All provisions of that division to apply to source plasma within the meaning of this bill.

44) States that this bill does not apply to products of either of the following:

    a) A laboratory licensed by the Public Health Service, Department of Health and Human Services.

b) A laboratory licensed by the Animal and Plant Health Inspection Service, United States Department of Agriculture.

45) Provides that the violation of any provision of this bill is a misdemeanor punishable by a fine of not less than one hundred dollars ($100) nor more than one thousand dollars ($1,000), or by imprisonment for not more than 30 days, or by both.

46) Authorizes DPH may promulgate any regulations it deems necessary to implement this chapter.

**Definitions**

47) Defines the following for purposes of the bill:

a) "Department" to mean DPH.

b) "Medical director" to mean the California licensed physician and surgeon designated by the licensee to direct and control personnel and relevant procedures concerning the determination of donor eligibility, collection of source plasma, the immunization of a donor, and the return of red blood cells or other blood components to the donor during collection of source plasma by plasmapheresis.

c) "National Donor Deferral Registry" to mean the database of deferred plasma donors in North America owned by the Plasma Protein Therapeutics Association.

d) "Person" to mean any individual, blood bank, source plasma donation center, hospital, firm, corporation, or any other entity.

e) "Plasmapheresis" to mean a procedure in which, during a single visit to a source plasma donation center, blood is removed from a donor, the plasma separated from the formed elements, and at least the red blood cells are returned to the donor.

f) "Source plasma" to mean the fluid portion of human blood collected by plasmapheresis that is intended as source material for further manufacturing use. Specifies that "Source plasma" does not mean single donor plasma products intended for intravenous use.

g) "Source plasma donation center" to mean a facility, other than a licensed blood bank, where source plasma is collected by plasmapheresis.

h) "Source plasma donor phlebotomist" to mean a suitably qualified individual who has received appropriate training on venipuncture, blood sample collection, and collection of source plasma via automated plasmapheresis which has been approved by the medical director of the donation center.

**Fees**

48) Requires source plasma donation centers to pay fees to the Clinical Laboratory Improvement Fund, which is established within the State Treasury.

**EXISTING LAW**:

**State Law**

1) Defines "blood bank" to mean any place where human whole blood, and human whole blood derivatives specified by regulation, are collected, prepared, tested, processed, or stored, or from which human whole blood or human whole blood derivatives specified by regulation are distributed. [Health and Safety Code (HSC) § 1600.2]

2) Defines "blood collection center" to mean a stationary auxiliary to a blood bank which is designed, equipped, and staffed to procure human whole blood or blood components which are to be transported to the blood bank for processing, storing, and distribution. [HSC § 1600.21]

3) Provides for the licensure of the place, establish, or establishment in which biologics production is planned and 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 the department may require. [HSC § 1613]

4) Requires, if DPH does not within 60 days after the filing of the application issue a license, it shall state the grounds and reasons for its refusal in writing, serving a copy upon the applicant. Authorizes the notice to be served by registered mail addressed to the applicant at their last known address. [HSC § 1614]

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 the provisions of this chapter and regulations pertaining thereto. [HSC § 1615]

6) Requires proceedings for denial of license to be conducted in accordance with existing law below. [HSC § 1615]

7) Establishes, notwithstanding any other provision of law, procedures for proceedings that take place, whenever DPH is authorized or required by statute, regulation, due process, or a contract, to conduct an adjudicative hearing leading to a final decision of the director or DPH, as specified. [HSC § 100171]

8) Prohibits an individual from being compelled in any state, county, city, or other local civil, criminal, administrative, legislative, or other proceedings to identify or provide identifying characteristics that would identify any individual who is the subject of an HIV test, as specified. [HSC § 120975]

9) Requires the director of DPH to, in order to protect the public health and in order to make blood and blood components safe for transfusion, to designate counties that are required to establish alternative testing sites, within the funds available. Authorizes, when designating a county, the director to consider whether the county contains a permanent operational blood bank. Requires all alternative test sites to be under the supervision of a physician and surgeon or be a clinic or health facility licensed by DPH, as provided. [HSC § 120895]

10) Requires each county, designated by the director, to make testing for the presence of antibodies of the causative agent of acquired immune deficiency syndrome (AIDS) available within its jurisdiction without charge, in an accessible manner. Requires the tests to be made available by the county on an anonymous basis through use of a coded system with no linking of individual identity with the test request or results. Requires the number and location of sites in each county designated by the director to be approved by the director. The test shall be made available by the county either directly or by contract with a physician and surgeon or with any clinic or health facility licensed by the department. Prohibits the county and anyone else administering the test from asking for the name, social security number, or any other information that could reveal the identity of the individual who takes the test. Each alternative test site shall make available confidential information and referral services, within the funds available, to individuals who seek testing. Authorizes a county to subcontract with individuals or entities to provide information and referral services. [HSC § 120895]

11) Requires DPH to develop and annually review, and if necessary revise, a standardized written summary which explains the advantages, disadvantages, risks, and descriptions of autologous blood, and directed and nondirected homologous blood from volunteer donors. [HSC § 1645]

12) Requires a person engaged in the production of human whole blood or human whole blood derivatives to be licensed by the state, and requires licensed blood banks and blood transfusion services to meet specified standards. [HSC § 1600, *et. seq*]

13) Authorizes DPH to establish and require compliance with additional requirements, as specified. [HSC § 1602.5]

14) Establishes the Clinical Laboratory Improvement Fund and requires specified fees collected from the licensing and regulation of blood banks and blood transfusion services to be deposited in the fund, available upon appropriation, for the purpose of regulating blood banks and blood transfusion services. [Business and Professions Code (BPC) § 1302]

15) Requires specified establishments that receive specified human whole blood and derivatives to be considered blood bank depositories and require specified procedures on blood for transfusion to be the sole responsibility of the blood bank depository. [HSC § 1605]

16) Defines "clinical laboratory bioanalyst" or "bioanalyst" means a person licensed to engage in clinical laboratory practice and direction of a clinical laboratory, as provided. [BPC § 1203]

17) Defines a "vocational nurse", to mean a person who has met all the legal requirements for a license as a vocational nurse in this state and who for compensation or personal profit engages in vocational nursing, as provided. [BPC § 2859]

18) Defines "the practice of nursing" to mean those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems or the treatment thereof, and that require a substantial amount of scientific knowledge or technical skill, as specified. [BPC § 2725]

19) Authorizes a person to perform a total protein test using a digital refractometer in a licensed plasma collection center if DPH as part of its routine, fee-supported inspection of the licensed plasma collection center, as specified, determines that the person has earned a high school diploma or equivalent as determined by the federal Centers for Medicare and Medicaid Services and the person has training sufficient to determine that the individual has the required skills and abilities, as provided. [BPC § 1246.7]

20) Requires blood bank or plasma center shall require as identification either a photographic driver's license or other photographic identification that is issued by the Department of Motor Vehicles, 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]

21) Defines "payment" means the transfer by a blood bank or plasma center to any person of money or any other valuable consideration that can be converted to money by the recipient, except that payment does not include any of the following: Cancellation or refund of the nonreplacement fees or related blood or blood components transfusion charges; blood assurance benefits to a person as a result of a blood or blood components donation to a donor club or blood assurance program; and, time away from employment granted by an employer to an employee in order to donate blood or blood components. [*Ibid*.]

22) Requires, before donation of blood or blood components, a donor to be notified in writing of, and to have signed a written statement confirming the notification of, all of the following:

    a) That the blood or blood components is required to be tested for evidence of antibodies to HIV;

    b) That the donor is required to be notified of the test results, as specified;

    c) That the donor blood or blood component that is found to have the antibodies is prohibited from being used for transfusion;

    d) That blood or blood components is prohibited from being donated for transfusion purposes by a person if the person may have reason to believe that he or she has been exposed to HIV or AIDS;

    e) That the donor is required to complete a health screening questionnaire to assist in the determination as to whether he or she may have been exposed to HIV or AIDS. [HSC § 1603.3]

23) Requires a blood bank or plasma center to incorporate voluntary means of self-deferral for donors. Authorizes the means of self-deferral to include, but not be limited to, a form with checkoff boxes specifying that the blood or blood components are for research or test purposes only and a telephone callback system for donors to use in order to inform the blood bank or plasma center that blood or blood components donated should not be used for transfusion. Requires the blood bank or plasma center to inform the donor, in a manner that is understandable to the donor, that the self-deferral process is available and should be used if the donor has reason to believe that he or she is infected with HIV. [HSC § 1604.6]

24) Establishes the Sherman Food, Drug, and Cosmetic Law governs the safety, effectiveness, manufacturing and labeling of food, drugs, medical devices, and cosmetics. [HSC § 109875, *et seq.*]

25) Prohibits, except as specified, blood or blood components from being used in vivo for humans in this state, unless the blood or blood components have been testing and found nonreactive for HIV or blood or blood components are used for research or vaccination programs pursuant to an informed consent. [HSC § 1603.1]

26) Requires blood banks and plasma centers requires to make laboratory tests of all human whole blood and blood components received to detect the presence of viral hepatitis and HIV in the manner specified in 22) above. Requires, if the blood bank or plasma center finds the presence of viral hepatitis, or an antigen thereof, in the blood or blood components tested, the blood bank or plasma center to report that finding, the date of the human whole blood or blood components donation, the name, address, and social security number of the person who donated the blood or blood components, and the name and address of the blood bank or plasma center that received the human whole blood or blood components from the person and any additional information required by DPH to the local health officer within 72 hours of the confirmation of the presence of viral hepatitis, or an antigen thereof, in the blood or blood components tested. [*Ibid.*]

**Federal Law**

27) Establishes requirements for the collection, processing, compatibility testing, storage, distribution of blood and blood components, as provided. [Title 21, Code of Federal Regulations (CFR) § 606]

28) Establishes the minimum current good manufacturing practice requirements for the preparation of drug products for administration to humans or animals. [Title 21, CFR § 211]

29) Establishes the Clinical Laboratory Improvement Amendments (CLIA) which include 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]

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author, the regulatory framework surrounding source plasma donation centers has not been updated since the 1990s despite significant

advancement in donation methods. The author continues that as a result, regulations no longer reflect current technology, creating unnecessary burdens in the way of patient care. The author states that these outdated laws restrict the availability of source plasma, which is necessary for producing plasma-derived therapies. The author continues that these therapies are essential for treating hundreds of thousands of people with rare and severe health conditions and are vital in critical-care settings. The author states that this bill aims to streamline the licensing process for source plasma donation centers and update current law to reflect current practice. The author concludes that ensuring that California can keep its place on the cutting-edge of developing and manufacturing life-saving treatments for patients across the state and around the world.

**2) BACKGROUND.**

**a) What is plasma?** According to Stanford Medicine Children's Health, plasma is the largest component of blood, making up about 55% of its content. Plasma carries water, salts and enzymes. Plasma also contains important components including antibodies, clotting factors, and the proteins albumin and fibrinogen. The main role of plasma is to take nutrients, hormones, and proteins to the parts of the body that need it. Cells also put their waste products into the plasma. The plasma then helps remove this waste from the body. Blood plasma also carries all parts of the blood through the circulatory system.

**b) Therapeutic Uses of Plasma.** According the University of Rochester, when individuals donate blood, healthcare providers can separate different components of the plasma, which can be concentrated into various products. These products are then used as treatments that can help save the lives of people suffering from burns, shock, trauma, and other medical emergencies. According to information provided by the sponsors, the use of medicine made from plasma is expected to continue to increase due to a growing number of diagnoses, easier access to care, and improved coverage of medicines. Use of plasma-derived therapies to treat primary immune deficiencies increased in the E.U. by 42% and in the U.S. by 67% from 2014 to 2020.

For instance, immune globulins (IGs) are gamma globulins purified from the plasma of human donors, containing primarily immune globulin G (IgG) as well as trace amounts of immune globulin A (IgA) and immune globulin M (IgM). IG products were first used in 1952 to treat immune deficiencies and later became an important treatment option in a variety of immune-related and inflammatory disease. A descriptive study titled, "*Assessment of Immune Globulin Utilization in Commercially insured and Medicare Populations*", reviewed temporal trends in IG use from 2009 to 2019 and found substantial increase in IG administrations overall, reflecting both an increase in individuals receiving IG and an increase in average annual administrations and dose per recipient.

**c) How are source plasma donation centers currently regulated in California?** DPH's Laboratory Field Services Biologics Program is responsible for license application review, approval, renewal, survey and investigation of: community blood banks and collection centers; hospital blood banks; blood and blood components collection centers; cord blood banks and collection entities; plasma collection centers; and, biologics processing and/or storage facilities.

Currently, source plasma donation centers are regulated as plasma collection centers. According to information provided by DPH, plasma collection centers operate under a blood bank license and a clinical laboratory license, both valid for one year.

Blood bank licensees must apply for a renewal of the license not less than 10 days prior to the license expiration date. Blood bank renewal applications require completing two forms and paying the fee. Clinical laboratory licensees have up to 60 days after the license expires to apply for renewal. The clinical laboratory license requires four to five forms and paying the fee. The renewal process looks for changes in personnel and operations. Some changes may require additional review or submission of documentation to ensure compliance with the law. If the facility simply maintains the operations which it was originally approved for, the renewal review is quick and straightforward. Plasma centers, due to their use of clinical laboratory testing, are subject to the federal CLIA requirement to hold a CLIA certificate. The CLIA certificate is valid for two years.

**d) How would this bill change how source plasma donation centers are regulated?** This bill creates a separate licensure category for source plasma donation centers. Further, this bill seems to seek alignment between the state license duration with that of the federal CLIA certificate.

Current law requires DPH, if DPH does not within 60 days after the filing of an application for a blood bank license issue the license, to state the grounds for its refusal in writing and serve a copy to the applicant. According to information provided by DPH, applications are reviewed within a few weeks for completeness. DPH verifies whether all required forms and documents have been submitted, are accurate, and meet state requirements. A more comprehensive review of the technical aspects of the application may take longer. In both cases, the applicant is informed if any forms are filled out incorrectly, required documents are missing, or additional information is required. Applicants are given several opportunities to rectify the application before it is considered abandoned, at which point they will need to reapply. Resolving a deficient application may take many months depending on the responsiveness of the applicant and DPH's caseload.

Denial of an application must be conducted according to existing law. Applicants denied a license have the right to appeal. This process involves a hearing in an administrative court and can take three years or more to resolve.

Existing law does not require the license to be automatically granted at the end of the 60 day period, whereas this bill does.

In terms of revocation, existing law states that a blood bank's license is required to be shall be automatically revoked when there is a change of address, ownership, or person in charge of biologics production. However, a new license may 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 this chapter and regulations pertaining thereto.

Per regulations, the license is issued to individuals and requires that the building be ready for operations, and for the operation to be supervised by a competent person. Modifications in ownership or directorship directly impact the issuance of the license. According to information provided by DPH, when a new director is appointed, it requires

significant attention to whether a qualified individual will effectively oversee the health and safety of both donors and recipients. Additionally, relocating the facility prompts thorough assessment about the new site's adequacy of preparedness to sustain operations. Given the stringent regulations governing blood banks, aimed at safeguarding donor health and ensuring product safety, any change in the licensed individual providing the oversight would render 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.

Current law is strict, providing for automatic revocation when there is a change in ownership due to the consequences of improper processing or handling of the blood or blood products. 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 in the manner described by the DPH designating the new medical director. 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.

In terms of the requirements for the medical director, state regulations require a blood bank to be under the direction of a physician and surgeon duly licensed by the State of California, and who shall have a minimum of six months experience in blood bank methods, transfusion principles, and transfusion practices, satisfactory to the department. 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. The Plasma Protein Therapeutics Association (PPTA), the sponsor of this bill, 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 defines the medical director for purposes of this bill to be a California licensed physician and surgeon designated by the licensee to direct and control personnel and relevant procedures concerning the determination of donor eligibility, collection of source plasma, the immunization of a donor, and the return of red blood cells or other blood components to the donor during collection of source plasma by plasmapheresis.

Currently, source plasma donation centers are required to hold a state clinical laboratory license. This bill exempts a source plasma donation center from licensure as a clinical laboratory if a source plasma donation center performing only a total protein test using a digital total protein refractometer classified as a moderate complexity test and performing no other test of a moderate or high complexity classification under CLIA.

**e) National Donor Deferral Registry.** This bill requires the licensed source plasma donation center to notify the donor in writing that test results from testing of transfusion-transmitted infections (which may include HIV, Hepatitis B or HBV, and Hepatitis C or HCV) may result in the donor being deferred from future donations and being placed on the National Donor Deferral Registry. The National Donor Deferral Registry is owned by the PPTA, the sponsor of this bill. According to PPTA, the NDDR is a database of donors

who test reactive for the viral agents for HIV, HBV, and HCV and are permanently prohibited from donating plasma at participating licensed and industry-certified centers in the U.S. and Canada. PPTA states that it is one of the voluntary, self-regulating initiatives taken by the plasma collection industry and is an important component of the industry-driven safety measures that help ensure the safety of the final therapies.

f) **Other States.** New York and Connecticut created unique licenses for source plasma donation centers recently. New York requires licensees to renew their licenses every two years, while Connecticut requires a source plasma collection center to biennially apply to renew its license during the 20th month, consistent with what it requires for blood collection facilities and clinical laboratories within the state.

3) **SUPPORT.** PPTA is the sponsor of this bill. PPTA states that this bill creates a separate section of the law in HSC to govern source plasma donation centers, where source plasma is donated for the purpose of manufacturing plasma-derived medicines. Source plasma is used to produce a number of life-saving PDMs that treat rare, chronic and life-threatening conditions. PDMs are used to treat shock, trauma, and burns. PPTA continues that the patient need for PDMs has steadily increased over the years. PPTA states that an expert panel of clinicians concluded it is imperative that the regulatory environment be improved to promote increased plasma donation. PPTA notes that California applies a mix of laws written for other entities (blood banks for transfusion, clinical labs, biologics manufacturers) to govern source plasma donation centers. PPTA continues that some of these laws are from a time when source plasma donation was a manual process. PPTA states the process has been automated since the 1990s. PPTA contends that the requirements for these entities limit source plasma donation because they unnecessarily require source plasma donation centers to meet requirements designed for different entities. PPTA notes that California licenses source plasma donation centers as clinical laboratories and biologics manufacturers. As a result, some PPTA members report they are audited three times by DPH and often by different people. PPTA concludes by stating that creating a unique licensure and legal category for source plasma donation centers could help streamline the DPH's inspections, audits, and resources.

4) **RELATED LEGISLATION.** ACR 43 (Pacheco) proclaims the month of March 2025 "Bleeding Disorders Awareness Month" in California and makes related findings and declarations.

5) **PREVIOUS LEGISLATION.** 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.

6) **SUGGESTED AMENDMENTS.** In order to provide for a comprehensive review of an applicant for a source plasma donation center license, the Committee may wish to consider to striking the requirement that a license be automatically granted within 60 days. In order to create parity with other blood banks and biologics licensees in the state, the Committee may wish to require renewal annually rather than every two years. The Committee may also wish to amend the bill to correct an incorrect cross-reference to the definition of "medical director" in the bill from HSC § 1631.1 to HSC § 1631. The Committee may also wish to delete an incorrect cross-reference to HSC § 1633.4, which does not exist. The Committee may wish to amend the bill to require, in the event that the medical director dissociates from

the licensed source plasma donation center, the source plasma donation center to identify a substitute medical director who meets the qualifications specified in 47) b) and notify DPH within 24 hours of the dissociation. Moving forward, the author may also wish to consider explicitly requiring testing to detect the presence of transfusion-related diseases such as viral hepatitis and HIV as is required in 25) of existing law.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

Plasma Protein Therapeutics Association (sponsor)
Aiarthritis
Bay Area Cancer Connections
California Chronic Care Coalition
California Life Sciences Association
Center for Inherited Blood Disorders
Grifols, Inc.
Hemophilia Council of California
Jeffrey Modell Foundation
Liver Coalition of San Diego
National Bleeding Disorders Foundation
Patient Advocates United in San Diego County
Rare Disease Access Coalition
Takeda Pharmaceuticals America

**Opposition**

None on file

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