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**AB-725 Source plasma donation.** (2025-2026)

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Date Published: 05/01/2025 09:00 PM

AMENDED IN ASSEMBLY MAY 01, 2025

CALIFORNIA LEGISLATURE— 2025–2026 REGULAR SESSION

**ASSEMBLY BILL**

**NO. 725**

Introduced by Assembly Member Solache  
(Coauthors: Assembly Members Carrillo, Castillo, Nguyen, and Tangipa)

February 18, 2025

An act to amend Section 1302 of the Business and Professions Code, *and* to amend Section 1605 ~~of the Health and Safety Code, of~~, and to add Chapter 4.05 (commencing with Section 1631) to Division 2 ~~of~~ *of*, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 725, as amended, Solache. Source plasma donation.

Existing law 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. Existing law authorizes the State Department of Public Health to establish and require compliance with additional requirements, as specified.

This bill, the California Source Plasma Donation Centers Act, would authorize a person to operate a source plasma donation center for the purpose of collecting source plasma, as defined. The bill would, among other things, authorize a source plasma donation center to offer payment to a donor of money or other valuable consideration. The bill would require the operator of a source plasma donation center to obtain a license from the State Department of Public Health, as specified. The bill would authorize the department 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. The bill would authorize the department to promulgate any regulations it deems necessary to implement the bill's provisions. The bill would make a violation of the bill's provisions a misdemeanor, and would authorize a district or city attorney to prosecute a violation of the bill's provisions. By creating a new crime, the bill would impose a state-mandated local program.

This bill would require a local health officer, if they obtained records from a source plasma donation center of a plasma donor who had a reactive result to HIV antibody testing, upon completion of the officer's efforts to locate and notify the plasma donor, to expunge all of the individual's records. By imposing additional duties on local health officials, this bill would impose a state-mandated local program.

Existing law 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.

This bill would additionally require fees collected from the licensing and regulation of source plasma donation centers to be deposited in the fund for the purpose of regulating source plasma donation centers, upon appropriation by the Legislature.

Existing law 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.

This bill would exempt source plasma donation centers from these provisions.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

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## THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** This act shall be known, and may be cited as, the California Source Plasma Donation Centers Act.

**SEC. 2.** Section 1302 of the Business and Professions Code is amended to read:

**1302.** (a) There is hereby established in the State Treasury, the Clinical Laboratory Improvement Fund.

(b) All fees established under this chapter and Chapters 4 (commencing with Section 1600) and 4.05 (commencing with Section 1631) of Division 2 of the Health and Safety Code shall be collected by and paid to the department, and shall be deposited by the department in the Clinical Laboratory Improvement Fund, along with any other moneys received by the department for the purpose of licensing, certification, inspection, proficiency testing, or other regulation of clinical laboratories, blood banks, or clinical laboratory personnel. Notwithstanding Section 16305.7 of the Government Code, all interest earned on moneys deposited in the fund shall be maintained in the fund.

(c) Moneys deposited in the Clinical Laboratory Improvement Fund that are appropriated in the annual Budget Act, or any other appropriation, for support of, or expenditure by, the state department shall, upon appropriation, be expended by the state department to administer this chapter and Chapters 4 (commencing with Section 1600) and 4.05 (commencing with Section 1631) of Division 2 of the Health and Safety Code. All fees collected pursuant to this chapter shall, upon appropriation, be expended to administer this chapter and shall not be redirected for any other purpose. All fees collected pursuant to Chapters 4 (commencing with Section 1600) and 4.05 (commencing with Section 1631) of Division 2 of the Health and Safety Code shall, upon appropriation, be expended to administer its respective chapter and shall not be redirected for any other purpose.

**SEC. 3.** Section 1605 of the Health and Safety Code is amended to read:

**1605.** Establishments which receive human whole blood and human whole blood derivatives specified by regulation and are not subject to license in accordance with this chapter shall be considered as blood bank depositories. Laboratory tests and other procedures with respect to the preparation of blood for transfusion shall be the sole responsibility of the blood bank depository. This section does not apply to source plasma donation centers licensed pursuant to Chapter 4.05 (commencing with Section 1631).

**SEC. 4.** Chapter 4.05 (commencing with Section 1631) is added to Division 2 of the Health and Safety Code, to read:

### **CHAPTER 4.05. Source Plasma** **Article 1. Definitions**

**1631.** For the purposes of this chapter, the following terms have the following meanings:

(a) "Department" means the State Department of Public Health.

(b) "Medical director" or *"permanent medical director"* means 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" means the database of deferred plasma donors in North America owned by the Plasma Protein Therapeutics Association.

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

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

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

(h) "Source plasma donor phlebotomist" means 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.

*(i) "Substitute medical director" means the California licensed physician and surgeon designated by the licensee to temporarily direct and control personnel and procedures in the stead of the permanent medical director if a permanent medical director dissociates from a source plasma donation center.*

## **Article 2. Donations**

**1632.** (a) (1) Notwithstanding any other ~~provision of~~ law, a person may operate a source plasma donation center for the purpose of collecting source plasma if they are licensed under this chapter and the source plasma is collected in accordance with this chapter.

(2) A source plasma donation center that is licensed pursuant to this chapter is exempt from licensure as described in Chapter 4 (commencing with Section 1600).

(b) A source plasma donation center may 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.

**1632.1.** A source plasma donation center shall 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, pursuant to Division 6 (commencing with Section 12500) of the Vehicle Code, or other acceptable identification issued by any other state or federal government agency, or tribal government, as specified in regulation.

**1632.2.** Before a donor donates source plasma for the first time, a source plasma donation center shall 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 shall 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.

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

**1632.3.** (a) A source plasma donation center shall 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 Chapter 3 (commencing with Section 120885) of Part 4 of Division 105 may be administered without charge.

(b) (1) Notwithstanding any other ~~provision of~~ law, civil liability or criminal sanction shall not be 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.

(2) 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, shall be expunged by the local health officer.

**1632.4.** (a) (1) Notwithstanding Chapter 7 (commencing with Section 120975) of Part 4 of Division 105, or any other ~~provision of~~ law, no public entity or ~~any~~ private source plasma donation center shall be liable for an inadvertent, accidental, or otherwise unintentional disclosure of the results of an HIV test.

(2) As used in this section, "public entity" includes, but is not limited to, any publicly owned or operated source plasma donation center, local health officer, and the department.

(b) Neither the department nor any source plasma donation center, including a source plasma donation center owned or operated by a public entity or a local health officer, shall be held liable for any damage resulting from the disclosure of test results obtained pursuant to subdivision (a).

**1632.5.** 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.

### **Article 3. Administration of Source Plasma Donation Centers**

**1632.6.** (a) (1) 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 may obtain a predonation health history and perform predonation screening, including nondiagnostic general health assessments for which blood collection is performed by skin puncture.

(2) When unlicensed personnel perform the duties described in paragraph (1), the review of work required by federal regulations relating to good manufacturing practices, as described in Parts 211 and 606 of Title 21 of the Code of Federal Regulations, shall be performed by a staff member who is a licensed health care professional.

(b) Notwithstanding any other law, a licensed clinical laboratory bioanalyst, as described in Section 1203 of the Business and Professions Code, a licensed clinical laboratory technologist, a registered clinical laboratory technologist trainee, a licensed vocational nurse, as described in Section 2859 of the Business and Professions Code, a registered nurse, as described in Section 2725 of the Business and Professions Code, 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.

(c) The acts described in subdivisions (a) and (b) shall be performed under both of the following conditions:

(1) 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.

(2) Under the general supervision of a licensed physician and surgeon. The licensing and registration described in this section shall be licensing and registration pursuant to the Business and Professions Code.

(d) Notwithstanding paragraph (2) of subdivision (a), source plasma may be collected at a source plasma donation center when a physician or surgeon is not physically present on the premises. The physician and surgeon may delegate the general supervision duties to a registered nurse, but shall remain responsible for ensuring that all those duties and responsibilities are properly performed.

**1632.7.** (a) A source plasma donation center shall have a medical director.

(b) Notwithstanding any other ~~provision of~~ law, the medical director shall meet the definition in Section ~~1631.1~~ 1631 and be designated in the source plasma donation center license as the medical director.

(c) Notwithstanding any other ~~provision of~~ law, a source plasma donation center is authorized to employ a person to perform total protein tests using a digital refractometer pursuant to Section 1246.7 of the Business and Professions Code.

(d) 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 (42 U.S.C. Sec. 263a) is exempt from licensure as a clinical laboratory.

**1632.8.** Notwithstanding any other ~~provision of~~ law, a person who has attained ~~the age of~~ 18 *years of age* may 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 subdivision (b) of Section 1632.

**1632.9.** This chapter does not repeal or in any manner affect any provision of the Business and Professions Code relating to the practice of medicine.

#### **Article 4. Licenses**

**1633.** The ~~Department~~ *department* shall develop a form for the application for a source plasma donation center license issued pursuant to this chapter. The form shall 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.
- (e) Any additional information as the department may require by regulation.

**1633.1.** If the department does not, within 60 days after the filing of the application, issue a license, it shall state the specific grounds and reasons for its refusal in writing, serving a copy upon the applicant. ~~If the department does not issue its written refusal of the application for the license within this period, the application shall be deemed approved and a license issued following expiration of the 60-day application review period.~~ The notice of refusal may be served by registered mail addressed to the applicant at their last known address.

**1633.2.** (a) 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. However, a licensee may 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.

(b) (1) In the event the medical director of a source plasma donation center disassociates from the licensed source plasma donation center, the licensee shall, within 24 hours of the date of the disassociation, *identify a substitute medical director*, notify the department in writing of the ~~disassociation. The~~ *disassociation, and provide the department with the substitute medical director's name and address.*

(2) (A) *The* licensee shall have 45 days in which to replace the *substitute* medical ~~director. To~~ *director with a permanent medical director.*

(B) (i) *To* replace the medical director, the licensee shall file an application for amendment of the existing license in the manner prescribed by the department designating the new medical director. ~~Upon~~

(ii) *Upon* failure of the licensee to submit an application to the department naming the new medical director within 45 days of the disassociation date of the former *permanent* medical director, the license for the source plasma donation center shall be automatically revoked.

(c) A new license may 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.

(d) A license may be denied for any reason applicable to the revocation and suspension of licenses.

(e) Proceedings for the denial of a license or a license amendment shall be conducted in accordance with Section 100171.

**1633.3.** (a) Each application for a license, a license amendment, or a license renewal pursuant to this chapter shall 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.~~ *costs.*

(b) (1) The department shall receive and account for all moneys received pursuant to this chapter and shall deposit them with the State Treasurer for deposit in the Clinical Laboratory Improvement Fund established pursuant to Section 1302 of the Business and Professions Code.

(2) All funds received pursuant to this chapter shall, upon appropriation by the Legislature, be expended to administer this chapter.

(c) Each license issued under this chapter shall expire ~~24~~ 12 months from the date of its issuance. Application for renewal of license accompanied by the fee shall be filed with the department not less than 10 days prior to its expiration. Failure to make a timely renewal shall result in expiration of the license.

#### **Article 5. Enforcement**

**1634.** (a) The department shall administer this chapter.

(b) In order to carry out this chapter, a duly authorized representative of the department may do any of the following:

(1) 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 chapter or the regulations adopted pursuant to this chapter.

(2) 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.

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

**1634.1.** (a) A license shall be suspended or revoked by the department for the violation of any provision of this chapter, or of any rule or regulation made by the department adopted pursuant to this chapter. The proceedings shall be conducted in accordance with Section 100171.

(b) A district or city attorney may prosecute a violation of this chapter upon evidence of a violation within their respective jurisdictions submitted by the department.

**1634.2.** It is the intent of the Legislature that this chapter does not conflict with Part 5 (commencing with Section 109875) of Division 104 of this code. All provisions of that division shall apply to source plasma within the meaning of this chapter.

**1634.3.** This chapter shall 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.

**1634.4.** The violation of any provision of this chapter 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.

**1634.5.** The department may promulgate any regulations it deems necessary to implement this chapter.

**SEC. 5.** No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution for certain costs that may be incurred by a local agency or school district because, in that regard, this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

However, if the Commission on State Mandates determines that this act contains other costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.