HEALTH AND SAFETY CODE - HSC

DIVISION 2. LICENSING PROVISIONS [1200 - 1796.70] *(Division 2 enacted by Stats. 1939, Ch. 60.)*

CHAPTER 4. Human Whole Blood, Human Whole Blood Derivatives, and Other Biologics [1600 - 1630] *(Chapter 4 repealed and added by Stats. 1963, Ch. 1055.)*

ARTICLE 2. Human Whole Blood and Human Whole Blood Derivatives [1602.5 - 1608] *(Article 2 added by Stats. 1963, Ch. 1055.)*

1602.5. (a) No person shall engage in the production of human whole blood or human whole blood derivatives unless the person is licensed under this chapter and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with both of the following:

(1) The standards set forth in the 13th Edition of “Standards for Blood Banks and Transfusion Services,” as published by the American Association of Blood Banks and in effect on November 15, 1989, or any amendments thereto or later published editions or amendments thereto. These shall be the standards for all licensed blood banks and blood transfusion services in the state.

(2) Those provisions of Title 17 of the California Code of Regulations that are continued in effect by subdivision (c) or that are adopted pursuant to subdivision (b).

(b) The department may, by the adoption of regulations, establish and require compliance with requirements in addition to, or in lieu of, those in subdivision (a) as the department deems appropriate to reflect changing technology or to improve the safety of human whole blood or human whole blood derivatives. Any standards adopted pursuant to this subdivision shall be adopted after consultation with representatives of the American Association of Blood Banks.

(c) Until the time superseded by any regulation adopted pursuant to this section, all of the provisions of Group 1 (commencing with Section 950) of Subchapter 1 of Chapter 2 of Part 1 of Title 17 of the California Code of Regulations shall remain in effect with the exception of the following:

(1) Subdivisions (i) to (k), inclusive, of Section 997.

(2) Sections 999 and 1001.

(3) Subdivisions (a) to (c), inclusive, of Section 1002.

(4) Paragraphs (2) and (3) of subdivision (e) of Section 1002.

(5) Subdivisions (f) and (g) of Section 1002.

(6) Paragraphs (2) to (6), inclusive, of subdivision (h) of Section 1002.

(7) Subdivisions (i), (k), and (l) of Section 1002.

(8) Subdivisions (a) to (c), inclusive, of Section 1004.

(9) Sections 1010, 1012, 1013, 1014, 1024, and 1024.1.

(10) Subdivisions (a), (b), and (e) of Section 1025.

(11) Paragraphs (1) to (3), inclusive, of subdivision (c) of Section 1025.

(d) (1) Any amendment to the 13th Edition of "Standards for Blood Banks and Transfusion Services," any later editions, or any amendments thereto, published by the American Association of Blood Banks shall become effective in California 90 days after the effective date of this section, or 90 days after publication by the association, unless the department sends written notice, within such a 90-day period, to all persons licensed under this chapter to engage in the production of human whole blood or human whole blood derivatives, indicating which portions shall not become effective.

(2) The department may determine that no portion of any amendments or later editions shall become effective. The department shall determine that no portion of an amendment or later edition shall become effective pursuant to this section whenever the department has not received a copy of the amendment or later edition by the date it is published by the American Association of Blood Banks.

(e) This section does not apply to a clinical trial site storing or preparing for patient administration human whole blood and human whole blood derivatives intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with the requirements of Section 505(i) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Sec. 360j(g)) and the regulations adopted pursuant to the federal act.

(Amended by Stats. 2022, Ch. 955, Sec. 1. (SB 1500) Effective January 1, 2023.)

1602.6. (a) No person shall import any human whole blood or human whole blood derivative produced outside the state unless that blood or blood product meets the standards set forth in the latest edition of the "Standards for Blood Banks and Transfusion Services," as published by the American Association of Blood Banks, or any later published editions or amendments thereto.

(b) Any later editions of the "Standards for Blood Banks and Transfusion Services," or amendments thereto, published by the American Association of Blood Banks, shall become effective for purposes at this section 90 days after the effective date of this section, or 90 days after publication by the association, whichever is later, unless the department sends written notice, within the 90-day period, to all persons who import human whole blood or human whole blood derivatives produced outside the state that have requested this notice, stating the portions of those later editions or amendments that shall not become effective.

(c) The department may determine that no portion of any later editions or amendments shall become effective for purposes of this section. The department shall determine that no portion of a later edition or amendment shall become effective for purposes of this section whenever the department has not received a copy of the later edition or amendment by the date it is published by the American Association of Blood Banks.

(d) The department shall administer and enforce this section in accordance with this chapter and in a manner that assures, to the greatest degree, consistency with Section 1602.5.

(Added by Stats. 1992, Ch. 760, Sec. 1. Effective January 1, 1993.)

1603.1. (a) Except as provided in this subdivision, no blood or blood components shall be used in vivo for humans in this state, unless the blood or blood components have been tested and found nonreactive for HIV or the blood or blood components are used for research or vaccination programs pursuant to an informed consent.

Additional exceptions to the requirement of this subdivision are as follows:

(1) Blood or blood components released for transfusion in emergency circumstances, as determined by the department.

(2) Blood or blood components used for autologous purposes.

(b) Blood banks and plasma centers shall 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 Section 1603.3. If the blood bank or plasma center finds the presence of viral hepatitis, or an antigen thereof, in the blood or blood components tested, it shall 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 the department, 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.

(c) A physician, hospital, or other health care provider shall report all AIDS cases, HIV infections, and viral hepatitis infections, including transfusion-associated cases or infections, to the local health officer with the information required, and within the timeframes established by the department, pursuant to Title 17 of the California Code of Regulations.

(d) Upon receipt of a report concerning any transfusion-associated hepatitis or transfusion-associated HIV or AIDS cases, the local health officer shall identify which blood bank or plasma center is the source of the infectious blood or blood components and shall report this fact to the blood bank or plasma center that issued the blood or blood components. The blood bank or plasma center shall undertake an investigation to determine the donor source of the infectious blood or blood components.

(e) Local health officials shall contact all persons who have confirmed cases of AIDS, as determined by a person responsible for the care and treatment of the person with AIDS, to suggest appropriate treatment alternatives and for the purposes of epidemiological studies and followup.

(f) The department may adopt regulations governing the procedures in this section as it deems necessary to protect the public health and safety.

(g) "Plasma center," as used in this chapter, means any place where the process of plasmapheresis is conducted, as defined in Section 1025 of Title 17 of the California Code of Regulations and includes a place where leukopheresis or platelet pheresis, or both, is conducted.

(h) "AIDS," as used in this chapter, means acquired immune deficiency syndrome.

(i) "HIV," as used in this chapter, means human immunodeficiency virus.

(j) "Blood components," as used in this chapter, means preparations separated from single units of whole blood or prepared for hemapheresis and intended for use as final products for transfusions.

(k) A local health officer may disclose to a blood bank or plasma center, on a confidential basis, whether blood or blood components previously transfused may have been donated by a person infected with HIV, in order to implement the blood bank's or plasma center's program to notify a recipient of blood or blood components that might have transmitted HIV. The blood bank or plasma center may not disclose information that would identify a donor to which this subdivision applies and shall destroy information communicated to it as authorized by this subdivision immediately after reviewing its records as necessary to implement this program.

(Amended by Stats. 2003, Ch. 419, Sec. 1. Effective January 1, 2004.)

1603.2. (a) Each 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, pursuant to Division 6 (commencing with Section 12500) of the Vehicle Code, from all donors of human whole blood or blood components who receive payment in return for the donation of that blood or blood components.

(b) For the purposes of this section, "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 shall not include any of the following:

(1) Cancellation or refund of the nonreplacement fees or related blood or blood components transfusion charges.

(2) Blood assurance benefits to a person as a result of a blood or blood components donation to a donor club or blood assurance program.

(3) Time away from employment granted by an employer to an employee in order to donate blood or blood components.

(Amended by Stats. 2003, Ch. 419, Sec. 2. Effective January 1, 2004.)

1603.3. (a) Before donation of blood or blood components, a donor shall be notified in writing of, and shall have signed a written statement confirming the notification of, all of the following:

(1) That the blood or blood components shall be tested for evidence of antibodies to HIV.

(2) That the donor shall be notified of the test results in accordance with the requirements described in subdivision (c).

(3) That the donor blood or blood component that is found to have the antibodies shall not be used for transfusion.

(4) That blood or blood components shall not be 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.

(5) 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.

(b) A blood bank or plasma center shall incorporate voluntary means of self-deferral for donors. The means of self-deferral may include, but are not 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. The blood bank or plasma center shall 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.

(c) Blood or blood components from any donor initially found to have serologic evidence of antibodies to HIV shall be retested for confirmation. Only if a further test confirms the conclusion of the earlier test shall the donor be notified of a reactive result by the blood bank or plasma center.

The department shall develop permissive guidelines for blood banks and plasma centers on the method to be used to notify a donor of a test result.

(d) Each blood bank or plasma center operating in California shall prominently display at each of its collection sites a notice that provides the addresses and telephone numbers of sites, within the proximate area of the blood bank or plasma 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.

(e) The department may promulgate any additional regulations it deems necessary to enhance the safety of donated blood and blood components. The department may also promulgate regulations it deems necessary to safeguard the consistency and accuracy of HIV test results by requiring any confirmatory testing the department deems appropriate for the particular types of HIV tests that have yielded “reactive,” “positive,” “indeterminate,” or other similarly labeled results.

(f) 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 blood or blood components donor of a reactive result if reasonable efforts by the blood bank or plasma center to locate the donor have failed. Upon completion of the local health officer’s efforts to locate and notify a blood or blood components donor of a reactive result, all records obtained from the blood bank or plasma 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.

(Amended by Stats. 2017, Ch. 537, Sec. 1. (SB 239) Effective January 1, 2018.)

1603.4. (a) 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 blood bank or plasma center shall be liable for an inadvertent, accidental, or otherwise unintentional disclosure of the results of an HIV test.

As used in this section, “public entity” includes, but is not limited to, any publicly owned or operated blood bank or plasma center, local health officer, and the department.

(b) Neither the department nor any blood bank or plasma center, including a blood bank or plasma center owned or operated by a public entity, or local health officer shall be held liable for any damage resulting from the notification of test results, as set forth in paragraph (2) of subdivision (a) of, or in subdivision (c) of, Section 1603.3.

(Amended by Stats. 2003, Ch. 419, Sec. 4. Effective January 1, 2004.)

1603.5. (a) Notwithstanding any other provision of law, every person engaged in the production of blood shall, if the product is intended for transfusion, label each container of blood which the person produces with a label, upon which the following designations shall be printed in letters the size of which shall be no less prominent than the proper name of the product.

(1) If the person giving the blood received no payment for the blood, the designation shall be “volunteer donor.”

(2) If the person giving the blood received payment for the blood, the designation shall be “paid donor.”

(b) As used in this section:

(1) “Blood” means human whole blood or components of human blood, including plasma, which are prepared from human whole blood by physical, rather than chemical processes, but does not include blood derivatives manufactured or processed by industrial use.

(2) “Industrial use” means a use of blood in which the blood is modified by physical or chemical means to produce derivatives for therapeutic or pharmaceutic biologics, laboratory reagents, or in vitro diagnostics.

(3) “Payment” means the transfer by a blood bank, or any other party, to any person of money or any other valuable consideration which can be converted to money by the recipient, except that “payment” shall not include any of the following:

(i) Cancellation or refund of the nonreplacement fees or related blood transfusion charges.

(ii) Blood assurance benefits to a person as a result of a blood donation to a donor club or blood assurance program.

(iii) Time away from employment granted by an employer to an employee in order to donate blood.

(c) Any blood bank receiving blood from a blood bank outside of California shall comply with the labeling requirements of this chapter. Any blood bank receiving this blood may label the blood as “volunteer donor” blood only if the blood bank receives with the blood a certificate from the out-of-state blood bank which states either that the particular shipment of blood was acquired from volunteer donors not receiving payment or that all blood processed by the out-of-state blood bank is acquired from volunteer donors not receiving payment. If the blood bank receiving such blood receives no such certificate with the blood, the blood shall be labeled as “paid donor” blood.

(d) No warranty shall be implied from the fact that any blood is labeled in accordance with the requirements of this section.

(Amended by Stats. 1989, Ch. 513, Sec. 1.)

1604. The distribution or release for distribution by blood banks of human whole blood, or those human whole blood derivatives specified by regulation, shall be made only to blood bank depositories or to other licensed blood banks.

(Repealed and added by Stats. 1963, Ch. 1055.)

1604.6. (a) Notwithstanding any other provision of law, in order to provide umbilical cord blood banking storage services, a blood bank shall be licensed pursuant to this chapter. Any additional standards for blood banks to store umbilical cord blood may be implemented by the department through the adoption of regulations.

(b) (1) The department may adopt emergency regulations to implement and make specific subdivision (a) in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For purposes of the Administrative Procedure Act, the adoption of regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare.

(2) (A) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, these emergency regulations shall not be subject to the review and approval of the Office of Administrative Law. Notwithstanding Sections 11346.1 and 11349.6 of the Government Code, the department shall submit these regulations directly to the Secretary of State for filing.

(B) Emergency regulations adopted pursuant to this section shall become effective immediately upon filing by the Secretary of State, shall be subject to public hearing within 120 days of filing with the Secretary of State, and shall comply with Sections 11346.8 and 11346.9 of the Government Code, or shall be repealed by the department.

(3) The Office of Administrative Law shall provide for the printing and publication of emergency regulations adopted pursuant to this section in the California Code of Regulations.

(4) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, and subject to subparagraph (B) of paragraph (2), the emergency regulations adopted pursuant to this subdivision shall not be repealed by the Office of Administrative Law and shall remain in effect until revised or repealed by the department.

(Amended by Stats. 2007, Ch. 130, Sec. 160. Effective January 1, 2008.)

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.

(Repealed and added by Stats. 1963, Ch. 1055.)

1606. The procurement, processing, distribution, or use of whole blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing the same, or any of them, into the human body shall be construed to be, and is declared to be, for all purposes whatsoever, the rendition of a service by each and every person, firm, or corporation participating therein, and shall not be construed to be, and is declared not to be, a sale of such whole blood, plasma, blood products, or blood derivatives, for any purpose or purposes whatsoever.

(Repealed and added by Stats. 1963, Ch. 1055.)

1607. (a) Notwithstanding any other law, licensed clinical laboratory bioanalysts, licensed clinical laboratory technologists, registered clinical laboratory technologist trainees, licensed vocational nurses, registered nurses, and blood donor phlebotomists, as defined by the American Association of Blood Banks, may perform skin puncture and venipuncture for the purposes of collecting human blood if both of the following are satisfied:

(1) The acts are performed in a blood bank licensed pursuant to this chapter and personnel training and standards meet accreditation requirements of the American Association of Blood Banks.

(2) The acts are performed under the direct and responsible supervision of a licensed physician and surgeon. The licensing and registration referred to in this section shall be licensing and registration pursuant to the Business and Professions Code.

(b) (1) Notwithstanding paragraph (2) of subdivision (a), blood may be collected at a blood bank when a physician or surgeon is not physically present on the premises if both of the following conditions are met:

(A) The medical director and their medical advisory committee, if one exists, approves of blood collection without a physician or surgeon present on the premises.

(B) The employee placed in charge, in the absence of a physician or surgeon, is a registered nurse.

(2) The registered nurse placed in charge pursuant to subparagraph (B) of paragraph (1) may be physically present on the premises or may be available via telehealth, as defined in Section 2290.5 of the Business and Professions Code, so long as the method of telehealth used is synchronous.

(3) (A) A blood bank shall annually report to the department any adverse donor events requiring emergency medical intervention that occur pursuant to this subdivision, including the date, location, type of adverse event, onsite response, and whether a registered nurse was physically present on the premises.

(B) At the request of the department, a blood bank shall provide written procedures for managing adverse donor reactions.

(4) This subdivision shall become inoperative on January 1, 2028.

(c) In accordance with the American Association of Blood Banks standards, the medical director of the blood bank shall be responsible for all medical and technical policies and procedures that relate to the safety of staff members, donors, and patients, including, but not limited to, ensuring that the blood bank has a qualified and competent staff to perform all tasks involved in the collection, storage, processing, and distribution of blood and blood components. The employer blood bank shall be responsible for determining the appropriate mix of qualified, competent employees that meets the accreditation requirements of the American Association of Blood Banks and is consistent with the services rendered.

(d) Personnel who are explicitly authorized by the blood bank and who meet the education, training, and competency standards of the blood bank, may obtain a predonation medical history and perform predonation screening. When unlicensed personnel perform these duties, the review of work required by federal regulations relating to good manufacturing practices, as set forth in Part 211 and Part 606 of Title 21 of the Code of Federal Regulations, shall be performed by those staff members who are licensed health care personnel.

(e) The collection of blood from autologous patients and other individuals who do not meet the American Association of Blood Banks criteria for regular volunteer donation shall be conducted by licensed health care personnel.

(f) This chapter does not prohibit the collection of blood at a state institution, a blood bank licensed pursuant to this chapter, or other establishment, under conditions established and acceptable to the department, by the personnel of the collecting entity.

(g) A staff position for a blood donor phlebotomist created as a consequence of this section shall not be the only cause for the displacement of any licensed personnel employed in a licensed blood bank. As used in this section, the term “displacement” shall mean a reduction in hours of nonovertime work, the loss of wages, or the loss of employment.

(h) This section does not limit the rights of employees or employee organizations to bargain in good faith on matters of wages, hours, or other terms and conditions of employment, including the negotiation of workplace standards within the scope of collective bargaining as authorized by state and federal law.

(i) For purposes of this section, “American Association of Blood Banks” means the American Association of Blood Banks or its successor organization.

(Amended by Stats. 2022, Ch. 726, Sec. 1. (SB 1475) Effective January 1, 2023.)

1607.5. (a) Notwithstanding any other provision of law, a person who has attained the age of 17 may consent to the donation of his or her blood and to the penetration of tissue which is necessary to accomplish such donation, and a blood bank may accept such donation.

(b) Notwithstanding any other provision of law, a person who has attained the age of 15 may consent to the donation of his or her blood and to the penetration of tissue which is necessary to accomplish such donation, and a blood bank may accept such donation, if he or she has the written consent of his or her parents or a guardian, and the written authorization of a physician and surgeon.

(c) As used in this section “donation of blood” means a giving of blood in which the donor of the blood receives no payment therefor.

(Amended by Stats. 1981, Ch. 23.)

1608. This chapter does not repeal or in any manner affect any provision of the Business and Professions Code relating to the practice of medicine.

(Repealed and added by Stats. 1963, Ch. 1055.)