Senate Bill No. 1081

CHAPTER 419

An act to amend Sections 1603.1, 1603.2, 1603.3, 1603.4, 1621.5, and 120990 of the Health and Safety Code, relating to human blood.

[Approved by Governor September 16, 2003. Filed with Secretary of State September 17, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1081, Committee on Health and Human Services. Human blood.

(1) Existing law requires any person engaged in the production of human whole blood or human whole blood derivatives to be licensed by the State Department of Health Services. Existing law also contains various provisions relating to consent to, and the disclosure of results of, testing for antibodies to the human immunodeficiency virus (HIV), the probable causative agent of acquired immune deficiency syndrome (AIDS), and the presence of viral hepatitis.

Existing law requires each blood bank or plasma center to notify the department and county health officer, as specified, if the presence of viral hepatitis, or the antigen thereof, is found in the blood tested, and in these cases, to provide additional information, as prescribed. Existing law also requires a physician to report to the department and the county health officer certain information regarding all carriers of viral hepatitis under his or her treatment, and requires a hospital to report to the department and to the county health officer certain information regarding all confirmed cases of AIDS carriers and all carriers of viral hepatitis hospitalized for treatment of viral hepatitis or AIDS.

This bill would instead require a physician, hospital, or other health care provider to report to local health officers all AIDS cases, HIV infections, and viral hepatitis infections, as prescribed.

It would delete the requirement that the report be made to the department. By imposing new duties on local health officers, this bill would create a state-mandated local program.

(2) Existing law requires the county health officer to investigate all transfusion-associated hepatitis cases and transfusion-associated AIDS cases and to trace the sources of human whole blood that was transfused.

This bill would instead require the local health officer, upon receipt of a report concerning any transfusion-associated hepatitis or transfusion-associated HIV or AIDS case, to identify which blood bank or plasma center is the source of the infectious blood or blood

components and to report this fact to the blood bank or plasma center that issued the blood or blood components. It would require the blood bank or plasma center to undertake an investigation to determine the donor source of the infectious blood or blood components. By expanding the duties of local health officers, this bill would impose a state-mandated local program.

(3) Existing law requires the department to compile a list of carrier donors, possible carrier donors, and carriers of viral hepatitis and persons who test reactive for HIV and to distribute that list, known as the Donor Deferral Register, to blood banks and plasma centers, as specified. Existing law requires blood banks and plasma centers, after a confirmation test, to report information to the department to be included in the Donor Deferral Register, as specified. Existing law also requires the department, if possible, to contact carrier donors to inform them that they may be carriers of viral hepatitis and should not make blood donations, and to suggest appropriate treatment alternatives.

Existing law prohibits blood banks from receiving human whole blood from a person listed as a carrier donor or carrier of viral hepatitis on a list distributed by the department.

This bill would delete these requirements.

(4) Existing law requires blood banks to require a photographic identification, as specified, from all donors of human whole blood who receive payment, as defined, in return for the donation of that blood.

This bill would also apply these requirements to plasma centers, and would expand the category of donors required to present photographic identification to include donors of blood components.

(5) The bill would also make various technical, nonsubstantive, and conforming changes.

(6) 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, including the creation of a State Mandates Claims Fund to pay the costs of mandates that do not exceed $1,000,000 statewide and other procedures for claims whose statewide costs exceed $1,000,000.

This bill would provide that, if the Commission on State Mandates determines that the bill contains costs mandated by the state, reimbursement for those costs shall be made pursuant to these statutory provisions.

The people of the State of California do enact as follows:

SECTION 1. Section 1603.1 of the Health and Safety Code is amended to read:

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.

SEC. 2. Section 1603.2 of the Health and Safety Code is amended to read:

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.

SEC. 3. Section 1603.3 of the Health and Safety Code is amended to read:

1603.3. (a) Prior to a donation of blood or blood components, each 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. The blood bank or plasma center shall also inform the donor that it is a felony pursuant to Section 1621.5 to donate blood if the donor knows that he or she has a diagnosis of AIDS or knows that he or she has tested reactive to 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, no civil liability or criminal sanction shall be imposed for disclosure of test results to a local health officer when 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.

SEC. 4. Section 1603.4 of the Health and Safety Code is amended to read:

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.

SEC. 5. Section 1621.5 of the Health and Safety Code is amended to read:

1621.5. (a) It is a felony punishable by imprisonment in the state prison for two, four, or six years, for any person to donate blood, body organs or other tissue, semen to any medical center or semen bank that receives semen for purposes of artificial insemination, or breast milk to any medical center or breast milk bank that receives breast milk for purposes of distribution, whether he or she is a paid or a volunteer donor, who knows that he or she has acquired immune deficiency syndrome, as diagnosed by a physician and surgeon, or who knows that he or she has

tested reactive to HIV. This section shall not apply to any person who is mentally incompetent or who self-defers his or her blood at a blood bank or plasma center pursuant to subdivision (b) of Section 1603.3 or who donates his or her blood for purposes of an autologous donation.

(b) In a criminal investigation for a violation of this section, no person shall disclose the results of a blood test to detect the etiologic agent of AIDS or antibodies to that agent to any officer, employee, or agent of a state or local agency or department unless the test results are disclosed as otherwise required by law pursuant to any one of the following:

(1) A search warrant issued pursuant to Section 1524 of the Penal Code.

(2) A judicial subpoena or subpoena duces tecum issued and served in compliance with Chapter 2 (commencing with Section 1985) of Title 3 of Part 4 of the Code of Civil Procedure.

(3) An order of a court.

(c) For purposes of this section, ''blood'' means ''human whole blood'' and ''human whole blood derivatives,'' as defined for purposes of this chapter and includes ''blood components,'' as defined in subdivision (k) of Section 1603.1.

SEC. 6. Section 120990 of the Health and Safety Code is amended to read:

120990. (a) Except in the case of a person treating a patient, no person shall test a person's blood for evidence of antibodies to the probable causative agent of AIDS without the written consent of the subject of the test or the written consent of the subject, as provided in Section 121020, and the person giving the test shall have a written statement signed by the subject or conservator or other person, as provided in Section 121020 confirming that he or she obtained the consent from the subject. In the case of a physician and surgeon treating a patient, the consent required under this subdivision shall be informed consent, by the patient, conservator, or other person provided for in Section 121020.

This requirement does not apply to a test performed at an alternative site, as established pursuant to Sections 120885 to 120895, inclusive. This requirement does not apply when testing is performed as part of the medical examination performed pursuant to Section 7152.5.

(b) Nothing in this section shall preclude a medical examiner or other physician from ordering or performing a blood test to detect antibodies to the probable causative agent of AIDS on a cadaver when an autopsy is performed or body parts are donated pursuant to the Uniform Anatomical Gift Act, provided for pursuant to Chapter 3.5 (commencing with Section 7150) of Part 1 of Division 7.

(c) The requirements of subdivision (a) do not apply when blood is tested as part of a scientific investigation conducted either by medical researchers operating under institutional review board approval or by the department in accordance with a protocol for unlinked testing. For purposes of this section, unlinked testing means that blood samples are obtained anonymously or that the individual's name and other identifying information is removed in a manner that precludes the test results from ever being linked to a particular individual in the study.

SEC. 7. Notwithstanding Section 17610 of the Government Code, if the Commission on State Mandates determines that this act contains 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. If the statewide cost of the claim for reimbursement does not exceed one million dollars ($1,000,000), reimbursement shall be made from the State Mandates Claims Fund.

O