

Senate Bill No. 1184

CHAPTER 347

An act to amend Section 1644.5 of, and to add Section 121023 to, the Health and Safety Code, relating to infectious disease reporting, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor September 26, 2008. Filed with
Secretary of State September 26, 2008.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1184, Kuehl. Public health.

Existing law prohibits the transfer of any tissues, as defined, into the body of another person by means of transplantation, unless the donor of the tissues has been screened and found nonreactive for evidence of infection with human immunodeficiency virus (HIV), agents of viral hepatitis (HBV and HCV), human T lymphotropic virus-1 (HTLV-1), and syphilis, except as provided.

Existing law requires that all donors of sperm be screened and found nonreactive under the above provisions, except as provided. Existing law further requires the physician providing insemination or advanced reproductive technologies to, among other things, provide, as appropriate, antiretroviral treatment to a donor who tests reactive for HIV or HTLV-1, as prescribed.

This bill would, instead, require a physician providing insemination or advanced reproductive technologies to, among other things, verify, and document in the recipient's medical record, that the donor of sperm who tests reactive for HIV or HTLV-1 is under the care of a physician managing the HIV or HTLV-1 to minimize the risk of transmission during the course of insemination or advanced reproductive technology services.

Existing law requires health care providers and laboratories to report cases of HIV infection to local public health officers using patient names. Local health officers are required to report unduplicated HIV cases by patient name to the State Department of Public Health.

This bill would require each clinical laboratory to report all CD4+ T-Cell test results, as defined, to the local health officer within 7 days of the completion of the CD4+ T-Cell test. If a CD4+ T-Cell test result is related to a case of HIV infection, the local health officer would be required to report the case of HIV infection or AIDS to the department within 45 days of receipt of the laboratory report. By increasing the duties of local officials, this bill would create a state-mandated local program.

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, 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.

This bill would declare that it is to take effect immediately as an urgency statute.

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

SECTION 1. Section 1644.5 of the Health and Safety Code is amended to read:

1644.5. (a) No tissues shall be transferred into the body of another person by means of transplantation, unless the donor of the tissues has been screened and found nonreactive by laboratory tests for evidence of infection with HIV, agents of viral hepatitis (HBV and HCV), human T lymphotropic virus-1 (HTLV-1), and syphilis, except as provided in subdivision (c). The department may adopt regulations requiring additional screening tests of donors of tissues when, in the opinion of the department, the action is necessary for the protection of the public, donors, or recipients.

(b) Notwithstanding subdivision (a), infectious disease screening of blood and blood products shall be carried out solely in accordance with Article 2 (commencing with Section 1601) of Chapter 4.

(c) All donors of sperm shall be screened and found nonreactive as required under subdivision (a), except in the following instances:

(1) A recipient of sperm, from a sperm donor known to the recipient, may waive a second or other repeat testing of that donor if the recipient is informed of the requirements for testing donors under this section and signs a written waiver.

(2) A recipient of sperm may consent to therapeutic insemination of sperm or use of sperm in other advanced reproductive technologies even if the sperm donor is found reactive for hepatitis B, hepatitis C, syphilis, HIV or HTLV-1 if the sperm donor is the spouse of, partner of, or designated donor for that recipient. The physician providing insemination or advanced reproductive technology services shall advise the donor and recipient of the potential medical risks associated with receiving sperm from a reactive donor. The donor and the recipient shall sign a document affirming that each comprehends the medical repercussions of using sperm from a reactive donor for the proposed procedure and that each consents to it. Copies of the document shall be placed in the medical records of the donor and the recipient.

(3) (A) Sperm whose donor has tested reactive for syphilis may be used for the purposes of insemination or advanced reproductive technology only after the donor has been treated for syphilis. Sperm whose donor has tested reactive for hepatitis B may be used for the purposes of insemination or advanced reproductive technology only after the recipient has been vaccinated against hepatitis B.

(B) (i) Sperm whose donor has tested reactive for HIV or HTLV-1 may be used for the purposes of insemination or advanced reproductive technology for a recipient testing negative for HIV or HTLV-1 only after the donor's sperm has been effectively processed to minimize the infectiousness of the sperm for that specific donation and where informed and mutual consent has occurred.

(ii) The department shall adopt regulations by January 1, 2010, regulating facilities that perform sperm processing, pursuant to this subparagraph, that prescribe standards for the handling and storage of sperm samples of carriers of HIV, HTLV-1, or any other virus as deemed appropriate by the department. Until the department adopts these regulations, facilities that perform sperm processing shall follow facility and sperm processing guidelines developed by the American Society of Reproductive Medicine.

(iii) Prior to insemination or other advanced reproductive technology services, the physician shall inform the recipient of sperm from a donor who has tested reactive for HIV or HTLV-1 that sperm processing may not eliminate all risks of HIV or HTLV-1 transmission, and that the sperm may be tested to determine whether or not it is free of HIV or HTLV-1. The physician shall also inform the recipient of potential adverse effects the testing may have on the processed sperm.

(iv) The physician providing insemination or advanced reproductive technology services shall provide, as appropriate, prophylactic treatments, including, but not limited to, antiretroviral treatments, to the recipient to reduce the risk of acquiring infection during, and subsequent to, insemination or advanced reproductive technology. The physician providing advanced reproductive technology services shall also verify, and document in the recipient's medical record, that the donor of sperm who tests reactive for HIV or HTLV-1 is under the care of a physician managing the HIV or HTLV-1 to minimize the risk of transmission during the course of insemination or advanced reproductive technology services. The physician shall perform appropriate followup testing of the recipient for HIV or HTLV-1 following the insemination or other advanced reproductive technology, and recommend ongoing monitoring by a physician during treatment and pregnancy. The physician shall also recommend in the sperm recipient's medical record that the recipient be monitored during treatment and pregnancy.

(v) In the event that the recipient tests reactive for HIV or HTLV-1 following insemination or other advanced reproductive technology, the physician shall inform the recipient of appropriate treatments during and after pregnancy, and of treatments or procedures that may reduce the risk of transmission to the offspring.

(vi) Sperm whose donor has tested reactive for HIV or HTLV-1 may be used for the purposes of insemination or advanced reproductive technology if the recipient already has been previously documented with HIV or HTLV-1 infection, and where informed and mutual consent has occurred.

(4) The penalties of Section 1621.5 shall not apply to a sperm donor covered under this subdivision.

(d) Subdivision (a) shall not apply to the transplantation of tissue from a donor who has not been tested or, with the exception of HIV and HTLV-1, has been found reactive for the infectious diseases listed in subdivision (a) or for which the department has, by regulation, required additional screening tests, if both of the following conditions are satisfied:

(1) The physician and surgeon performing the transplantation has determined any one or more of the following:

(A) Without the transplantation the intended recipient will most likely die during the period of time necessary to obtain other tissue or to conduct the required tests.

(B) The intended recipient already is diagnosed with the infectious disease for which the donor has tested positive.

(C) The symptoms from the infectious disease for which the donor has tested positive will most likely not appear during the intended recipient's likely lifespan after transplantation with the tissue or may be treated prophylactically if they do appear.

(2) Consent for the use of the tissue has been obtained from the recipient, if possible, or if not possible, from a member of the recipient's family, or the recipient's legal guardian. For purposes of this section, "family" shall mean spouse, adult son or daughter, either parent, adult brother or sister, or grandparent.

(e) Human breast milk from donors who test reactive for agents of viral hepatitis (HBV and HCV), human T lymphotropic virus-1 (HTLV-1), HIV, or syphilis shall not be used for deposit into a milk bank for human ingestion in California.

SEC. 2. Section 121023 is added to the Health and Safety Code, to read: 121023. (a) Each clinical laboratory, as defined in Section 1206 of the Business and Professions Code, shall report all CD4+ T-Cell test results to the local health officer for the local health jurisdiction where the health care provider facility is located within seven days of the completion of the CD4+ T-Cell test.

(b) The clinical laboratory report with CD4+ T-Cell test results shall also include, if provided by the ordering health care provider, all of the following:

(1) The patient's name.

(2) The patient's date of birth.

(3) The patient's gender.

(4) The name, telephone number, and address of the local health care provider that ordered the test.

(c) The clinical laboratory report with CD4+ T-Cell test results shall also include all of the following information:

(1) CD4+ T-Cell test results expressed as an absolute count (the number of lymphocytes containing the CD4 epitope per cubic millimeter) and, if available, the relative count (the number of lymphocytes expressing the CD4 epitope as a percentage of total lymphocytes).

(2) The type of laboratory test performed.

(3) The date the laboratory test was performed.

(4) The name, telephone number, and address of the clinical laboratory that performed the test.

(5) The laboratory CLIA number.

(6) The laboratory report number.

(d) (1) Each local health officer shall inspect each clinical laboratory CD4+ T-Cell test report to determine if the test is related to a case of HIV infection.

(2) If the clinical laboratory CD4+ T-Cell test result is related to a case of HIV infection, the local health officer shall report the case of HIV infection or AIDS, as appropriate, to the State Department of Public Health within 45 days of receipt of the laboratory report.

(3) If the clinical laboratory CD4+ T-Cell test result is not related to a case of HIV infection, the local health officer shall destroy the laboratory CD4+ T-Cell test report.

(e) Pursuant to Section 121025, CD4+ T-Cell test reports shall not be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding.

(f) CD4+ T-Cell test reports shall be considered confidential public health records as defined in Section 121035.

(g) For the purposes of this section, “CD4+ T-Cell test” means any test used to measure the number of lymphocytes containing the CD4 epitope.

SEC. 3. 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.

SEC. 4. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to make the necessary programmatic, regulatory, and statutory changes to implement an HIV reporting system that produces data that will be accepted by the federal Centers for Disease Control and Prevention and to ensure that California remains competitive for funding allocations under the federal Ryan White Comprehensive AIDS Resources Emergency Act (CARE) of 1990 (Public Law 101-381), as amended October 20, 2000, (Public Law 106-345) at the earliest possible time, it is necessary that this act take effect immediately.