AMENDED IN SENATE MAY 4, 2016

AMENDED IN SENATE APRIL 18, 2016

AMENDED IN SENATE APRIL 4, 2016

SENATE BILL No. 1408

Introduced by Senator Allen

February 19, 2016

An act to amend Section 1644.5 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1408, as amended, Allen. Tissue donation.

(1) 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 (HTLV), 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 authorizes the transplantation of tissue from a donor who has not been tested for specified infectious diseases or, with the exception of HIV and HTLV, has been found reactive, if specified conditions are satisfied.

This bill would delete the exception of HIV from this provision. *The bill would require a physician and surgeon performing the transplantation of tissue from an HIV-reactive donor to ensure that the recipient is also HIV reactive and complying with federal law, as specified.*

(2) Under existing law, it is a felony for a person to donate blood, body organs or other tissue, or semen to a medical center or semen bank who knows that he or she has acquired immunodeficiency syndrome (AIDS) except if the person is a sperm donor who has been screened and found nonreactive under the above provisions. Under existing law, a person afflicted with any contagious, infectious, or communicable disease who willfully exposes himself or herself to another person, and any person who willfully exposes another person afflicted with the disease to someone else, is guilty of a misdemeanor, except as provided.

This bill would exempt those sperm donors and tissue donors from those criminal provisions.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

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) Except as provided in subdivision (c) or (d), 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 human immunodeficiency virus (HIV), agents of viral hepatitis (HBV and HCV), and syphilis. For tissues that are rich in viable leukocytes, the tissue shall be tested for evidence of infection with human T lymphotropic virus (HTLV) and found nonreactive. 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 1602.5) 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 assisted reproductive technologies even if the sperm donor is found reactive for hepatitis B, hepatitis C, syphilis, HIV, or HTLV if the sperm donor is the spouse of, partner of, or designated donor for that recipient. The physician providing insemination or assisted 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 potential medical risks 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 assisted 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 assisted reproductive technology only after the recipient has been vaccinated against hepatitis B.

(B) (i) Sperm whose donor has tested reactive for HIV or HTLV may be used for the purposes of insemination or assisted reproductive technology for a recipient testing negative for HIV or HTLV 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 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, or any other virus as deemed appropriate by the department. The department may propose to adopt, as initial regulations, the recommendations made within the "Guidelines for Reducing Risk of Viral Transmission During Fertility Treatment" as published by the American Society for Reproductive Medicine. Notice of the department's proposed adoption of the regulations shall be posted on the department's Internet Web site for at least 45 days. Public comment shall be accepted by the department for at least 30 days after the conclusion of the 45-day posting period. If a member of the public requests a public hearing during the 30-day comment period, the hearing shall be held prior

to the adoption of the regulations. If no member of the public requests a public hearing, the regulations shall be deemed adopted at the conclusion of the 30-day comment period. Comments received shall be considered prior to the adoption of the final initial regulations. The department may modify any guidance published by the American Society for Reproductive Medicine. Adoption of initial regulations by the department pursuant to this subdivision shall not be subject to the rulemaking requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code and written responses to public comments shall not be required. Updates to the regulations shall be adopted pursuant to the same process. Until the department adopts these regulations, facilities that perform sperm processing pursuant to this section shall follow facility and sperm processing guidelines for the reduction of viral transmission developed by the American Society for Reproductive Medicine. Nothing in this section shall prevent the department from monitoring and inspecting facilities that process sperm to ensure adherence to the regulations, or, until regulations are adopted, to the guidelines set forth by the American Society for Reproductive Medicine.

(iii) Prior to insemination or other assisted reproductive technology services, the physician providing the services shall inform the recipient of sperm from a spouse, partner, or designated donor who has tested reactive for HIV or HTLV of all of the following:

(I) That sperm processing may not eliminate all of the risks of HIV or HTLV transmission.

(II) That the sperm may be tested to determine whether or not it is reactive for HIV or HTLV.

(III) That the recipient must provide documentation to the physician providing insemination or assisted reproductive technology services prior to treatment that she has established an ongoing relationship with another physician to provide for her medical care during and after completion of fertility services.

(IV) The recommendations made within the “Guidelines for Reducing the Risk of Viral Transmission During Fertility Treatment” published by the American Society for Reproductive Medicine regarding followup testing for HIV and HTLV after use of sperm from an HIV or HTLV reactive donor and have the

recommendations regarding followup testing be documented in the recipient's medical record.

(iv) The physician providing insemination or assisted 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 is under the care of a physician managing the HIV or HTLV.

(v) The physician providing insemination or assisted reproductive technology services shall recommend to the physician who will be providing ongoing care to the recipient recommended followup testing for HIV and HTLV according to the "Guidelines for Reducing the Risk of Viral Transmission During Fertility Treatment" published by the American Society for Reproductive Medicine, which shall be documented in the recipient's medical record.

(vi) If the recipient becomes HIV or HTLV positive, the physician assuming ongoing care of the recipient shall treat or provide information regarding referral to a physician who can provide ongoing treatment of the HIV or HTLV.

(4) A recipient of sperm donated by a sexually intimate partner of the recipient for reproductive use may waive a second or repeat testing of that donor if the recipient is informed of the donor testing requirements of this section and signs a written waiver. For purposes of this paragraph, "sexually intimate partner of the recipient" includes a known or designated donor to whose sperm the recipient has previously been exposed in a nonmedical setting in an attempt to conceive.

(d) Subdivision (a) shall not apply to the transplantation of tissue from a donor who has not been tested or, with the exception of HTLV, 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~~ *all* 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) The physician and surgeon performing the transplantation has ensured that tissue from an individual who has been found reactive for HIV may be transplanted only into an individual who satisfies both of the following:

(A) The individual has been found reactive for HIV before receiving the tissue.

(B) The individual is either participating in clinical research approved by an institutional review board under the criteria, standards, and regulations described in subsections (a) and (b) of Section 274f-5 of Title 42 of the United States Code, or, if the United States Secretary of Health and Human Services determines under subsection (c) of Section 274f-5 of Title 42 of the United States Code that participation in this clinical research is no longer warranted as a requirement for transplants, the individual is receiving the transplant under the standards and regulations under subsection (c) of Section 274f-5 of Title 42 of the United States Code.

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(3) 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) The penalties ~~of~~ prescribed in Sections 1621.5 and 120290 do not apply to a sperm donor covered under subdivision (c) or a tissue donor covered under subdivision (d).

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

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