AMENDED IN ASSEMBLY MAY 23, 2016

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~~ *Section 2221.1 of the Business and Professions Code, and to amend Sections 1621.5, 1635, 1635.1, 1644.5, and 120290* of the Health and Safety Code, relating to public ~~health.~~ *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~~ *an organ* 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~~ *organ* donors from those criminal provisions.

(3) Existing law authorizes the Medical Board of California and the California Board of Podiatric Medicine to take disciplinary action against a physician, surgeon, and other licensed or regulated individual who knowingly fails to protect patients by failing to follow infection control guidelines and risks transmission of blood-borne infectious diseases, as specified.

This bill would exempt the performance of an organ transplant, as authorized by this bill, from disciplinary action.

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 2221.1 of the Business and Professions Code is amended to read:

2221.1. (a) The board and the *California* Board of Podiatric Medicine shall investigate and may take disciplinary action, including, but not limited to, revocation or suspension of licenses, against physicians and surgeons and all others licensed or regulated by the board, or by the *California* Board of Podiatric Medicine, whichever is applicable, who, except for good cause, knowingly fail to protect patients by failing to follow infection control guidelines of the applicable board, thereby risking transmission of blood-borne infectious diseases from the physician and surgeon or other health care provider licensed or regulated by the applicable board to patients, from patients, and from patient to physician and surgeon or other health care provider regulated by the applicable

board. In so doing, the boards shall consider referencing the standards, regulations, and guidelines of the State Department of Health Services developed pursuant to Section 1250.11 of the Health and Safety Code and the standards, guidelines, and regulations pursuant to the California Occupational Safety and Health Act of 1973 (Part 1 (commencing with Section 6300), Division 5, Labor Code) for preventing the transmission of HIV, hepatitis B, and other blood-borne pathogens in health care settings. As necessary, the board and the *California* Board of Podiatric Medicine shall consult with the Board of Dental Examiners, the Board of Registered Nursing, and the Board of Vocational Nursing and Psychiatric Technicians, to encourage appropriate consistency in the implementation of this section.

(b) Subdivision (a) shall not apply to an organ transplant performed in compliance with subdivision (d) of Section 1644.5 of the Health and Safety Code.

~~(b)~~

(c) The board shall seek to ensure that licentiates and others regulated by the board are informed of the responsibility of licentiates to follow infection control guidelines and of the most recent scientifically recognized safeguards for minimizing the transmission of blood-borne infectious diseases.

SEC. 2. Section 1621.5 of the Health and Safety Code is amended to read:

1621.5. (a) It is a felony punishable by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code for two, four, or six years, for any person to donate ~~blood, body organs or other~~ *blood or* 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 immunodeficiency syndrome (AIDS), 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.

(d) For purposes of this section, "tissue" shall have the same meaning as defined in paragraph (1) of subdivision (c) of Section 1635.

SEC. 3. Section 1635 of the Health and Safety Code is amended to read:

1635. (a) "Donor" means an individual, living or deceased, from whom tissue is removed.

(b) "Person" means an individual, corporation, business trust, estate trust, partnership, association, state or local government, or subdivision or agency thereof, or any other legal entity.

(c) *(1)* "Tissue" means a human cell, group of cells, including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human ~~body.~~ *body, but shall not include an organ when recovered for transplantation or research purposes.*

(2) For purposes of paragraph (1), "organ" means a human kidney, liver, heart, lung, pancreas, intestine (including the esophagus, stomach, small or large intestine, or any portion of the gastrointestinal tract), or vascularized composite allograft, and associated blood vessels recovered from an organ donor during the recovery of the organ.

(d) "Tissue bank" means a place, establishment, or institution that collects, processes, stores, or distributes tissue for transplantation into human beings.

(e) "Transplantation" means the act or process of transferring tissue, including by ingestion, from a donor to the body of the donor or another human being.

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

SEC. 4. Section 1635.1 of the Health and Safety Code is amended to read:

1635.1. (a) Except as provided in subdivision (b), every tissue bank operating in California on or after July 1, 1992, shall have a current and valid tissue bank license issued or renewed by the department pursuant to Section 1639.2 or 1639.3.

(b) This chapter does not apply to any of the following:

(1) The collection, processing, storage, or distribution of human whole blood or its derivatives by blood banks licensed pursuant to Chapter 4 (commencing with Section 1600) or any person exempt from licensure under that chapter.

(2) The collection, processing, storage, or distribution of tissue for autopsy, biopsy, training, education, or for other medical or scientific research or investigation, when transplantation of the tissue is not intended or reasonably foreseeable.

(3) The collection of tissue by an individual physician and surgeon from his or her patient or the implantation of tissue by an individual physician and surgeon into his or her patient. This exemption shall not be interpreted to apply to any processing or storage of the tissue, except for the processing and storage of semen by an individual physician and surgeon when the semen was collected by that physician and surgeon from a semen donor or obtained by that physician and surgeon from a tissue bank licensed under this chapter.

(4) The collection, processing, storage, or distribution of fetal tissue or tissue derived from a human embryo or fetus.

(5) The collection, processing, storage, or distribution by an organ procurement organization (OPO), as defined in Section 485.302 of Title 42 of the Code of Federal Regulations, if the OPO, at the time of collection, processing, storage, and distribution of the ~~organ,~~ *tissue*, has been designated by the Secretary of Health and Human Services as an OPO, pursuant to Section 485.305 of Title 42 of the Code of Federal Regulations, and meets the requirements of Sections 485.304 and 485.306 of Title 42 of the Code of Federal Regulations, as applicable.

(6) The storage of prepackaged, freeze-dried bone by a general acute care hospital.

(7) The storage of freeze-dried bone and dermis by any licensed dentist practicing in a lawful practice setting, if the freeze-dried bone and dermis has been obtained from a licensed tissue bank, is stored in strict accordance with a kit's package insert and any other manufacturer instructions and guidelines, and is used for the express purpose of implantation into a patient.

(8) The storage of a human cell, tissue, or cellular- or tissue-based product, as defined by the federal Food and Drug Administration, that is either a medical device approved pursuant to Section 510 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Secs. 360 and 360e) or that is a biologic product approved under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262) by a licensed physician or podiatrist acting within the scope and authority of his or her license and practicing in a lawful practice setting. The medical device or biologic product must have been obtained from a California licensed tissue bank, been stored in strict accordance with the device's or product's package insert and any other manufacturer instructions, and used solely for the express purpose of direct implantation into or application on the practitioner's own patient. In order to be eligible for the exemption in this paragraph, the entity or organization where the physician or podiatrist who is eligible for the exemption is practicing shall notify the department, in writing, that the practitioner is licensed and meets the requirements of this paragraph. The notification shall include all of the following:

(A) A list of all practitioners to whom the notice applies.

(B) Acknowledgment that each listed practitioner uses the medical device or biologic product in the scope and authority of his or her license and practice for the purposes of direct patient care as described in this paragraph.

(C) A statement that each listed practitioner agrees to strictly abide by the directions for storage in the device's or product's package insert and any other manufacturer instructions and guidelines.

(D) Acknowledgment by each practitioner that the medical device or biologic product shall not be resold or distributed.

(9) The collection, processing, storage, or distribution of any organ, as defined in paragraph (2) of subdivision (c) of Section 1635, within a single general acute care hospital, as defined in subdivision (a) of Section 1250, operating a Medicare-approved transplant program.

~~SECTION 1.~~

SEC. 5. 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 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~~ *an organ* 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.~~ *organ.*

(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.

(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 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).~~ *(c) or an organ donor who donates an organ for transplantation or research purposes.*

(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.

SEC. 6. Section 120290 of the Health and Safety Code is amended to read:

120290. *(a)* Except as provided in Section 120291 or in the case of the removal of an afflicted person in a manner the least dangerous to the public health, any 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.

(b) This section shall not apply to a person who donates an organ for transplantation or research purposes.

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