AMENDED IN SENATE JULY 23, 2009

AMENDED IN SENATE JUNE 30, 2009

AMENDED IN ASSEMBLY MAY 11, 2009

AMENDED IN ASSEMBLY MAY 5, 2009

AMENDED IN ASSEMBLY APRIL 13, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 995

Introduced by Assembly Member Block

February 27, 2009

An act to amend Section 1635.1 of the Health and Safety Code, relating to tissue banks.

LEGISLATIVE COUNSEL'S DIGEST

AB 995, as amended, Block. Tissue bank licensing.

Existing law requires all tissue banks, with certain specified exceptions, to be licensed by the State Department of Public ~~health~~ *Health*.

This bill would add to the list of licensure exceptions the storage of ~~federal Food and Drug Administration (FDA)-regulated tissue-engineered products~~ *a human cell, tissue, or cellular- or tissue-based product that is either a medical device or a biologic product, as defined,* by a ~~person~~ licensed *physician or podiatrist* ~~to provide health care services,~~ acting within the scope of ~~their~~ *his or her* license and practicing in a lawful practice setting, ~~provided that the federal FDA-regulated tissue-engineered product has been obtained from a licensed tissue bank and is stored in strict accordance with federal~~

~~FDA regulations and guidelines and is used for the express purpose of implantation into or application on a patient and is not intended for further distribution~~ *as specified. The bill would also require, to be eligible for this exemption, that the entity where the physician or podiatrist practices notify the department of specified information.*

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

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

SECTION 1. 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 shall 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, where 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, 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, providing that the freeze-dried bone and dermis has been obtained from a licensed tissue bank and 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. Sec. 360,, 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.

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~~(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 a 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, where 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, 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 a licensed dentist practicing in a lawful practice setting, providing that the freeze-dried bone and dermis has been obtained from a licensed tissue bank and 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 federal Food and Drug Administration (FDA)-regulated tissue-engineered products by a person licensed to provide health care services, acting within the scope of their license and practicing in a lawful practice setting, provided that the federal FDA-regulated tissue-engineered product has been obtained from a licensed tissue bank and is stored in strict accordance with federal FDA regulations and guidelines and is used for the express purpose of implantation into or application on a patient and is not intended for further distribution.~~

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