ASSEMBLY BILL No. 1822

Introduced by Assembly Member Bonta

February 18, 2014

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

LEGISLATIVE COUNSEL'S DIGEST

AB 1822, as introduced, Bonta. Tissue banks.

Existing federal law governs the processing, storage, and use of human tissue and human cell, tissue, or cellular- or tissue-based products (HCT/P), as specified, and imposes certain regulatory duties relating to HCT/P upon the federal Food and Drug Administration (FDA).

Existing state law requires the State Department of Public Health to license and regulate tissue banks, which process, store, or distribute human tissue for transplantation into human beings. Existing law generally requires every tissue bank operating in this state to have a current and valid tissue bank license issued or renewed by the department, but exempts certain activities from that requirement, including the storage of HCT/P by a licensed physician or podiatrist, as specified, if the products were obtained from a California licensed tissue bank, stored in strict accordance with manufacturer instructions, and used solely for the express purpose of direct implantation into or application on the practitioner's own patient, among other criteria.

This bill would create an additional exemption from the tissue bank licensing requirement for the storage of HCT/P regulated by the FDA, as specified, by a person who is licensed to provide health care services, if specified circumstances apply, including that the HCT/P are obtained from a licensed tissue bank, stored in strict accordance with FDA

regulations, and used for the express purpose of implantation into or application on a patient.

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~~ *486.302* 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,~~ *OPO* and

meets the requirements of Sections ~~485.304 and 485.306~~ *486.304 and 486.306* 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,~~ *product (HCT/P),* as defined by the federal Food and Drug ~~Administration,~~ *Administration (FDA),* 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)~~ *360 et seq.)* 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 storage of an HCT/P regulated by the FDA pursuant to Parts 1270 and 1271 of Title 21 of the Code of Federal Regulations by a person who is licensed to provide health care services, acting within the scope of the license and practicing in a lawful practice setting, if all of the following apply:

(A) The HCT/P has been obtained from a licensed tissue bank.

(B) The HCT/P is stored in strict accordance with federal FDA regulations and guidelines.

(C) The HCT/P is used for the express purpose of implantation into or application on a patient, and not intended for further distribution.

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