Assembly Bill No. 1822

Passed the Assembly August 28, 2014

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Chief Clerk of the Assembly

Passed the Senate August 27, 2014

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Secretary of the Senate

This bill was received by the Governor this _____ day of _____, 2014, at _____ o'clock ___M.

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Private Secretary of the Governor

CHAPTER _____

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

LEGISLATIVE COUNSEL'S DIGEST

AB 1822, 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 by a person if that person is a hospital or outpatient setting and the HCT/P meets specified requirements, including, among other things, that the HCT/P was obtained from a tissue bank licensed by the state, is stored in the original unopened enclosure for one finished unit of transplantable tissue and in strict accordance with the package insert and any other manufacturer instructions and guidelines, and is intended for the express purpose of implantation into or application on a patient.

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 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 and meets the requirements of Sections 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 have been obtained from a licensed tissue bank and are stored in strict accordance with a kit's package insert and any other manufacturer instructions and guidelines and are used for the express purpose of implantation into a patient.

(8) The storage of a human cell, tissue, or cellular- or tissue-based product (HCT/P), as defined by the federal Food and Drug 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 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 by a person if both of the following apply:

(A) The person, as defined in Section 1635, is a hospital, or an outpatient setting regulated by the Medical Board of California

pursuant to Chapter 1.3 (commencing with Section 1248), including an ambulatory surgical center.

(B) The HCT/P meets all of the following:

(i) The HCT/P was obtained from a tissue bank licensed by the state.

(ii) The HCT/P is stored in the original unopened enclosure for one finished unit of transplantable tissue and is stored in strict accordance with the package insert and any other manufacturer instructions and guidelines.

(iii) The HCT/P is intended for the express purpose of implantation into or application on a patient.

(iv) The HCT/P is not intended for further distribution.

(v) The HCT/P is regulated by the FDA pursuant to Parts 1270 and 1271 of Title 21 of the Code of Federal Regulations.

Approved _____, 2014

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Governor