HEALTH AND SAFETY CODE - HSC

DIVISION 2. LICENSING PROVISIONS [1200 - 1796.70] *(Division 2 enacted by Stats. 1939, Ch. 60.)*

CHAPTER 4.1. Tissue Banks [1635 - 1643.2] *(Chapter 4.1 added by Stats. 1991, Ch. 801, Sec. 2.)*

ARTICLE 1. Definitions, Licensure, and Exceptions [1635 - 1635.2] *(Article 1 added by Stats. 1991, Ch. 801, Sec. 2.)*

1635. (a) “Department” means the State Department of Public Health.

(b) “Donor” means an individual, living or deceased, from whom tissue is removed.

(c) “Gamete bank” means a tissue bank that collects, processes, stores, or distributes sperm, oocytes, or embryos, including a facility that provides professional reproductive services, other than those facilities exempt from tissue bank licensure.

(d) “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.

(e) (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, oocytes, embryos, blood, other fluids, and any other portion of a human 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.

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

(g) “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.

(Amended by Stats. 2019, Ch. 539, Sec. 1. (AB 785) Effective January 1, 2020.)

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 their patient or the implantation of tissue by an individual physician and surgeon into their 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

tissue, 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, if the freeze-dried bone and dermis have been obtained from a licensed tissue bank, 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 their 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 their 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.

(10) The storage of allograft tissue by a person if all 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 person maintains a log that includes the date on which the allograft tissue was received, the expiration date of the allograft tissue, the date on which each allograft tissue is used for clinical purposes, and the disposition of any allograft tissue samples that remain unused at the time the allograft tissue expires.

(C) The allograft tissue meets all of the following:

(i) The allograft tissue was obtained from a tissue bank licensed by the state.

(ii) Each allograft tissue is individually boxed and labeled with a unique identification number and expiration date so that opening the shipping container will not disturb or otherwise alter any of the allograft tissue that is not being utilized.

(iii) The allograft tissue is intended for the express purpose of implantation into or application on a patient.

(iv) The allograft tissue is not intended for further distribution.

(v) The allograft tissue is registered with the FDA and designated to be maintained at ambient room temperature requiring no refrigeration.

(11) The storage or preparation for patient administration of tissue performed at a clinical trial site that is intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with the requirements of Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Sec. 360j(g)) and the regulations adopted pursuant to the federal act.

(12) The storage or distribution of pasteurized donor human milk that was obtained from a tissue bank, licensed pursuant to this chapter, by a general acute care hospital. A general acute care hospital that is exempt from licensure as a tissue bank pursuant to

this paragraph shall comply with the requirements of subdivision (b) of Section 1648.

(Amended by Stats. 2024, Ch. 975, Sec. 2. (AB 3059) Effective January 1, 2025.)

1635.2. The Legislature hereby declares its intent that the collection, processing, storage, or distribution of tissue for the purpose of transplantation, as regulated by this chapter, shall be deemed a service by those persons engaged in these activities. Therefore, the collection, processing, storage, or distribution of tissue for the purpose of transplantation, as regulated by this chapter, shall not be subject to the requirements of Division 2 (commencing with Section 2101) of the Commercial Code.

(Added by Stats. 1991, Ch. 801, Sec. 2.)