AB-3059 Human milk. (2023-2024)

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Assembly Bill No. 3059

CHAPTER 975

An act to amend Sections 1635.1 and 1648 of, and to add Section 1367.624 to, the Health and Safety Code, and to add Section 10123.864 to the Insurance Code, relating to human milk.

[Approved by Governor September 29, 2024. Filed with Secretary of State September 29, 2024.]

LEGISLATIVE COUNSEL'S DIGEST

AB 3059, Weber. Human milk.

Existing law licenses and regulates tissue banks and generally makes a violation of the requirements applicable to tissue banks a crime.

This bill would specify that a general acute care hospital is not required to have a license to operate a tissue bank to store or distribute pasteurized donor human milk that was obtained from a tissue bank licensed by the State Department of Public Health. The bill would exempt from licensing requirements a hospital storing or distributing human milk obtained from a licensed tissue bank. The bill would require hospitals that collect, process, store, or distribute human milk in any other circumstance to obtain a tissue bank license. To the extent that the bill would expand the class of hospitals subject to tissue bank licensing requirements, thereby expanding a crime, the bill would impose a state-mandated local program.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, requires the Department of Managed Health Care to license and regulate health care service plans and makes a willful violation of the act a crime. Other existing law requires the Department of Insurance to regulate health insurers. Existing law requires health care service plans and health insurers, as specified, to provide certain health benefits and services, including, among others, maternity hospital stays, inpatient hospital and ambulatory maternity services, and maternal mental health programs. Existing law generally requires a health care service plan or health insurance policy to provide an enrollee or insured with basic health care services, as specified.

This bill would include, in the above-described basic health care services, medically necessary pasteurized donor human milk obtained from a tissue bank licensed by the State Department of Public Health.

Because a violation of the bill's provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1367.624 is added to the Health and Safety Code, to read:

1367.624. The provision of medically necessary pasteurized donor human milk obtained from a tissue bank licensed pursuant to Chapter 4.1 (commencing with Section 1635) is a basic health care service, as defined in subdivision (b) of Section 1345 and any regulations adopted thereunder.

SEC. 2. 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 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.

SEC. 3. Section 1648 of the Health and Safety Code is amended to read:

1648. (a) A hospital collecting, processing, storing, or distributing human milk collected from a mother exclusively for the mother's own child, or a hospital storing or distributing human milk obtained from a tissue bank that is licensed pursuant to Chapter 4.1 (commencing with Section 1635), is exempt from the requirements of Chapter 4.1 (commencing with Section 1635). Hospitals that collect, process, store, or distribute human milk in any other circumstance shall obtain a tissue bank license pursuant to Chapter 4.1 (commencing with Section 1635).

(b) A hospital that is exempt from tissue bank licensure pursuant to subdivision (a) shall comply with the most current standards established for the collection, processing, storage, or distribution of human milk by the Human Milk Banking Association of North America or other standards approved by the department.

(c) Notwithstanding any other provision of law, no screening tests shall be required to be performed on human milk collected from a mother exclusively for the mother's own child.

(d) The department shall assess hospital processes for collecting, processing, storing, or distributing human milk pursuant to its current practice, as required by Chapter 2 (commencing with Section 1250).

SEC. 4. Section 10123.864 is added to the Insurance Code, to read:

10123.864. The provision of medically necessary pasteurized donor human milk obtained from a tissue bank licensed pursuant to Chapter 4.1 (commencing with Section 1635) of Division 2 of the Health and Safety Code is a basic health care service, as described in Sections 10112.27 and 10112.281 and any regulations adopted thereunder.

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.