

AMENDED IN SENATE MAY 23, 2016

AMENDED IN ASSEMBLY APRIL 7, 2016

AMENDED IN ASSEMBLY MARCH 17, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 2750

Introduced by Assembly Member Gomez

February 19, 2016

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

LEGISLATIVE COUNSEL'S DIGEST

AB 2750, as amended, Gomez. 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 allograft tissue~~ by a person if that person is a hospital or outpatient ~~setting~~ *setting, the person maintains a log including specified information pertaining to the allograft tissue, and the ~~HCT/P allograft tissue~~ meets specified requirements, including, among other things, that the ~~HCT/P allograft tissue~~ was obtained from a California-licensed tissue bank licensed by the state; bank, 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, individually boxed and labeled with a unique identification number and expiration date, and is intended 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:

- 1 SECTION 1. Section 1635.1 of the Health and Safety Code is
- 2 amended to read:
- 3 1635.1. (a) Except as provided in subdivision (b), every tissue
- 4 bank operating in California on or after July 1, 1992, shall have a
- 5 current and valid tissue bank license issued or renewed by the
- 6 department pursuant to Section 1639.2 or 1639.3.
- 7 (b) This chapter does not apply to any of the following:
- 8 (1) The collection, processing, storage, or distribution of human
- 9 whole blood or its derivatives by blood banks licensed pursuant
- 10 to Chapter 4 (commencing with Section 1600) or any person
- 11 exempt from licensure under that chapter.
- 12 (2) The collection, processing, storage, or distribution of tissue
- 13 for autopsy, biopsy, training, education, or for other medical or
- 14 scientific research or investigation, when transplantation of the
- 15 tissue is not intended or reasonably foreseeable.
- 16 (3) The collection of tissue by an individual physician and
- 17 surgeon from his or her patient or the implantation of tissue by an
- 18 individual physician and surgeon into his or her patient. This
- 19 exemption shall not be interpreted to apply to any processing or
- 20 storage of the tissue, except for the processing and storage of semen
- 21 by an individual physician and surgeon when the semen was
- 22 collected by that physician and surgeon from a semen donor or

1 obtained by that physician and surgeon from a tissue bank licensed
2 under this chapter.

3 (4) The collection, processing, storage, or distribution of fetal
4 tissue or tissue derived from a human embryo or fetus.

5 (5) The collection, processing, storage, or distribution by an
6 organ procurement organization (OPO), as defined in Section
7 486.302 of Title 42 of the Code of Federal Regulations, if the OPO,
8 at the time of collection, processing, storage, and distribution of
9 the organ, has been designated by the Secretary of Health and
10 Human Services as an OPO and meets the requirements of Sections
11 486.304 and 486.306 of Title 42 of the Code of Federal
12 Regulations, as applicable.

13 (6) The storage of prepackaged, freeze-dried bone by a general
14 acute care hospital.

15 (7) The storage of freeze-dried bone and dermis by any licensed
16 dentist practicing in a lawful practice setting, if the freeze-dried
17 bone and dermis have been obtained from a licensed tissue bank,
18 are stored in strict accordance with a kit's package insert and any
19 other manufacturer instructions and guidelines, and are used for
20 the express purpose of implantation into a patient.

21 (8) The storage of a human cell, tissue, or cellular- or
22 tissue-based product (HCT/P), as defined by the federal Food and
23 Drug Administration (FDA), that is either a medical device
24 approved pursuant to Section 510 or 515 of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. Sec. 360 et seq.) or that is a
26 biologic product approved under Section 351 of the federal Public
27 Health Service Act (42 U.S.C. Sec. 262) by a licensed physician
28 or podiatrist acting within the scope and authority of his or her
29 license and practicing in a lawful practice setting. The medical
30 device or biologic product must have been obtained from a
31 California-licensed tissue bank, been stored in strict accordance
32 with the device's or product's package insert and any other
33 manufacturer instructions, and used solely for the express purpose
34 of direct implantation into or application on the practitioner's own
35 patient. In order to be eligible for the exemption in this paragraph,
36 the entity or organization where the physician or podiatrist who is
37 eligible for the exemption is practicing shall notify the department,
38 in writing, that the practitioner is licensed and meets the
39 requirements of this paragraph. The notification shall include all
40 of the following:

1 (A) A list of all practitioners to whom the notice applies.

2 (B) Acknowledgment that each listed practitioner uses the
3 medical device or biologic product in the scope and authority of
4 his or her license and practice for the purposes of direct patient
5 care as described in this paragraph.

6 (C) A statement that each listed practitioner agrees to strictly
7 abide by the directions for storage in the device’s or product’s
8 package insert and any other manufacturer instructions and
9 guidelines.

10 (D) Acknowledgment by each practitioner that the medical
11 device or biologic product shall not be resold or distributed.

12 (9) The storage of ~~an HCT/P~~ *allograft tissue* by a person if ~~both~~
13 *all* of the following apply:

14 (A) The person, as defined in Section 1635, is a hospital, or an
15 outpatient setting regulated by the Medical Board of California
16 pursuant to Chapter 1.3 (commencing with Section 1248), including
17 an ambulatory surgical center.

18 (B) *The person maintains a log that includes the date on which*
19 *the allograft tissue was received, the expiration date of the allograft*
20 *tissue, the date on which each allograft tissue is used for clinical*
21 *purposes, and the disposition of any allograft tissue samples that*
22 *remain unused at the time the allograft tissue expires.*

23 ~~(B)~~

24 (C) The ~~HCT/P~~ *allograft tissue* meets all of the following:

25 (i) The ~~HCT/P~~ *allograft tissue* was obtained from a tissue bank
26 licensed by the state.

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

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

35 (iii) The ~~HCT/P~~ *allograft tissue* is intended for the express
36 purpose of implantation into or application on a patient.

37 (iv) The ~~HCT/P~~ *allograft tissue* is not intended for further
38 distribution.

39 (v) The ~~HCT/P~~ *allograft tissue* is ~~regulated by~~ *registered with*
40 *the FDA pursuant to Part 1270 and Part 1271 of Title 21 of the*

- 1 ~~Code of Federal Regulations.~~ *and designated to be maintained at*
- 2 *ambient room temperature requiring no refrigeration.*

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