

AMENDED IN SENATE JUNE 13, 2016

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 allograft tissue by a person if that person is a hospital or outpatient setting, the person maintains a log including specified information pertaining to the allograft tissue, and the allograft tissue meets specified requirements, including, among other things, that the allograft tissue was obtained from a California-licensed tissue bank, is 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
 23 obtained by that physician and surgeon from a tissue bank licensed
 24 under this chapter.

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

3 (5) The collection, processing, storage, or distribution by an
4 organ procurement organization (OPO), as defined in Section
5 ~~485.302~~ 486.302 of Title 42 of the Code of Federal Regulations,
6 if the OPO, at the time of collection, processing, storage, and
7 distribution of the tissue, has been designated by the Secretary of
8 Health and Human Services as an ~~OPO, pursuant to Section~~
9 ~~485.305 of Title 42 of the Code of Federal Regulations~~, *OPO* and
10 meets the requirements of Sections ~~485.304~~ 486.304 and ~~485.306~~
11 ~~486.306~~ of Title 42 of the Code of Federal Regulations, as
12 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 ~~has~~ *have* been obtained from a licensed tissue
18 bank, ~~is~~ *are* stored in strict accordance with a kit's package insert
19 and any other manufacturer instructions and guidelines, and ~~is~~ *are*
20 used for the express purpose of implantation into a patient.

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

1 requirements of this paragraph. The notification shall include all
2 of the following:

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

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

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

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

14 (9) The collection, processing, storage, or distribution of any
15 organ, as defined in paragraph (2) of subdivision (c) of Section
16 1635, within a single general acute care hospital, as defined in
17 subdivision (a) of Section 1250, operating a Medicare-approved
18 transplant program.

19 *(10) The storage of allograft tissue by a person if all of the*
20 *following apply:*

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

25 *(B) The person maintains a log that includes the date on which*
26 *the allograft tissue was received, the expiration date of the allograft*
27 *tissue, the date on which each allograft tissue is used for clinical*
28 *purposes, and the disposition of any allograft tissue samples that*
29 *remain unused at the time the allograft tissue expires.*

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

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

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

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

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

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

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16 ~~for autopsy, biopsy, training, education, or for other medical or~~
17 ~~scientific research or investigation, when transplantation of the~~
18 ~~tissue is not intended or reasonably foreseeable.~~

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20 ~~surgeon from his or her patient or the implantation of tissue by an~~
21 ~~individual physician and surgeon into his or her patient. This~~
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26 ~~obtained by that physician and surgeon from a tissue bank licensed~~
27 ~~under this chapter.~~

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34 ~~the organ, has been designated by the Secretary of Health and~~
35 ~~Human Services as an OPO and meets the requirements of Sections~~
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37 ~~Regulations, as applicable.~~

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 8 ~~tissue-based product (HCT/P), as defined by the federal Food and~~
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 10 ~~approved pursuant to Section 510 or 515 of the Federal Food,~~
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 - 32 ~~(C) A statement that each listed practitioner agrees to strictly~~
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 34 ~~package insert and any other manufacturer instructions and~~
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 - 36 ~~(D) Acknowledgment by each practitioner that the medical~~
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2 outpatient setting regulated by the Medical Board of California
3 pursuant to Chapter 1.3 (commencing with Section 1248), including
4 an ambulatory surgical center.
- 5 (B) The person maintains a log that includes the date on which
6 the allograft tissue was received, the expiration date of the allograft
7 tissue, the date on which each allograft tissue is used for clinical
8 purposes, and the disposition of any allograft tissue samples that
9 remain unused at the time the allograft tissue expires.
- 10 (C) The allograft tissue meets all of the following:
- 11 (i) The allograft tissue was obtained from a tissue bank licensed
12 by the state.
- 13 (ii) Each allograft tissue is individually boxed and labeled with
14 a unique identification number and expiration date so that opening
15 the shipping container will not disturb or otherwise alter any of
16 the allograft tissue that is not being utilized.
- 17 (iii) The allograft tissue is intended for the express purpose of
18 implantation into or application on a patient.
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