

AMENDED IN ASSEMBLY APRIL 7, 2016  
AMENDED IN ASSEMBLY MARCH 17, 2016  
CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

**ASSEMBLY BILL**

**No. 2750**

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**Introduced by Assembly Member Gomez**

February 19, 2016

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~~An act to amend Section 68130.5 of the Education Code, relating to postsecondary education. 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. ~~Postsecondary education: exemption from nonresident tuition.~~ *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.*

~~(1) Existing law exempts a student, other than a nonimmigrant alien, as defined, from paying nonresident tuition at the California State University and the California Community Colleges if the student meets certain requirements. These requirements include either high school attendance in California for 3 or more years or the attainment of credits earned in California from a California high school equivalent to 3 or more years of full-time high school coursework and a total of 3 or more years of attendance in California elementary or secondary schools, or a combination of those schools.~~

~~This bill would delete the requirement of a total of 3 or more years of attendance in California elementary or secondary schools, or a combination of those schools, as referenced above. The bill would also add the requirement that a student be born after January 1, 1980.~~

~~The bill would request the Regents of the University of California to enact exemptions from requirements to pay nonresident tuition for its students that are equivalent to those applicable to students of the California Community Colleges and the California State University pursuant to this bill.~~

~~Because the bill would impose new duties on community college districts with respect to determining eligibility for exemptions from paying nonresident tuition, the bill would constitute a state-mandated local program.~~

~~(2) 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, if the Commission on State Mandates determines that the bill contains costs mandated by the state, reimbursement for those costs shall be made pursuant to these statutory provisions.~~

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: *yes-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.

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

27     (5) The collection, processing, storage, or distribution by an  
28 organ procurement organization (OPO), as defined in Section  
29 ~~485.302~~ 486.302 of Title 42 of the Code of Federal Regulations,  
30 if the OPO, at the time of collection, processing, storage, and  
31 distribution of the organ, has been designated by the Secretary of  
32 Health and Human Services as an ~~OPO~~, pursuant to Section  
33 ~~485.305~~ of Title 42 of the Code of Federal Regulations, *OPO* and  
34 meets the requirements of Sections ~~485.304~~ 486.304 and ~~485.306~~

1 486.306 of Title 42 of the Code of Federal Regulations, as  
 2 applicable.

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

5 (7) The storage of freeze-dried bone and dermis by any licensed  
 6 dentist practicing in a lawful practice setting, if the freeze-dried  
 7 bone and dermis ~~has~~ *have* been obtained from a licensed tissue  
 8 bank, ~~is~~ *are* stored in strict accordance with a kit’s package insert  
 9 and any other manufacturer instructions and guidelines, and ~~is~~ *are*  
 10 used for the express purpose of implantation into a patient.

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

- 32 (A) A list of all practitioners to whom the notice applies.
- 33 (B) Acknowledgment that each listed practitioner uses the  
 34 medical device or biologic product in the scope and authority of  
 35 his or her license and practice for the purposes of direct patient  
 36 care as described in this paragraph.
- 37 (C) A statement that each listed practitioner agrees to strictly  
 38 abide by the directions for storage in the device’s or product’s  
 39 package insert and any other manufacturer instructions and  
 40 guidelines.

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

3 (9) *The storage of an HCT/P by a person if both of the following*  
4 *apply:*

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

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

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

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

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

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

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

21 ~~SECTION 1. Section 68130.5 of the Education Code is~~  
22 ~~amended to read:~~

23 ~~68130.5. Notwithstanding any other law:~~

24 (a) ~~A student, other than a nonimmigrant alien within the~~  
25 ~~meaning of paragraph (15) of subsection (a) of Section 1101 of~~  
26 ~~Title 8 of the United States Code, who meets all of the following~~  
27 ~~requirements shall be exempt from paying nonresident tuition at~~  
28 ~~the California State University and the California Community~~  
29 ~~Colleges:~~

30 (1) ~~Satisfaction of either of the following:~~

31 (A) ~~High school attendance in California for three or more years.~~

32 (B) ~~Attainment of credits earned in California from a California~~  
33 ~~high school equivalent to three or more years of full-time high~~  
34 ~~school coursework.~~

35 (2) ~~Graduation from a California high school or attainment of~~  
36 ~~the equivalent thereof.~~

37 (3) ~~Registration as an entering student at, or current enrollment~~  
38 ~~at, an accredited institution of higher education in California not~~  
39 ~~earlier than the fall semester or quarter of the 2001-02 academic~~  
40 ~~year.~~

1 ~~(4) Was born after January 1, 1980.~~

2 ~~(5) In the case of a person without lawful immigration status,~~  
3 ~~the filing of an affidavit with the institution of higher education~~  
4 ~~stating that the student has filed an application to legalize his or~~  
5 ~~her immigration status, or will file an application as soon as he or~~  
6 ~~she is eligible to do so.~~

7 ~~(b) A student exempt from nonresident tuition under this section~~  
8 ~~may be reported by a community college district as a full-time~~  
9 ~~equivalent student for apportionment purposes.~~

10 ~~(c) The Board of Governors of the California Community~~  
11 ~~Colleges and the Trustees of the California State University shall~~  
12 ~~prescribe rules and regulations for the implementation of this~~  
13 ~~section.~~

14 ~~(d) Student information obtained in the implementation of this~~  
15 ~~section is confidential.~~

16 ~~SEC. 2. The Regents of the University of California are~~  
17 ~~requested to enact exemptions from requirements to pay~~  
18 ~~nonresident tuition for its students that are equivalent to those~~  
19 ~~applicable to students of the California Community Colleges and~~  
20 ~~the California State University pursuant to Section 68130.5 of the~~  
21 ~~Education Code, as amended pursuant to this act.~~

22 ~~SEC. 3. If the Commission on State Mandates determines that~~  
23 ~~this act contains costs mandated by the state, reimbursement to~~  
24 ~~local agencies and school districts for those costs shall be made~~  
25 ~~pursuant to Part 7 (commencing with Section 17500) of Division~~  
26 ~~4 of Title 2 of the Government Code.~~