



KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

October 20, 2016

Dear California Tissue Bank Director,

On September 9, 2016, Assembly Bill 2750 was signed into law by the Governor. This bill created an exemption from current California tissue bank licensing laws regarding the storage of allograft tissue under certain conditions, as explained below.

The new exemption becomes effective on January 1, 2017. It will be found in the California Health and Safety Code section 1635.1.

(b) This chapter does not apply to any of the following:

(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.

(8) 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.

If your facility meets the requirements cited above and is NOT storing any tissue that requires a refrigerator, a freezer, or liquid nitrogen, and your facility is NOT transferring any tissue to another facility, your facility will not need to renew your current California tissue bank license.

If your facility qualifies for the exemption and will no longer require California tissue bank licensure, please complete the included affirmation letter



(<http://www.cdph.ca.gov/programs/lfs/documents/TissueBankAffirmationLetter.pdf>) and return to:

CDPH / LFS
Tissue Bank Program
850 Marina Bay Parkway, Building P, 1st Floor
Richmond, CA 94804-6403

Please include a cover letter stating that your facility will not be renewing your tissue bank license because your facility meets the exemption criteria. If in the future your facility wants to store tissue which cannot be stored at ambient temperature, you will need to apply for a new CA tissue bank license.

If you have any questions, please email LFSTissue@cdph.ca.gov.

Sincerely,

A handwritten signature in black ink that reads "Ronald M. Harkey". The signature is written in a cursive style with a long, sweeping underline that extends to the right.

Ronald M. Harkey
Section Chief, Tissue Bank Program