

## Tissue Bank License for Handling Mother's Own Milk for Her Infant

November 17, 2005

Colleagues:

Earlier this month, Dr. Jon Rosenberg sent a message to CACC [California APIC (Assoc. for Professionals in Infection Control) Coordinating Council] members indicating that any healthcare facility that stores human milk, even for administration to the mother's own child, is required by California law to be a licensed tissue bank.

The tissue bank law is found in Chapter 4.1 of the California Health and Safety Code (Sections 1635-1643.2):

1635. (a) "Donor" is an individual, living or deceased, from whom **tissue** is removed.

(b) "Person" is an individual, corporation, business trust, estate trust, partnership, association, state or local government, or subdivision or agency thereof, or any other legal entity.

(c) "**Tissue**" is any human cell, group of cells, tissue or organ including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human body.

(d) "**Tissue bank**" is any place, establishment, or institution that collects, processes, stores, or distributes **tissue** for transplantation into human beings.

(e) "Transplantation" is the act or process of transferring **tissue**, including by ingestion, from a donor to the body of the donor or another human being.

(f) "State department" is the State Department of Health Services.

(Underlining added by me)

According to this law, human milk for a mother's own infant, stored (definition is overnight or change of date) would require a tissue bank license. Although most of us consider the definition of milk bank to be a facility that processes human milk, we are all milk banks/tissue banks by the above definition. Blood banks are exempt because they have their own more extensive regulations. Sperm banks are not exempt, only individual physicians who directly implant the sperm.

I have gone to the California Health and Safety Code (All 1600 sections pertain to Tissue Banks – primarily 1635-1635.2) (<http://www.leginfo.ca.gov/cgi-bin/waisgate?WAIISdocID=19999916188+1+0+0&WAIISaction=retrieve>) and related codes, emailed and spoken with Jon Rosenberg MD, Division of Communicable Disease Control, CA DHS, and Tuesday 11/15/05 participated in a conference call with Ron Harkey, Chief of the DHS Tissue Bank Licensing Program, and Jan Otey and Clint Venable of that program.

The law in question and its regulations are not new. The DHS Tissue Bank Licensing Program has been licensing homologous milk banks since the beginning of the program in 1992. Recently a number of new commercial for-profit milk banks have caused them to look at existing facilities more closely. Any hospital that accepts and stores milk from one of these facilities must also be a milk bank. They did not realize, but soon found out, that storage of milk for a mother's own child by the hospital was quite common, and that in some instances record keeping, labeling, and storage requirements for this activity were somewhat lax. Historically, the tissue banking licensing program has been a slowly evolving program to which new activities are continuously added as the program becomes aware of their existence.

Mr. Harkey did clarify that a consent form would not be needed or appropriate for mother's own milk. Mr. Venable clarified that a separate tissue bank license (with a separate fee) would be appropriate for those hospitals who already have a tissue bank license for other tissues (skin, eye, kidneys) as the policies/ procedures and medical direction would be quite different and should there be any problems with the other tissue bank, any program on the same license would need to be shut down.

I think we all are in agreement that a mother's own milk can be literally lifesaving for her preterm infant and results in improved short and long-term outcomes for all infants. We also agree that there must be quality control policies/procedures and guidelines as to how to store and use mother's own milk safely for her own infant. Most of us believe we do a good job, using recognized national ([www.hmbana.org](http://www.hmbana.org)) and California ([www.cpqcc.org](http://www.cpqcc.org)) guidelines. Where we disagree is the appropriateness of classifying the storage and use of a mother's own milk as a "tissue bank". As physicians, lactation consultants, nurses and hospitals, we are concerned that the gains we have made in the use of mother's milk for preterm and ill infants in California's NICUs will be lost due to burdensome regulations that discourage hospitals from collecting, storing and providing the mother's own milk to feed her own infant.

It appears that a mother's own milk for her infant does fall within the current law as a "tissue bank". Until we amend the law (if that is what we wish to do), Mr. Harkey and his colleagues must operate by that law, now that they are aware of current NICU milk storage and usage. I believe they truly want to ensure safe milk for our infants and see the wide variation in handling and storage a danger to our patients. I am confident that they will work with us to make the process as painless as possible, as we discuss our options further.

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#### Resources:

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**From:**  
**Mary Applegate, MD MPH**  
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To provide a perspective from another state, New York's regulations governing milk banking (Section 52-9 of the NY Code of Rules & Regulations - Title 10, Health) explicitly exempts collection of milk to be fed to the woman's own infant. Here's the regulation's definition of a milk bank: human milk bank means an organized service for the selection of donors and the collection, processing, storage or distribution of human breast milk for infants or children other than the donor's own infant.

Elsewhere in the code is a long section spelling out requirements for perinatal services in hospitals (405.21). I assume that the California regulations have a similar section. It seems to me that that would be the more appropriate context for regulating the handling of mother's milk to be given to her own infant. Mother's milk is significantly different from other kinds of autologous tissue in the amount of antibodies and other anti-infective components it includes. And the donor-recipient relationship is unique: the baby has just spent months awash in any infectious agents the mother is carrying.

We haven't felt that regulation of mother's milk handling was necessary at all. Our hospital code is silent on the subject. We recently finished a complete review and update of the perinatal regs, including extensive input from clinical and public health colleagues. Nobody recommended adding rules about that. During my tenure here (since '92), we've never had any reports of inappropriate handling of milk.

Please let me know if you have any questions about our experience.

Mary

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**Update January 29, 2006**  
**TO ALL CALIFORNIA NICUs:**

A letter was sent to Sandra Shewry, Director of the CA DHHS. It was referred to Paul B. Kimsey, PhD, Assistant Deputy Director of the Division of Laboratory Science for response. The response is that the Tissue Bank law is a law, and not a regulation, so cannot be "suspended".

He states that the tissue bank program in LFS (Laboratory Field Services) "is committed to assuring that babies in hospitals continue to receive their mother's own milk or any other medically recommended human milk that may be provided by a licensed milk bank." He suggests a "partnership" between the hospitals and the tissue bank licensure program whereby LFS can provide oversight to assure that consistent standards of practice are met.

He adds:

"Additionally, LFS tissue bank program will take care to assure that nothing in the licensing process will impede the safe delivery of a mother's milk to her own child." If there are any

problems he requests we contact him (Dr. Kimsey) at 510-412-5846 or Ron Harkey, Section Chief for the Tissue Bank Program at 510-620-3808. He mentions that Jan Otey of the Tissue Bank staff will be at the Pac-Lac meeting in LA Jan 31, 2006.

The CA Hospital Association is taking the lead in drafting legislation to fix the problem. In the meantime, I would recommend that every hospital handling a mother's own milk for her own infants apply for a tissue bank license. Ron Harkey and his staff are very reasonable people and I am sure will make it as easy as possible for you. Please pass this on to all CA breastfeeding advocates.

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