American Association of Tissue Banks®

July 20, 2017

The Agency for Health Care Administration
Bureau of Health Facility Regulation
2727 Mahan Drive
Tallahassee, Florida, 32308

In Re: Proposed Changes to 59A, Standards for organ, tissue and eye procurement organizations

Submitted via e-mail at zach.masters@ahca.myflorida.com

Dear Madams and Sirs:

The American Association of Tissue Banks (AATB) submits these comments related to the proposed changes to 59A, Standards for organ, tissue and eye procurement organizations.

The AATB is a professional, non-profit, scientific and educational organization. It is the only national tissue banking organization in the United States, and its membership totals more than 125 accredited tissue banks and 2,100 individual members. These banks recover tissue from more than 30,000 deceased donors and distribute in excess of 1.75 million allografts for more than one million tissue transplants performed annually in the U.S. More than 90 percent of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

Before detailing our particular recommendations, the AATB offers our sincere appreciation for the due consideration that the Florida Agency for Health Care Administration (AHCA) demonstrated with the latest round of changes. It is clear from the revised draft that our previous comments were all reviewed and considered.

That being said, the AATB would like to provide a list of key priority areas for improvement. The key priority is ensuring that the donor screening and testing provisions are appropriate for tissue banks. As you are aware, the initial comments focused on deleting the list of donor screening requirements and instead relying upon a reference to the federal regulations (specifically, those of the Food and Drug Administration as they relate to tissue banking). **Given that you have opted to retain the list of donor screening requirements, the AATB urges you to make modifications to ensure that the AHCA regulations are in line with current tissue practice.** Specifically, the AATB requests that you clarify when certain diseases or conditions should be ruled out (including hepatitis, pneumonia, and immune complex disorders) and delete donor screening protocols that are not relevant to tissues (namely, Rh determination, given the general lack of red blood cells in most tissue products). To aid your deliberations, please find specific language changes in the chart in the Appendix.

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The AATB remains concerned with the arbitrary nature requiring Medical Directors to have a relationship with a limited the number of banks. While the AATB acknowledges that your recent round of changes increased the number of total number of banks, **the AATB still feels as if it is inappropriate to set an arbitrary limit on the number of tissue banks a Medical Director can assist**, especially given that there is no systematic problem with the current relationships. Therefore, the AATB continues to urge you to delete these restrictions altogether.

Finally, the AATB notes that you did not include any of our proposed changes to deal with informed consent and authorization. Given our previous discussion on the topic, the AATB urges you to provide further clarity regarding your intent for these key definitions.

In addition to these major concerns, we would also note that we have a series of additional general technical improvements, which are included in the Appendix.

We hope that you will find these comments useful in your deliberations related to the proposed revisions to 59A. The AATB stands ready and willing to assist the AHCA with its deliberations in any way that the AHCA deems appropriate.

Respectfully,

Frank Wilton
President & CEO
American Association of Tissue Banks

Appendix A – Proposed Changes (in the order they appear in the regulation)

Regulation Reference -- Topic	Latest AHCA Proposed Language	AATB Proposed Revisions	Rationale
(1) (c)(2) -- Director requirements	If the director appointed does not have medical licensure, the OPO, eye bank, or tissue bank shall have at least one physician under contract to ensure compliance with all medical-legal aspects and with all requirements for specialist knowledge of the particular organs and tissues processed.	If the director appointed does not have medical licensure, the OPO, eye bank, or tissue bank shall have at least one physician ~~under contract~~ to ensure compliance with all medical ~~legal~~ aspects and with all requirements for specialist knowledge of the particular organs and tissues processed.	Technical change The physician relationship may be as an employee. While it is appropriate to discuss the medical aspects with a physician, it is unclear whether it is also appropriate to discuss the legal aspects.
(1)(f) -- Employee training	Such training shall be recorded in the employees personnel file.	Such training shall be recorded in the employee**'**s personnel file.	Technical change Add an apostrophe to clarify the possessive nature of employee.
(10) -- Donor selection	Donor selection. Each OPO, tissue bank, or eye bank engaged in the retrieval or recovery of organs or tissues, shall have written procedures regarding donor selection.	Donor selection. Each OPO, ~~tissue bank, or eye bank~~ **eye bank, or tissue bank** engaged in the retrieval or recovery of organs or tissues, shall have written procedures regarding donor selection.	Technical change The rest of the regulation uses the order OPO, eye bank, or tissue bank.
(31) – Tissue bank requirements	Each tissue bank shall comply with 21 CFR Part 1270, 2010 Edition. . . .	Each tissue bank shall comply with 21 CFR Part 1270 **and 1271**, 2010 Edition. . . .	Technical change Key FDA requirements are included within 21 CFR 1271.
(33)(b) – Medical Directors	(b) Medical Directors for Tissue Banks are limited to performing their responsibilities for multiple banks under the following criteria: 1. Medical Directors for Tissue Banks where at least one of the Tissue Banks is performing Recovery, Processing and Distribution are not permitted to act as Medical Director for more than five (5) Tissue Banks at one time; 2. Medical Director for Tissue Banks which perform any one of the following (but no single Tissue Bank performing all three activities): Recovery, Processing or Distribution are not permitted to act as Medical Director for more than ten (10) Tissue Banks at one time;	~~(b) Medical Directors for Tissue Banks are limited to performing their responsibilities for multiple banks under the following criteria:~~ ~~1. Medical Directors for Tissue Banks where at least one of the Tissue Banks is performing Recovery, Processing and Distribution are not permitted to act as Medical Director for more than five (5) Tissue Banks at one time;~~ ~~2. Medical Director for Tissue Banks which perform any one of the following (but no single Tissue Bank performing all three activities): Recovery, Processing or Distribution are not permitted to act as Medical Director for more than ten (10) Tissue Banks at one time;~~	Policy change Unclear why this arbitrary limit is added, especially in light of no systemic problem.
(34)(d)(1)(f) – Tissue donor selection (Hepatitis)	(f) Active hepatitis;	(f) Active **viral** hepatitis;	Policy change Hepatitis can also be alcohol-induced, which is not transmittable. Therefore, it would be good to clarify the rule out is related to viral hepatitis.

Regulation Reference -- Topic	Latest AHCA Proposed Language	AATB Proposed Revisions	Rationale
(34)(d)(2)(c) – Tissue donor selection (pneumonia)	(c) Pneumonia (other than non-confluent bronchopneumonia)	(c) Pneumonia **associated with sepsis or systemic infection** ~~(other than non-confluent bronchopneumonia)~~	Policy change Nearly every patient who receives ventilation will have signs of pneumonia. The key issue is whether the pneumonia is associated with system infection (such as sepsis).
(34)(d)(4) – Tissue donor selection (immune complex disorders)	(d) Collagen and immune complex diseases such as:	(d) Collagen and immune complex diseases **determined by the Medical Director to impact the specific tissues being distributed** such as:	Policy change Not all tissue types will be affected by immune complex diseases. This allows the Medical Director to better ascertain when donor deferral is appropriate.
	(8) Recipients of organ transplants. Recipients or organ transplants shall not be automatically eliminted because of the transplant per se, but must be carefully evaluated because of the drug therapy they receive and the disease processes they might have.	(8) Recipients of organ transplants. Recipients ~~or~~ **of** organ transplants shall not be automatically elimin**a**ted because of the transplant per se, but must be carefully evaluated because of the drug therapy they receive and the disease processes they might have.	Technical change Misspellings
(35)(a)(4) – Tissue donor selection (Rh determination)	4. Rh determination shall be provided cautioning about the possibility of sensitization.	~~4. Rh determination shall be provided cautioning about the possibility of sensitization.~~	Policy change Given that the vast majority of tissue products do not include red blood cells and, as such, will not create sensitization, it is unclear why this requirement is retained. If it must be retained, then it should be clarified to note that the testing should only be for tissues processed in a manner to retain a significant quantity of red blood cells.
(40) Tissue Bank Facilities and Equipment.	(40) Tissue Bank Facilities and Equipment. Environmental monitoring procedures shall be established in writing as part of the quality assurance program, when applicable. Monitoring procedures, at minimum, shall include equipment and personnel monitoring where tissue contact occurs, work-surface cultures, and, where appropriate, static and dynamic air particulate air sampling.	(40) Tissue Bank Facilities and Equipment. Environmental monitoring procedures shall be established in writing as part of the quality assurance program, when applicable. Monitoring procedures **for processing tissue**, at minimum, shall include equipment and personnel monitoring where tissue contact occurs, work-surface cultures, and, where appropriate, static and dynamic air particulate air sampling.	Technical change The AATB guidance related to microbiological testing applies only to tissue processing facilities and not tissue procurement.