



RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

**Organ and Tissue
Procurement and Transplantation
Advisory Board (Advisory Board)
Meeting Minutes – DRAFT**

Date: Friday, June 8, 2012
Time: 1:30pm – 4:00pm
Location: TELECONFERENCE CALL ONLY
Dial In Number: 1(888)808-6959
Conference Code: 8509227761

Advisory Board Members present:

Joseph A Hegleh, M.D., F.A.C.S. – Chairman
Michael Angelis, M.D., F.A.C.S. – V. Chairman
Beth Fetter
Susan S. Ganz, M.D.
Caroline A. Hartill
Leslie Lang, C.T.B.S.
Jason K. Woody, C.E.B.T.

Advisory Board Members absent:

David M. Levi, M.D., F.A.C.S.
Janice B. McCall, M.D., F.C.A.P.
Stephen J. Nelson, M.D., F.C.A.P.
Vijay Reddy, M.D., Ph.D.
Pamela M. Shuler, M.D.
H. Thomas Temple, M.D.

Agency for Health Care Administration (Agency) staff present:

Rebecca B. Folsom, B.S., M.T., A.S.C.P.
Jamie Jackson
Bill McCort
Dayle D. Mooney

Note: This meeting was open to members of the public.

AGENDA

I. Call to Order/Roll

- The Chairman opened the meeting at 1:31pm

II. Opening Comments

- Mrs. Mooney noted there is no statute stating a need to establish quorum for meetings of the Advisory Board.
- It was also noted there would be an opportunity for public comment at the end of the meeting.
- The Chair noted that this was a recorded, public meeting; therefore governed by the Florida Sunshine Law and directed to keep all conversation to board members and directed to the Agency.



III. Approval of Minutes from the December 16, 2011 Meeting

- The Chair motioned to approve the previous meeting minutes – all present accepted.

IV. Old Business

There was an introduction to provided meeting materials.

- **Adverse Reactions**

- Mrs. Mooney commented on translating the prior meeting's recommendations regarding Adverse Reactions to include the Advisory Board considerations, Scott Brubaker of AATB's comments with the European Union and FDA definitions for Board's review. Will result in the Advisory Board's final recommendation for changes to the rule to be given to the Secretary.
 - Ms. Mooney explained versions 1 and 2.
 - A discussion concerning version 1 language, considerations prior passed without objection from the Board, was held and all had no problem.
 - A discussion of version 2, an expansion of version 1 to include language from the European Union definition, was held concerning its restrictions.
 - The Chair motioned to adopt and keep original version 1 in how to define adverse reactions- moved without objection.
- Mrs. Mooney informed the Chair of the additional information regarding policy and procedure of the definition regarding facility responsibility.
 - Recommendation to comply with FDA adverse reactions reporting requirement to report within 15 calendar days to report the adverse reaction back to the Agency, replacing surgeons, recipients, and distributing banks.
 - Does not apply to out-of-state Organ Procurement Organizations (OPO) under UNOS.
 - For out-of-state tissue bank distributors, they are held responsible to notify the Agency of the potential adverse reaction.
 - Mrs. Mooney circulated a word document for review by each board member to formulate a final motion regarding policies, procedures, and any changes to the form reflecting proposed regulatory language.
 - The Chair adopted the changes on the form to reflect "15 calendar days" and the language to policies and procedure to include the word "certified."

- **Medical Director Qualifications**

- General consensus of initial qualification being a currently active licensed physician
- The discussion on tissue banks having a definitive qualification for medical directors
- Mrs. Mooney brought up the question of secondary distributors (storage and distribution centers) still being held to the same standard as medical directors of tissue banks providing all services.
- There was significant discussion between the Advisory Board members.
- The Chair motioned to table the subject for future review without objection. Requesting more feedback from the tissue banking association, from OPO board members, and input from Dr. Temple. There is a general consensus from the eye bank Advisory Board members on the general qualifications.

V. New Business

• Plasma Dilution Criteria

- Clarification of any discrepancies or further definitions of plasma dilution formulas being in agreement with the standards set by the FDA.
- Mrs. Mooney briefly explained the AATB Quality/Donor Suitability Workshop PowerPoint presentation on Plasma Dilution from Gregory Ray, M.D., F.C.A.P., of CryoLife, Inc.
- From the tissue bank board members, the compliance of FDA requirements or at the discretion of the medical director regarding exceptions to the limitations of the FDA requirement.
- From the OPO board members, medical director's decision can overrule the FDA requirements for an organ to be procured, in effect "bumping it into the CDC high-risk criteria" and labeling the organ as such.
- All Board members are in agreement of using the same guidelines for plasma dilution that are nationally accepted as universal formulas.

• HIV and other Communicable Disease Testing Methodologies

- Discussion on the need to update testing standards between the current antibody testing of various communicable diseases as opposed to more recently developed methodologies that are industry standard.
- Extensive discussion among the Advisory Board members took place regarding the matter.
- Mrs. Mooney brought up a scenario where antigen testing for communicable diseases as a requirement has changed in favor of a more direct testing methodology citing section 59A-1.005, FAC .
- Many of the board members felt the current antibody testing standards are not antiquated and still the most appropriate testing method.
- One board member felt the problem with using any other current method is the access for OPOs to laboratories with antigen testing within an appropriate timeframe.
- The Chair reaffirmed the position on antibody testing remaining the standard for testing of HIV and other communicable diseases for the organ transplantation process.

VI. Planning for Future Meetings and Calendar

- Mrs. Mooney reminded the Advisory Board of its duty to develop and recommend to the Agency on changes to statute.
- Citing Chapter 765, Part V, F.S., as potential 2013 legislative initiative for review by individual Advisory Board members so possible changes can be addressed at the next Advisory Board meeting for consideration.
- The Chair proposed August 17th or 24th as the next available meeting. All Board members were asked to respond to the Chair or Mrs. Mooney for their most available date.

VII. Announcements and Public Comment

- The Chair opened the floor for public comments
 - Gregory Ray, M.D., FCAP at CryoLife – spoke on the behalf of Physicians Council at AATB on possible future recommendations from AATB on Medical Director's qualifications.

- Dan Shultz at Lifelink Tissue Bank – mentioned the restrictions would eliminate quite a number of potential individuals who may not be able to be grandfathered into a new ruling.
- Rebecca Folsom, B.S., M.T., A.S.C.P. of AHCA – brought up the original circumstance of off-site secondary tissue bank’s Medical Director’s qualifications. Access and availability to the medical director from where the tissue originated was of more importance than revising the qualifications of these individuals.
- Dan Shultz brought up language in statute relating to medicine on eliminating the word “surgery” from .305, F.S. the Chair pointed out that it is antiquated verbiage and does not imply the need for a surgeon of an OPT bank.
- Gregory Ray brought up the previously discussed plasma dilution algorithms used according to the FDA guidelines and how the extremes are interpreted. The Chair addressed the statement and how the extremes are interpreted at the facility’s medical director’s discretion.
- No more public comments were voiced and further discussed.
- The Chair asked Mrs. Mooney if there was a need for another meeting necessary besides the earlier proposed scheduled meeting. Proposed a meeting on December 7th or 14th to review the 59A-1, F.A.C.

VIII. Adjournment

- The Chair adjourned the meeting at 4:00pm

Minutes submitted by: Christopher Stroman

Minutes revised on:

Minutes approved on: