



**ORGAN AND TISSUE PROCUREMENT AND TRANSPLANTATION
ADVISORY BOARD (ADVISORY BOARD)
MEETING MINUTES - DRAFT**

Date: Friday, December 16, 2011
Time: 1:00 p.m. – 4:00 p.m.
Location: TELECONFERENCE CALL ONLY
Dial In Number: 1(888)808-6959
Conference Code: 8509227761

**Advisory Board Members present:
(alphabetically arranged)**

Beth Fetter
Susan S. Ganz, M.D.
Caroline A. Hartill
Joseph A. Hegleh, M.D., F.A.C.S. – Chair
Lesley Lang
David M. Levi, M.D., F.A.C.S.
Vijay Reddy, M.D., Ph.D.
H. Thomas Temple, M.D.
Jason K. Woody, C.E.B.T.

**Advisory Board Members absent:
(alphabetically arranged)**

Michael Angelis, M.D., F.A.C.S. – Vice Chair
Janice B. McCall, M.D., F.C.A.P.
Stephen J. Nelson, M.D., F.C.A.P.
Pamela M. Schuler, M.D.

Agency for Health Care Administration (Agency) Staff present (alphabetically arranged):

Jamie Jackson
Bill McCort
Dayle D. Mooney
Karen Rivera

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

AGENDA

- I. Call to Order
 - The meeting was called to order by the Chair at 1:05 p.m..
 - A quorum was established.
- II. Opening Comments
 - The Chair welcomed the Advisory Board members and members of the public.
 - Members of the public were asked to withhold comments until the end of the meeting.
 - Advisory Board members were asked to limit comments to 2-5 minutes with allowances for response.
- III. Old Business
 - Section 4(c), First Bullet, page 3 of 12, Petition to Initiate Rulemaking regarding organ donation by a potential donor whose blood tests positive for hepatitis or HIV
 - Prior to this meeting, Advisory Board members were provided with a method of accessing the “Draft 2011 Public Health Service (PHS) Guideline for Reducing the Transmission of HIV, HBV, and HCV through Solid Organ Transplantation”. Additionally, the Department of Health, Bureau of HIV/AIDS provided the Advisory Board with a copy of draft language for Section

64D-2.005, Florida Administrative Code and its incorporated document entitled “The Model Protocol for Counseling Blood, Tissue or Organ Donors” for review and comment.

- Robbie Bouplon, Senior Human Services Program Specialist and Sherry Riley, Program Administrator from the Florida Department of Health, Bureau of HIV/AIDS, Operations and Management Section were present to report on recent activities regarding Section 64D-2.005, Florida Administrative Code. Ms. Bouplon advised that the Bureau of HIV/AIDS has reviewed this section of rule and is considering revisions as indicated in draft language provided. They are seeking comment and recommendations from the Advisory Board before proceeding with rule promulgation activities.
- There was significant member discussion regarding both the Draft PHS Guideline and the draft language for 64D-2.005, F.A.C..
- Dr. Hegleh, Dr. Ganz, Beth Fetter, Jason Woody, Carrie Hartill, and Dr. Levi represented areas of concern with the Draft PHS Guideline such as:
 - The additional testing requirements proposed commonly cannot be performed in a timely manner. This lack of access may result in a “loss” of transplantable organs.
 - Proposed Guideline appears to disallow transplants in patients who have false positive initial test results.
 - Extensive donor history screening would significantly enlarge the “high risk donor pool” i.e. a potential donor who has had two or more sexual partners within the previous 12 months would be considered a high risk donor. High risk donors must be reported to potential recipients as such. Advisory Board members expressed the belief that this designation without supporting clinical indications may result in patients inappropriately refusing a potential organ for transplant.
 - More than 50% of the original workgroup assigned to collaborate on the document abjured the process before completion citing a lack of evidence based medicine. Public comment indicates strong opposition from the scientific and medical community.
- Ms. Fetter, Dr. Ganz and Dr. Levi represented areas of concern with draft language for Section 64D-2.005, Florida Administrative Code which continues to require organs donated by Hepatitis positive individuals to be discarded. Current OPO practice, notwithstanding Florida’s regulatory restrictions, is to transplant organs procured from patients with certain types of viral Hepatitis based on established clinical considerations. Dr. Hegleh expressed concern with a complete removal of “Hepatitis” from the proposed language as other body substances i.e. blood, plasma, semen would be impacted.
- MOTION made to recommend that DOH Bureau of HIV/AIDS strike the word Hepatitis from the draft document, seconded, and passed without objection.
- Section 4(a), page 2 of 12, Petition to Initiate Rulemaking related to the definition of adverse reaction
 - In response to specific request made at the September 23, 2011 meeting, Dayle Mooney reported that the terms “adverse reaction” and “adverse incident” are not defined elsewhere in Florida Statute or Florida Administrative Code. Research indicated that subsection 395.0197(5), Florida Statute’s definition of “adverse incident” is the most approximate terminology.
 - There was discussion among the members regarding mechanisms and procedure for reporting adverse events and adverse reactions. Ms. Hartill noted that the FDA allowed tissue banks up to 15 days from receiving notification to determine if a reported event is allograft related. Current Florida regulation requires the Agency to be notified immediately of a potential adverse reaction and follow-up reporting once a final outcome is made. Mr. Woody, Dr. Reddy and Ms. Hartill confirmed that issues such as primary graft failures are not reported as adverse reactions.
 - There was discussion about the possibility of eliminating duplicative reporting requirements. Ms. Mooney indicated that the Agency has a statutory responsibility to monitor certified programs for program compliance and a confirmed adverse reaction is a possible indicator for deficient practice.

- When asked by Ms. Fetter, Ms. Mooney indicated that the Agency reviews and monitors received reports of adverse reactions to 1.) ensure compliance with reporting requirements, 2.) conduct epidemiological surveillance, 3.) evaluate certified programs' quality assurance procedures, and 4.) verify indicated allografts were eliminated as a causal agent.
 - Ms. Mooney informed the Advisory Board that the only identifiable trend in adverse reactions has been inconsistent reporting. When asked by Dr. Levi, Ms. Mooney informed the Advisory Board that there is not a suggested listing of reportable events.
 - There was extensive discussion on various occurrences that are federally reportable, occurrences that should be considered as meeting Florida reporting requirement, and possible mechanisms for complying with the statutory requirement to monitor Florida facilities for program compliance without exceeding federal reporting guidelines.
 - Ms. Mooney advised that while no formal position has been taken at this time, the Agency's goal in any changes proposed for Chapter 765, Part V, Florida Statutes or any made to Chapter 59A-1, Florida Administrative Code will be to act in the best interest of Florida's transplant recipients. It was further indicated that proposals may include changes that exceed current federal requirements should they be deemed necessary to meet this goal.
 - MOTION made to recommend amending the definition of adverse reaction to an event where there is potential for the unanticipated transmission of communicable disease or malignancy and to require adverse reactions be reported to the Agency within 15 days of notification, seconded, and passed without objection.
- Section 4(c), page 3 of 12, Petition to Initiate Rulemaking regarding the maintenance of the original consent for donation.
 - Ms. Mooney reported on research conducted since the September 23, 2011 meeting:
 - Request for CMS guidance indicated that "legally reproduced copy" was not defined in federal regulations.
 - Agency General Counsel's research found no instance of "legally reproduced copy" being defined elsewhere in Florida Statute or Administrative Code.
 - A definition of "legally reproduced copy" was found in Texas Administrative Code and appears to exclude Xerox copy.
 - Agency staff contacted Bill Bell, General Counsel for the Florida Hospital Association to ascertain its opinion. It was communicated that hospitals generally maintain responsibility for a patient even after death and as organ and tissue procurement is routinely performed on hospital premises the original consent for donation should be maintained in the hospital's medical record. Exception was indicated in instances where consent maintenance was specifically stipulated in agreements between the hospital and designated procurement organization(s).
 - There was discussion among the Advisory Board members regarding various barriers to obtaining original consent forms for inclusion in the hospital record.
 - Advisory Board members representing organ, tissue and eye procurement organizations were unaware of any instance of a hospital resisting or objecting to maintaining a copy of the donation consent.
 - MOTION made to recommend amending sub-paragraph 59A-1.005(7)(a)4., Florida Administrative Code to require that a copy of the consent be maintained in the hospital record, seconded, passed without objection.
- Section 4(c), page 4 of 12, Petition to Initiate Rulemaking regarding incorporation of accreditation organization standards
 - Ms. Mooney reported on the findings of 2010's reported Florida tissue distribution.
 - Ms. Hartill refuted allegations, which have been represented to the Agency, that secondary tissue distributors are not eligible for accreditation and indicated that accreditation standards are applied based on services performed. She further reported that tissue processors, accredited by the American Association of Tissue Banks (AATB) have a responsibility to ensure that their tissue distribution intermediary partners employ systems meeting AATB standards.
 - Accredited tissue processors satisfy this responsibility through inspection.

- It was noted with concern, that they only inspect the next level of consignee and as there are multiple layers of distribution there may be distributors who are not visible to the processing bank or the Agency.
- Mr. Woody indicated that the Eye Bank of America's accreditation process is applied in the same manner as AATB's.
- There was discussion supporting the requirement of accreditation by the Association of Organ Procurement Organization, AATB, and EBAA for Florida certified facilities.
- Advisory Board members generally agreed that all certified facilities should be required to comply with the requirement but, specific language should be included that allowed sufficient time for currently non-accredited certified entities to obtain accreditation.
- Ms. Mooney indicated that the maximum timeframe which could be allowed would be 12 months from the effective date of the Rule.
- It was noted that separate conversations with the accepted accreditation organizations should be held to determine impact and feasibility before specifying time requirements.
- MOTION made recommending the Agency move to require accreditation by the appropriate organization for distribution within a timeframe determined by the Agency, seconded, passed without objection.

II. New Business

- Medical Director Qualifications
 - Ms. Hartill expressed concern with current Florida requirement for a Medical Director to be licensed to practice medicine and surgery.
 - Ms. Mooney explained that this item was included in the meeting agenda based on an increasing number of tissue bank applicants' Medical Directors not being in compliance with Florida's medical licensure requirements while appearing to have adequate experience or training within their fields to function in the designated capacity.
 - There was significant discussion between the Advisory Board members.
 - It was agreed that active medical licensure, not limited by a specific state requirement, be required.
 - Dr. Temple volunteered to obtain information regarding medical director qualification requirements from various governmental or accreditation bodies.
 - Item TABLED to a future meeting.

III. Planning for Future Meetings and Calendar

- Next meeting date proposed for late February or March.
- Ms. Mooney will contact Advisory Board members to schedule.

IV. Announcements and Public Comment

- Scott Brubaker with the American Association of Tissue Banks thanked Ms. Hartill for her expertise, encouraged Advisory Board members and any member of the public to submit comments to the CDC on the Draft PHS Guideline before the deadline of December 23, 2011, and he encouraged the Advisory Board to adapt terminology that will be harmonious with global definitions such as those developed by the European Union (EU) and World Health Organization (WHO).
 - When requested by Ms. Mooney, Mr. Brubaker agreed to forward a document containing the EU directives, the FDA's definition, and AATB's definitions with the understanding that AATB is currently considering updates to their language to correlate with the newest global versions.
 - Liz Lehr with Lifelink OPO reported that Florida is a "net importer" of organs and indicated that the Advisory Board's current proposal placed an unfair burden on Florida's OPOs. She stated that statistics obtained through federal reporting entities would allow global tracking and better serve Floridians and suggested that the Agency satisfy its statutory responsibility to ensure program compliance by monitoring OPOs' compliance with federal reporting requirements.
- Dan Shultz from Lifelink Tissue Bank expressed concern that requiring distributorships to obtain AATB accreditation would 1.) be onerous for AATB to handle the influx of applicants, 2.) significantly increase the cost of tissue placement, and 3.) potentially harm the industry as facilities, such as medical device manufacturers that are also involved in tissue distribution, would shift their

focus away from tissue. Mr. Schultz encouraged the Advisory Board to discuss the matters with AATB further before implementing changes.

- Mark Strong with Lifelink Tissue Bank expressed reservations regarding requiring accreditation for tissue distribution. He believes that tissue availability would be impacted, at least in the short term, for certain specialized tissue types. Mr. Strong also stated that none of the tissue banks that obtain telephonic consents for donation are actually providing copies of that consent to the hospital. He encouraged the Advisory Board to only require a copy of consent to be included in the hospital record when the procedure occurs at the hospital.
- Dr. Wayne Daniels with Cryolife thanked the Advisory Board for inclusion in the meeting and encouraged consideration of AATBs comments regarding the Draft PHS Guideline.

V. Other Action

- Point of Order: Approval of Minutes from the September 23, 2011 Meeting
- MOTION made to approve minutes as written, seconded, passed without objection.

VI. Adjournment

Minutes submitted by: Dayle D. Mooney