



Organ and Tissue Procurement and Transplantation Advisory Board Meeting Minutes

Date: Friday, September 23, 2011

Time: 8:30 a.m. – 4:30 p.m.

Location: Hurston Complex, South Tower
Conference Rooms A-C
400 West Robinson Street
Orlando, Florida 32801

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

Michael Angelis, M.D., F.A.C.S.
Beth Fetter
Susan S. Ganz, M.D.
Joseph A. Hegleh, M.D., F.A.C.S.
Lesley Lang
Janice B. McCall, M.D.
Stephen J. Nelson, M.D.
Vijay Reddy, M.D., Ph.D.
Pamela M. Schuler, M.D.
H. Thomas Temple, M.D.
Jason K. Woody, C.E.B.T.

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

Caroline A. Hartill
David M. Levi, M.D., F.A.C.S.

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

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

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

PROCEEDINGS

I. OPENING COMMENTS

- Dayle Mooney welcomed Advisory Board Members and thanked them for agreeing to travel to Orlando the meeting.
- Ms. Mooney noted that some members would be late joining the meeting.
- There was an introduction to provided meeting materials.
- It was noted that there would be an opportunity for public comment if time permitted in the discussion area in order to address any missing information that was pertinent to the discussion.
- Ms. Mooney also asked members to be considering possible nominations for a chair and vice chair of the Advisory Board as they would be asked to elect these positions at the end of the meeting.
- She noted that this was a public meeting and therefore noticed in the Florida Administrative Weekly and added that all of the meeting materials and presentations are available on the Agency's website.

II. INTRODUCTIONS

- Ms. Mooney introduced the Advisory Board Members and indicated the areas of expertise that they represent.
 - **CORRECTION:** The PowerPoint presentation indicated that Dr. H. Thomas Temple represents musculoskeletal tissue procurement, processing and distribution when he in fact represents musculoskeletal tissue transplant surgery.
- Ms. Mooney noted that although section 765.543, F.S. establishes a 14-member advisory board, the 14th seat is currently vacant.
 - She indicated that the Agency was unable to identify enough qualified individuals at the time of selection/appointment to fill both positions representing musculoskeletal tissue transplant surgery.
 - She also indicated that the Agency does wish to fill this seat and asked members to forward her the names of individuals who should be considered.
- Ms. Mooney introduced the Agency staff members and their areas of expertise.
 - She noted that additional Agency staff members will be asked to participate as needed to facilitate future conversations.

III. PRESENTATIONS

- Ms. Mooney and Jamie Jackson reviewed information contained in PowerPoint presentations.
- ***Note: Points emphasized or not expressly indicated in the presentations are summarized below.***
- a. **Advisory Board Overview**
 - Ms. Mooney noted that the members' appointment letters indicated terms-of-office expire in 2013 however, they actually expire in 2014.
 - She stressed that this Advisory Board does not have a required meeting frequency/interval.
 - It was noted that there is another council created by Chapter 765, Florida Statutes that does include a specified meeting requirement.
 - She also emphasized the fact that this advisory board has the ability to develop with and recommend to the Agency changes to statute and administrative rules whereas most statutorily created boards/councils are limited to making recommendations for changes to administrative rules.
- b. **Florida in the Sunshine**
 - Ms. Jackson emphasized that the advisory board is subject to the Sunshine Law and therefore any gathering of two or more of the board's members to discuss board business or matters which are likely to come before the board is required to be open to the public with advanced notice.
 - She stressed that "meeting" is broadly defined and could include e-mail exchange and telephone conversations.
 - She also indicated that members are authorized to discuss matters of the board with a third party as long as that third party is not acting as a liaison between board members.
 - She advised board members to forward any documents or information that he/she would like the board to consider to Ms. Mooney who would then be able to distribute them to the other members, add it to the agenda for the next meeting and make it available to the public via the Agency's website.
 - Ms. Jackson notified the board members that information in their personal e-mail accounts could be included in a public records request if used to create or receive documents or materials related to the Board's official business.
- c. **Background Information**
 - Ms. Mooney indicated that the Florida Organ and Tissue Certification program is impacted by the Department of Health's communicable disease laws/regulations and that the Florida Department of Highway Safety and Motor Vehicles is involved in Florida's Donor Registry program.
 - Ms. Mooney noted Chapter 408, Part II, Florida Statutes as the Health Care Licensing Procedures Act which applies to all health care facilities regulated by the Agency.
 - A copy of Chapter 408, Part II, F.S. was not included in the meeting materials but, Ms. Mooney stated that it could be distributed if desired.
 - Likewise, the administrative rules promulgated under Chapter 408, Part II, F.S., Chapter 59A-35, Florida Administrative Code, were not included in the meeting materials but, could be distributed if desired.

- Ms. Mooney noted that accreditation organizations are not “regulatory entities” in that they are not operations of state or federal government.
- While reviewing the inspection requirements for Florida certified OPOs, Eye Banks and Tissue Banks, Ms. Mooney pointed out that Florida law and regulation requires facilities to be inspected prior to initial licensure and therefore operation whereas accreditation organizations wait until a facility has been operating for one (1) year before initial accreditation inspections are performed.
- Ms. Mooney also noted that acceptance of documentation from an accreditation inspection in lieu of the Agency performing their own on or off-site inspection does not mean that a facility is in compliance with all of Florida’s laws/regulations.
- During review of the Legislative Declaration found in section 765.510, F.S., Ms. Mooney emphasized that since 1969 the Florida Legislature has intended to “regulate the gift or a body or parts of a body, the gift to be made after the death of a donor.”

d. Status of the Organ and Tissue Certification Program Today

- Ms. Mooney reviewed information regarding the currently certified OPOs, Eye Banks and Tissue Banks.
 - She emphasized the fact that 49% of the currently certified tissue banks are limited to storage and distribution activities only.
 - She also emphasized the fact that a large number of currently certified tissue banks are not physically located within Florida and are not accredited by AATB.

e. Agency Objectives

- Ms. Mooney noted that the Agency has not formulated an opinion on any of the information presented to the Advisory Board.

f. Petition to Initiate Rulemaking and Associated Documents

IV. DISCUSSION ON PRESENTED INFORMATION

a. Section 4(a), page 2 of 12, Petition to Initiate Rulemaking related to the definition of adverse reaction.

- There was lengthy discussion amongst advisory board members and Agency staff on this topic.
- Public comment indicated that the intent of the recommended language was to reflect the current federal regulations which have been updated more recently than Chapter 59A-1, F.A.C..
- Points of concern were raised regarding:
 - The implied focus of adverse reaction vs. adverse event
 - Ambiguity of terms such as untoward, undesirable or unanticipated
 - The differences in what is considered to be an adverse reaction or event in a solid organ transplant recipient vs. a tissue or bone marrow transplant recipient.
 - The inconsistent interpretation and therefore reporting of adverse reactions as currently defined.
 - Agency staff related that in the past six years no adverse reactions have been reported from an OPO, there was no immediate recollection of any adverse reactions having been reported from an Eye Banks.
 - Agency staff did indicate that there are almost daily reports of adverse reactions from tissue banks however, these are all being reported from the same eight facilities, and most are reporting post-operative surgical infections in transplant recipients which are later found to be unrelated to the tissue itself.
 - The ability to draft definition language that would be appropriate for OPOs, Eye Banks and Tissue Banks alike.
- Advisory board members agreed that there are not any adverse incidents that must be reported to the Agency which would not also need to be reported to a federal counterpart.
- Dr. Angelis asked Ms. Mooney to see if “adverse reaction” or “adverse incident” is defined elsewhere in Florida Statute.
- Advisory board members agreed that the current definition of “adverse reaction” requires amendment.
- In the interest of time advisory board members agreed that further discussion of the matter should be postponed to a future meeting.

b. Section 4(b), page 2 of 12, Petition to Initiate Rulemaking requesting Rule 59A-3.274 be deleted.

- There was discussion of the matter amongst board members.
- Public comment indicated that recommendation to delete the rule was made as the provisions are covered by federal regulations and currently Florida regulation does not exactly match federal regulations however, recent revision to Florida Statute on this topic does align statute with federal requirements.
- Points of concern were raised regarding:
 - The current referral reporting mandate being limited to hospitals.
 - Repeal of the entire rule in deferment to federal regulations, which are a requirement for Medicare/Medicaid reimbursement, as there are some Florida facilities that are not Medicare/Medicaid certified.
 - Certain portions of current rule language, particularly those related to education and training of individuals making donation requests, are mandated by statute.
- Additional research into federal requirements vs. Florida requirements related to donation referral/request/requestor education, training and procedures is needed.
- Additional advisory board member discussion surrounding the possibilities of expanding referral mandates to include other health care facility types (i.e. Nursing Homes, Hospices) through a recommendation for statutory amendment should be considered. *Note: Such conversations would need to include Agency staff members from any indicated program areas.*
- Advisory Board members agreed that future conversations related to recommendations for statutory vs. regulatory amendments should be considered.

c. 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.

- There was discussion of the topic amongst board members.
- It was pointed out by several advisory board members and the Public participants that the term “eligible donor” is intended for OPO reporting purposes only. The term does not mean that a hepatitis positive patient would be medically ineligible for solid organ donation.
- Points of concern were raised regarding:
 - Certain hepatitis positive individuals are commonly being used in solid organ donation today.
 - Transplanting surgeons are likely unaware that Florida law and regulation prohibits these transplants.
 - The Department of Health has oversight of the laws and regulations which prohibit organs and tissue donated by HIV and hepatitis positive individuals from being used in transplants.
 - Regulatory changes to Chapter 59A-1, F.A.C. language alone would be insufficient.
 - Time necessary to effectuate meaningful change in this and many other areas may not be sufficient given the current board members’ terms-of-office.
- Advisory board members agree that this is a serious issue and a major point of concern which deserves priority considerations whenever possible.
- Advisory board members agree that organ and tissue from HIV positive patients is currently prohibited by applicable federal regulations for use in transplantation.
- Additional research into the federal regulations prohibiting use of
- Attempts should be made to include the appropriate staff within the Department of Health in conversations regarding this matter in an effort to encourage amendments to laws and regulations.
 - Such a meeting, if arranged, should probably bring DOH personnel and Advisory Board members together in person rather than teleconference.
- Beth Fetter indicated that, at a minimum, the advisory board should go on record as recommending changes to s.381.0041, F.S. and 64D-2.005, F.A.C.. (Note: There was no vote taken on this matter.)

d. Section 4(c), Second Bullet, page 3 of 12, Petition to Initiate Rulemaking regarding HTLV testing.

- There was lengthy discussion amongst the advisory board members on the topic.
- Points of concerns were raised regarding:
 - The lack of appropriate testing methods for potential donors.
 - Potential for screening methods that do not include donor testing (i.e. medical history review) to omit HTLV status for various reasons.

- Recent changes to federal regulations have removed the requirement for donor HTLV testing by OPOs, Eye Banks and Tissue Banks who are not engaged in procurement of viable leukocyte-rich cells/tissue.
 - Incomplete knowledge on whether or not Florida certified Tissue Banks are currently or have the potential to engage in procurement of viable leukocyte-rich cells/tissue from cadaveric donors.
 - Additional discussion on this topic is required.
 - Advisory Board members agree that sections of Chapter 59A-1, F.A.C. which address donor testing for HTLV require amendment.
 - There are no circumstances in which a Florida certified Eye Bank would be engaged in the procurement activities involving viable leukocyte-rich cells/tissue.
 - There are no currently available testing methods appropriate for donor HTLV testing.
 - Advisory board members should consider applicable standards of practice, clinical presentation of potential donors and recipients, and life-saving vs. life enhancing procedures when preparing recommendations.
- e. Section 4(c), Third Bullet, page 3 of 12, Petition to Initiate Rulemaking regarding exclusion of potential donors who have received chronic blood transfusions.**
- There was discussion of the topic amongst advisory board members.
 - The advisory board members agreed that a recommendation should be made to remove chronic blood transfusion recipients from those excluded from donation.
- f. Section 4 (c), Fourth Bullet, page 3 of 12, Petition to Initiate Rulemaking regarding autopsy requirements for donors.**
- There was discussion of the topic amongst advisory board members.
 - Advisory board members representing vascular organ transplant surgery and vascular organ procurement, preservation and distribution agree that a recommendation should be made to remove s. 59A-1.005(23), F.A.C. which requires an OPO to attempt full medical autopsy when not required by the medical examiner.
 - Dr. H. Thomas Temple did not feel that there was a need to revise current regulatory language related to a Tissue Banks requirements' for full medical autopsy when not required by the medical examiner.
- g. Section 4(c), Fifth Bullet, page 3 of 12, Petition to Initiate Rulemaking regarding data collection requirements.**
- There was discussion of the topic amongst advisory board members.
 - Points of concern were raised regarding:
 - The Agency's use and availability of data collected.
 - Data is to be used to determine annual assessment amounts as required by statute, satisfy statutory obligations, and determine or monitor the legitimate expenses associates with organ and tissue procurement.
 - Similar data required to be reported by hospitals is made available to the public at www.flhealthfinder.gov.
 - The workload associated with current reporting requirements.
 - Potential duplication of data collection between state and national entities and across program types (i.e. hospitals vs. OPOs, Eye Banks and Tissue Banks).
 - The need for statutory revision in order to effectuate meaningful changes.
 - Additional review of this topic is required.
 - Members indicated that the advisory board should consider review and possible recommendations to currently incorporated Agency forms.
 - Members also indicated that the advisory board should consider the possibility of recommending statutory amendments to eliminate the reporting requirements.
- h. Section 4 (c), Sixth Bullet, page 3 of 12, Petition to Initiate Rulemaking regarding maintenance of the original consent for donation.**
- There was significant discussion of the topic amongst advisory board members.

- Points of concerns were raised regarding:
 - Given federal regulations applicable to hospital medical record retention, it appears possible that amending current regulations in ss. 59A-1.005(7)(a)(4), F.A.C. may result in compliance issues for hospitals that allow copies of consents to be maintained in the hospital record instead of the original.
 - There is no known definition of a legally reproduced form.
 - There doesn't seem to be a significant benefit in maintaining an original vs. a copy.
 - OPO personnel are using OPO generated forms in order to obtain consent and therefore, should maintain "ownership" of the original document.
 - There have been instances of hospitals resisting use of OPO generated forms within their facility.
 - The applicability of requirements in electronic medical records, telephone consents, and contents obtained which must be faxed to the facility.
 - Advisory board members could not reach consensus on the topic.
 - Advisory board members agree that a recommendation for amendment to ss. 59A-1.005(7)(a)(4), F.A.C. appear necessary.
 - Additional discussion of this matter is necessary to develop recommended language.
- i. Section 4 (c), Seventh Bullet, page 4 of 12, Petition to Initiate Rulemaking regarding routine inquiry and timely referral standards.**
- There was discussion of the topic amongst advisory board members.
 - Current statutory and regulatory language in s. 765.522, F.S., ss. 59A-1.005(5)(a), F.A.C., and ss. 59A-1.005(7)(a)(3), F.A.C. do not conflict or exceed federal regulations.
 - The advisory board members agree that recommendations should be made to amend ss. 59A-1.005(5)(a), F.A.C. and ss. 59A-1.005(7)(a)(3), F.A.C. to both clarify existing language and to substitute "routine referral" for "routine inquiry".
- j. Section 4 (c), Eighth Bullet, page 4 of 12, Petition to Initiate Rulemaking regarding existence of the Florida Statewide Organ and Tissue Procurement and Transplantation Advisory Board.**
- There was brief discussion of the topic amongst the advisory board members.
 - Advisory board members agreed that the board should continue to exist but, should consider recommending amendments to areas of current rule that indicate the board should meet annually.
- k. Section 4 (c), Ninth Bullet, page 4 of 12, Petition to Initiate Rulemaking regarding incorporation of accreditation organization standards.**
- There was significant discussion of the topic amongst advisory board members.
 - Points of concern were raised regarding:
 - Patient safety issues associated with tissue distribution.
 - Fiscal impact of the Agency performing on-site inspections of out-of-state, non-accredited facilities in order to determine compliance with Florida laws/regulations.
 - Applicability of accreditation standards to all facilities specifically, tissue banks that only store and/or distribute tissue.
 - Applicability of Florida's laws/regulations to facilities that do not procure or process tissue within Florida but provide tissue to another facility for distribution to Florida.
 - Impact of requiring accreditation to tissue availability in Florida.
 - Obtaining permission from all accreditation organizations in order to use their standards.
 - Incorporating accreditation standards into Agency rule would require amendments whenever the accreditation standards were changed.
 - Advisory board members agreed that additional discussion and consideration is warranted to determine if a recommendation should be made to require all OPOs, Eye Banks and Tissue Banks be accredited as a condition of Florida certification.
 - It was forwarded that if accreditation was required a time period should be specified to allow non-accredited facilities to apply for and obtain accreditation before being considered out of compliance.
 - Advisory board members agreed that patient safety issues should be given priority over access issues.

- Advisory board members asked Ms. Mooney to try and analyze Agency data to determine the number of tissue grafts that originated from out-of-state accredited and non-accredited tissue banks.

I. Changes requested in documents submitted to the Agency after the Petition to Initiate Rulemaking

- Ms. Mooney asked board members to review the requested changes to s. 59A-1.005 for future discussion.
 - She noted that the requested changes touch on areas that were not addressed in the Petition to Initiate Rulemaking.
- Ms. Jackson clarified that these requested changes were submitted to the Agency and do not reflect the Agency's position or Agency recommendations.
- There was significant discussion of these topics amongst advisory board members.
- Points of concern were raised on:
 - Rule promulgation timeframes.
 - Practicality of updating regulations every time accreditation standards or federal regulations changed.
 - Copyright issues with using accreditation standards.
 - Requested changes would require statutory changes.
 - As requested changes essentially strike all standards for OPOs, Eye Banks, and Tissue Banks, if enacted the Agency would not be meeting current statutory requirements.
 - Statute currently requires the Agency to monitor the facilities for compliance with standards. It is unclear at this time whether or not the Agency has authority to determine compliance with a federal regulation if an identical state regulation does not exist.
- Additional conversation on the individual matters is required.

V. PLANNING FOR FUTURE MEETINGS

- Future meetings are expected to be held by webinar or teleconference.
- Advisory board members agreed that the next meeting should happen as soon as possible.
- Advisory board members were asked to forward comments or matters which should be discussed at the next meeting to Ms. Mooney before the end of October.

VI. ELECTION OF CHAIR AND VICE CHAIR

- Role of the Chair and Vice Chair were discussed.
 - Chair is intended to act as a liaison between the advisory board members and the Agency.
 - Chair is intended to preside over advisory board meetings.
 - Can be as formal or informal as the chair desires.
 - Vice Chair is intended to act the absence of the Chair.
- Dr. Hegleh was nominated as Chair. The nomination was seconded. No opposition was expressed. Dr. Hegleh accepted the nomination.
- Dr. Angelis volunteered to act as Vice Chair. Advisory board members accepted the offer.

VII. CALENDAR

- Preliminary review of calendars indicates that December 2, 2011 from 1:00 p.m. – 4:00 p.m. may be an acceptable day/time for the next meeting.

VIII. ADJOURNMENT

Minutes submitted by Dayle D. Mooney

Minutes revised on:

Minutes approved on: