I. Meeting Called to Order

The meeting was called to order at 10:00 a.m. by Eliot Rosenkranz, M.D., chairperson.
The meeting was facilitated by Dr. Rosenkranz.

II. Minutes

A motion was made, seconded and passed to approve the minutes from the May 5, 2008, meeting without correction.

III. Report on State Plan Progress

AHCA staff reported the progress of the State Plan changes proposed by the Agency with recommendations from the Organ Transplant Advisory Council (OTAC). The Centers for Medicare and Medicaid Services (CMS) had two minor recommendations for changes. These recommendations were:

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1. In the 1st Paragraph, last sentence, please remove “...undocumented aliens, illegal aliens, and legal non-immigrants” and replace with “5-year bar qualified aliens and non-qualified aliens.” The state may also want to consider adding the statutory cite for this exception which is 1903(v).
We would also like to bring to your attention that language relating to this exception is not actually needed and the last sentence could be deleted if you so choose.

2. We note the state mentions “cornea” transplants but they were not included in the Supplemental pages. Please clarify.

Staff proposed adopting the wording suggested in the first paragraph as suggested by CMS for aliens and adding the following sentences to the first paragraph to clarify the statement on cornea transplants:

Cornea transplants involve tissue and not solid organs. Medicaid enrollment is required for those facilities that provide cornea transplants but separate transplant facility designation is not required.

The OTAC members found this acceptable.

IV. Site Visit Requirements

The OTAC reviewed their previous discussion on site visit requirements. AHCA staff presented a form for consideration of the council that will be used to request information from facilities who are requesting Medicaid transplant program designation. The requirements for site visits were listed on this form to include CMS approval, Organ Procurement Transplantation Network/United Network for Organ Sharing (UNOS) approval, a current Organ Procurement Organization (OPO) certificate, Foundation for the Accreditation of Cell Therapy (FACT) certification if needed, the current status of these approvals and a space to list the following:

Transplant Leadership:
- Director’s Name
- Coordinator’s Name
- Name of Transplant Surgeon(s) and Transplant Physicians

Discussion then revolved around the need for site visits and what requirements may be necessary for the visit.

The discussion then turned to gathering data for transplant facilities on outcomes and ways to measure data based on demographics, particularly the Medicaid population.

Dr. Rosenkranz summed up with two perspectives to consider. One is validating or perhaps revalidating elements that have already been reviewed by OPTN or CMS; or the other perspective where it’s a given that the previous review has taken place, but looking at the specific characteristics of Medicaid populations and how those specific characteristics have been addressed by the program. The OTAC also discussed gathering outcome data and how to explore this possibility.
The council included surrogate markers as a validation of transplant program performance.

Dr. Rosenkranz listed some items for specific planning as follows:

- First is how to develop a specific list of elements for a site visitor. And some of the suggestions that we've heard today are to look at some of the guidelines that perhaps already exist, and maybe we can form even a small work group after we've been delivered some of these lists, and perhaps a small group can come up with a distilled list of elements such that it's not onerous.\(^1\)
- Two, there was the question raised; What do you do when there is a new team whose outcomes are not really reflected by the hospital data that perhaps has been submitted?\(^2\)
- Third is to inquire about what data currently exists in Florida that would allow us to use some comparison of outcomes for Medicaid versus non-Medicaid patients, and then as a subpart of that; What would be surrogate markers that we would perhaps want to identify?\(^3\)
- The final item is reevaluation of the program. This has come up several times so is mentioned here.\(^4\)
- Dr. Nieder volunteered to send a FACT checklist for usage.\(^5\)

The council asked staff to research what sort of data may be accessible for mining Medicaid patient outcomes. Dr. Kramer volunteered to come up with a list of around 15 elements to look at as well for distribution.\(^6\)

Further discussion centered on asking for information about the current approval status for CMS and OPTN when a program is applying for Medicaid program designation. The council asked for, and obtained a revised draft form for the transplant program application to be completed by staff over the lunch period. This was done and the council moved, seconded and passed a motion to approve the form with the changes.

V. Public Comment

Dr. Michael Angelis attended the meeting and commented on the recent CMS process that his organization, Florida Hospital, has undergone and the requirements for numbers of transplants for approval.

VI. Authorization of Global Payments and Handbook Review

Staff reported to the council that one of the changes that are planned to add to the Medicaid handbooks for organ transplantation is to add the following:

Report to Florida Medicaid any changes to:
- Medicare certification
- OPTN membership
• OPO certificate
• Transplant leadership
  – Director’s name
  – Coordinator’s name
  – Transplant surgeons and medical physicians

The council pointed out that not all organs are listed in the handbook including pancreas, intestine, multivisceral, etc.

After much discussion, the council moved, seconded and passed a motion to recommend the following statements for the Physician Services Coverage and Limitations Handbook:

• The section on In-state Transplants and Evaluations: Modify to “In-state transplants and determinations of eligibility, including the absence of contraindications, must be performed in an AHCA... (include the remainder of the statement in the handbook).

• Out-of-State transplant evaluations must be authorized by Medicaid after consultation with an OTAC physician prior to the recipient being transferred to the out-of-state facility for care.

• Out-of-State transplant procedures must be authorized by Medicaid after consultation with an OTAC physician prior to the recipient being transferred to the out-of-state facility for care.

• A patient referred for out-of-state transplantation must have been evaluated by an AHCA-designated transplant center.

• Delete the sentence, “Prior authorizations for out-of-state transplants must be initiated by the transplant physician at the AHCA-designated transplant center in Florida.”

• Revise the re-transplantation occurring at any time to be 100% of the global fee that is paid for a primary transplant.

• Delete the last bullet from the “Prior Authorization Process and Documentation section that states, “The name, address and contact person of the requested out-of-state facility and physician.” (This does not seem to apply to this section.)

• Amend the sentence in the section, “Where to Submit Prior Authorization Requests” that states that no facsimile prior authorizations are accepted to include except in emergency situations.
In the section, “Transplant Surgery,” amend the second bullet to include a psychologist and social worker as follows; “A comprehensive psychosocial evaluation of the recipient and family by a board-certified psychiatrist, psychologist or social worker including the recipient’s history...” This is in keeping with other similar guidelines, i.e. CMS, according to Dr. Ahsan and Dr. Angelis (public).

Delete the entire second paragraph from the section entitled, “Pretransplant and Post Transplant Care.”

Limit the second sentence in the section, “Anti-Rejection Medications” to medications must be FDA approved, and delete the rest of the sentence. In addition, label this section, “Anti-Rejection and Graft Versus Host Disease Medications.”

Delete the section entitled “Non-FDA Approved Medications.”

Amend the “Procurement” section to add the statement that Organ procurement costs are excluded in the reimbursement for the transplant procedure. These costs are a separately billable item.

For the section on “Donor Expenses” simply state, Medicaid reimburses for cadaveric and living donor expenses.

The OTAC asked for clarification on the prior authorization process that KePro does for transplant patients.7

VII. Planning for Next Meeting/New Business

Mr. Bolin reported that Mayo in Jacksonville has recently submitted an application for designation as a lung transplant program for Medicaid. There are other facilities expressing interest for Medicaid designation as well. The application will be forwarded to the council in the most convenient acceptable format and discussed at the next meeting.8

Ms. Kumar announced that some minor revisions will need to be made to the bylaws including wording that refers to the “Director” should be the “Secretary.”

Ms. Kumar also reviewed the process for replacing members on the council.

VIII. Adjourn

Meeting was adjourned at 4:10 pm.
The next Organ Transplant Advisory Council meeting will be scheduled for Orlando on February 2, 2009, pending meeting space availability.
These minutes are a summary of what transpired at the meeting. An actual transcript is available with Medicaid Services as produced by Executive Court Reporting Services.

**Action Items**

1. Form a workgroup to develop a specific list of elements for a site visitor. The workgroup will look at some of the guidelines that perhaps already exist, and come up with a distilled list of elements for the site review. This workgroup will include David Kramer, Pam Schuler and Michael Nieder. A telephone conference will be scheduled.
2. For review later is the question raised as to what is done when there is a new team whose outcomes are not really reflected by the hospital data that perhaps has been submitted.
3. Staff to inquire about what data currently exists in Florida that would allow us to use some comparison of outcomes Medicaid versus non-Medicaid patients, and then as a subpart of that what would be surrogate markers that we would perhaps want to identify.
4. The council will review later the need for reevaluation of the transplant programs.
5. Dr. Nieder to send in a checklist for FACT accreditation.
6. Dr. Kramer volunteered to come up with a list of around 15 elements for data mining and submit it to staff for distribution.
7. Staff to provide clarification on the KePro review process for transplant authorizations.