

**Agency for Health Care Administration  
Organ Transplant Advisory Council  
Minutes  
February 18, 2008**

Zora Neale Hurston Bldg. State Regional Service Center.  
400 W. Robinson St. South Tower, Conference Room S-309,  
First Floor, Orlando, FL 32801

**Members present:**

Dr. Nasimul Ahsan  
Dr. Thomas Beaver  
Dr. Winston Hewitt  
Dr. Robin Kim  
Dr. David Kramer  
Dr. Richard Neiberger  
Dr. Justin Nguyen  
Dr. Michael Nieder  
Dr. Eliot Rosenkranz  
Dr. Charles Sanders  
Dr. Pamela Schuler  
Dr. Juan Scornik

**Members absent:**

(None)

**AHCA staff present:**

Kim Kellum  
Beth Kidder  
Michael Bolin  
Theresa Kumar  
Mary McCullough  
Doc Kokol

**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 October 22, 2007, meeting without correction.

**III. Bylaws Revision**

A motion was made, seconded and passed to approve a revision to the bylaws for the creation of a position for a vice-chairperson on the Organ Transplant Advisory Council (OTAC). The revision is stated as follows:

Adding Section 3.6 to state, "Vice-Chairperson: The members of the council shall elect a vice-chairperson. The term of the chairperson shall be for two years, and an individual may not serve as vice-chairperson for more than two consecutive terms."

**IV. Election of Vice-Chairperson**

Dr. Kim expressed interest in serving as vice-chair. The council elected Dr. Kim as the vice-chair of the Organ Transplant Advisory Council (OTAC) by unanimous consent.

**V. Updates-Jackson Memorial Hospital Application**

There was discussion regarding the previous application for a pediatric lung transplant program at Jackson Memorial Hospital. The OTAC previously recommended approval for age 12 and older. Ms. Kidder reported to the council that the Agency for Health Care Administration (AHCA) Secretary approved the program for adult lung transplants, but due to wording in the State Plan and questions regarding the approval process for the Centers for Medicare and Medicaid Services (CMS) for pediatric facilities, the recommendation of the council's approval for pediatric patients down to age 12 was not ratified by the Secretary. Ms. Kidder invited the council to look at the application again. Dr. Rosenkranz suggested that this discussion be postponed until there is an opportunity to discuss the wishes of Jackson Memorial Hospital at this time, and after discussion on the State Plan changes.

**VI. Updates-Tampa General Hospital**

The council was notified by Ms. Kidder of the official approval by the AHCA Secretary for the Tampa General HealthCare Lung Transplant Program. Ms. Kidder thanked the council for their work on this application.

**VII. Updates-State Plan Change-2 Organ Requirement**

Ms. Kidder announced to the council that the change to the State Plan to eliminate the two organ requirement was approved by CMS. This change will facilitate the review of the application before them today from Shands/Jacksonville.

**VIII. Updates-OTAC Website**

Ms. McCullough displayed the new Organ Transplant Advisory Council website for the council's use and invited the council to recommend improvements on the site.

**IX. Presentation by AHCA Staff**

A discussion ensued after review of information presented by staff on questions previously asked by council. The discussion centered on out-of-state referrals and the mechanism involved in this process. Dr. Nieder suggested that AHCA staff meet with him to develop ideas for a central

approval process that would involve center directors who would have an opportunity to validate an out-of-state referral only after all efforts to do the procedure in Florida have failed.<sup>1</sup>

**X. Addition of Intestine and Multivisceral Standards to the State Plan**

Ms. Kidder introduced information on an urgent need by a Medicaid patient to have an intestinal transplant. Jackson Memorial Hospital is the center that is currently performing intestinal transplants. The issue is that, although the State Plan lists intestine transplants as a covered procedure by Medicaid, there are currently no guidelines for the approval of a facility to perform these transplants and there are no Medicaid designated intestinal transplant facilities. Dr. Rosenkranz introduced Dr. Andreas Tzakis, from Miami, who gave a presentation on his work with intestinal and multivisceral transplants.

Ms. Adrienne Ferguson, the transplant center finance administrator for Jackson Health Systems, commented on the costs of transplants including losses that have occurred and average costs for transplant procedures.

Ms. Maggie Dickens, an administrator from the University of Miami, addressed the council regarding the costs of caring for transplant patients.

After hearing the presentation, and discussion among the council members, the council moved seconded and passed a motion to recommend to AHCA that Jackson Memorial Hospital be given Medicaid approval for intestinal transplantation for one year; the OTAC subcommittee will come up with specific guidelines for intestinal and multivisceral transplants for patients; the OTAC will develop a specific methodology for subsequent centers who want to participate in providing multivisceral transplant services; and Jackson Memorial Hospital is to reapply under the new guidelines.

There are members of the public who are attending the meeting on behalf of this patient and are interested in the recommendation of the council. The family members thanked the council for their consideration.

**XI. Review of materials from Shands/Jacksonville and discussion of site visit**

Dr. Sanders was the lead reviewer for the Shands/Jacksonville kidney transplant program application and presented a review of this application, and a recommendation to approve the application. A motion was made, seconded, and passed, to recommend approval of the Shands/Jacksonville kidney transplant program for adults.

After discussion regarding a site visit for this facility, Dr. Sanders volunteered to go, using a similar template to the one that has been used in the past, developed by previous OTAC members.

## **XII. Public comment**

Dr. Michael Angelis from Florida Hospital addressed the council with a recommendation to the State government to attempt to set standards similarly across agencies so that criteria can be easily identified for each agency's needs. An example he gave was the Certificate of Need age for pediatric patients is 15 or under, whereas Medicaid sets the pediatric age as less than 21.

## **XIII. Review of State Plan**

Dr. Nieder reported information on the Foundation for the Accreditation of Cellular Therapy (FACT) and the rigorous standards that this organization sets for programs. He compared FACT to the National Marrow Donor Program (NMDP) and related the reasons for choosing FACT as the standard.

The council discussed the overall regulatory nature of the State Plan and ways to streamline the language. In addition, there was discussion regarding the prior authorization process. Staff is to review prior authorization language in the Medicaid provider handbook. Dr. Rosenkranz noted that the council may want to review the handbook language at a later date.<sup>2</sup>

The following changes to the State Plan were recommended by the council:

### **Attachment 3.1-E, Page 1**

First paragraph: Add pancreas, intestine and multivisceral to the second sentence and change "bone marrow" to "hematopoietic progenitor cell" throughout the document.

Delete the entire second paragraph that begins, "Prior authorization is requested..."

In the fourth paragraph, strike the words, "physician, outpatient, inpatient, laboratory, pharmacy and radiology." Add to this sentence at the end, "covered by the Medicaid program."

Add the following statement; "In order to be designated a Medicaid transplant facility, the facility must have the approval of Medicare and be certified by the Organ Procurement and Transplantation Network (OPTN)." There was mention of using "solid organ" in this statement.

**Attachment 3.1-E, Supplement I, Page 1, (TN No. 98-31)**

List the same organs on this page as on page 1 of attachment 3.1-E.

**Attachment 3.1-E, Supplement I, Page 2, Titled End-Stage Disease and Organ-Tissue Transplantation Hospitals Requirements**

The council moved, seconded and passed a motion to update all references to statute and rule in the State Plan.

**Guidelines for the Comprehensive Liver Failure and Transplantation Program**

Delete all previous edits and language.

Add the following statement; “In addition to approval by Medicare and OPTN, patients considered for liver transplantation are those who meet the American Association for the Study of Liver Diseases (AASLD) guidelines.”

The OTAC requested that the liver/multivisceral committee meet to formulate guidelines for intestinal and multivisceral guidelines.<sup>3</sup>

**Guidelines for the Hematopoietic Progenitor Cell Transplantation Program**

Dr. Nieder asked for more information on a state council that oversees modified stem cell transplantation.<sup>4</sup>

The council moved, seconded and passed a motion to approve this section as recommended by the bone marrow committee after updating the edits to replace the words “bone marrow” to hematopoietic progenitor cell.

**Guidelines for the Cardiac Transplantation Program**

The council accepted the edits by the heart/lung committee and a motion was moved, seconded and passed to move the section on multiple organ transplants that the committee recommended to the main section at the first of the State Plan to read “Multiple organ transplants performed simultaneously in an individual recipient must be done at centers that have approval for each individual organ transplant referenced herein.”

**Guidelines for the Renal and Pancreas Transplantation Programs**

There was discussion regarding a national or international organization or accrediting body for kidney transplantation. Apparently there are none, so

the committee moved, seconded and passed a motion to keep the general requirements for these programs including approval by Medicare and OPTN and adopt the Comprehensive Children's Kidney Center (CCKFC) program standards developed by the Children's Medical Services for pediatric patients.

### **Guidelines for the Lung Transplantation Program**

The council moved, seconded, and passed a motion to delete all previous edits and keep the following criteria:

1. Lung transplantation is indicated for patients with chronic end-stage lung disease in accordance with the International Society of Heart and Lung Transplantation guidelines.
2. Centers transplanting patients under age 12 must have pediatric sub-specialists in the areas indicated for program personnel referenced in the Organ Procurement and Transplantation Network guidelines. Programs wishing to transplant neonates must have a level 3 neonatal intensive care unit with neonatology support.

There was discussion about recommending a transition policy for pediatric patients to adulthood. It was decided that Medicaid would review the handbook policy to determine whether this is a good place to put this criterion.<sup>5</sup>

### **End-Stage Disease and Organ-Tissue Transplantation Hospitals Requirements**

The council went back to this previously edited section, and recommended the following changes. These changes include previous edits by the council. The transcript refers to a numbering system after previous edits where some sections were deleted in the past. For point of reference and clarification, the entire section of the State Plan as it exists currently with all past and current edits is listed here:

1. Delete
2. Delete.
3. Delete.
4. Delete
5. Delete.
6. Delete.
7. Delete.
8. Delete.
9. Delete.<sup>6</sup>

10. Change to “Provide evidence of certification by the Organ Procurement and Transplantation Network and CMS every three years.”
11. Delete.
12. Delete.
13. Delete.
14. Delete.
15. Change to “Have available a long-term economical housing for patients and families (a Ronald McDonald House as prototype). Staff to research whether this requirement for long-term economical housing is in the OPTN or CMS guidelines. Dr. Nieder reports that this requirement is in the FACT manual.”<sup>7</sup>
16. Delete.
17. Delete.
18. Delete.
19. Delete.
20. Delete.
21. Delete.
22. Delete.
23. Delete.
24. Delete.
25. Keep previous edit for now. Tabled the discussion of a site visit for a later date. This section remains, “Be designated as a transplantation hospital by the Director of the Agency for Health Care Administration with recommendation from the Organ Transplant Advisory Council, in writing. Such designation will be made following a site review by the Organ Transplant Advisory Council.”<sup>8</sup>
26. Delete.

#### **XIV. Other discussion regarding State Plan Changes**

Also discussed other concerns raised by the committees, some of which were resolved with the edits today. One other issue that was tabled is the closure or suspension of a program after a review. The council plans to discuss this on another date.<sup>8</sup>

Ms. Kidder asked for guidance for the AHCA personnel who review documentation for authorization for organ transplants. The non-transplant physician reviewer has questioned whether some of the patients have been suitable candidates for organ transplantation. Dr. Nieder educated the council on the way bone marrow patients are approved, and reported that there is a list of patient criteria at the state level. The council invited Ms. Kidder to put this issue on the next agenda.<sup>9</sup>

Dr. Beaver requests that the process of out-of-state referrals be discussed at a future date, and that there be discussion on “CMS” reimbursement vs. actual facility charges.

## **XV. Adjourn**

Meeting was adjourned at 3:53 pm.

The next Organ Transplant Advisory Council meeting will be scheduled for Orlando in May pending meeting space availability. The liver/multivisceral committee will meet with a phone conference to develop guidelines for intestinal and multivisceral transplants.

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. Staff to meet with Dr. Nieder to develop process for out-of-state referrals.
2. Staff to review prior authorization process including handbook language.
3. Arrange meeting of liver/multivisceral committee to formulate guidelines for intestinal and multivisceral organ transplants.
4. Staff to research to determine if there is a state committee for bone marrow or stem cell transplantation.
5. Medicaid staff to review handbook policy to include a plan for transition to adulthood for pediatric patients.
6. Ms. Kidder suggested that requirements for transplant hospitals for review be placed in the provider handbooks. These requirements would include reporting to AHCA any changes at the facility that are reported to OPTN or CMS.
7. Staff to research whether the requirement for long-term economical housing is in the OPTN or CMS guidelines.
8. Site visit requirement and closure/suspension of programs are to be topics for future discussion by the OTAC.
9. OTAC to address AHCA reviewer questions on patient selection criteria.