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 February 18, 2008, meeting without correction.

III. **Shands/Jacksonville Update**

Dr. Sanders reported the results of his site visit to Shands/Jacksonville. He was accompanied on the site visit by Michael Bolin. There was discussion regarding the approval of Shands/Jacksonville’s kidney transplant program for Medicaid designation at the last Organ Transplant Advisory Council (OTAC) meeting. It was moved, seconded and passed today to recommend approval of Shands/Jacksonville for Medicaid designation.

IV. **State Plan Changes**

Agency for Health Care Administration (AHCA) staff presented findings on requirements for housing by the Organ Procurement and Transplantation Network (OPTN) and the Centers for Medicare and Medicaid Services (CMS) to aid in the discussion of further changes in the State Plan. AHCA staff also briefed the council on the duties of the Bone Marrow Advisory Panel (BMAP). The BMAP advises AHCA on bone marrow transplant rules and

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**Members present:**
- Dr. Winston Hewitt
- Dr. Michael Nieder
- Dr. Eliot Rosenkranz
- Dr. Charles Sanders
- Dr. Pamela Schuler
- Dr. Juan Scornik

**Members absent:**
- Dr. Nasimul Ahsan
- Dr. Thomas Beaver
- Dr. Robin Kim
- Dr. David Kramer
- Dr. Richard Neiberger
- Dr. Justin Nguyen

**AHCA staff present:**
- Kim Kellum
- Dr. F. G. Huber
- Beth Kidder
- Michael Bolin
- Theresa Kumar
- Mary McCullough

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**May 5, 2008**
Renaissance Orlando Hotel-Airport
5445 Forbes Place
Orlando, FL 32801
regulations. Council requested that information on bone marrow regulation be added to the OTAC website.¹

After discussion regarding the validity of site visits, the council moved, seconded and passed a recommendation to require a site visit requirement for Medicaid designation of transplant programs. Dr. Schuler clarified the motion that this would be for any new programs; so that in a transplant facility that already has Medicaid designation for organ transplantation, any additional organ that the facility is transplanting must also go through the site visit process for Medicaid designation.

Further discussion centered on the review process for Medicaid designated transplant programs. After discussion about the merits of a review based on Medicaid patients alone, with the acknowledged lack of resources and support that Medicaid patients have, the council moved, seconded and passed a motion to add a periodic review of the programs organized by the specific subcommittees of the OTAC, and they will coincide with the CMS/OPTN reviews of the same program.

A motion was then seconded and passed for staff to draft wording for the conditional approval of a facility to include experience of personnel, adequacy of facilities, and patient resources. This will be reviewed later in the meeting today.

The council reviewed the issue of withdrawing Medicaid approval for facilities which have been closed by or lost approval from CMS or OPTN. A motion was made, seconded and passed to place in the State Plan that if a program is closed by CMS or OPTN that the program would have to reapply to Medicaid as if they were a new program, to reestablish transplants.

Dr. Hewitt presented to the OTAC some information on intestinal and multivisceral organ transplantation as a back-drop to the recommendations that the Intestine/Multivisceral transplant committee are making for the State Plan.

Dr. Hewitt then recited the Intestine/Multivisceral Transplant Committee’s recommendation for the State Plan as follows:

“In addition to the requirements recommended for the designation of an end-stage disease, an organ tissue transplantation hospital, the following guidelines are required of the intestinal and multivisceral transplant programs. Those patients with intestinal failure who have also failed total parenteral nutrition are candidates for intestinal or multivisceral transplantation in a center with CMS designation defined as; 1) Greater than or equal to ten intestinal/multivisceral transplants per year; 2) One year actuarial survival greater than 65%.”
The OTAC moved, seconded and passed a motion to accept the Intestine/Multivisceral Transplant Committee’s recommendation for the State Plan as recited by Dr. Hewitt.

The council reviewed the following language for conditional approval:

“The Organ Transplant Advisory Council reserves the right to recommend conditional Medicaid approval for transplant facilities based on the providers’ experience and qualifications relative to patient characteristics; adequacy of facilities and resources for the specific patient population; and any other consideration which would significantly impact outcomes.”

The council moved, seconded, and passed the conditional approval language as above for the state plan.

The council then went on to the section that is previously found in the “End-Stage Disease and Organ-Tissue Transplantation Hospitals Requirements.”

The council recommended striking essentially all the wording in this section except the following:

“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.”

This statement will be added to the first page of the State Plan and the remainder of the first section on End-Stage Disease and Organ-Tissue Transplantation Hospitals Requirements will be deleted. This section will now begin at “Guidelines for the Comprehensive Liver Failure and Transplantation Program.”

The council did not recommend any further changes to the section on Guidelines for the Comprehensive Liver Failure and Transplantation Program since the last meeting.

The council specified a preference for using the word “programs” instead of “facilities” where appropriate.

The council reviewed the following section on Guidelines for Intestinal Transplantation Programs with added language from staff:

“GUIDELINES FOR INTESTINAL AND MULTIVISCERAL TRANSPLANTATION PROGRAMS”
In addition to the requirements recommended for the designation of an End-Stage Disease and Organ-Tissue Transplantation Hospital, the following guidelines are required of the intestinal and multivisceral transplantation program:

Those patients with intestinal failure who have also failed total parenteral nutrition are candidates for intestinal or multivisceral transplantation in a center with CMS designation defined as:

1. Greater or equal to 10 intestinal/multivisceral transplants per year;
2. One year actuarial survival greater than 65%”

Staff recommended separating the renal and pancreas sections so that each organ would have its own section. The council concurred. These sections will be as follows:

**GUIDELINES FOR THE RENAL TRANSPLANTATION PROGRAM**

In addition to the requirements recommended for the designation of an End-Stage Disease and Organ-Tissue Transplantation Hospital, the following guidelines are required of the Renal Transplantation Hospitals.

**Pediatric Renal Transplantation Hospitals**

The Pediatric Renal Transplantation Hospital must meet all program requirements for a Comprehensive Children’s Kidney Failure Center (CCKFC) including pre-dialysis, dialysis, transplantation and post-transplantation services.

**GUIDELINES FOR THE PANCREAS TRANSPLANTATION PROGRAM**

Any facility performing pancreas transplantation must meet the requirements recommended for the designation of an End-Stage Disease and Organ-Tissue Transplantation Hospital.

The council moved, seconded and approved all the changes to the State Plan that were discussed today.
V. Discussion with AHCA Medical Consultant Regarding Patient Selection Criteria

Ms. Kidder introduced Dr. Huber to the OTAC. Dr. Huber discussed the types of documentation that he receives and the evaluation process that the centers follow in deciding whether or not to transplant an organ in a patient. The council recommended that a checklist be developed to request information from transplant facilities when they are submitting documentation for transplant payment authorization.2

The council also suggested that if there is a case that the Medical Consultant is prone to deny, that this case be presented to a member of the OTAC for further consideration.

VI. Presentation by AHCA Staff

AHCA staff presented wording that is being drafted on out-of-state referrals, prior authorization, notification of significant changes in transplant programs and a requirement for a transition plan for pediatric patients growing into adulthood. The OTAC approved of the draft wording as presented.

VII. Planning for Next Meeting

The council would like to be involved in the development of a standard format for submitting requests for authorization for global payment to the Medicaid office. Ms. Kidder states that the bylaws need to be reviewed for consistency with the changes in the State Plan. The council also expressed an interest in the process that Medicaid will develop for transplant programs to be reviewed on a regular basis.

Dr. Nieder suggested that the council members go back to their respective institutions and ask for information on reimbursement from different payer sources after discussion on finding out from these institutions the cost neutral amount that is needed to do a particular transplant, and how much money percentage-wise that is lost for different payers. Some comments from the public in the audience seemed to agree on the point that most transplant facilities would not want to disclose the amount paid from each payer source. Sue Ottinger, the vice-president for patient accounting for Lifelink Institute in Tampa, offered to attempt to extract this information, basically what they would need to sustain taking care of Medicaid patients, from her institution.3

VIII. Adjourn

Meeting was adjourned at 2:34 pm.
The next Organ Transplant Advisory Council meeting will be scheduled for Orlando in October 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. Staff to add regulation information for bone marrow transplantation to the OTAC website.
2. Staff to prepare checklist for facilities for submission for prior authorization.
3. Follow up with Ms. Ottinger to determine whether she was able to gather the appropriate information regarding financial aspect of transplants for Medicaid recipients.