OPTN/UNOS TRANSPLANT ADMINISTRATORS COMMITTEE REPORT June 19-20, 2008 SUMMARY

I. Action Items for Board Consideration:

· None

II. Other Significant Items:

- Improve OPTN Data Systems The Committee continues to work to facilitate communication between the transplant administrator community and the Operations Committee/Electronic Organ Placement Working Group (EOPWG) on DonorNet® implementation, including operations impact issues. (Item 1, Page 3)
- Oversight Role of OPTN The Committee worked to provide feedback to the Centers for Medicare and Medicaid (CMS) on its Conditions of Participation (CoPs) interpretive guidelines content and survey methodology. (Item 1, Page 3)
- The Committee has partnered with AOPO to define and disseminate Best Practices for flight standards and insurance by using a survey created by the University of Michigan that will be distributed to transplant administrators nationwide. (Item 1, Page 3)
- The Transplant Management Forum conducted in Dallas, TX in April 2008 was a success, and the 2009 Forum will be held in Seattle, WA. (Item 2, Page 4)
- The Committee continues to evaluate how the staffing survey might be useful for the MPSC as it evaluates new program applications or considers the performance of centers having lower than expected outcomes. (Item 3, Page 4)
- The Committee continues to explore how the Request For Information (RFI) payer group could assist UNOS in understanding the perspective and concerns of the payer while balancing the needs of transplant centers for adequate reimbursement. (Item 4, Page 4)
- The Committee considered policy proposals for public comment. (Item 5, Page 4)

This page is intentionally left blank.

REPORT OF THE

OPTN/UNOS TRANSPLANT ADMINISTRATORS COMMITTEE

TO THE BOARD OF DIRECTORS

June 19-20, 2008

Richmond, Virginia

Cassandra Smith-Fields RN, MSN, MBA, Chair

The Committee meets monthly by conference call except in April, when the Transplant Management Forum occurs, and July and October when the Committee meets in person.

- 1. Committee Goals- The Committee continues to devote considerable time to working on four program goals that were assigned by OPTN/UNOS President Timothy Pruett, MD in mid-2007. Those goals are:
 - To facilitate communication between the transplant administrator community and the Operations Committee/Electronic Organ Placement Working Group (EOPWG) on DonorNet® implementation issue, including operations impact issues. The Committee continued to discuss the implementation of DonorNet[®]. Numerous centers expressed concern with coverage/on call issues, hardware requirements, etc. Progress continues as the DonorNet® Workgroup met on April 23, 2008, with HRSA representative Ginny McBride and the UNOS DonorNet® representative, Blaine Hess. HRSA has agreed to sponsor an additional day to the next collaborative meeting on October 22, to devote to "Making the Match" collaborative session. The goals of the "Making the Match" collaborative is to develop best practices for both OPOs and transplant centers in utilizing DonorNet®; establishing DonorNet® user competencies; and providing guidance to the Electronic Workgroup for DonorNet® enhancements. Transplant centers and OPOs will be asked to send one or more of their "Super Users" of DonorNet® to the "Making the Match" session at the collaborative meeting in October. The DonorNet® workgroup will be working with Blaine Hess, AOPO, and Ginny McBride in formalizing the program for the collaborative. This will be an ongoing effort and the Committee will follow it carefully.
 - To work to provide feedback to the Centers for Medicare and Medicaid (CMS) on its Conditions of Participation (CoPs) interpretive guidelines content and survey methodology. A workgroup was created within the TAC to provide feedback to CMS about the interpretive guidelines content and survey methodology. A blast email from UNOS Communications was sent to transplant administrators informing them of how to provide constructive feedback to CMS on the survey process. A similar message was also sent out by Cassandra Smith-Fields on the Transplant Administrators' Listserve. The Committee continues to discuss CMS updates and feedback regarding regulatory and oversight activities on the monthly conference call.
 - To partner with AOPO to define and disseminate Best Practices for flight standards and insurance. The OPO/Transplant Center Transportation Safety workgroup was charged

with creating and administering a survey for OPO's and Primary Program Administrators that evaluates best practices for transportation and insurance with respect to organ recoveries, following the tragedy in Michigan. The subcommittee had several conference calls with AOPO and per AOPO's suggestion has partnered with Dr. Michael Englesbe, Assistant Professor of Surgery, Division of Transplantation at the University of Michigan Health System to develop the survey. UNOS has provided the transplant administrators' contact information from the UNOS database to the University of Michigan researchers to facilitate the survey process. The University of Michigan will collect the results and present them at a national meeting and they will also be used for a manuscript. The University of Michigan will make the survey results available to UNOS once completed for internal policy considerations until manuscript submission.

- 2. 2008 Transplant Management Forum. The 2008 Transplant Management Forum was held April 21-23 in Dallas, Texas. A total of 478 participants attended the meeting. There were a total of 42 abstracts accepted for the meeting. A record 39 exhibitors and sponsors supported the meeting. There was a closed executive session that allowed for program administrators to discuss the role of the newly formed Association for Transplant Administrators, a professional organization for transplant administrators. There was a plenary session dedicated to Medicare Conditions of Participation for transplant hospitals and a special keynote speaker plenary session to inform transplant administrators how to create a stronger transplant program. All of these newly added sessions were very well attended. Evaluations of the meeting are still being reviewed, however, on first review, are very positive.
- 3. Staffing Survey. The Committee continues to evaluate how the staffing survey might be helpful and useful for the OPTN/UNOS Membership and Professional Standards Committee (MPSC) as it evaluates new program applications or considers the performance of centers having outcome problems. The 2007 Staffing Survey was released on the Transplant Administrators section of the UNOS Secure Enterprise Web Site (https://portal.unos.org) several months ago. Comparison statistics for transplant program staffing benchmarks with the 2007 data are now available for any member who has already submitted a survey. As in prior years, only programs that complete surveys for their organ specific programs will have access to the summary and comparison data. The goal for the 2007 Staffing Survey is to have 75% of all transplant programs complete the surveys in each organ specific grouping. As expected, there was an increase in submissions since early April, most likely due to exposure at the Forum. The rates of participation in the survey are up roughly 20% across programs. The current rates range from 17% for pancreas up to 24% for kidney. The comparative survey reports are now available on the Transplant Administrators website, along with updates to the FAQ page.
- 4. Request for Information Payer Group. The Committee continues to explore how the Request For Information (RFI) payer group could assist UNOS in understanding the perspective and concerns of the payer while balancing the needs of transplant centers for adequate reimbursement. The bi-annual meeting of the Committee with all major payers in the transplant field will be held in July 2008. There is ongoing communication with the Committee Workgroup on the RFI to hear concerns of payers and to make changes as warranted. The release of the 2008 RFI was in January.
- 5. <u>Public Comment Proposal Distributed on November 12, 2007.</u> The Committee discussed and made recommendations for the proposal released for public comment:

1. OPTN/UNOS Proposed Resource Document for the Medical Evaluation of Living Kidney Donors (Living Donor Committee)

The TAC recommends that the Resource Document for Medical Evaluation be less prescriptive and include the general categories only, rather than the detailed testing.

The Transplant Administrators Committee appreciates the tremendous effort of the living donor committee in preparing this resource document and we agree that that the care of living donors is an important responsibility of our community. We do have several concerns about the content of the proposed document. Although the revised document purports to not carry the weight of policy, we believe that the level of detail is similar to that of guidelines and thus approval by the UNOS Board of Directors will give the document "standard of care" status.

Care standards or guidelines are evidenced-based and written by disease-specific experts in their fields. These experts make recommendations based on their review and evaluation of the relevant scientific literature. The proposed document does not cite such a body of work. It is a consensus document of current practice which may or may not be based on the best medical evidence available. As such, the level of detail in this document does not seem appropriate.

The Transplant Administrators Committee believes that every patient, and certainly every donor, deserves an individualized plan of care based on the patient's needs and circumstances. We are also concerned that the extreme level of detail in this document severely restrains health professionals in creating such a plan or exercising best medical judgment. This granularity such as naming specific diagnostic tests as opposed to the goals of testing also limits the lifetime of the document as new diagnostic testing becomes available. We are also concerned that a "one size fits all" approach will unnecessarily add cost to Transplant Centers.

We believe that the proposed document would best meet its goals of being a resource document by being less detailed and prescriptive in its content. As a resource, the document should outline the basic, over-arching principles and goals of the evaluation and care of the living kidney donor, not specific elements of the physical, psychosocial and diagnostic testing. Judgment of how to best meet these principles and goals should be left to the individual physician.

The TAC recommended revisions are provided in Exhibit A.

<u>Public Comment Proposal Distributed on February 8, 2008.</u> The Committee discussed and made recommendations for the proposals released for public comment:

1. Proposal to Change the OPTN/UNOS Bylaws to Require Written Notification (or Disclosures) to Living Donors from the Recipient Transplant Programs (Proposed Modifications to Appendix-B, Section II, (F) "Patient Notification" of the OPTN Bylaws and Appendix B, Attachment I, XIII, D (13) of the UNOS Bylaws)

The TAC recommends changing the language to read "recipient transplant centers must provide written notification to living organ donors no later than ten business days following their donation date to include the following:" with the understanding that most centers will put this information in the evaluation or consent document rather than in a document sent after the transplant.

2. Proposal to the OPTN and UNOS Bylaws: Restoration of Membership Privileges Following an Adverse Action (Proposed Changes to Appendix A, Section 3.01A Paragraphs (1) and (3) and Section 5.05A, Addition of Section 5.07A.)

The TAC supported this proposal with no further comment.

3. Proposal to Require Transplant Centers to Inform Potential Recipients about Known High Risk Donor Behavior. (Proposed Revisions to Policy 4.0 - Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Recipient Diseases Or Medical Conditions, Including Malignancies, of Donor Origin)

After discussion, the Committee determined the ASTS was better suited to comment on this topic.

OPTN/UNOS Transplant Administrators Committee July 19-20, 2007 Chicago, IL

Committee Members in Attendance

Cassandra Smith-Fields RN, MBA, MSN

Gene E. Ridolfi BA, RN

Chair

Vice Chair

Michael Sinacola MBA
Region 1 Representative
Robin S. Pastush RN, BSN
Region 3 Representative
Gary Sigle RN, MBA, BSN
Region 4 Representative
Pam Gillette MPH, RN
Region 5 Representative
Timothy Stevens RN, BSN, CCTC
Region 6 Representative
Gwen McNatt MS RN, CNN, CFNP
Region 7 Representative

Gene E. Ridolfi BA, RN

Colleen O'Donnell MHA

Janie Morrison FACHE

Kimberly Nicoll RN, BSN

Region / Representative
Region 8 Representative
Region 9 Representative
Region 10 Representative
Region 11 Representative

Elaine R. Berg MPA, FACHE

Betty Crandall MS, RN

At Large

Ex Officio

Jade K. Perdue MPA

Division of Transplantation,

Ex Officio, non-voting Division of Transplantation,

Non-voting

Committee Members Unable to Attend

Rachael S. Wong MPH At Large

Mesmin Germain, MBA, MPH Division of Transplantation,

Ex Officio, non-voting

Staff in Attendance

Christopher McLaughlin

William G. Lawrence JD

Angel Carroll MSW

UNOS Staff
Jude Maghirang MS

UNOS Staff
Cherri Carwile

Jennifer Mekolichick

UNOS Staff

UNOS Staff

OPTN/UNOS Transplant Administrators Committee October 25-26, 2007 Chicago, IL

Committee Members in Attendance

Cassandra Smith-Fields RN, MBA, MSN Chair

Gene E. Ridolfi RN Vice Chair/Region 8 Representative

Michael Sinacola MBA
Region 1 Representative
Marla Rodgers MBA
Region 2 Representative
Robin S. Pastush RN, BSN
Region 3 Representative
Pam Gillette MPH, RN
Region 5 Representative
Timothy J. Stevens RN, BSN, CCTC
Region 6 Representative

Gwen E. McNatt MS, RN, CNN, CFNP
Janie Morrison FACHE
Kimberly Nicoll RN, BSN
Region 7 Representative
Region 10 Representative
Region 11 Representative

Elaine R. Berg MPA, FACHE
Rachael S. Wong MPH
At Large
Betty Crandall MS, RN
Ex Officio

Ginny McBride MBA, MPH

Division of Transplantation,
Ex Officio, non-voting

Committee Members Unable to Attend

Gary Sigle, RN MBA, BSN

Colleen O'Donnell MHA

Mesmin Germain MBA, MPH

Region 4 Representative

Region 9 Representative

Division of Transplantation,

Ex Officio, non-voting

Staff in Attendance

Angel Carroll MSW Liaison

Cherri Carwile Assistant Liaison

Mary D. Ellison Ph.D., MSHA UNOS Assistant Executive Director

for Federal Affairs, OPTN Project

Director
Jude Maghirang MS
UNOS Staff
Jennifer Mekolichick
UNOS Staff
Erma Edmiston
UNOS Staff

Guests Attending

Greg Levine SRTR