

This is an Addendum to the MPSC report distributed on CD to the Board of Directors on February 1, 2008, and contains additional action items recommended by the MPSC at its January 31 – February 1, 2008, meeting.

**OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE REPORT
February 20-21, 2008
SUMMARY - Addendum**

I. Action Items for Board Consideration:

- The Board of Directors is asked to approve designated program status for two new programs in existing member centers. (Item 1, Page 3).
- The Board of Directors is asked to approve continued membership for two medical/scientific organizations, and two new individual members. (Item 1, Page 3).
- The Board of Directors is asked to grant full approval to one kidney transplant program, one heart transplant program, one pancreas transplant program, and four liver programs that perform living donor transplants. The Board is also asked to grant a six-month extension of conditional status to one pancreas transplant program as permitted in the Bylaws. (Item 1, Pages 3).
- The Board of Directors is asked to approve the reinstatement of active status for a program that had previously voluntarily inactivated. (Item 1, Page 3).
- The Board of Directors is asked to approve a pediatric hospital to perform pancreas transplants as part of a multi-visceral transplant procedure. (Item 1, Page 3)
- The Board of Directors is asked to release a Member from Probationary status (Item 2, Page 4).

II. Other Significant Items:

- Program Related Actions and Personnel Changes: The Committee reviewed personnel change applications and members that had less than expected patient and graft survival rates. (Item 1, Page 3).
- Live Donor Adverse Events Reporting: As required in Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data) transplant programs must report all instances of live donor deaths and failure of the live donor's native organ function within 72 hours after the program becomes aware of the live donor death or failure of the live donors' native organ function. The Committee reviewed the first year of data on these reviews and is seeking input from the Board of Directors on the process. (Item 3, Page 4).

- Common Policy Violations: At the Committee's request, staff prepared a list of the most frequent policy violations found during site surveys, as well as other violations that resulted in MPSC action during 2007. The Committee agreed that this information should be distributed to the members in an educational format. (Item 4, Page 4-5).

**REPORT OF THE
OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE
TO THE
BOARD OF DIRECTORS
Orlando, FL
February 20-21, 2008
Robert S. D. Higgins, M.D., M.S.H.A., Chair
Carl L. Berg, M.D., Vice Chair**

- I. Regular Committee Meetings. The Membership and Professional Standards Committee (MPSC) met on January 31- February 1, 2008, in Chicago, Illinois. Its deliberations and recommendations are provided below. This report contains additional information and recommendations of the Committee and supplements the report distributed to the Board on February 1, 2008.
1. Membership Application Issues: The Committee recommends that the Board of Directors approve two new transplant programs in existing member centers. In addition to considering applications for institutional membership, the Committee reviewed applications for continued medical/scientific organization and individual membership (two-year terms), and recommends approval by the Board of Directors.

The Committee reviewed four liver transplant programs holding conditional approval for performing living donor transplants based on the qualifications of the second primary surgeon. In addition, the Committee reviewed one kidney, one heart, and one pancreas transplant program that were each conditionally approved based on the qualifications of the primary physician. The Committee recommends that the Board of Directors now grant full approval to each of these programs.

The Committee also reviewed and approved a six month extension to the Conditional Approval status of a pancreas transplant program that was initially granted Conditional Approval based on the qualifications of the primary physician. Additionally, the Committee reviewed one pancreas transplant program that had previously voluntarily inactivated and approved reinstatement of the program's active status.

The Committee reviewed bimonthly progress reports for two transplant programs (one kidney and one pancreas program) that were conditionally approved for 12 months to provide time for the primary physician to meet the full primary physician criteria or to allow the program to recruit a physician who fully meets primary physician criteria. The Committee also reviewed a progress report from a kidney program whose primary surgeon was approved under the pediatric pathway with bi-monthly reporting stipulations, and determined that the program had fulfilled the reporting requirement with no further reports needed.

The Committee also recognized that the pancreas is transplanted as part of a multi-visceral procedure in a particular pediatric hospital. This acknowledgement enables a facility to access UNetsm as necessary for data reporting purposes without requiring that the hospital receive designated program status for a pancreas transplant program. The Committee is recommending that the Board of Directors recognize this program.

2. Recommendation to Release Member from Probation: The MPSC is recommending that the Board of Directors release a transplant center from Probation, effective February 21, 2008.
3. Live Donor Adverse Events: As required in Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data) transplant programs must report all instances of live donor deaths and failure of the live donor's native organ function within 72 hours after the program becomes aware of the live donor death or failure of the live donors' native organ function. Live donors' native organ failure is defined as listing for transplant for liver donors, and as transplant, listing for transplant or the need for dialysis in renal donors. Transplant centers must report these incidents through the UNetSM Patient Safety System for a period of two years from the date of the donation. The MPSC will review and report all adverse events to the Board. The MPSC has been reporting live donor adverse outcomes to the Board of Directors for one year. During this period, 12 cases were reported. Ten cases involved living kidney donors with six deaths and four donors losing native kidney function. Two cases involved living liver donors with one death and one requiring and successfully receiving a liver transplant. Upon MPSC review, no cases were determined to have involved policy violations or entail patient safety concerns. The MPSC requests input from the Board regarding the adequacy of this review process. The Board did not initially provide guidance regarding what is considered a policy violation or patient safety issue, so the reviewers applied their own transplant experience and knowledge when assessing these cases.
4. Common Policy Violations: At the Committee's request, staff prepared a list of the most frequent policy violations found during on site surveys, as well as other violations that resulted in MPSC action during 2007 (list provided below). The Committee agreed that this information should be distributed to the members in an educational format.

Top Five Policy Violations on Site Surveys that resulted in MPSC action in 2007

- OPTN Bylaws, Appendix B, Section II F (Patient Notification): Transplant Centers do not have records of notifying patients within 10 days of listing or removal from the list for reasons other than transplant or death, do not include the date of listing or removal in the body of the letter, or do not include the telephone number that is available to patients and others to report concerns or grievances through the OPTN.
- 3.1.2 (Transplant Center): Centers do not maintain records of verification of the recorded donor ABO with the recorded ABO of the intended recipient upon receipt of an organ, prior to implantation.
- 3.1.4.2 (Waiting List): Centers do not appropriately ensure that each transplant candidate is ABO typed on two separate occasions prior to listing.
- 3.6.4.1 (Adult Candidate Status): Liver programs may not correctly enter information into UNetSM justification forms or MELD exceptions, or may not have the required medical record documentation to support candidates' listings.
- 3.6.6 and 3.7.14 (Removal of Liver and Thoracic Transplant Candidates from Waiting Lists When Transplanted or Deceased): Centers do not remove candidates from the OPTN Waiting List within 24 hours of transplant or death.

Top Five Other Policy Violations that resulted in MPSC action in 2007

- 3.2.4 (Match System Access): The MPSC cited both transplant centers and OPOs. An organ was either allocated or transplanted into a recipient who did not appear on a match run.
- 3.3.6 (Center Acceptance of Organ Offers): The MPSC cited both transplant centers and OPOs. Transplant Centers or OPOs withdraw acceptance or offers respectively once the official offer has been accepted.
- 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials Labeling Specifications): OPOs sent organs or tissue typing material with insufficient information or erroneous package labeling.
- 3.5.5.3 (Kidney Payback Debt Limit): OPOs exceeded the payback debt threshold of nine total debts across all blood groups.
- 7.8.1 (Data Submission Standard): OPOs, Transplant Centers, and Labs do not submit 100% of expected forms within six months of the due date.*

*The MPSC acted on this specific violation multiple times during 2006 and 2007.

**Attendance at the Membership and Professional Standards Committee Meeting
January 31 – February 1, 2008**

NAME	POSITION	Attended Aug 1-2, 2007	Attended Nov 13-14, 2007	Attended Jan 31 – Feb 1, 2008
Robert S Higgins MD,MSHA	Chair	X	X	X
Carl Berg MD	Vice Chair	X	X	
Paul Morrissey MD	Regional Rep.	X	X	X
Lynt Johnson MD	Regional Rep.	X	X	X
George Loss Jr, MD,PhD	Regional Rep.	X	X	X
John Goss MD	Regional Rep.			
Chris Freise MD	Regional Rep.	X	X	X
Jorge Reyes MD	Regional Rep.	X		X
Yolanda Becker MD, FACS	Regional Rep.	X	X	X
Michael Voigt MD	Regional Rep.	X	X	X
Patricia Sheiner MD	Regional Rep.	X		X
Lynn Driver CPTC	Regional Rep.	X	X	X
Tim Brown	At Large	X	X	X*
Jonathan Chen MD	At Large		X	X
Niloo Edwards MD	At Large	X	X	X
James Gleason	At Large	X	X	X
Julie Heimbach MD	At Large	X	X	X
John Herre MD	At Large	X	X	X
Donald Hricik MD	At Large	X	X	X
John Lake MD	At Large	X	X	X
Geoffrey Land PhD	At Large	X	X	X
Richard Luskin MPA	At Large	X	X	X
Jill Maxfield RN, CPTC	At Large	X		
Patricia McDonough RN, CPTC, CCTC	At Large	X	X	X
Brendan McGuire MD	At Large	X	X	X
Jennie Perryman RN, PhD	At Large	X	X	X
Fuad Shihab MD	At Large		X	X
Randall Starling MD, MPH	At Large	X	X	X
Randolph Steadman M.D.	At Large	X	X	X
David Weill MD	At Large		X	X
James Burdick MD	Ex Officio			
Christopher McLaughlin	Ex Officio	X	X	X
Charlotte Arrington MPH	SRTR Liaison	X	X	X
Jack Kalbfleisch	SRTR Liaison		X	
Robert Wolfe Ph.D.	SRTR Liaison	X	X	X

NAME	POSITION	Attended Aug 1-2, 2007	Attended Nov 13-14, 2007	Attended Jan 31 – Feb 1, 2008
Sally Harris Aungier	Committee Liaison	X	X	X
David Kappus MAS	Committee Liaison	X	X	X
Doug Heiney	Support Staff	X		
Terri Bessom	Support Staff		X	X
Heather Bowman	Support Staff		X	X
Elizabeth Coleburn	Support Staff	X	X	X
Jerry DeSanto	Support Staff	X	X	
Rosey Edmunds	Support Staff	X		X
Leah Edwards, Ph.D.	Support Staff	X		
Mary D. Ellison, Ph.D.	Support Staff	X	X	X
Shelia Foster	Support Staff			X
Alex Garza	Support Staff	X	X	X
Suzanne Gellner JD, CHC	Support Staff	X	X	X
Walter K. Graham	Support Staff	X		
Karl McCleary Ph.D., M.P.H.	Support Staff	X	X	X
Joel Newman	Support Staff	X		X
Jacqueline O'Keefe MBA	Support Staff	X	X	X
Anne Paschke	Support Staff		X	
John Persons, Esq.	Support Staff	X		
John Rosendale	Support Staff		X	X
Leah Slife	Support Staff	X	X	
Donna Whelan	Support Staff		X	X

* Participated by conference call