

OPTN/UNOS Membership and Professional Standards Committee (MPSC)
Report to the Board of Directors
November 14-15, 2011
Atlanta, GA

Summary

I. Action Items for Board Consideration

- The Board of Directors is asked to approve the following center-specific actions. (Item 1, Page 2):
 - Fully approve 3 new programs in existing transplant hospitals;
 - Conditionally approve 1 transplant program for 12 months;
 - Approve changes in program status in existing transplant centers:
 - o Fully approve 2 new living donor components in existing transplant hospitals;
 - o Conditionally approve one living donor component in an existing transplant hospital;
 - The Committee will also notify the board of directors that two transplant hospitals closed and terminated membership, nine programs inactivated and that one additional program temporarily ceased performing kidney and living donor kidney transplants.

I. Other Significant Items

- Program-Related Actions and Personnel Changes: The Committee reviewed 56 and approved 51 key personnel change applications during its July meeting. The Committee was also notified that nine programs or living donor components inactivated, two members/programs withdrew from membership. (Item 3, Page 3)
- Update of Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data): As required in Policy 12.8.4 (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 eight reported instances. (Item 5, Page 3)
- Bylaws Rewrite of Due Process Provisions: During its July meeting, the Committee was informed that a workgroup had been created to review and revise the processes currently available for consideration of issues that pose an imminent and/or substantial threat to patient health or public safety. (Item 10, Page 4)
- Proposal to Improve the Reporting of Living Donor Status: The Committee discussed the proposal to amend Policy 12.8.3.1 (Reporting Requirements) during its June 8, meeting, and agreed to support the proposal as written. (Item 11, Pages 4-5)

OPTN/UNOS Membership and Professional Standards Committee
Report to the Board of Directors
November 14-15, 2011
Atlanta, GA

John P. Roberts, M.D., Chair
Alan I. Reed, M.D., Vice Chair

I. Regular Committee Meetings. The Membership and Professional Standards Committee (MPSC) met on June 8, 2011, and August 4 by conference call and Microsoft Live Meeting, and on July 12-14 and September 27-28, 2011, in Chicago, Illinois. The Committee's deliberations and recommendations are provided below.

1. Membership Application Issues: The Committee is charged with determining that member clinical transplant programs, organ procurement agencies, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants. The Committee took the actions reported below during its meetings.

The Committee recommends that the Board of Directors approve three new programs and three new living donor components in existing member centers.

The Committee reviewed the following changes in status and recommends approval by the Board of Directors:

- Fully approve one existing transplant program that had been conditionally approved;
 - Change one fully approved living donor component in an existing transplant hospital to conditional approval;
2. Overview of Annual Committee Projects: Updates were provided to the Committee on the projects that were approved to be undertaken in 2010-2011. A list of the projects is provided below, and most are addressed in more detail later in this report.
 - OPO Performance Metrics – The Board approved this metric during its July 2011 meeting. Implementation is pending programming by the SRTR, availability of the donor evaluator tool, and OPTN member notification (Item 19).
 - Review the living donor program requirements for currency and relevance and to determine if the original goal of the requirements (to improve the process of living donation and transplantation through standardized levels of experience and quality) is being met. The review and modifications for living donor kidney are complete and have been implemented. Living Donor Liver will be addressed in Phase 2 Bylaws Rewrite, Item 9).
 - Develop and consider use of pre-transplant program performance metrics for flagging (Item 6).
 - Develop criteria for Directors of Liver Transplant Anesthesiology (Completed).

- Revise bylaws to better define “transplant hospital” (Further discussion needed).
 - Develop qualification criteria for Pediatric Organ Transplant Program approval. (Under development by the Pediatric Transplantation Committee).
 - Develop and implement Intestinal Transplant Program requirements in conjunction with the Liver and Intestinal Organ Transplantation Committee. (Under development by the Liver and Intestinal Organ Transplantation Committee).
 - Modify bylaws related to flagging methodology (Item 10).
 - Review bylaws pertaining to program certification and key personnel for currency and relevance (Item 9).
 - Create a pathway for kidney transplant programs to qualify as the primary kidney physicians who have completed a transplant nephrology research fellowship. This issue will be further discussed during Phase 2 of the Bylaws review (Item 9).
3. Program-Related Actions and Personnel Changes: The Committee reviewed and accepted programs changing status by voluntarily inactivating or withdrawing designated program status. Additionally, during the July meetings the Committee reviewed 56 and approved 51 Key Personnel Changes. The Committee also considered several hospital and OPO specific issues:
 4. Interviews, Hearings, and Informal Discussions: During its July 27-28 meeting, the Committee conducted eight interviews with member transplant centers and organ procurement organizations. In addition, the Committee conducted three hearings in a special meeting that was held on September 27-28, 2011.
 5. Update on Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data): As required in Policy 12.8.4 (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 eight reported instances (Events #61-68) and is not recommending any further action to the Board for three of them. One kidney program voluntarily closed. One liver program received a letter of uncontested violation for improper reporting. The other three instances involve a program that interviewed before the Committee, and is being recommended for Probation.
 6. Composite Pre-Transplant Metric (CPM): During the July 13-14, 2011, meeting staff presented an overview of the CPM to the Committee members, noting the upcoming study period. Specifics regarding the study of this metric were not discussed during this meeting. The work group will meet in October to discuss the final survey tool and other specifics relating to the study.
 7. Patterns and Trends of Member Compliance and Committee Actions: During the Committee’s July meeting, staff presented summaries of trends of policy violations on OPO and transplant hospital site surveys and a summary of issues reviewed by allocation analysts. Site survey information included top policy violations found during site surveys broken down by program, and whether the violations remained during the follow up site survey. The allocation information

included types of issues the allocation analysts review, the trends in numbers of issues identified, and the methods by which these issues come to the attention of the allocation analysts. In addition, staff presented types of allocation deviations found through other reports to UNOS, as well as Committee actions on past potential policy violations. Staff analyzed data by region and method of reporting.

8. Recommendation to Change Committee Appointment Terms: During its July meeting, the Committee discussed the terms of its at large members and is considering making a recommendation to the Board of Directors that the bylaws be amended to describe the terms of at large MPSC members as three, rather than two years. This change would provide for more continuity with the Committee. The Committee asked that the staff to first provide a plan for conducting more of the work on the Policy Compliance Subcommittee (PCSC) electronically or by conference call. This subcommittee historically meets in person on the day proceeding the in person meetings of the full committee. Changes to the subcommittee's work process would allow the in person meeting duration of the Committee to be shortened by up to one day. Once a plan has been developed, the Committee will consider advancing this proposal to amend the terms.
9. Bylaws Rewrite Project: The bylaws rewrite project is intended to improve clarity and organization of the bylaws documents. The initial phase of the project focuses on reorganizing the bylaws into in a logical arrangement and using plain language, rather than substantive changes. The second phase will focus on changes where there may be contradictions, revisions are needed, and/or additional provisions are required. An MPSC work group reviews the proposed changes to the bylaws as each section is drafted and provides feedback that will be incorporated into the final draft that in turn will be presented to the full Committee for its approval prior to the proposal being distributed for public comment review.

During the Committee's meeting on June 8, 2011, it approved the plain language versions of Appendices A-D for public comment. It had previously approved Articles I through XI. During the July meeting, the staff presented an update of the ongoing rewrite project for the OPTN and UNOS Bylaws. Additional sections are scheduled to be reviewed by the Committee during an October 27, 2011, conference call.

10. Bylaws Rewrite of Due Process Provisions: During its July meeting, the Committee was informed that a workgroup had been created to review and revise the processes currently available for review of issues that pose an imminent and/or substantial threat to patient health or public safety. The goals of this revision are to:
 - Make the member rights and responsibilities clear and understandable.
 - Provide more clarity to the term *imminent threat to patient health or public safety*.
 - Create another process for expedited review of matters that present a threat to patient health or public safety but are not imminent.
 - Clarify the process for referral of issues to the Secretary of Health and Human Services and for the performance of special reviews at the request of the Secretary.

Proposed language was provided to the Committee for its input. Following discussion, the Committee concluded that the workgroup needed more time to fine-tune the separate review pathways and the Committee would review the work group's product later this year.

11. Proposal to Improve the Reporting of Living Donor Status: The Committee discussed the proposal to amend Policy 12.8.3.1 (Reporting Requirements) during its June 8 meeting. The

OPTN currently relies on Living Donor Follow-up (LDF) forms to collect data on the short-term health status of living donors. Data on living donors who donated in 2006 through 2008 demonstrate that many programs do not report the status of their living donors at required reporting intervals. Under this proposal, transplant programs would be required to accurately report if the living donor is alive or dead at the required post operative reporting periods (6, 12 and 24 months).

The Committee agreed to support the proposal as written.

12. UNOS Actions: The Committee unanimously agreed during June meeting that actions regarding Bylaws, Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions.

** RESOLVED, that the Committee accepts those program specific determinations made during the meeting as UNOS recommendations. FURTHER RESOLVED, that the Committee also accepts the recommendations made relative to Bylaw and Policy changes.

The Committee unanimously approved the same resolution during its meeting on July 13-14, 2011, and during the Hearing Committee meeting on September 27-28, 2011.

Participation at the Membership and Professional Standards Committee Meetings

Name	Committee Position	July 13-14, 2011	Sept 28-29, 2011
John Roberts, MD	Chair	X	X
Alan Reed, MD	Vice Chair	X	X
David Hull, MD	Regional Rep.	By phone	X
Michael Shapiro, MD	Regional Rep.	X	X
Devin Eckhoff, MD	Regional Rep.		X
Marlon Levy MD, FACS	Regional Rep.	X	X
David Douglas, MD	Regional Rep.	X	X
Michael Mulligan, MD	Regional Rep.		
Dixon Kaufman, MD, PhD	Regional Rep.	X	
Harvey Solomon, MD	Regional Rep.	X	
Mark Orloff, MD	Regional Rep.	X	X
Marwan Abouljoud, M.D., FACS	Regional Rep.	X	X
David Shaffer, MD	Regional Rep.	X	X
Patricia Adams, MD	At Large	X	X
Allen Anderson, MD	At Large	X	
Sharon Bartosh, MD	At Large	X	X
A. Michael Borkon, MD	At Large	X	X
Margarita Camacho, MD	At Large	X	X
Richard Hasz Jr , MFS	At Large	X	X
Hassan Ibrahim, MD	At Large	X	X
Diane Jakobowski, MSN, CRNP	At Large	X	X
Megan Lewis, PhD	At Large		
Lori Markham, RN, MSN, CCRN, CPTC	At Large	X	X
David Marshman, CPTC,BS	At Large	X	X
Jennifer Milton, RN,BSN, MBA, CCTC	At Large	X	X
Isabel Neuringer, M.D.	At Large	X	X
Claus Niemann, M.D.	At Large	X	X
Kevin O'Connor, MS, PA	At Large		X
Sean Pinney, MD	At Large	X	X
Dianne LaPointe Rudow, ANP, DrNP, CCTC	At Large	X	X
Lesley Smith, M.D., MBA	At Large	X	
Dolly Tyan, PhD	At Large	X	X
Betsy Walsh, J.D., M.P.H.	At Large	X	X
Brenda Welsch, BSN, CPTC	At Large	X	X
Debbie Williams, RN	At Large	X	X
David Zaas MD, MBA	At Large	X	X
Christopher McLaughlin	Ex Officio	X	X

Name	Committee Position	July 13-14, 2011	Sept 28-29, 2011
Robert Walsh	Ex Officio	X	X
Sven Peterson	Ex Officio		X
Nicholas Salkowski	SRTR Liaison	X	
Jon Snyder, PhD, MS	SRTR Liaison	X	
Sally Aungier	Committee Liaison	X	X
David Kappus ,MAS	Committee Liaison	X	X
Jacqueline O'Keefe, MBA	Committee Liaison	X	X
Rosey Adorno	Support Staff	X	
Rebecca Anderson, PhD	Support Staff	X	
Manny Carwile	Support Staff	X	X
Betsy Coleburn	Support Staff		X
Cynthia Coleman	Support Staff		X
Erick Edwards, PhD	Support Staff	X	
Leslee Garland	Support Staff	X	
Sheran Goodman	Support Staff		X
Nicole Kleiman, MPH	Support Staff	X	
Jason Livingston	Support Staff	X	X
Diana Marsh	Support Staff		X
Maureen McBride	Support Staff	X	
Joel Newman	Support Staff	X	
Heather Neil	Support Staff	X	
Amy Putnam	Support Staff	X	
Sharon Shepherd, J.D., M.S.N., R.N.	Support Staff	X	X
Brian Shepard	Support Staff	X	X
Christi Wong	Support Staff	X	