

**Interim Report of the
OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE REPORT
July 22-23, 2009
Chicago, IL**

The Membership and Professional Standards Committee met on July 21-22, 2009, and considered the following items:

I. Action Items for Board Consideration:

The Committee will ask the Board of Directors to approve the following recommendations during the November 16-17, 2009, meeting:

- Grant approval to 1 new independent laboratory and 4 new non-institutional members;
- Grant full approval to 4 new programs in existing transplant centers;
- Approve changes in program status
 - Grant full approval to a program that has reactivated.
 - Approve an extension of inactive status
 - Change the status of a fully approved program to conditional status.

The Committee also anticipates asking the Board of Directors to approve the following proposals pending final consideration by the Committee during a conference call scheduled for September 25.

- Proposed Bylaw Modifications to Clarify the Process for Reporting Changes in Key Personnel. (Appendix B, Section II, E (Key Personnel); Bylaws, Appendix B, Attachment 1, Section III (Changes in Key Personnel)). This proposal was circulated for public comment February 6 – April 24, 2009. The MPSC approved amendments to the original proposal post public comment. The Committee has asked representatives of the Transplant Administrators Committee to review the revised proposal prior to its final consideration. A conference call has been schedule for August 20, 2009.
- Proposed Bylaw Modifications to Reconcile Volume Requirements for Primary Transplant Physicians: The MPSC reviewed an amendment to the bylaws that will reconcile the requirements in the conditional pathways with those for training and experience. The proposed changes were circulated for public comment in July. The Committee considered preliminary feedback on the proposal and will reconsider it once the public comment period closes on September 14, 2009.
- Preventing the Appearance of Potential Conflicts of Interest Regarding Declaration of Death and Organ Procurement: The Committee reviewed the proposal that was circulated for public comment in July. The Committee considered preliminary feedback on the proposal and will reconsider it once the public comment period closes on September 14, 2009.
- OPTN Notification of Potential Adverse Action by other Regulatory Agencies: During its July 2009, meeting, the Committee reviewed the proposal distributed for public comment in early July and recommended additional modifications to clarify the proposed bylaw language that requires transplant programs, OPOs, and histocompatibility laboratories to notify the OPTN of threatened or real adverse actions taken by regulatory agencies. The Committee will reconsider it once the public comment period closes on September 14, 2009.

II. Old Business

- Annual Committee Goals: During its July meeting, the Committee was presented with the goals that had been approved for the year and the progress made on those goals that were already in process.
- Program-Related Actions and Personnel Changes: The Committee reviewed 51 and approved 49 personnel change applications.
- Due Process Proceedings and Informal Discussions: During the July meeting, the Committee conducted three interviews with member transplant centers. Additionally, the Data Subcommittee, which met on July 21, convened two informal discussions with member transplant centers.
- Living Donor Related Bylaws: The Committee was updated on the plans to review the bylaws related to living donor transplantation. A joint work group comprised of members from the MPSC, Living Donor Committee, Pediatric Transplantation Committee, Kidney Transplantation Committee, and the Liver and Intestinal Organ Transplantation Committee was formed to discuss this issue. The Committee also reviewed preliminary feedback from the Liver and Intestinal Organ Transplantation Committee on some questions regarding potential changes that had been discussed at a previous meeting and its status of developing requirements for intestinal transplant programs.
- Living Donor Applications: The Committee received a progress report on the status of the application process for the transplant programs that perform living donor kidney transplants. The Committee is on schedule to present the living donor kidney transplant program applications to the Board in November for approval consideration.
- Inactive Bylaw Modification: During the July meeting, the MSPC was informed that the Executive Committee approved its request that the Board approved bylaw language have an effective date of August 1, 2009. Additionally, the Committee affirmed the Data Subcommittee recommendation to review the reports of programs with inactive waiting lists and programs with candidates still on the waiting list after program inactivation before codifying a process for Data Subcommittee review.
- OPO Performance Metrics: The Committee was updated on the work of the OPO Performance Metrics Work Group, which is comprised of members of the OPO Committee and the MPSC. It is tasked with developing performance metrics to maximize the utilization of organs.
- Center Specific Reports: The SRTR presented a summary of the Organ Specific Committee work regarding improving the center/program specific reports. The SRTR representatives will continue to update the MPSC on the progress of the improvements and when changes will be implemented into the model.
- Modified Flagging Methodology: OPTN staff presented a retrospective analysis of the modified flagging criteria proposed by the SRTR. In summary, the analysis showed that using the proposed method, the MPSC would flag fewer programs overall, while flagging

more medium and high volume programs. The analysis also showed that the proposed method would flag > 80% of the programs considered to be “true positives” using the current flagging method and would flag fewer of the current false positives. The Data Subcommittee will consider the issue in more detail.

- Acceptance Rates: The SRTR presented a brief overview of the methodology for calculating organ and offer acceptance rates. Only organs that were accepted for transplant within the first 50 offers, or to the first 3 centers are included. Additional exclusions such as DCD, ECD and others ensure that only “good” organs are used in the analysis. Organ acceptance rates are based on offers to centers while offer acceptance rates are based on offers to individual candidates. The Committee had no issues to discuss based on the presentation.
- Scanning Serologies in DonorNet®: The Committee requested that the OPO Committee consider requiring that OPOs scan serology source documents (as PDFs) into DonorNet® so that source documents may be viewed by the staff at potential recipients’ transplant centers and OPOs during the organ offer process. The MPSC reviewed the OPO Committee’s response at its July 2009 meeting.
- Data Subcommittee Report: The Data Subcommittee met on July 21, 2009, and continued its review of transplant programs that exhibited lower than expected patient and/or graft survival rates; small volume programs that experienced at least one death and/or graft failure within one year of transplant; and functionally inactive programs. The Subcommittee made its recommendations to the full MPSC during the July 22-23, 2009 meeting.
- Policy Compliance Subcommittee Report: The Policy Compliance Subcommittee (PCSC) met on July 21, 2009. The PCSC discussed general issues as well as standard, periodic site surveys; member complaints; observed or reported potential policy violations, and organ specific committee referrals. In addition, the PCSC received updates on members that are continuing in monitoring.

III. New Business

- 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 three reported instances.

OPTN staff presented an analysis of living donor deaths not reported to the Patient Safety System (PSS). Between 2006 and 2008, there were 26 living donor deaths that occurred within 2 years of donation. Of these deaths, 15 were not reported to the PSS. Several programs did not know of the deaths and knowledge of them came from the Social Security Death Master File. Other programs reported the deaths to the OPTN via the Living Donor Follow Up form and stated that they were unaware of the policy requirement to report these deaths in the PSS. The Committee discussed the reasons centers report losing living donors to follow up and then not providing desired information. The Committee expressed support for the ongoing work of the Living Donor Committee to develop minimum standards for complete data reporting and thresholds for center review.

- Composite Pre-Transplant Metric (CPM): OPTN staff presented a proposal for a new way to monitor program specific pre-transplant outcomes. The CPM takes into account risk-adjusted mortality rates, transplant rates and acceptance (organ and offer based) rates provided by SRTR. Programs are ranked on a single composite score that is a weighted sum of their pre-transplant observed to expected ratio of all four metrics. A working group will consider the merits of this approach for monitoring of pre-transplant performance.
- Data Coordination Responsibilities and Guidelines: The MPSC was informed that a memo had been sent to the OPO, Histocompatibility, Transplant Administrators, and Transplant Coordinators committees requesting feedback on the necessity to codify in the bylaws responsibilities and expectations for primary data coordinators. No feedback was provided to the MPSC during the July meeting, but will likely be discussed in December.
- Voting Status of Hospital Based OPOs and Laboratories: The Committee discussed a request that hospital based OPOs be granted OPTN voting rights as a part of their membership under the parent transplant center. The Committee agreed to form a work group to explore this issue.
- Patterns and Trends of Member Compliance and MPSC Actions: Staff presented a summary of trends of OPO and transplant center site survey results. Information included top policy violations found during site surveys, as well as the percentages of programs and centers that meet MPSC thresholds for performance on routine and follow up surveys. Staff presented a possible path for future trend analysis to the Committee.
- Process for Letters of Reprimand, Probation, and Member Not in Good Standing: If the Committee considers recommending an adverse action such as Probation or Member Not in Good Standing or is considering issuing a Letter of Reprimand, the applicant or member is entitled to an interview. Historically, if a member waived its right to an interview for a proposed action, the department of evaluation and quality would, on behalf of the Committee, issue the proposed sanction without further committee deliberation. Staff requested that the Committee consider whether to formally standardize this practice in all cases where a member waives its right to an interview. The Committee decided that, in the case of Letters of Reprimand, it would proceed with the proposed sanction. For recommendations of Probation or Member Not in Good Standing, if the member waives its right to an interview the Committee will re-evaluate the resolution.
- UNOS Actions: The Committee members agreed that actions regarding Bylaws and Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions.

Charles Alexander, RN, BSN, MBA, CPTC
 The Living Legacy Foundation of Maryland
 (443) 883-1017

David Mulligan, M.D.
 Mayo Clinic Hospital
 (480) 342-0437