

**Interim Report of the
OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE
REPORT
December 7-8, 2011
Chicago, IL**

The Membership and Professional Standards Committee (MPSC) met on December 7-8, 2011, in Chicago, Illinois 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 June 25-26, 2012, meeting:

New Membership

- Grant approval to 1 new independent laboratory
- Grant new two-year terms to 7 non-institutional members;

Existing Membership

- Fully approve 4 new programs in existing transplant hospitals;
- Fully approve 2 new program component in existing transplant hospitals;
- Approve changes in program status
 - Grant full approval to seven programs that reactivated.
 - Change the status of 3 conditionally approved programs to full approval. The committee will also notify the board of directors that 11 programs inactivated and that 14 programs ceased performing organ transplants.

II. Old Business

- Annual Committee Goals: During its December 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 and approved 111 transplant program personnel change applications. Additionally, the Committee reviewed eight applications for changes in primary laboratory directors and approved seven; and was notified that the five OPO's had changed either their medical director or executive director.
- Due Process Proceedings and Informal Discussions: During the December meeting, the Committee conducted seven interviews with member transplant hospitals and organ procurement organizations.
- Bylaws Rewrite Project: The work group chair and the staff updated the committee on the status of the bylaws rewrite project. The proposal was released for public

comment on December 2, 2011 and responses are due by January 31, 2012.

- Modifications to Appendix A of the Bylaws: The work group chair and staff presented proposed revisions to the due process provisions of Appendix A of the OPTN Bylaws. The MPSC approved the proposal for public comment distribution. It will be released on February 1, 2012, and will be renamed Appendix L.
- Inactive Waitlist Focus Group Report: A focus group comprised of MPSC, Transplant Administrators Committee, and Patient Affairs Committee members met on October 13, 2011, to discuss modifications to the bylaw requirements for patient notification of cessation of portions of a program and inactive waiting lists. The MPSC approved the proposed modifications for public comment distribution.
- Composite Pre-Transplant Metric (CPM): During the December 7-8, 2011, meeting staff notified the Committee that the survey's were distributed to 77 kidney and liver transplant programs on December 1. The work group will reconvene after the responses have been received, likely in January/February 2012, to consider the results/feedback.
- OPO Metrics: The MPSC reviewed a summary of suggested changes for improving the SRTR models. The changes relate to the statistical analysis, and not the flagging algorithm approved by the Board in June 2011. The proposed changes included dropping the aggregate model for yield. The expected aggregate yield will be obtained by summing the expected yields from each organ specific model. Additionally, the SRTR recommended that lungs count as either zero or one organ transplanted (not 2) in the lung model. The final change the SRTR recommended related to a small subset of donor characteristics that are associated with low yield probabilities. The SRTR recommends that the expected yield for the rare donors with these characteristics be set to the overall national average (unadjusted). With this approach, OPOs get credit for any organs transplanted from the donors with these characteristics.

The MPSC approved these modifications to the model, as well as the donor evaluator tool.

- Continuous Outcomes Monitoring (CUSUM): The SRTR presented the concepts of control charting for monitoring process improvement in post-transplant survival rates. The need for implementing different criteria for different types of programs (e.g., small volume versus large volume) was emphasized. The fact that all programs will eventually "signal" was also pointed out. The MPSC took no action based on the presentation.
- Bylaw Requirements for Currency: The bylaws for primary surgeon and physician training and experience describe the requirements an individual must meet to be considered "current" in the field. It has been pointed out that these criteria are not adequate for the committee and staff when dealing with proposed primaries who cannot demonstrate a present involvement in transplant activities and services. The

currency standards and definitions need to be updated. It had been planned to review these requirements along with the other surgeon and physician requirements during Phase 2 of the Bylaws Rewrite project. The Committee asked the staff to develop a strategy for accomplishing this project before the Phase 2 process begins.

- Compliance with Bylaws regarding Key Personnel Changes: The staff presented the Committee with information regarding bylaw changes approved by the Board in December 2009. These bylaws were implemented to better define expectations for timely key personnel change notification and application submission. Data was presented to show that there has been an improvement in key personnel application submission, but there is a 9.5% rate of late submission (day of departure or after departure notification) that needs to be improved upon. The Committee directed staff to obtain information from the program that explained why a notification is late and then report these cases to the Committee for discussion regarding possible actions for non-compliance with the bylaw requirements. Staff agreed to provide this information going forward.

The Committee reviewed the following bylaw and policy proposal that had been distributed for public comment (9/16/11 – 12/23/11).

- Revision of the UNOS Bylaws, the OPTN Bylaws and the OPTN Policies that Govern HLA Laboratories: This proposal, sponsored by the Histocompatibility Committee, revises the UNOS Bylaws and Policies that apply to histocompatibility laboratories to more closely align OPTN/UNOS requirements for member laboratories with current laboratory practices.

The Committee only reviewed the portions of this proposal that address the laboratory director qualifications, and it is offering several suggested modifications.

The Committee also reviewed three proposals sponsored by the Living Donor Committee.

- Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors. This proposal would establish policy requirements for the informed consent of living kidney donors.

The Committee expressed its support for improvements to the informed consent policies but overall it was concerned about the level of detail in the proposed changes, that it is proscriptive of clinical practice, and had concerns about ability for the OPTN/UNOS to monitor/audit level clinical judgment, etc. The Committee offered the LDC the several suggestions regarding the proposal.

- Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-Up: This proposal would require transplant programs to report required fields on the Living Donor Follow-Up (LDF) form at required post-operative reporting periods (6, 12, and 24 months).

The Committee made several suggestions/comments about the proposal such as developing a method for hospitals to document all attempts to comply since there may be donors who desire to opt out of follow up; concern about changing the policy to require clinical tests that may have financial implications for the donors; clarifying which hospital is responsible for following up the donor in a pair exchange; and documenting post donation psychosocial issues.

- Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors. This proposal would establish policy requirements for the medical evaluation of living kidney donors. The Committee recommended the following changes to this proposal.
 - The Committee thought it would be more appropriate for a mental health clinical nurse specialist or advanced practice nurse trained in the psychosocial and psychiatric assessment to conduct the psych/social evaluation.
 - The proposed policy would add “Untreated psychiatric conditions, including suicide risk” to the list of exclusion criteria. The Committee was concerned that this was not sufficient and that there would be interpretation issues. The proposed language needs to be very clear about what is meant by “including suicide risks,” and the LDC needs to develop a separate document or guidelines that address suicide risks among living donors and how to deal with that from the standpoint of detection and treatment.
 - The Committee also suggested developing guidelines for potential living donors that they could discuss with their physicians.
- Performance Analysis and Improvement Subcommittee (PAIS) Report: The PAIS met on October 24, and November 7, 2011, to continue 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 December 7-8, 2011, meeting.
- Policy Compliance Subcommittee Reports: The Policy Compliance Subcommittee (PCSC) met on December 6. 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. The PCSC made its recommendations to the full MPSC during the December 7-8, meeting.

III. New Business

- 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.

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