

**OPTN/UNOS Membership and Professional Standards Committee (MPSC)**  
**Report to the Board of Directors**  
**June 25-26, 2012**  
**Richmond, VA**

**I. Action Items for Board Consideration**

- The Board of Directors is asked to approve the following center-specific actions. (Item 1, Page 3):

New Memberships:

- Grant approval to 2 new transplant hospital members, including approval of 3 new programs and one living donor program component in these hospitals.
- Grant approval to 1 new independent histocompatibility laboratory.
- Fully approve 5 new programs in existing transplant hospitals.
- Fully approve 3 new program components in existing transplant hospitals.
- Grant two-year terms to 13 non-institutional members.
- Recognize one new pancreas program approved under the multi-visceral program criteria.

Approve Changes in Program Status:

- Grant full approval to 19 programs and living donor program components that reactivated.
  - Change the status of 3 conditionally approved programs or living donor program components to full approval.
- The Board of Directors is asked to approve modifications to the OPTN Bylaws, including Appendices A-K and M. (Item 2, Pages 3-4).
  - The Board of Directors is asked to approve modifications to the OPTN Bylaws, Appendix L, addressing reviews, actions, and due process. (Item 3, Pages 4-5).

**I. Other Significant Items**

- Program-Related Actions and Personnel Changes: The Committee reviewed and approved 156 key personnel change applications during its December 2011 and March 2012 meetings. The Committee was also notified that 32 programs or living donor components inactivated; 18 transplant programs or living donor components and 2 histocompatibility laboratories withdrew from membership; 1 intestinal transplant program was registered; and 1 pediatric hospital without an approved pancreas transplant program was registered to perform multi-visceral transplants that include a pancreas. The Committee also reviewed and approved 10 applications for changes in primary laboratory directors, and was notified that the nine OPOs had changed either their medical director or executive director. (Item 4, Page 5)
- 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 23 reported instances. (Item 7, Page 6)
- Inactive Waitlist Focus Group Report: The Committee reviewed and approved

- recommendations from a focus group regarding modifications to the bylaw requirements for patient notification of cessation of portions of a program and inactive waiting lists. A proposal will be distributed for public comment. (Item 8, Page 6).
- OPO Metrics: The Committee approved a focus group's recommendations for codifying the review process and tools for use by the Performance Analysis and Improvement Subcommittee (PAIS), upon implementation of OPO Metrics in July 2012. (Item 9, Page 6).
  - Pancreas Outcomes Model: The Committee agreed that all pancreas programs will be notified in the fall of 2012, that the Committee will begin implementing the pancreas outcomes review process in January 2013. (Item 12, Page 7).
  - Modified Flagging Methodology: The Performance Analysis and Improvement Subcommittee (PAIS) reviewed two cycles of SRTR simulation results regarding modified outcome triggers. The PAIS reported the results of its review to the Committee during the March 2012 meeting. (Item 13, Page 7).
  - Compliance with Requirements for Director of Liver Transplant Anesthesia: On February 1, 2012, each approved liver transplant program (128 programs) was asked to supply the name of an individual who would meet the designation requirements as director of liver transplant anesthesia. The Committee agreed that non-compliant hospitals will be sent a final notice informing the programs that failure to comply will result with referral to the Committee for discussion and possible consequences at the July meeting. (Item 16, Page 8).
  - Peer Visit Definitions: The Committee approved new definitions for peer visits as well as the proposed committee process when a peer visit is recommended. (Item 20, Pages 8-9).

**OPTN/UNOS Membership and Professional Standards Committee**  
**Report to the Board of Directors**  
**June 25-26, 2012**  
**Richmond, VA**

**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 October 27, 2011, February 29, 2012, and April 20, 2012, by conference call and Microsoft Live Meeting, and on December 6-8, 2011, and March 27-29, 2012, 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 two new transplant hospitals, one new histocompatibility laboratory, 5 new programs, and 3 new living donor components in existing member hospitals, as set forth in the following resolutions:

In addition to considering applications for institutional membership, the Committee reviewed applications for new and continued membership for existing non-institutional members. The Committee also reviewed the following changes in status and recommends approval by the Board of Directors:

- Approve 17 previously inactive programs/ living donor components in existing member hospitals for active status;
- Fully approve 3 existing transplant programs/living donor components that had been conditionally approved;

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 UNet<sup>sm</sup> as necessary for data reporting purposes without requiring that the hospital receive designated program status for a pancreas transplant program. The Committee recommends one program be approved by the Board of Directors.

2. OPTN Bylaws Plain Language Rewrite: The OPTN Bylaws rewrite was undertaken after a Member survey indicated that members wanted bylaws to be written in plain language with information that was easier to understand, access, and use. To meet this goal, the OPTN Bylaws have been analyzed, reorganized, and rewritten for better clarity and usability. This rewrite does not make any substantive changes to the content of the current Bylaws.

A work group consisting of Committee members, supported by UNOS staff began work on the project in October 2010. Work group members met frequently by phone and reviewed and commented on several drafts of the rewritten bylaws to ensure clarity and that no substantive changes were made.

Some sections of the current Bylaws have been moved to OPTN Policies as part of the reorganization during the Bylaws Plain Language Rewrite project. In addition, several sections of the current *UNOS* Bylaws that were not included in the current *OPTN* Bylaws are being included in the rewritten *OPTN* Bylaws, so that all *OPTN* membership requirements are in both the *UNOS* and *OPTN* Bylaws.

The rewrite affects the entire *OPTN* Bylaws, except the current *Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs*. This section underwent both a substantive and plain language rewrite and was presented for public comment as the new *Appendix L: Reviews, Actions, and Due Process* during a special public comment period from February 2, 2012 – April 2, 2012. (See Item 3 below).

The plain language rewrite was presented for public comment from December 2, 2011 – January 31, 2012. The vast majority of the comments received were positive and in support of the proposal. A copy of the Briefing Paper, which addresses the details of the proposal and the Committee's response to the comments, is attached as **Exhibit J** of this report.

The entire Committee, after reviewing the rewritten Bylaws and public comment, made minor revisions and unanimously agreed during its April 20, 2012, meeting, to forward the rewritten Bylaws to the Board for consideration.

**\*\* RESOLVED, that the plain language rewrite of the OPTN Bylaws, including Appendices A-K and M, as set forth in Exhibit J, having been distributed for public comment with subsequent reconsideration by the Committee, are approved and shall be effective September 1, 2012.**

The Committee Voted 22 For, 0 Against, 0 Abstentions.

3. OPTN Bylaws – Reviews, Actions, and Due Process: This proposal represents a substantive rewrite of the current *Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs*. This rewrite will become the new *Appendix L: Reviews, Actions, and Due Process*, to fit with the new organization of the *OPTN* Bylaws Plain Language Rewrite (Item 2 above).

This proposal represents a substantive rewrite of the procedures for reviewing potential violations of and non-compliance with *OPTN* obligations. All content of the former *Appendix A* also underwent a plain language rewrite and reorganization for clarity and usability. A Committee based work group began meeting by phone in March 2011. Work group and staff worked together to draft new review pathways and to better outline *OPTN* member responsibilities and requirements. Members reviewed and commented on several drafts of the rewritten bylaws to ensure clarity and accuracy.

The *OPTN* Bylaws Substantive Rewrite of the bylaws addressing reviews, actions, and due process accomplishes the following objectives:

- Outlines the three possible review pathways for potential violations of *OPTN* obligations and requirements.
- Clarifies the role of Secretary of the U.S. Department of Health and Human Services (HHS) in reviewing and acting on potential violations, particularly those that may pose a threat to patient health and public safety.

- Clarifies when the Secretary may request that the OPTN Contractor perform special reviews of a Member for non-compliance.
- Adds a new monitoring tool to aid Members who may need time and assistance from the OPTN to come into compliance.
- Clarifies notice requirements after an adverse action is taken by the OPTN.
- Provides information to Members about their rights in plain language with logical organization.

The proposal was presented for public comment from February 2, 2012 – April 2, 2012. A copy of the Briefing Paper, which addresses the details of the proposal and the Committee’s response to the comments, is attached as **Exhibit K** of this report. The entire MPSC, after reviewing the rewritten Appendix A Bylaws and considering public comment, made several revisions and voted on April 20, 2012 to forward the rewritten Bylaws, as amended, to the Board for consideration.

**\*\* RESOLVED, that the OPTN Bylaws, Appendix L (Reviews, Actions, and Due Process), as set forth in Exhibit K, having been distributed for public comment with subsequent reconsideration by the Committee, are approved and shall be effective September 1, 2012.**

The Committee Voted 20 For, 0 Against, 1 Abstention.

4. Overview of Annual Committee Projects: Updates were provided to the Committee on the projects that were approved to be undertaken in 2011-2012. A list of the projects is provided below, and most are addressed in more detail later in this report.
  - Bylaws Rewrite – Phase I (Items 2)
  - OPTN Bylaws Phase II Rewrite (Item 3)
  - Develop criteria for Directors of Liver Transplant Anesthesiology(Item 16). Completed.
  - OPO Performance Metrics (Item 9). Implementation pending July 2012.
  - Develop and consider use of pre-transplant program performance metrics for flagging (Item 10).
  - Modify bylaws related to flagging methodology (Item 13).
  - Review the requirements for programs that perform living donor liver transplantation currency and relevance to current practice. The review and modifications for living donor kidney are complete and have been implemented. Living Donor Liver will be addressed in Phase II, Bylaws Rewrite.
5. Program-Related Actions and Personnel Changes: The Committee reviewed and accepted programs changing status by voluntarily inactivating or withdrawing designated program status, and newly registered intestinal transplant programs. Additionally, during the December and March meetings the Committee reviewed 175 Key Personnel Changes.

6. Interviews, Hearings, and Informal Discussions: During its December 7-8, 2011, meeting, the Committee conducted seven interviews with member transplant hospitals and organ procurement organizations. During its March 28-29, meeting the Committee conducted five interviews. Interviews and hearings were convened as provided for in Appendix A of the Bylaws.
7. 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. During its October meeting, the Committee reviewed thirteen reported instances and recommended no further action for nine of them. Four programs were issued a Notice of Uncontested Violation for improper reporting

During its March 2012 meeting, the Committee reviewed ten additional reported instances and recommended no further action for nine of them. One program was issued a Notice of Uncontested Violation for improper reporting.

8. Inactive Waitlist Focus Group Report: A focus group comprised of members of the MPSC, Transplant Administrators Committee, and Patient Affairs Committee 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. During its meeting in December, the Committee approved the proposed modifications for public comment distribution, by a vote of 23 for, 8 against, 0 Abstentions. This item will be distributed during the Fall 2012 public comment period.
9. OPO Metrics: During the October 2011 meeting, the Committee was provided with 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. 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 0 or 1 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 Committee approved these modifications to the model, as well as the donor evaluator tool, by a vote of 22 For, 0 Against, and 0 Abstentions.

During the March 2012 meeting, the focus group reported on its progress in codifying the review process and tools for use by the PAIS, upon implementation in July 2012. The focus group recommended that upon initial identification of an OPO performing below expected, an inquiry letter will be sent to the OPO asking for it to provide an assessment of its performance, results of reviews conducted, and resolutions implemented. The focus group also created an Expanded Questionnaire for some situations where the PAIS may want to gain additional/more detailed information regarding OPO operations and copies of procedures and protocols. The focus group also identified data elements to aid PAIS members when reviewing an OPO's response to an inquiry. Finally, the focus group recommended that the development of a formal process diagram be postponed until after the PAIS gained some experience with the reviews. The Committee approved the focus group recommendations to proceed with implementation in July 2012, with a unanimous vote of 31.

10. 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. During the March meeting, staff reported that most members in the CPM survey were slow to respond, with less than one-third completing the survey. As a result, the deadline for completion was extended to allow for a better response rate. A meeting for the work group will be set once a preliminary analysis of the survey results has been completed.
11. Continuous Outcomes Monitoring (CUSUM): During the March meeting, 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 vs. large volume) was emphasized. The fact that all programs will eventually "signal" was also pointed out. The Committee took no action based on the presentation.
12. Pancreas Outcomes Model Update: During the December 2011 meeting, the Committee was informed that the Pancreas Transplantation Committee has completed graft and patient survival models for reviewing pancreas outcomes. The SRTR contractor is currently refining the model strategy and will be presenting the final recommendations to the Pancreas Transplantation Committee, with updated data based on the January 11 CSR.

During the March 2012 meeting, the SRTR presented proposed modifications to the 1-year graft and patient pancreas survival outcomes models. The SRTR will release the July 2012 PSR outcomes data to programs' private sites and will also make this data available to the Committee. All pancreas transplant programs will be notified in the Fall 2012, that the Committee will begin implementing the pancreas outcomes review process in January 2013.

13. Modified Flagging Project: During the March 2012 meeting, the Committee reviewed the second cycle of simulation data comparing the results of the proposed modified flagging methodology with the existing flagging methods. Based on this review, the Committee recommended adopting the proposed modified flagging methodology as the sole flagging method, with a vote of 26 For, 0 Against, 0 Abstentions. Proposed bylaw language will be drafted for the Committee's approval during the July 2012 meeting, and will be distributed for public comment upon approval.
14. Transplant Program Quality and Surveillance: A consensus conference was held in February 2012 to discuss the current SRTR Program Specific Reports (PSR), risk adjustment factors, additional statistical methods, data collection elements, and types of monitored outcomes. During the March 2012, meeting, the SRTR presented recommendations from the consensus conference work groups. The Committee took no action based on the presentation.
15. Collaboration between the Living Donor Committee and DEQ for the Implementation of New Living Donor Policies: Over the course of the three-day Committee meeting (including the Policy Compliance Subcommittee (PCSC)) meeting, implementation of the living donor policies scheduled for presentation to the Board of Directors in June was discussed a number of times. The Chair and various members of the Committee expressed concern that transplant hospitals may have difficulty implementing the new policies based on the review of current issues that were presented to the Committee for a number of living donor kidney programs. As a result, the Committee asks the Living Donor Committee to work with the Department of Evaluation and Quality to develop, in effect, an implementation plan including forms, the DEQ monitoring and evaluation plan, and other resources.

16. Compliance with Requirements for Director of Liver Transplant Anesthesia: On February 1, 2012, each of the 128 approved liver transplant program was asked to supply the name of an individual who would meet the designation requirements as director of liver transplant anesthesia. The Committee agreed that non-compliant hospitals would be sent a final notice informing the programs that failure to comply will result with referral to the Committee for discussion and possible consequences at the July meeting.
17. Bylaw Requirements for Currency: The bylaws describe the requirements for the primary surgeon and physician training and experience and how an individual may be considered “current.” These criteria have not proven adequate for the Committee and staff when dealing with proposed primaries who cannot demonstrate a present involvement in transplant activities and services. For this reason 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 II of the Bylaws Rewrite project. The Committee asked the staff to develop a strategy for how to accomplish this project.
18. Compliance with Bylaws regarding Key Personnel Changes: During the December 2011 meeting, the Committee was given an update regarding bylaw changes approved by the Board in December 2009. These bylaws 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. The Committee directed staff to ask programs to supply a reason for the notification being submitted late and then report these cases to the Committee for discussion regarding possible actions for non-compliance with the bylaw requirements.
19. Recommendation to Change Committee Appointment Terms: During its July 2011 meeting, the Committee discussed the Terms of its at-large members and considered 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. During the March 2012 meeting, the Committee was informed, that after additional discussion about the number and priority of Committee projects, it was determined that a bylaw change was not necessary and that the President could continue to appoint members to extended terms as needed.
20. Peer Visit Definitions: Changes in Committee processes have resulted in an increased use of peer visits and recent feedback from peer team participants has identified a need for clear definitions of peer visits and the type of peers selected to serve, as well as a clear focus of the particular peer visit. During the March meeting, the Committee considered new definitions for peer visits, and a proposed process for obtaining clear and detailed purpose of the peer visit at the time of the recommendation, as summarized below. The Committee unanimously approved these new definitions and process (31 For, 0 Against, 0 Abstentions).

**Investigative Peer Visits:** Investigative peer visits are used to identify the problem or issue at the facility, including potential patient safety issues.

**Advisory Peer Visits:** Advisory peer visits are used for providing feedback to the member on Committee reviews and for providing a method for the Committee to monitor the member’s improvement efforts. Typically, advisory peer visits are conducted for transplant programs with lower than expected outcomes, OPOs with lower than expected yield, as well as frequent poor site survey compliance rates.

Based on the Committee recommendation for a peer visit, the Committee will identify the following at the time of recommendation:

- Type of visit: Is it advisory or investigative?
- Peer team members: What type of individuals should serve on the team?
- Peer focus: Are there specific questions to be addressed, i.e. what are the peers looking at/for?
- Other OPTN Staff participation: Should site surveyors accompany the team?
- Timing: If applicable, during what timeframe should the peer visit be conducted?

During the discussions, the Committee also discussed the role of the peers serving on the team, to include providing real time and relevant feedback to the Committee, examining the issue, determining corrective or improvement actions, and the potential for recurrence.

21. Informational Committee Agenda: During the March 2012 meeting, the Committee agreed to implement a new agenda type for future committee meetings. The purpose of the new agenda type is to more accurately represent the information that is currently provided as a consent agenda. For example, program status changes and reports for removing candidates from an inactivated or withdrawn program are informational reports for the Committee. These informational reports will be provided to the Committee on the new Informational Agenda. If, based on staff review of submitted reports, concerns are identified, then the item will instead be listed on the Discussion Agenda for Committee consideration.
22. Revision of the UNOS Bylaws, the OPTN Bylaws, and the OPTN Policies that Govern HLA Laboratories (Histocompatibility Committee). This proposal revises the Bylaws and Policies that apply to histocompatibility laboratories to more closely align OPTN/UNOS requirements for member laboratories with current laboratory practices.

During its December meeting, the Committee considered this proposal, which had been distributed for public comment. It focused its review and comments on the suggested changes to the Director requirements:

- The Committee noted that the current language in A.1. Director Credentials states that the Director training must have occurred in an “*OPTN/UNOS approved training program or that they have three years experience under a qualified OPTN/UNOS Histocompatibility Director.*”

The Committee agreed that changing this language was appropriate because the OPTN/UNOS does not approve training programs for lab directors.

- The Committee also considered the proposed change to I. Key Personnel Qualifications, which states the following:
  - (i) *The Director must be an MD, DO, or PhD in science, and must meet the qualifications of director of high complexity testing according to Federal CLIA requirements defined in 42CFR 493.1441. An M.D. or D.O. must also have a license to practice medicine in the state where the laboratory is located.*
  - (ii) *In addition to A1 (i), ~~at least two of the years of the Director’s training and/or experience must be in histocompatibility testing in a OPTN/UNOS an approved~~*

*training program or Three years experience if the candidate is also the technical supervisor of the laboratory, they must have completed two years general immunology plus two years histocompatibility experience under a qualified OPTN/UNOS Histocompatibility Director doing histocompatibility testing for solid organ transplantation.*

The Committee suggested changing part (i) to state that the “Director must meet the state requirements for licensure.” This change would then cover Ph.D.’s that are only required to be certified in some states.

The Committee also agreed that the unintended consequences of changing the wording in part (ii) would need to be resolved. Striking the entire first sentence means that the director would not be required to have training or experience in histocompatibility testing. The Committee understood that the intent was only to remove the reference to “an OPTN/UNOS approved training program,” since they do not exist.

23. Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors: This proposal, sponsored by the Living Donor Committee (LDC), would establish policy requirements for the informed consent of living kidney donors.

During its December meeting, the Committee considered this proposal, which had been distributed for public comment. 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 being too prescriptive 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 following observations and suggestions regarding the proposal:

- The proposal would change what the Independent Donor Advocate (IDA) needs to explain to potential donors. The proposed language goes into greater detail about the risks and benefits than Medicare’s requirements.
- The current proposal gives hospitals some leeway in how they want to define the IDA role. The Committee suggested that the LDC consider changes to the IDA requirements that would further clarify their level of involvement in the care of the donor.
- Develop standardized consent form so that process is uniform across hospitals to improve compliance and ability to audit. The form should include all the elements but utilization of the form would be voluntary.
- Need to balance the risks and benefits descriptions. For example, add more about the benefits of live donation – could include length of wait time, improved performance of live versus deceased donors organs, life expectancy of live donor compared to general population. Also, provide more information about the long-term risks and relative risks for end stage renal disease (ESRD).
- Add to the consent form - if information is discovered during the evaluation process that the donor has the right to withdraw from consideration without any details being provided to the recipient.
- The Committee was concerned about the standards for reviewing the programs and asked the LDC to take into consideration the department of evaluation and quality’s (DEQ) proposal for developing the standards for reviewing hospitals for compliance.

- The Committee pointed out that kidney paired donation (KPD) needed to be addressed and they were informed that the Kidney Transplantation Committee is working on a separate proposal that will specifically address KPD.
- A committee member suggested that the proposal is clinically prescriptive – the donor has to be informed of potential long-term medical risks, but the medical staff does not have leeway to interpret. Information seems more appropriate for guidelines rather than policy.

24. Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-Up: This proposal, sponsored by the Living Donor Committee (LDC), 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).

During its December meeting, the Committee considered this proposal, which had been distributed for public comment. The Committee offered the LDC the following comments on the proposal:

- The Committee was concerned that the requirements for donor follow-up creates a potential conflict between the donor hospital and the donor, where the donor hospital feels pressure to meet the 90% follow-up requirement while the donor may not want to participate.
- There needs to be a method for hospitals to document all attempts to comply since there may be donors who desire to opt out of follow up. Do not be overly prescriptive. Establish what is considered a reasonable effort to achieve compliance and if the attempts to follow up with the donor are documented in patient record then the hospital has complied.
- Changing the policy to require clinical tests may have financial implications for the donors (such as serum creatinine and urinalysis). Donors may live outside the area or even outside the United States, making 90% of lab values a high number to achieve.
- Modify the language to clarify which hospital is responsible for following up the donor in a pair exchange.
- Is the transplant hospital or the donor hospital responsible for any fees (e.g. lab test charges) if the donor loses their insurance and has no funding?
- Any complications regarding post donation psychosocial issues should be documented.

25. Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors: This proposal, sponsored by the Living Donor Committee (LDC), would establish policy requirements for the medical evaluation of living kidney donors.

During its December meeting, the Committee considered this proposal, which had been distributed for public comment. The Committee offered the LDC the following comments on the proposal:

- The Committee recommended changing section 12.3.1 (Psychosocial Evaluation of the Living Kidney Donor). The proposal currently states, “This evaluation must be performed by a psychiatrist, psychologist, clinical social worker, clinical nurse specialist or advanced practice nurse with experience in transplantation.” While an advance practice trained nurse with experience in transplant could do the psychosocial evaluation, 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 this 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.” Furthermore, 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 should be developed.
- The Committee suggested modifying the language of section 12.3.1 to indicate that the donor may be monitored for post-transplant donor depression for extended period after donation.
- The Committee also suggested developing guidelines for potential living donors that they could discuss with their physicians.
- Under Exclusion Criteria the first bullet current reads “Age less than 18 years and mentally incapable of making an informed decision” The Committee questioned whether or not it should have been an “or” instead of “and.” This section may need to be clarified.
- Consider including “gestational diabetes” and “gestational hypertension” in the assessment of risks.

26. Proposal to Require Reporting of Unexpected Potential or Proven Disease Transmission Involving Living Organ Donors (LDC): Under this proposal, existing policy would be modified to require members to report to the OPTN Contractor any unexpected potential or proven living donor-derived disease transmission, including infections or malignancies. Current policy requires specific infectious disease testing for all deceased organ donors. It also requires that any unexpected potential or proven disease transmission, including infections and malignancies, discovered after donation be reported to the OPTN Contractor.

During its March meeting, the Committee considered this proposal, which had been distributed for public comment. It agreed to support the proposal by a vote of 24 For, 1 Against, 0 Abstentions, and asks that the Living Donor Committee to work with DEQ staff to produce sample forms or templates in order to improve compliance.

27. Proposal to Establish Kidney Paired Donation (KPD) Policy: During its March meeting, the Committee considered this proposal, which had been distributed for public comment. This proposal sponsored by the Kidney Transplantation Committee converts the existing OPTN Kidney Paired Donation (KPD) Pilot Program rules, housed in the OPTN KPD Pilot Program Operational Guidelines, into Policy. The full range of adverse actions will be available to the Committee for violations of KPD policy, up to and including designation of member not in good standing. The policy also includes additional elements of potential donor informed consent that are specific to KPD and requirements for how the OPTN Contractor will conduct matching in the OPTN KPD Program. The proposed changes would consolidate all rules for the OPTN KPD Program into a single location and allow the Committee to follow its standard processes for potential violations of KPD policy.

The Committee agreed to support the proposal by a vote of 29 For, 0 Against, 0 Abstentions. The Committee did ask how or if an OPO that plays a role in the transportation (packaging, shipping, and labeling) of the organ might be audited since Policy 13.8 (Transportation of Kidneys) only refers to the hospital's responsibility.

28. Proposal to Require Documentation of Second Unique Identifier: During its April meeting, the Committee considered this proposal, which had been distributed for public comment. This proposal, sponsored by the OPO Committee, will require OPOs and living donor recovery centers to document all unique identifiers used to label any tissue typing specimen in the donor record. This change will also allow transplant hospitals to validate the unique identifier information. This problem exists in part because frequently the donor data is not entered into DonorNet® until after the OPO has sent the tissue typing specimen to the lab and a donor ID has been assigned.

The Committee voted to support the proposal by a vote of 19 For, 1 Against, 0 Abstentions, and made several recommendations for changes. The Committee was concerned that there is not a place to record the second unique identifier in DonorNet® and recommends that another field be programmed into the system. The Committee also requested clarification about what can serve as the source document if the information is not in DonorNet®.

29. Proposal to Require Extra Vessel(s) Disposition to be Reported to the OPTN within Five Days of Transplant or Disposal. During its April meeting, the Committee considered this proposal, which had been distributed for public comment. The Operations and Safety Committee (OSC) is proposing language within Policy 5.10.2 (Vessel Storage) to require transplant hospitals to report the disposition of extra vessels to the OPTN within five days of transplant or disposal. Presently, the policy does not describe a specific time by which the disposition must be reported.

The Committee voted to support the proposal by a vote of 20 For, 0 Against, 0 Abstentions, with the condition that programming be completed before implementation. The Committee also made the following comments.

- The electronic system should allow the hospital to record the vessel being used in part. A section of vessel may be used and the remainder later discarded. Presently, the electronic record system does not allow both actions to be recorded although it can be recorded on the (written) Vessel Transplantation/Destruction form.
- The OSC should continue to work with DEQ to provide education to the members that will help them comply with the policy (webinars, evaluation plan, fact sheets have already been provided to the members).

30. UNOS Actions: The Committee unanimously agreed during its December 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 meetings in March and April.

**Participation at the Membership and Professional Standards Committee Meetings**

<b>Name</b>	<b>Committee Position</b>	<b>July 13-14, 2011</b>	<b>Sept 28-29, 2011</b>	<b>Oct 27, 2011</b>	<b>Dec 7-8, 2011</b>	<b>Feb 29, 2012</b>	<b>Mar 27-29, 2012</b>	<b>Apr 20, 2012</b>
John Roberts, MD	Chair	X	X		X	X	X	X
Alan Reed, MD	Vice Chair	X	X	X	X	X	X	
David Hull, MD	Regional Rep.	By phone	X	X	X	X	X	X
Michael Shapiro, MD	Regional Rep.	X	X		X	X	X	X
Devin Eckhoff, MD	Regional Rep.		X		X		X	X
Marlon Levy MD,	Regional Rep.	X	X	X	X		X	X
David Douglas, MD	Regional Rep.	X	X		X	X	X	X
Michael Mulligan, MD	Regional Rep.					X	X	
Dixon Kaufman, MD, PhD	Regional Rep.	X		X		X	X	
Harvey Solomon, MD	Regional Rep.	X		X	X		X	X
Mark Orloff, MD	Regional Rep.	X	X	X	X	X	X	X
Marwan Abouljoud, M.D	Regional Rep.	X	X	X	X	X	X	
David Shaffer, MD	Regional Rep.	X	X		X	X	X	X
Patricia Adams, MD	At Large	X	X	X	X	X	X	X
Allen Anderson, MD	At Large	X		X	X	X	X	
Kenneth Andreoni, MD	At Large	NA	NA	NA	NA	NA	X	X
Sharon Bartosh, MD	At Large	X	X	X	X	X	X	X
A. Michael Borkon, MD	At Large	X	X		X	X	X	X
Margarita Camacho, MD	At Large	X	X	X	X	X	X	X
Richard Hasz Jr , MFS	At Large	X	X	X		X	X	X
Hassan Ibrahim, MD	At Large	X	X	X	X	X	X	
Diane Jakobowski, MSN, CRNP	At Large	X	X	X	X	X	X	
Megan Lewis, PhD	At Large			X	X	X		
Lori Markham, RN, MSN, CCRN, CPTC	At Large	X	X	X	X	X	X	X
David Marshman, CPTC,BS	At Large	X	X	X	X			

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Jennifer Milton, RN,BSN, MBA, CCTC	At Large	X	X		X		X	
Isabel Neuringer, M.D.	At Large	X	X	X	X	X	X	X
Claus Niemann, M.D.	At Large	X	X	X	X	X		X
Kevin O'Connor, MS, PA	At Large		X	X	X	X	X	
Sean Pinney, MD	At Large	X	X		X	X	X	
Dianne LaPointe Rudow, ANP, DrNP, CCTC	At Large	X	X	X	X	X	X	X
Lesley Smith, M.D., MBA	At Large	X		X	X		X	X
Dolly Tyan, PhD	At Large	X	X	X	X	X	X	
Betsy Walsh, J.D., M.P.H.	At Large	X	X	X	X	X	X	X
Brenda Welsch, BSN, CPTC	At Large	X	X	X	X	X	X	
Debbie Williams, RN	At Large	X	X	X	X	X	X	X
David Zaas MD, MBA	At Large	X	X		X		X	
Christopher McLaughlin	Ex Officio	X	X					
Robert Walsh	Ex Officio	X	X	X	X	X	X	X
Sven Peterson	Ex Officio		X					
Raelene Skerda	Ex-Officio				X	X	X	X
Nicholas Salkowski	SRTR Liaison	X		X	X			X
Jon Snyder, PhD, MS	SRTR Liaison	X		X	X		X	
Sally Aungier	Committee Liaison	X	X	X	X	X	X	X
David Kappus, MAS	Committee Liaison	X	X	X	X	X	X	X
Jacqueline O'Keefe, MBA	Committee Liaison	X	X	X	X	X	X	X
Rosey Adorno	Support Staff	X		X		X		
Rebecca Anderson, PhD	Support Staff	X		X	X	X	X	X
Manny Carwile	Support Staff	X	X		X		X	
Betsy Coleburn	Support Staff		X	X		X		
Cynthia Coleman	Support Staff		X	X	X	X	X	X

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Michelle Drumm	Support Staff				X			
Erick Edwards, PhD	Support Staff	X		X	X	X	X	X
Rich Endert	Support Staff		X		X			
Leslee Garland	Support Staff	X						
Sheran Goodman	Support Staff		X					
Walter Graham	Support Staff			X				
Leigh Kades	Support Staff			X	X	X	X	X
Nicole Kleiman, MPH	Support Staff	X						
Jason Livingston	Support Staff	X	X	X	X	X	X	
Tiffany Lord	Support Staff						X	X
Diana Marsh	Support Staff		X					
Maureen McBride	Support Staff	X						
Joel Newman	Support Staff	X						
Heather Neil	Support Staff	X		X		X	X	X
Amy Putnam	Support Staff	X		X	X	X		X
Sharon Shepherd, J.D., M.S.N., R.N.	Support Staff	X	X	X	X	X	X	X
Brian Shepard	Support Staff	X	X	X	X	X	X	X
Leah Slife	Support Staff				X	X		
Christi Wong	Support Staff	X				X	X	