

**OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE
REPORT
June 19-20, 2008 SUMMARY**

I. Action Items for Board Consideration:

- The Board of Directors is asked to approve designated program status for one liver program performing living donor transplants and two new programs in existing member centers. (Item 1, Pages 6-7).
- The Board of Directors is asked to grant full approval to one liver program that performs living donor transplants. (Item 1, Pages 6-7).
- The Board of Directors is asked to approve two pediatric hospitals to perform pancreas transplants as part of a multi-visceral transplant procedure. (Item 1, Pages 6-7).
- The Board of Directors is asked to approve modifications to the Bylaws, Appendix B, Attachment I, Section XIII, D, (4) Liver Transplant Programs that Perform Living Donor Liver Transplants, Part C (Conditional Approval Status). This modification will make it easier for members to understand that a center is expected to inactivate or stop performing living donor transplants if the Bylaws requirements are not met by the end of the conditional approval period. (Item 4, Pages 8-11).
- The Board of Directors is asked to approve modifications to the OPTN and UNOS Bylaws to Restore Full Membership Privileges Following an Adverse Action (Bylaws Appendix A, Section 3.01A Paragraphs (1) and (3) and Section 5.05A, Addition of Section 5.07A). The purpose of the proposal is two-fold: to better define how a Member may be considered for restoration of full membership privileges, and to clarify the way to move from “Member Not in Good Standing” to a lesser action, such as Probation. (Item 5, Pages 11-13).
- The Board of Directors is asked to approve modifications the Bylaws Article I (Members), Section 2 (Board of Directors), and Section 6 (Officers). The proposed Bylaw modifications would permit each Histocompatibility Laboratory and Medical/Scientific Member to receive one vote in the OPTN/UNOS and remove the need for separate national elections for both the Histocompatibility Member and Medical/Scientific Member electors. (Item 6, Pages 13-14).

II. Other Significant Items:

- Annual Committee Goals: During its January/February meeting, the Committee was presented with the Goals that had been approved for the year and the progress that had been made on those goals that were already underway. (Item 2, Pages 7-8).
- Program-Related Actions and Personnel Changes: The Committee reviewed and approved personnel change applications and accepted a report of a member that had voluntarily changed status. Additionally, the Committee rescinded its recommendation of Probation and issued a Letter of Reprimand to a member transplant center. A work group will conduct

quarterly reviews of the center's adherence to all elements of its improvement plan and any updated outcomes data until the January 2009 cohort is released, at which time the MPSC will re-evaluate its recommendation. (Item 3, Page 8).

- In February 2008, The Board of Directors released a Member from Probationary status based on compliance with the corrective action plan and the Member meeting all elements of Probation when they met in February. (Item 3, Page 8).
- Due Process Proceedings: During the January/February meeting Committee conducted interviews with two member organizations. During the May meeting, the Committee conducted seven interviews with member organizations. (Item 7, Page 14).
- Living Donor Applications: The Committee was updated on the status of implementing the application process for the transplant programs that perform living donor kidney. (Item 8, Pages 14-15).
- Update on Enforcement of Mandatory Donation after Cardiac Death (DCD) Protocols: The Committee was updated on the submission of certification statements from all member OPOs and transplant hospitals, attesting that they have and employ a DCD organ recovery protocol. (Item 9, Page 15).
- Review of Events under Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data): Staff updated the Committee on the status of events surrounding one live donor death that was reviewed by an MPSC Subcommittee. It agreed that no further action was required because there was not any evidence of a policy violation and no patient safety issues were indicated. (Item 10, Pages 15-17).
- Questions regarding Policies 6.3 (Audit) and 6.5 (Violations of Policies): The Committee received an update on a proposed memo to the Ad Hoc International Relations Committee inquiring about possible changes to Policies 6.3 and 6.5. Further investigation discovered that Congress did not want the MPSC to review these situations except as currently outlined in Policies 6.3 and 6.5. The current Policy language will not be changed. (Item 11, Pages 17-18).
- Pancreas Outcome Analysis Model: The Committee discussed the issue of pancreas (including kidney/pancreas and pancreas after kidney) transplant program outcome monitoring. During the January/February meeting, the MPSC was informed of the Pancreas Transplantation Committee feedback on the development of the model and the MPSC's recommendation to utilize the currently published SRTR reports for kidney/pancreas outcome monitoring. (Item 12, Pages 18-19).
- Review of Active Programs with Inactive Wait Lists: The Committee discussed the Data Subcommittee's study of potentially reviewing programs that have an active membership status but have inactive wait lists. The Committee reviewed potential Bylaw modifications and will continue to refine the proposed changes for public comment distribution in June 2008. (Item 13, Pages 19-21).
- Goals for Bylaws Rewrite: Staff updated the Committee on one of the new goals established for the committee by the President: the re-write of the existing Bylaws. The purpose of the revision is to improve clarity regarding member rights and responsibilities, and OPTN/UNOS

responsibilities. Clarity will be achieved by the use of plain language and logical organization of the content. (Item 14, Page 21).

- 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 15, Pages 21-22).
- MPSC Summary Explanation: During its January/February meeting, the Committee reviewed the final version of a summary document that clarifies the MPSC's charge. This document briefly explains the role and function of the Committee in plain language that is easily understood by the medical professionals and public who are affected by its deliberations and decisions. It was agreed that the list of Frequent Policy Violations should be sent out to the members along with this summary. This information was emailed to the transplant community on April 4, 2008. (Item 16, Page 22).
- 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 and it was distributed to the members with the MPSC Summary Explanation. (Item 17, Pages 22-23).
- Referral to the Histocompatibility Committee – Policies 3.1.4 and 3.1.4.2: At its January 2008 meeting, the Committee reviewed an ABO discrepancy issue in which a histocompatibility laboratory listed a candidate on behalf of a transplant center but did not use two source documents to verify the candidate's ABO. Policies 3.1.4 and 3.1.4.2 (Waiting List) currently place the responsibility of using and maintaining two source documents on the transplant center. The Committee expressed concern about this practice and asked the Histocompatibility Committee to review Policies 3.1.4 and 3.1.4.2 for possible modification. In March of 2008, the Histocompatibility Committee determined that the current language in Policies 3.1.4 and 3.1.4.2 is clear and no further modifications are necessary. (Item 20, Page 23).
- Update on Policy 2.5.5 (Organ Procurement Quality): At its meeting on November 14, 2007, the Committee considered OPTN Policy 2.5.5 (Organ Procurement Quality) because of complaints. The Committee discussed the issue and decided to ask the Histocompatibility Committee to consider whether Policy 2.5.5 should be revised. During its May meeting, the Committee was updated on the work of a Histocompatibility Subcommittee, which identified that a majority of the errors in providing sufficient tissue typing materials occurred during organ recovery. (Item 21, Pages 23-24).
- MPSC Feedback- Vascularized Composite Allografts: On March 3, 2008, the Department of Health and Human Services (DHHS), published a Federal Register Notice, Vol. 73, No 42, for the purpose of soliciting feedback from stakeholders and the public on whether vascularized composite allografts should be included within the definition of organs covered by the regulations governing the operation of the Organ Procurement and Transplantation Network (OPTN) and whether vascularized composite allografts should be added to the definition of human organs covered by section 301 of the National Organ Transplant Act of

1984 (NOTA). The Committee provided feedback to the Executive Committee on this matter. (Item 22, Pages 24-26).

- Performance and Certification Maintenance Work Group: The Certification Maintenance and Performance Metric Work Groups was charged with addressing the Committee Goals, specifically the review of the efficiency and effectiveness of the methods that are used for member evaluation on an ongoing basis, and making recommendations on improvements to the process. (Item 23, Pages 26-27).
- OPO Performance Metrics (Goal 1): The Committee was updated on the work of the OPO Performance Metrics Work Group, which is made up of members of the OPO Committee and the MPSC. It is tasked with developing performance metrics to maximize the utilization of organs. (Item 24, Page 27).
- Other Committee Goals: The Committee discussed the goals related to surgeon/physician surveys and program coverage plans and their implementation status. They also discussed the goals related to Bylaws, performance metrics, and network measures and agreed to merge two work groups to further these discussions. (Item 25, Pages 27-28).
- Referral to Thoracic Organ Transplantation Committee – Policy 3.7.3: The Committee reviewed a memorandum requesting that the Thoracic Organ Transplantation Committee reevaluate Policy 3.7.3 (Adult Candidate Status) and clarify its intent. In addition, The Committee requested that the Thoracic Organ Transplantation Committee review site surveyors’ interpretation of Policy 3.7.6.3 (Candidate Variables in UNetSM). The Thoracic Organ Transplantation Committee reviewed these referrals and submitted a response to the Committee. (Item 27, Pages 28-29).
- Update on Policy 3.7.6.3 (Candidate Variables in UNetSM): The Committee requested that the Thoracic Organ Transplantation Committee review the site surveyors’ interpretation of Policy 3.7.6.3 (Candidate Variables in UNetSM). The Thoracic Organ Transplantation Committee stated that if the Center marks “no diabetes” on the justification form, and site surveyors do not find evidence of diabetes in the chart, the program should not be cited for a policy violation. (Item 28, Page 29).
- Directed Donation Data Request: The Committee reviewed data on the distribution of directed donations across the country. The Committee decided to evaluate those OPOs with greater than three percent of donors with at least one organ allocated as a directed donation. (Item 29, Page 29).
- Proposed Modifications to Policies 3.2.4 (Match System Access), 3.1 (Definitions), and 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates): The Committee reviewed proposed policy modifications that would provide instruction to members about what to do when a candidate does not appear on a match run, and when a candidate cannot appear on a match run. The purpose of providing this instruction is to increase the safety of transplants for recipients who cannot appear on the match run, and to prevent future policy violations by promoting a clear understanding of what a member is required to do when a candidate does not appear on a match run. The Committee’s suggestions will be incorporated into the draft document and the proposal will be referred to the Operations Committee and the Policy Oversight Committee for their input. (Item 30, Page 30).

- Proposal to Change the Bylaws to Require Written Notification (or Disclosures) to Living Donors from Recipient Transplant Programs. The Committee considered and provided feedback to the Living Donor Committee on the public comment proposal item. The goal of this proposal is to provide living donors with the same information and protections given to candidates on the national transplant waiting list. (Item 31, Pages 31-32).
- Patient Notification of UNOS Patient Services Line: The MPSC discussed and supported the Patient Affairs Committee's proposal to develop a separate letter or brochure that could be distributed with the patient listing letters rather than including the patient hotline information in the listing letter itself. (Item 32, Page 32).
- Additional Concerns Noted During Peer Site Visit: During the course of its review, a peer visit team noted concerns relating to a single surgeon being involved in the declaration of death in organ donors, procurement of the organs, and in transplant surgeries. The Committee discussed this issue in light Uniform Anatomical Gift Act and agreed to communicate its concerns to the OPO and the center, and to address possible changes to the policies and/or bylaws regarding this practice. (Item 33, Pages 32-33).
- UNOS Actions: During both the January/February and May meetings, 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. (Item 35, Page 33).

**REPORT OF THE
OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE
TO THE BOARD OF DIRECTORS
RICHMOND, VA
June 19-20, 2008
Robert S. D. Higgins, M.D., 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 and May 5-7, in Chicago, Illinois. The Data Subcommittee and the Policy Compliance Subcommittees also met on the days preceding the full committee meetings. The Committee’s deliberations and recommendations are provided below.
1. Membership Application Issues: The Committee (MPSC) is charged with determining that member clinical transplant centers, independent organ procurement agencies, independent tissue typing laboratories, and non-institutional members meet and remain in compliance with OPTN/UNOS Criteria for Institutional Membership. During each meeting, it considers actions regarding the status of current members and new applicants. The actions related to applications that were taken during the January/February and the May meetings are described below.

January/February Meeting:

During its January/February meeting, the Committee recommended 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 recommended 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 recommended that the Board of Directors 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 from 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 recommended that the Board of Directors recognize this program.

The above action items were reported to and approved by the Board of Directors in a special report on February 20-21, 2008.

May 2008 Meeting

During its May 6-7 meeting, the Committee recommended that the Board of Directors approve one liver transplant program to perform living donor transplants, and two new programs in existing member centers.

The Committee reviewed one liver transplant program holding conditional approval for performing living donor transplants based on the qualifications of the second primary surgeon. The Committee recommends that the Board of Directors now grant full approval to this program:

The Committee reviewed and accepted a bimonthly progress report for a pancreas program that was initially conditionally approved for 12 months, and later granted a 6-month extension 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 recognized that the pancreas is transplanted as part of a multi-visceral procedure in two pediatric hospitals. 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 recommends recognition of programs that fulfilled the “Multi-visceral Program Criteria.”

2. Overview of Annual Committee Goals: During both meetings, updates were provided to the Committee on the goals that were approved for the year. A list of the goals is provided below and each one is addressed in more detail later in this report.

Performance Measures

- Goal 1: Evaluate the use of OPO Metrics to assess performance.
- Goal 2: Complete a retrospective review of current processes and implementation of new performance measures.

Bylaws

- Goal 3: Review the transplant program bylaws related to staff and infrastructure requirements for changes to further ensure patient safety.
- Goal 4: Rewrite Bylaws to update format, use plain language.

Network Measures

- Goal 5: Initiate the application process for live donor kidney transplantation, and obtain additional information from programs that perform living donor liver transplants.
- Goal 6: Initiate and complete the audit of transplant surgeons and physicians & update the database accordingly to indicate which individuals meet the new criteria for the program to designate them as “additional” or “other” surgeon/physician.
- Goal 7: Collect and process Program Coverage Plans (primary physician, additional physician, etc.) from all existing transplant programs.

- Goal 8: Review transplant centers and OPOs that are not in compliance with the new Donation after Cardiac Death (DCD) Bylaws requiring that they have protocols to facilitate the recovery of organs from DCD donors.

3. Program-Related Actions and Personnel Changes: During both its January/February and May meetings, the Committee reviewed and accepted programs changing status by voluntarily inactivating or withdrawing from designated program status.

Additionally, during the January/February meeting, the Committee reviewed 42 Key Personnel Changes and approved 31, and during the May meeting, it reviewed 64 Key Personnel Changes and approved 56. Four applications for change in primary histocompatibility laboratory directors remain in process.

The Committee also reviewed reports of five transplant programs that had not submitted an application for a change in key personnel by the given deadline. Each of these programs had experienced a departure of a primary surgeon or physician. The Committee was informed that each program had been sent a second notice letter stating that a Key Personnel Change application must be submitted to UNOS within 14 days of receipt of the letter.

During its February 20-21, 2008, meeting, the Board of Directors considered and approved the Committee's recommendation to release a transplant center from Probation.

The Committee was informed that a liver transplant program with one year of conditional approval to perform living donor liver transplants did not submit a request for a second year of conditional approval or demonstrate that the program had met the requirements for full approval by the conditional approval expiration date (2/19/2008). The program was notified by letter that its conditional approval status had expired, and the program must reapply if it wishes to continue performing living donor liver transplants. To date, no response has been received from the transplant center.

The Committee also reviewed a letter from a liver transplant program requesting an additional extension beyond the second year of conditional approval to perform living donor liver transplants. The Committee reaffirmed its prior determination that a maximum of two one-year periods of conditional approval could be granted for living donor liver transplantation and that requests for further extensions beyond that period would not be granted.

Request for Extension of Inactive Status from Center 01280B: The Committee reviewed a request for a nine-month extension of the voluntary inactivation period of the heart transplant program. It approved the request with stipulations for reactivation.

4. Living Donor Liver Requirements: When the MPSC met in November 2007, it considered the status of 14 living donor liver transplant centers that had received conditional approval. Conditional approval was granted to programs that do not have a second living donor liver surgeon who fully meets the Bylaws. The Committee noted that about half of these programs had nearly completed their second year in this status. It appeared that there are several that may not meet the requirements for full approval at the end of their term because the programs have performed few or no living donor liver transplants since conditional approval was granted.

When a term-limited approval status ends, a program is expected to fully meet the requirements, inactivate, or relinquish designated program status. In the case of the living donor liver requirements, the Bylaws do not clearly delineate the path forward for programs that reach the

end of the two-year conditional approval period (initial year plus a one-year extension) and still do not meet the requirements for full approval. When the language for the living donor conditional pathway was proposed to the Board of Directors, the Board did not support further extensions of conditional approval past the second year.

The MPSC considered adding language to the conditional approval pathway to make it clearer to the programs what the expectations are for them. This change would be consistent with other similar sections of the program specific Bylaws

Following its Fall 2007 meeting the MPSC asked the Liver and Intestinal Organ Transplantation Committee to provide input on several related questions as described below.

Update from the January/February Meeting: During the January/February meeting, the Committee considered the response from the Liver and Intestinal Organ Transplantation Committee, which recommended, “that programs that do not meet the criteria for approval by the end of the second year of conditional approval should voluntarily inactivate the living donor aspect of their program.” It further supported the MPSC’s proposal to add this language to the Bylaws. Additionally, any changes to a program’s key personnel during the approval process should require the submission of a new application.

Additionally, during the Liver and Intestinal Organ Transplantation Committee’s discussion during their November 28, 2007, meeting, they identified a couple of areas of concern and asked the Living Donor Committee and MPSC to consider and provide feedback. These issues include:

The criteria outlined in the Bylaws deal with initial approval of programs that wish to do living donor liver transplants. The question was raised about how the Living Donor Committee and MPSC will handle programs that are approved but might be considered “low volume” programs. *The Committee recommends that in order to maintain patient safety, your Committee(s) define what might be considered low volume and evaluate how to handle these programs. One recommendation from our Committee was to apply the same standards used for initial approval.*

The requirements currently outlined in the Bylaws do not differentiate between adult-to-adult live donor procedures and adult-to-pediatric donor procedures. The morbidity and mortality associated with right lobe donation is significantly higher than left lobe or left lateral segment donation. In addition, follow-up for left lateral segment live liver donors exceeds right lobe donors by nearly a decade. For this reason, the Committee recommends that criteria be separated to distinguish between the experience required to safely perform adult-to-adult (right lobe) procedures and adult-to-pediatric (left lateral segment) procedures.

MPSC Response: The Committee proposed that language be added to the pathway that makes it clear that if the program is unable to meet the requirements at the end of allowed conditional period that the program will be expected to voluntarily inactivate or withdraw designated approval status the living donor liver component of its program.

The Committee provided input on draft bylaw language that was similar to language used in other sections of the bylaws related to program requirements. It was suggested that the proposed language be slightly amended before being circulated further. The Committee agreed in principle to the following:

RESOLVED, that that the Bylaws, Attachment I, Appendix B, Section D, (4) Liver Transplant Programs that Perform Living Donor Liver Transplants be modified, to clarify

that the center is expected to inactivate or stop performing living donor transplants if the Bylaws are not met by the end of the conditional approval period. FURTHER RESOLVED, that the Committee proposes that this change be circulated for public comment.

The Committee voted 24 for, 1 Against, 0 Abstentions.

May Update: During the May meeting, the Committee reviewed specific changes to the Bylaws and agreed on language that should be forwarded to the Board of Directors for approval concurrent with public comment. This request is made because a number of the programs that are conditionally approved will reach the end of their terms in June. This new language will make it easier for the member centers to understand their options.

The MPSC approved the following resolution to submit the proposed Bylaw modifications for public comment:

** RESOLVED, that the Bylaws, Appendix B, Attachment 1, Section XIII, D, (4), c be amended as shown below.

The Committee voted 26 For, 0 Against, 0 Abstentions.

Proposed Modification to OPTN/UNOS Bylaws, Appendix B, Attachment 1, Section XIII, D (4)

(4) Liver Transplant Programs that Perform Living Donor Liver Transplants.

a. No Changes

b. No Changes

c. Conditional Approval Status: If the transplant center does not have on site a second surgeon who can meet the requirement for having performed 7 live donor liver procedures within the prior 5-year period, but who has completed the requirement for obtaining experience in 20 major hepatic resection surgeries (as described above), as well as all of the other requirements to be designated as a primary liver transplant surgeon, the program may be eligible for Conditional Approval Status. The transplant program can be granted one year to fully comply with applicable membership criteria with a possible one year extension. This option shall be available to new programs as well as previously approved programs that experience a change in key personnel. During this period of conditional approval, both of the designated surgeons must be present at the donor's operative procedure.

The program shall comply with such interim operating policies and procedures as shall be required by the Membership and Professional Standards Committee (MPSC).

This may include the submission of reports describing the surgeon's progress towards meeting the requirements and such other operating conditions as may be required by the MPSC to demonstrate ongoing quality and efficient patient care. The center must provide a report prior to the conclusion of the first year of conditional approval, which must document that the surgeon has met or is making sufficient progress

to meet the objective of performing 7 live donor liver procedures or that the program is making sufficient progress in recruiting and bringing to the program a transplant surgeon who meets this criterion as well as all other criteria for a qualified live donor liver surgeon. Should the surgeon meet the requirements prior to the end of the period of conditional approval, the program may submit a progress report and request review by the MPSC.

The transplant program must comply with all applicable policies and procedures and must demonstrate continuing progress toward full compliance with Criteria for Institutional Membership.

The program's approval status shall be made available to the public.

If the program is unable to demonstrate that it has two designated surgeons on site who can fully meet the primary living donor liver surgeon requirements [as described in above] at the end of the 2-year conditional approval period, it must stop performing living donor liver transplants by either

- (i) inactivating the living donor part of the program for a period up to 12 months, or
- (ii) relinquishing the designated transplant program status for the living donor part of the liver transplant program until it can meet the requirements for full approval.

The requirements for making changes in program status are described in Section II, C.

The Committee approved a second motion asking the Board of Directors to approve this modification to the Bylaws concurrent with public comment.

**** RESOLVED, that the proposed modifications to the Bylaws, Appendix B, Attachment I, Section XIII, D (4) c as set forth above, shall be approved June 20, 2008, and concurrent with public comment. FURTHER RESOLVED, that live donor liver transplant program criteria shall be applied retroactively to Living Donor Liver Transplant Program applications received since March 1, 2005.**

The Committee voted 26 For, 0 Against, 0 Abstentions.

5. Proposal to Change the Bylaws to Restore Full Membership Privileges Following an Adverse Action (Bylaws Appendix A, Section 3.01A Paragraphs (1) and (3) and Section 5.05A, Addition of Section 5.07A)

Background:

At its August 1-2 meeting, the Committee reviewed the draft proposal that would better define how a Member may be considered for restoration for full Membership privileges, and provide a way for a Member to move from an adverse action to a lesser action or status. The proposal provides that in order to be released from "Member Not in Good Standing" or "Probation" the Member must demonstrate that it is in (i) substantial compliance with OPTN requirements; (ii) its approved corrective action plan has been fully implemented; and (iii) the root cause of the violation that was the basis for the adverse of action of "Member Not in Good Standing" has been corrected or eliminated. That original proposal did not provide a set time period for the adverse

action to be in effect. Rather, it provided the flexibility for the MPSC and the Board to consider each Member's specific circumstances. At its August meeting, the Committee asked that the concept of "trial reinstatement" be added and that the proposal be re-circulated to the Committee Members on the Committee Management system for further review.

The Committee reviewed the draft on the Committee Management System and in general, supported the updated language. Several committee members raised the concern that the section 5.07A (Changes in Membership Adverse Action Status) needed further amendment. Based on the MPSC's comments, the Committee changed the three-month period for "Changes in Membership Adverse Action Status" to six months.

In September 2007, the Executive Committee reviewed the draft proposal and commented that the MPSC did not discuss status reductions for those already on Probation. This was resolved by making trial reinstatement the next step down from Probation in 5.07A. The Executive Committee also noted that six months may not be a long enough time period in lower than expected outcomes cases. Specifically, six months may not be long enough when only one more cohort of SRTR data will be available. The Executive Committee suggested that there may need to be a 12-month minimum (two cohorts) for low outcome situations, but this should be discussed by the MPSC.

The Committee discussed the updated draft document during its November 2007 meeting. The Committee proposed additional changes to the document. These changes included making the time a uniform 12 months for a Member to request each upgrade in status, and clarifying that the member may be required to undergo a peer conducted site visit and/or site survey before the MPSC recommends a change in status. The Committee also asked UNOS to develop a timeline diagram for education, to help explain the proposal. The Committee voted to support the proposal with the suggested modifications. The Committee also discussed the patient notification aspects involved when a Member is placed on Probation or declared Member Not in Good Standing, and supported the proposed addition of the sentence "Patient notification is not required when a Member transitions from Member Not in Good Standing to Probation" to section 5.07A. The modifications were incorporated into the draft document.

At its meeting on February 1, 2008, the Committee reviewed the completed public comment document with all changes incorporated. The document was distributed for public comment on February 8, 2008. In addition, the Committee viewed a slide presentation to be provided to the regional representatives for use at the Regional Meetings. The Chair requested a change to the visual representation in the slide presentation, which staff incorporated.

Post Public Comment Consideration: During its May 2008 meeting, the Committee discussed the responses to the proposal that were received during the public comment period. The Committee specifically responded to the recommendation and questions raised by the Policy Oversight Committee and amendments were made to improve the readability of the bylaws thereby making it easier for members to interpret the requirements and under the process.

Changes included:

- 5.05A – the content of this section was divided into four subsections with headers including 1) Request for Restoration of Membership Privileges, 2) Time Limits, 3) Additional Requirements, 4) Hearing.
 - 1) Request for Restoration of Membership Privileges: Language was added that clarifies when
 - a member can request restoration of privileges; and

- that the burden is on the member to demonstrate that restoration of privileges is appropriate.
- 2) Time Limits: Language was added to address when a member can make an initially or subsequent request.
 - 3) Additional Requirements: Section header was the only change.
 - 4) Hearing: New language clarifies that if requested a hearing will be scheduled at the next regularly scheduled meeting of the MPSC after the request is submitted and at the member's expense. Costs of participating in a hearing are already addressed in Appendix A, Section 6 (Costs and Expenses).
- 5.07A – Lesser Adverse Actions: Changes were made consistent with Section 5.05A as described above

The Committee recommends the following resolution for consideration by the Board of Directors:

**** RESOLVED, that the modifications to the Bylaws, Appendix A, Sections 3.01A Paragraphs (1) and (3) and 5.05A, and new Section 5.07A, as set forth in Exhibit M-1, are hereby approved, effective June 20, 2008.**

The Committee voted 19 For, 0 Against, 0 Abstentions.

6. Proposed Modifications to the Bylaws Article I (Members); Section II (Board of Directors); and Section VI (Officers): During its January/February meeting, the Committee reviewed the final proposal to eliminate the current elector system for voting privileges and responsibilities for Histocompatibility Laboratory Members and Medical/Scientific Organizations. This proposal permits each histocompatibility laboratory and each medical/scientific member a single vote in the affairs of the OPTN/UNOS and removes the need for separate national elections for both the histocompatibility member and medical/scientific member electors.

Background and Significance of Proposal:

In November 2003, the Board of Directors adopted the OPTN Charter and Bylaws and related modifications to the UNOS Bylaws. These changes created a need for member histocompatibility laboratories to nominate and elect both regional and national electors. According to Article I (Members) Section 1.9(c) (Voting Privileges and Responsibilities – Histocompatibility Laboratory Members) as a class, were to be represented by 33 separate histocompatibility laboratory member electors. Each histocompatibility laboratory member elector was to be entitled to one vote on OPTN or UNOS affairs and the electors would be elected by the histocompatibility laboratory members. Presently, there are 58 independent histocompatibility laboratories. Under the former bylaws, each histocompatibility laboratory received a single vote.

In November 2003, the Board of Directors also adopted changes to the bylaws that created a need for member medical/scientific organizations to elect national electors. According to Article I (Members) Section 1.9(d) (Voting Privileges and Responsibilities-Medical/Scientific Members) of the bylaws, the medical/scientific members that provide services and/or are involved in activities on an interregional or national basis, as a class, would be represented by 24 separate national medical/scientific member electors. Each medical/scientific member elector would be entitled to one vote on OPTN/UNOS affairs requiring a vote of the membership. Medical/scientific member electors were to be elected by and from among the medical/scientific members. Presently, there are 21 medical/scientific members. Under the former bylaws, each medical/scientific member received a single vote.

Each of the separate elections required under the electors system creates unnecessary complexity, adds additional burden to UNOS staff, and increases costs. Moreover, there is no evidence to support that allowing each independent histocompatibility laboratory or each medical/scientific member to have voting eligibility would increase the voting potential of the membership group substantially. Thus, voting eligibility would remain fair among the voting classes absent the elector system for these classes of member. Therefore, the Membership and Professional Standards Committee is proposing bylaw modifications that would permit each histocompatibility laboratory and medical/scientific member to receive one vote and remove the need for separate national elections for both the histocompatibility member and medical/scientific member electors.

At its meeting on February 1, 2008, the Committee reviewed the completed public comment document. The document was distributed for public comment on February 8, 2008.

Post Public Comment Consideration: The Committee met on May 6-7, 2008, to discuss feedback to this public comment proposal. There being no substantive comments submitted that directly pertained to the amended language the Committee decided not to make any changes to the bylaw language that was sent out for public comment. The Committee voted to send the proposal to the Board of Directors for approval in June 2008.

**** RESOLVED, that the modifications to the OPTN Bylaws, Article I, (Members); Article II (Board of Directors), Article VI (Officers), as set forth in Exhibit M-2, and corresponding modifications to the UNOS Articles of Incorporation, are hereby approved, effective June 20, 2008.**

The Committee voted 26 For, 0 Against, 0 Abstentions.

7. Due Process Proceedings and Informal Discussions: During its January/February meeting, the Committee conducted two interviews with member transplant centers and discussed one program's adherence to its corrective action plan. During the May meeting, interviews were held with 7 members. The Data Subcommittee held four informal discussions during the same period. The Committee also agreed to continue a center under the adverse action of Probation and requested submission of a plan for quality improvement.
8. Living Donor Applications (Goal 6): The Committee discussed the implementation of the newly passed bylaw modifications that establish additional minimum criteria for granting designated program status to programs that perform living donor kidney and liver transplants. These revised bylaws further ensure that kidney and liver transplant programs have essential elements in place for the evaluation, consent, and follow-up of living donors.

The kidney and liver transplant program applications have been written and given to HRSA for review and approval by the Office of Management and Budget (OMB). Each one contains a section addressing living donor transplantation. Final approval by the OMB is expected in mid-February 2008. Subsequent to the meeting, OMB approval was received on February 6.

May Meeting Update:

Membership staff has been down one Assistant Coordinator since March and is currently striving to complete its regular application workload in addition to the program coverage plan information being submitted from over 925 transplant programs. The plan for sending out the living donor applications is still scheduled to occur on a staggered basis by region, but cannot begin until at

least July 1, 2008. The intent remains to get all the applications turned in by the centers, and finally approved simultaneously early in 2009.

9. Goal 9: Verification of the Presence of Donation after Cardiac Death (DCD) Organ Recovery Protocols at Organ Procurement Organizations (OPO) and Transplant Centers: During the January/February meeting the Committee received an update regarding progress in obtaining certification statements from all member OPOs and transplant hospitals attesting that they have and utilize a mandatory DCD organ recovery protocol. The requirement was effective July 1, 2007, and is required as a condition for OPTN/UNOS membership.

All 58 OPOs had certified compliance with the DCD protocol requirement. 259 of the 261 member transplant hospitals have either affirmed compliance or are positively working on their protocols and intend on affirming compliance when they meet the model elements. Two transplant programs notified UNOS that they were not in compliance and were not planning to comply with the mandatory DCD organ recovery protocol. They were referred to the DCD Advisory Group and it is currently advising and assisting them with addressing any issues that they are having. One transplant hospital's medical staff declined to support doing DCD organ recoveries at the hospital and is backing a protocol calling for these cases to be transferred to another facility. The other transplant hospital had a bad experience when it followed its DCD protocol earlier in the year, so a decision was made by the physicians not to do any more DCD cases. The issues appear to be philosophical and ethical. The DCD Advisory Group will continue briefing the MPSC on the success of their consultation with these members until they adopt a DCD organ recovery protocol or finally fail to comply with the requirement to have one determined.

The DCD Advisory Group understands that if a transplant hospital absolutely refuses to comply with the mandatory DCD organ recovery protocol this will lead to an adverse action recommendation being made to the Board of Directors by the MPSC. Understanding that the adverse action process should only start after the member is given the time and resources to comply, the Committee agreed that a Letter of Reprimand with the option for an interview with the MPSC be sent to any transplant center that does not comply with the Bylaw requiring that it develop a protocol to facilitate the recovery of organs from DCD donors.

May Meeting Update:

The DCD Advisory Group is actively working with the two transplant hospitals who initially indicated that they would not comply with the requirement to have and implement a DCD organ recovery protocol. Appropriate medical specialists are scheduled to visit these centers and advise them on how to overcome their concerns and comply with this requirement. A progress report will be given to the MPSC at its July 2008 meeting.

10. Update on Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data): During its January/February meeting, the MPSC reviewed Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data). This policy states that all 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. Consistent with the plan the Committee laid out in September

2006, it has completed a one-year trial using the Committee Management System and a standard protocol for completing these assessments.

During the January/February meeting, staff reported the results of the one-year trial period. It reviewed the reporting process with the Committee and provided an update on all the cases that had been reviewed during the first year of utilizing this process. Twelve 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. During the first year, the Committee did not review any cases that were finally determined to have involved policy violations or involve patient safety concerns.

The Committee considered the following questions:

- Are the MPSC reviewers finding policy violations and/or patient (donor) safety issues among the reported cases?
Response: No. Each case was found to be within reasonable transplant program practice.
- Are transplant programs compliant in reporting these cases?
Response: An initial analysis comparing living donor Social Security Numbers (SSN) against the SSN of patients being waitlisted for transplant or appearing on the Social Security Administration's Death Master File revealed all reportable cases were received. No additional cases were discovered. This data will be monitored on an ongoing basis.
- Does the MPSC need to define what is a policy violation or patient (living donor) safety issue?
Response: This is currently left to the discretion and expertise of peers reviewing each case.

Since the process for reviewing events was initially developed, additional living donor specific bylaws and policies have been approved that provide increased oversight of living donor programs. These new requirements should be incorporated into the review process.

The Committee suggested the following additional questions for inclusion in the review process:

- Was the donor's death related to the donation procedure? If yes, then is scrutiny over or expanded reporting required of that program to see if there are any other events or patterns needing consideration?
- Does it trigger a critical incident/sentinel event process in the donor hospital?
- What happened? Was it recognized? Were the appropriate people available?
- Require/request that the centers submit results of root cause analysis/critical event that is undertaken and have it part of the information reviewed? Staff requests this type of information, but cannot require the centers to provide their actual reports because they are subject to their own peer review process.
- Based on the current Bylaws, did the center do everything they should have done to evaluate the living donor?

The Committee also suggested improvements to the headers on a summary table used to present the 12 cases in a de-identified fashion. Recommendations include changing titles or adding the following:

- Recommendations column – do not use “no patient safety issues” versus operative complication.

- MPSC approval column – change to “MPSC accepted report.”
- Was the incident related to the transplant or not?
- Was the event predictable or unpredictable?
- Did the center meet the standard of care?
- Was it a preventable or unpreventable event?

The staff will incorporate the Committee’s recommendations in a new report format for the Committee when it meets in May.

The Board of Directors was asked for guidance regarding the current review process and the definition of a patient safety issue. During its February meeting, the Board did not offer any new considerations that needed to be addressed with the process. A very general summary of the incidence of adverse outcomes during 2007 will be provided to the Board.

May Meeting Update: The MPSC was briefed on what is the current, actual reporting requirement for living donor transplant programs’ to submit live donor adverse outcomes as required in Policy 7.3.3. There seems to be some confusion in the transplant community since the policy changed from its original form. The reporting requirement states:

- for a period of two years from the date of the donation.
- within 72 hours of the program knowing about it the program must report ALL living donor deaths.
- for living kidney donors, the program must report ALL native organ failures defined as requiring transplant, listing for transplant or a need for dialysis post donation.
- for living liver donors, the program must report ALL native organ failures defined as listing for transplant.
- these reports must be made in the UNetSM Patient Safety System.

If a program takes the time to voluntarily report a living donor adverse outcome event, the case will be reviewed and kept as part of the database. The MPSC does review and report all adverse events to the Board of Directors. The Committee’s May consent agenda contained two kidney cases, which were greater than two years from donation, but still reported by their programs. A discussion ensued regarding expanding the scope of Policy 7.3.3 to all live donor adverse outcomes and there was sentiment to move the reporting process beyond just data collection. No actions regarding this were taken.

A spreadsheet of the 15 cases reported since July 1, 2006, was presented with the addition of some of the columns suggested during the February meeting. Discussion ensued regarding how it is determined if the live donor adverse outcome is a direct result of the donation. Initial determination is made by UNOS staff upon receipt and can be revised later based on reviewer comments regarding the case. Sentiment was expressed for greater scrutiny of these cases regarding program responsibility or contribution to these adverse outcomes instead of just cursory review for policy violations and patient safety issues. An agreement was not reached regarding making any changes to the process at this time. The spreadsheet will be further refined and made available at future meetings.

11. Questions regarding Policies 6.3 Audit and 6.5 Violations of Policies: Audit of centers where non-resident alien transplant recipients constitute more than 5 percent of recipients of any particular organ type.

During its November 2007 meeting, the Committee reviewed its proposed memo to the Ad Hoc International Relations Committee. The memo inquired about Policies 6.3 and 6.5, which describe the review process for centers performing non-resident alien transplants.

The Committee's proposed memo requested that, in the spirit of continuous process improvement, it collaborate with the Ad Hoc International Relations Committee to reevaluate the process for review of non-resident alien transplants in the United States. Specifically, the Committee had the following requests of the Ad Hoc International Relations Committee:

1. to routinely forward the results of its review of centers where non-resident alien recipients constitute more than 5 % of recipients of any particular type of deceased organ, including the actions taken by the Ad Hoc International Relations Committee in response to centers above the 5 % threshold; and
2. to consider participating in a joint MPSC-International Relations Committee effort to review policies 6.3 and 6.5, the current non-resident alien review process, and develop recommendations to improve this process.

The Committee endorsed moving forward with this request to the Ad Hoc International Relations Committee that it reevaluate the process for review of non-resident alien transplants.

At its meeting on February 1, 2008, the Committee reviewed an update on this issue. Further staff investigation discovered that Congress did not want the MPSC to review these situations except as currently outlined in Policies 6.3 and 6.5. Thus, the current Policy language will not be changed.

12. Pancreas Outcome Analysis Model: During the July 12, 2006, meeting, the Data Subcommittee discussed the issue of pancreas (including kidney/pancreas and pancreas after kidney) transplant program outcome monitoring. A number of committee members suggested that the Committee consider implementation of pancreas outcome monitoring. In turn, the Committee asked the SRTR to evaluate potential models and possibilities available for increasing the sample size so the analytical model could be applied to pancreas programs. Currently the SRTR does publish outcome data for kidney/pancreas programs but there is no model for the evaluation of pancreas alone or pancreas after kidney one year outcomes. The Committee understood that some pancreas programs may still fall below the 10 or more transplants performed threshold, in which case the Subcommittee will follow the process currently utilized for small volume outcome reviews for other organs.

During the October 11, 2006, meeting, the Committee was informed that the SRTR was prepared to begin work to create the model. However, the Committee believed that the Pancreas Transplantation Committee needed to review the variables, including recipient and donor risk factors, before the model is developed. The Committee asked the Pancreas Transplantation Committee to discuss the variables to be included in an outcome analysis model for pancreas alone, pancreas after kidney, and simultaneous kidney/pancreas transplantation.

During the November 13-14, 2007, meeting, the MPSC discussed options for proceeding with reviewing outcomes for pancreas programs. Currently, the SRTR conducts an analysis of kidney/pancreas outcomes and this information is provided to the MPSC for each meeting; the model does not include pancreas alone analyses. While waiting for the development of a model that analyzes both kidney/pancreas and pancreas alone outcomes, it was suggested that the Data Subcommittee utilize the current kidney/pancreas analysis. The MPSC agreed to send a memo to the Pancreas Transplantation Committee, the Kidney Transplantation Committee, and the

Executive Committee to solicit feedback regarding use of the current analysis until the Pancreas Subcommittee finishes development of a pancreas outcome analysis model; and to consider the MPSC's use of the current SRTR statistical analysis of one-year post transplant outcomes for programs that perform combined kidney/pancreas transplants until the Pancreas Transplantation Committee and SRTR finish development of the more inclusive pancreas alone, pancreas after kidney, and simultaneous kidney/pancreas outcome model.

January/February Update: During its January/February meeting the Committee was informed that the Kidney Transplantation Committee reviewed the MPSC's request during its December 3, 2007, meeting and deferred the issue to the Pancreas Transplantation Committee.

The Pancreas Transplantation Committee reviewed the November request during the December 7, 2007, conference call. The Pancreas Committee does not support moving forward with using the current kidney/pancreas outcome model for monitoring outcomes in kidney/pancreas programs, as suggested by the MPSC. The Pancreas Committee reported to the MPSC that the current kidney/pancreas SRTR model may not include all relevant factors for analyzing kidney/pancreas transplant outcomes.

Additionally, the Pancreas Transplantation Committee supplied a report from the Pancreas Outcomes Review Model Subcommittee updating the MPSC on the status of the development of the more inclusive pancreas outcome model. The Subcommittee is moving forward with development of a one-year post-transplant graft and patient survival analysis using pancreas alone, pancreas after kidney, and simultaneous kidney/pancreas transplants, including an indicator for which type of transplant was performed. The Subcommittee will continue to update the MPSC as the project proceeds.

Update from May Meeting: The MPSC and its Data Subcommittee were given an update on the Pancreas Transplantation Committee's progress in the development of the pancreas outcome model. The Pancreas Transplantation Committee will review the data analyses provided by the SRTR during its next meeting and will update the MPSC accordingly.

13. Number of Days a Program has its Wait List Inactive (But not Membership):

Background:

During its January/February 2007 meeting, staff presented the Committee with an overview of the programs that had periods when the Wait List Program Status field was set to "temporarily inactive" during 2006, but the program had not inactivated its membership status. There were 21 programs (representing all organs) that had their waitlist set to "temporarily inactive" for 15 or more days. Seven of these programs had a cumulative waitlist inactive time of greater than 100 days.

The Committee agreed that further review of this data should be performed by the Data Subcommittee as part of its review of functionally inactive programs. They also recommended that letters be sent to those programs that currently have their waitlist default set to temporarily inactive and 15 or more consecutive days have passed. The letter should explain the bylaws relating to functional inactivity and solicit information on the status of the program and its plans.

During the July 31, 2007, meeting, the Data Subcommittee discussed the potential to review active programs with inactive wait lists. Because of the extensive discussions, the Subcommittee

formed a work group to further evaluate and codify a process for reviewing this metric. The work group includes Drs. Voigt, Steadman, Reyes, and Mr. Gleason.

The Work Group met on October 12, 2007, to discuss the proposed metric and it presented its recommendations to the MPSC during the November 2007 meeting. The Work Group proposed sending inquiry letters to the programs identified to have inactivated the wait list for 15 consecutive days or more and to programs that inactivated a wait list frequently. The Work Group suggested the inquiries clearly state that no action would result from the Member's response regarding reasons for wait list inactivation, but would serve as a source of greater understanding before codifying a monitoring process. The MPSC did not support this recommendation, as the Committee was concerned with its ability to take action should a program appear to be egregious in inactivating the wait list.

Additionally, the MPSC noted concerns with existing Bylaw and Policy language regarding Member responsibilities for notifying candidates of wait list inactivation; specifically, whether the Members are required to notify candidates of a change to inactive status on the wait list and/or the entire wait list was inactivated. At the conclusion of the discussions, the MPSC recommended UNOS Staff review existing bylaw language and if appropriate, provide additional language to clarify Member responsibilities for review.

January/February Meeting Update:

The Work Group charged to codify the review of Active Members with Inactive Wait Lists met December 27, 2007, to review modifications to existing bylaw language that would specify the requirements and expectations for Members regarding functional inactivity. The existing bylaw language was unclear regarding candidate notification and membership requirements for transplant program activity, and did not reference wait list inactivation. During the December 2007 meeting, the work group suggested the bylaws be modified with the following:

- Define “functional inactivity” to include:
 - 1) no transplant performed during a specified time period (No Change);
 - 2) single instance of wait list inactivation greater than 14 days; and
 - 3) cumulative wait list inactivation of 28 days or more over any 365-day period.
- Clarify/Define Short Term and Long Term Voluntary Inactivation. Short term Inactivation is wait list inactivation in UNet for no more than 14 days and no notice in addition to program coverage requirement is needed. Long Term Inactivation is membership status inactivation when program will be inactive for greater than 14 days, and requires candidate notification for either definition #2 or #3 in functional inactivity definition.

In addition to the Work Group suggested modifications, staff incorporated language regarding requirements for members that inactivate membership status for a transplant program, including transferring candidates from the wait list over a specified time period, depending upon urgency and organ. This issue has been under development for several months, and considering it is pertinent to the inactive section of the bylaws, it was suggested this language be included in the work group's modifications.

During the discussions on December 27, work group members inquired into language already in the current bylaws relating to two areas:

- *“...candidates on the waiting list of a designated transplant program at the time of inactivation, relinquishment or loss of designated transplant status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation, relinquishment or loss of designated status of their program for a maximum of 90 days following that program's inactivation, relinquishment or loss of designated status.*
- *“This total acquired waiting time may be, with agreement of the accepting center, transferred to the candidate’s credit when s(he) is listed with a new program.”*

The work group members wanted further clarification regarding these clauses in the bylaws. It was recommended that the 90-day maximum accrual be removed from the bylaw, as it appears to potentially disadvantage candidates on an inactive program’s wait list if the program is not proactive in transferring the candidate, assuming the candidate will be accepted by another program. Additionally, the work group wondered what rationale was used to allow a center to accept a transferring candidate but not their accrued wait time.

During the DSC meeting on January 31, 2008, the Data Subcommittee agreed with the work group recommendations for bylaw modification, including the removal of the maximum wait time accrual and the allowance for a transplant center to not accept the candidates wait time transfer.

The proposed bylaw modifications were presented to the full MPSC on February 1, 2008. At the conclusion of the presentation, and to facilitate more thorough reviews, the Committee recommended the draft bylaw language be reposted to Committee Management for MPSC member review. The final proposal for bylaw modification was to be considered by the MPSC during the May meeting with the goal of distributing the proposal in the June 2008 release.

May Meeting Update: The MPSC members reviewed the draft bylaw modifications and recommended that the proposal be distributed for public comment in the June 2008 release. The Committee approved the following resolution:

- ** RESOLVED, that the Committee supports the language in the proposal to modify the Bylaws, and agrees that the recommended modifications should be distributed for public comment.

The Committee voted 26 For, 0 Against, 0 Abstentions.

The Committee will review responses during the October 2008 meeting.

14. Goals for Bylaws Rewrite: Staff updated the Committee on one of the new goals established for the Committee by the President: the re-write of the existing Bylaws. The purpose of the revision is to improve clarity regarding member rights and responsibilities, and OPTN/UNOS responsibilities. Clarity will be achieved by the use of plain language and logical organization of the content.
15. Review of Events under Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data): During the January/February meeting the staff updated the Committee on the status of events surrounding one live donor death that was reviewed under Policy 7.3.3. This Policy requires these reviews to ensure that there are no patient safety concerns or associated policy violations when a living organ donation results in an adverse outcome for the donor. If corrective

actions were required, they would be stated in the findings, and reported to the Board of Directors.

Utilizing the Committee Management System, a Subcommittee of the MPSC initially reviewed this case involving the death of a living kidney donor. In this case, the Subcommittee determined that no further action was required because there was not any evidence of policy violations and no patient safety issues were exposed. This case was placed on the consent agenda for the January/February MPSC meeting. The full Committee unanimously supported the findings of the Subcommittee. The final report was also disseminated to the Living Donor Committee and to the center where the event occurred.

During the May meeting, staff updated the Committee on the status of events surrounding 5 live donor adverse outcomes that were reviewed under Policy 7.3.3. The Committee Management System was utilized for the initial reviews by a subcommittee. In four cases, it was determined that no further action was required. The other case had a policy violation associated with it and it was being handled in conjunction with an interview with the center.

The case reports were unanimously approved by the MPSC.

16. MPSC Summary Explanation: During its January/February meeting, the Committee reviewed the final version of a summary document that clarifies the MPSC's charge. This document briefly explains the role and function of the Committee in plain language that is easily understood by the medical professionals and public who are affected by its deliberations and decisions. It was agreed that the list of Frequent Policy Violations should be send out to the members along with this summary. This information was emailed out to the transplant community on April 4, 2008.
17. 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 reviewed the lists during its January/February meeting and agreed that this information should be distributed to the members in an educational format. This information was emailed out to the transplant community on April 4, 2008.

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.

This list was distributed subsequent to the January/February meeting with the MPSC Summary document mentioned above.

19. MPSC Crisis Team Response: The Committee reviewed the current process for potential Category I violations. The process included both internal and external communication plans. The Committee also discussed the requirements for the ad hoc subcommittee that initially reviews the potential Category I issue and the need for Committee members to participate on this subcommittee if a Category I violation arises.
20. Referral of Policy 3.1.4 (Waiting list) and subpart 3.1.4.2 to the Histocompatibility Committee: At its January 2008 meeting, the Committee reviewed an ABO discrepancy issue in which a histocompatibility laboratory listed a candidate on behalf of a transplant center but did not use two source documents to verify the candidate's ABO. Policies 3.1.4 and 3.1.4.2 currently place the responsibility of using and maintaining two source documents on the transplant center. UNOS staff also indicated that histocompatibility laboratory or other outside agents listing candidates on behalf of transplant centers is common practice. The Committee expressed concern about this practice and asked the Histocompatibility Committee to review Policies 3.1.4 and 3.1.4.2 (Waiting List) for possible modification.

Update from May Meeting:

The Committee received an update on the status of the Histocompatibility Committee referral. In March of 2008, the Histocompatibility Committee determined that the current language in Policies 3.1.4 and 3.1.4.2 is clear and no further modifications are necessary. The Histocompatibility Committee recommended that an educational effort would improve compliance. Therefore, the Histocompatibility Committee will develop an informational e-mail reminding transplant centers and histocompatibility laboratories that two source documents must be maintained and used for listing transplant candidates. In addition, UNOS staff will develop an education plan that reinforces the importance of these policies. The Committee agreed with this path forward.

21. Update on Policy 2.5.5 (Organ Procurement Quality): At its meeting on November 14, 2007, the Committee considered OPTN Policy 2.5.5 (Organ Procurement Quality) because of complaints UNOS received regarding laboratories receiving insufficient tissue typing materials. The

complaint concerned an incident in which a transplant center and histocompatibility laboratory allegedly received no lymph nodes or spleen from the host OPO.

The Committee discussed the issue and decided to ask the Histocompatibility Committee to consider whether Policy 2.5.5 should be revised. The Committee suggested one potential change in Policy 2.5.5 requiring OPOs to provide some portion of the spleen for every donor.

At its meeting on February 1, 2008, the Committee viewed the memorandum referring this issue to the Histocompatibility Committee. It was informed that the Histocompatibility Committee had begun its review of the Policy.

May Meeting Update:

The Committee reviewed the Histocompatibility Committee's response to the initial referral. A subcommittee of the Histocompatibility Committee identified that a majority of the errors in providing sufficient tissue typing materials occurred during organ recovery. Therefore, the Histocompatibility Committee felt that it should develop a checklist that the recovery team would be required to fill out to make sure that the team is aware of the minimum requirements. The subcommittee will present the checklist to the full Histocompatibility Committee in July. The Committee supported the path forward.

22. MPSC Feedback- Vascularized Composite Allografts: On March 3, 2008, the Department of Health and Human Services (DHHS), published a Federal Register Notice, Vol. 73, No 42, for the purpose of soliciting feedback from stakeholders and the public on whether vascularized composite allografts should be included within the definition of organs covered by the regulations governing the operation of the Organ Procurement and Transplantation Network (OPTN) and whether vascularized composite allografts should be added to the definition of human organs covered by section 301 of the National Organ Transplant Act of 1984 (NOTA).

Comments were solicited from members of the Membership and Professional Standards Committee (MPSC) via email since they would not be meeting prior to the response deadline. The following responses were forwarded to the Executive Committee on April 14, 2008.

Individual Member Responses

Comment 1. *Vascularized composite allografts should certainly be under the OPTN. We would need more information about cold time, immunosuppression, surgical recovery time, and how it impacts on other organ recovery to make any recommendations.*

Comment 2. *The (OPO) has spent the last 18 months working with one of our local transplant centers to develop protocols for the recovery of partial face transplants. Composite allografts require that the blood supply be intact during the dissection and recovery. This means that they can only be taken from the same patients that make up the brain dead, heart-beating organ donor pool. In simple terms, that means the OPOs must be involved in the donor identification, consent, donor screening and recovery process, and that the composite allografts need to be treated as organs to assure that all the appropriate procedures and safeguards are followed; and perhaps most importantly, that the recovery of the composite allograft does not interfere with the recovery of organs for transplant.*

Comment 3. *Vascularized composite allografts should be included within the definition of organs covered by the regulations governing the operation of the OPTN and should be added to*

the definition of human organs covered by section 301 of the National Organ Transplant Act of 1984 (NOTA).

These allografts are like organs in every way but one – they are not a scarce commodity (i.e. – the waiting list of potential recipients is presently very small therefore leaving no donor shortage.)

In every other way they resemble organs for transplantation and require OPTN oversight re: need for consent, donor evaluation, serology testing, preservation, shipping, outcome analysis, etc. These allografts present a risk for disease transmission (not shared by bone and tissue allografts due to processing). They are therefore medically identical to organ transplants. Their use presently follows significant trauma and is not merely cosmetic. The aftercare re: immunosuppression, rejection, long-term function, also requires involvement and coordination with the transplantation community. I see a strong role for OPTN oversight.

Comment 4. I agree with earlier respondents that these composite allografts should be subject to regulation similar to solid organ transplants. The tissue requires revascularization and the recipients need immunosuppression.

Rather than a list of "body parts", I would suggest that the language include "'all composite tissue that requires revascularization in a recipient and/or the recipient may require immunosuppression for a reasonable period of time."

These types of transplants will certainly be a rare event in the foreseeable future, so allocation should be local and the MPSC should not need to review approved programs for "low volume." The metrics for review by outcome or volume would have to be very different than for more conventional transplants.

Comment 5. is right on all counts. As he points out, there is simply no clinical method of doing this without involving the brain-dead heart beating population. So OPOs must be involved. If OPOs must be involved, there should be some OPTN involvement, at least in terms of rules about minimum screening, infectious disease testing, etc.

At this point, in my opinion the OPTN should not be involved in allocation rulemaking, since these are extremely rare and most centers are (presumably) only going to do this locally. But there may be some value in preserving that option.

I don't know if the OPTN should get into the relationships between OPOs and donor families, other than to state something about informed consent.

The majority of patients from a financial perspective will be the workers' comp cases, since no one else would pay for it, so I don't see Medicare or Medicaid getting involved.

Comment 6. I think they should be under the watch of UNOS, but how to define programs for approval is a bigger problem, since the volume is small. I think just capturing transplants being done, with no intent of public reporting, site visits, etc is okay at this time, until (and if) practice grows.

Comment 7: The issues of vascularized allograft transplantation are similar to other "organ" transplantation. The Medical and ethical implications are similar, and therefore should be covered under section 301. As such, the ideal definition of a vascularized allograft should be broad enough such that any future innovations in the field should be covered. In addition, the

fact that organs would be combined with mechanical or other devices (6) would change the ethical or medical issues substantially, and therefore these should be included under section 301.

I think the definitions are sufficiently broad, and do not include extraneous situations where HRSA oversight would not be appropriate.

The Committee was provided with a summary of the comments when it met in May.

23. Certification Maintenance and Performance Metric Work Groups: In November 2007, two workgroups were formed and initially charged with addressing the Committee Goals, specifically the review of the efficiency and effectiveness of the methods that are used for member evaluation on an ongoing basis, and making recommendations on improvements to the process. One of the fundamental goals of the Work Group is to determine if a recertification process for transplant programs would result in fewer flags? For example, would recently identified center specific issues have been caught? The desire is to be more proactive in identifying programs that might come under review.

The Certification Maintenance Work Group was asked to consider whether or not the current level of program review is adequate to ensure ongoing compliance and competency, and if there are areas that could be improved. The Performance Metric Work Group was asked to evaluate existing metrics for monitoring transplant program performance for effectiveness and currency; and identifying additional metrics for measuring transplant program performance. During the January/February MPSC meeting, it became clear that the charge of the two groups was overlapping so to simplify the effort a new work group was formed.

The newly merged group met by conference call on April 14, to clarify the workgroup's goals and chart a path forward. The Work Group began by reviewing and prioritizing the list of issues previously identified by the individual Work Groups as summarized below.

Short Term:

- Are reviews applied evenly to all programs (i.e. standalone kidney, Intestine, etc)
- Are standalone programs identified for review more frequently than other programs?
- Inactivity: How long is too long without a transplant?
- Waitlist Status of listed patients? In recently approved programs?
- Triggers for recommending inactivation
- Consider Notification standards to OPTN for significant events.
- Formal process for programs that inactivate while under DSC review?
- Establish time limit for completing Personnel Change applications
- Committee (Performance) Metrics
- Repeat offenders (Programs flagged for outcomes or functional inactivity more than one time.)

Long Term Goals:

- Are current triggers for review still appropriate?
- Are current reviews adequate to ensure ongoing competency and compliance?
- Can competency be defined?
- Relationship of personnel changes, DSC, & PCSC issues in facilities.
- Should professional Education programs be part of recertification requirements?
- Performance triggers for requiring programs to recertify.
- Outcome Review Flags: Small volume and large volume.

- Review of peer visit recurring themes and policy violations.
- Identify common themes in programs reviewed.
- Organ Acceptance rate model development.

The Work Group summarized its efforts for the full Committee during the May 2008 meeting. It was agreed that the subcommittee would focus its next calls on one or two of the short-term goals.

24. The OPO Performance Metrics Work Group: The OPO Performance Metrics Work Group is made up of members of the OPO Committee and the MPSC and is tasked with developing performance metrics to maximize the utilization of organs. The group is going to begin with a retrospective analysis of donor demographics and co-morbidities that may predict organ yield. The group is in the process of choosing items collected on the Deceased Donor Registration (DDR) form to determine a group of risk factors to be tested in the initial models. Eventually actual vs. expected models could be created to assess OPO performance on this metric.
25. Other Committee Goals: The following Goals were also addressed by the Committee during its January/February and May meetings. Goals that are not otherwise mentioned in this report are addressed below.

Goal 2: Complete a retrospective review of current processes and implementation of new performance measures.

Status: The goal will be addressed with the formation of work groups as described below.

Goal 3: Review the transplant program bylaws related to staff and infrastructure requirements for changes to further ensure patient safety.

Status: This goal will be addressed with the formation of the Certification Maintenance Work Group as described below.

Goal 7: Initiate and complete the audit of transplant surgeons and physicians and update the database accordingly to indicate which individuals meet the new criteria for the program to designate them as “additional” or “other” surgeon/physician.

Status Update from May Meeting: The complete program transplant surgeons and physicians survey was sent out to all transplant programs with approved primary surgeons and physicians. It was sent out in early February 2008 with a submission deadline of February 29, 2008. The survey asked the programs to review and confirm physician information is currently on file in the UNOS database. Each transplant program updated the name of program transplant staff physicians; their designation with needed documentation as primary, additional or other; and certification by the required primary directors that the surgeons and physicians meet new criteria regarding their moral and ethical standing. This information is in final submission and its review is ongoing. Staff is updating information and is attempting to complete updating the program staff information in the Membership database no later than June 2008.

As of the May meeting 87.37% (740/847) primary surgeon and physician surveys have been returned and are being processed by staff. All programs that did not comply by submitting the staff survey information are being contacted and given a June deadline for submission. After the final deadline passes, the programs that did not comply will be referred to the MPSC for consideration of a possible adverse action.

Goal 8: Collect and process Program Coverage Plans (primary physician, additional physician, etc.) from all existing transplant programs.

Status: This goal is being accomplished in conjunction with Goal 7 above. A request for a Program Coverage Plan along with instructions and a description was sent to and expected to be returned by each program with the staffing report. Staff is processing program coverage information and the MPSC is attempting to complete reviewing these plans no later than June 2008.

As of the May meeting, Program Coverage plans have been submitted by 85.6% (725/847) of the transplant programs and the collection process is ongoing. All programs that did not comply by providing Program Coverage plans were contacted, and given a June deadline for submission. After the final deadline passes, the programs not complying will be referred to the MPSC for consideration of a possible adverse action to be taken.

26. OPO Committee Referral – Informal Discussions. During its May meeting, the Committee considered a request from the OPO Committee. In a February 5, 2008, memo the MPSC was informed that the OPO Committee agreed with the concept of Informal Discussions but asked that it be *“expanded to other areas of action and encourages informal discussions that might rectify situations prior to formal actions being taken.”* This proposal currently applies to only transplant centers for specific violations, and *“the committee agreed that this proposal should be reflective of the member as opposed to transplant center.”* The OPO Committee suggested that the MPSC consider including this provision for all members, for different infractions, and be written in policies that affect OPOs and other members as well.

During its May meeting, the MPSC considered this request but did not take an action. The mechanisms that are presently in place afford all members access to due process. The informal discussion bylaw pertains to specific studies that are undertaken by the Data Subcommittee and are not necessarily preliminary to an adverse recommendation.

27. Thoracic Organ Transplantation Committee: Clarification requested: At its meeting on November 14, 2007, in the course of reviewing standard, periodic site surveys, the Committee raised questions about the site survey process for reviewing compliance with Policy 3.7.3 (Adult Candidate Status), and whether the current process meets the intention of the Thoracic Organ Transplantation Committee. Currently, when a Center lists a candidate as a Status 1A, UNOS site surveyors expect that if the candidate changes criteria or no longer meets Status 1A criteria within the seven or 14-day approved listing, the Center must update the candidate’s information in UNetsm.

Citations for this potential violation may affect the transplant center’s review results as reported on the administrative and clinical scorecards, and thus contribute to a center falling below threshold and being referred to the Committee for review.

The Committee decided to ask the Thoracic Organ Transplantation Committee whether it intended that a candidate who meets a Status 1A qualification criterion qualifies for Status 1A for an entire 30, 14, or 7 days, as written in Policy 3.7.3. The current staff interpretation is that a Center must be able to substantiate a candidate’s qualification for Status 1A for each day of the candidate’s listing. The Committee also asked that policy specify whether a center was required to submit new forms if the patient’s condition changes.

At its meeting on February 1, 2008, the Committee viewed the memorandum referring this issue to the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee will receive this referral for review during its next meeting.

Update from May Meeting:

At its meeting on May 6, 2008, the Committee reviewed a response from the Thoracic Organ Transplantation Committee's consideration of this referral. The Thoracic Organ Transplantation Committee agreed with staff interpretation of Policy 3.7.3, and will explore modifying the policy language with the policy re-write effort. The Thoracic Organ Transplantation Committee stated that Centers should submit updates of candidate status if a candidate's qualification for Status 1A changes. The Thoracic Organ Transplantation Committee's intent is that a candidate must meet the requirements every day of the listing.

28. Update on Policy 3.7.6.3 (Candidate Variables in UNetSM): The Committee requested that the Thoracic Organ Transplantation Committee review site surveyors' interpretation of Policy 3.7.6.3 (Candidate Variables in UNetSM). The MPSC expressed concern that programs were being cited for potential policy violations for not documenting the absence of diabetes in a patient's chart. Documenting the absence of a condition is not standard medical practice. The Thoracic Organ Transplantation Committee considered this referral and stated that Centers should not be cited for not documenting the absence of diabetes. The Thoracic Organ Transplantation Committee stated that if the Center marks "no diabetes" on the justification form, and site surveyors do not find evidence of diabetes in the chart, the program should not be cited for a policy violation.
29. Directed Donations: During an interview at its November 2007 meeting, the Committee questioned why an OPO seemed to have a large number of directed donations. In order to assess this issue further, the Committee decided that it needed a better idea of what the directed donation landscape looked like around the country. The Committee requested data on the number of directed donations and the distribution of these directed donations among the DSAs across the country.

During its meeting on February 1, 2008, the Committee reviewed data describing the rates of directed donations for all OPOs from October 2006 through September 2007. During the 12 months of this analysis, there were 8020 donors, 123 (1.5 percent) of which had at least one organ that was allocated as a directed donation. There were three Donor Service Areas (DSAs) with directed donation rates that were significantly higher than that of the rest of the DSAs in the country. The Committee decided to investigate those OPOs with greater than three percent of donors with at least one organ allocated as a directed donation. The Committee is interested in identifying any specific practices that increased the incidence of directed donation.

The Committee approved the following resolution by a vote of 19 For, 0 Against, 0 Abstentions:

- ** RESOLVED, that the Committee asks the five OPOs with greater than three percent of donors with at least one organ allocated as a directed donation, to explain the circumstances of directed donation practice in its Donor Service Area.

Update from May Meeting:

The Committee discussed the responses received from those OPOs with greater than three percent of donors with at least one organ allocated as a directed donation. The responses addressed OPO processes and protocols for obtaining consent and handling directed donation requests. The Committee recommended that it should refer the issue of directed donations to the OPO

Committee for possible development of guidelines for OPOs to use during the directed donation process. In addition, the Committee suggested that the OPO Committee provide guidance on to what level OPOs should educate/advise families about the option of directed donations.

30. Proposed changes to Policy 3.2.4 (Match System Access), Policy 3.1 (Definitions), and Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates): At its meeting in November 2007, the Committee reviewed allocation issues including allocation of organs to recipients who did not appear on a match run. Through this review, the Committee has identified the need to provide instruction to members about what to do when a candidate does not appear on a match run, and when a candidate cannot appear on a match run. The purpose of providing this instruction, in the form of revised policy language, is to increase the safety of transplants for recipients who cannot appear on the match run, and to prevent future policy violations by promoting a clear understanding of what a member is required to do when a candidate does not appear on a match run.

Policy 3.2.4 currently requires all organ recipients to appear on an organ match run. However, there are other policies or situations that prevent the member from complying with this requirement. UNOS staff have identified three scenarios in which policies conflict or programming does not allow a recipient from appearing on a match run. These scenarios include directed donations, compatible transplants intended to prevent organ wastage, and multiple organ allocation to a single recipient. If these modifications are approved, an Organ Procurement Organization and Transplant Center would be required to determine why the intended recipient does not appear on the match run, maintain all related documentation, and provide written justification to the OPTN. The written justification must include:

- the rationale for transplanting a candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run; and
- documentation that the Transplant Center verified suitability between the donor organ and recipient prior to transplant.

The Committee reviewed the proposed modifications to the policies, and discussed whether the proposed language allowed too much freedom for OPOs and Transplant Centers to allocate organs inappropriately to candidates who do not appear on a match run. The Committee wanted to ensure that the policy changes did not undermine or create conflict with existing policies; that the language did not empower transplant centers to transplant candidates who do not appear on the match run; and that the legitimate reasons why a transplant center may transplant a candidate who does not appear on the match run were included in the language. The original proposal included striking some language requiring OPOs to exhaust the initial match run before offering transplant programs an opportunity to update candidate data and running a new match. The Committee proposed reinstating the stricken sentences:

“Organs shall be allocated only to candidates who appear on a match run. In the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates’ data, and the Host OPO may re-run the match system.”

The Committee’s suggestions will be incorporated into the draft document and the proposal will be referred to the Operations Committee and the Policy Oversight Committee. The Committee will review the document again before the proposal is distributed for public comment.

31. Proposal to Change the Bylaws to Require Written Notification (or Disclosures) to Living Donors from Recipient Transplant Programs. During the meeting on February 1, the Committee preliminarily considered the new public comment proposal entitled “*Proposal to Change the OPTN/UNOS Bylaws to Require Written Notification (or Disclosures) to Living Donors from the Recipient Transplant Programs...*” and asked that it be posted to the Committee Management System for review and comment following the meeting.

The goals of this proposal, which is sponsored by the Living Donor Committee, are to provide living donors with the same information and protections given to candidates on the national transplant waiting list. Under the proposed change, recipient transplant centers must provide written notification to living organ donors within ten business days following their donation date to include the following:

- the telephone number that is available for living donors to report concerns or grievances through the OPTN;
- disclosure that the recipient transplant center is required to submit Living Donor Follow-up (LDF) forms to the OPTN for a minimum of two years; and
- the plan for obtaining living donor data for completion of follow-up forms.

The MPSC considered this proposal from February 11, 2008 until March 13, 2008, using the Committee Management System. The MPSC members who reviewed the proposal supported it by a vote 8 For, 5 Against, 0 Abstentions. The following comments, which were made by individual members, were forwarded to the Living Donor Committee for their consideration.

- *This information is in the consent for evaluation, discharge instructions, and other educational material. Sending a letter after surgery is over kill.*
- *Donors should be notified of this at the time of the evaluation (just as recipients are), and not mailed to them within 10 days of the surgery. This allows for a uniform practice (more likely to have compliance, and also more easy to monitor for compliance). This also allows for notification of donors who are evaluated but ultimately do not go on to donate (some of them may wish to have this access to the grievance number also.)*
- *Strongly disagree. This information needs to be given to donors before the donation, not as a "by the way" after the fact. I think it serves no purpose.*
- *Prospective living donors should have the same avenues available to report concerns (and receive the same notification) as individuals who proceed to living donation. This would make the process analogous to that for prospective recipients, as not all prospective recipients proceed to transplant, yet all are notified of avenues available for reporting concerns. Simply because it's unlikely this information will be used does not mean it should be withheld until a more convenient time, regardless of new safeguards such as the Independent Donor Advocate. What if the Donor Advocate is the source of concern? After donation disclosures regarding the obligations of transplant centers that relate to the donor, and the donor's privacy, are ill timed. All disclosures should be provided during the consent process; otherwise, an informed consent cannot be obtained.*
- *Passing on the UNOS Patient Services phone number and that this is done within 10 days.*

- *Why 10 days? Many surgeons see post-op patient 2-3 weeks after surgery. Why not pass along any information at that visit, when the opportunity to address patient concerns face-to-face has occurred. Is the 10-day period anything but arbitrary?*
- *Most importantly: after major surgery, our emphasis should be on counseling the patient about what is a normal and expected post-operative course and getting the patient back to baseline health, not inviting them to litigation and grievance. UNOS fielding their concerns re: recovery, medical care, personal attention, analgesia, and outcomes strikes me as an uninvolved third party that is completely ill equipped to sort out the extent and validity of any complaint. I am appalled by the lack of trust in our system of qualified surgeons and the care we deliver to organ donors. Every hospital has a Patient Bill of Rights and system in place to address patient concerns. This is the logical regress for patients with complaints that are not satisfactorily addressed by the treating physician and transplant team.*

32. Patient Notification of UNOS Patient Services Line: Because of a modification of the OPTN/UNOS Bylaws in February of 2007, transplant centers were required to begin notifying their patients of the UNOS patient services line. During its May meeting, the Committee was informed that subsequent to the implementation of this requirement, the UNOS patient services staff members experienced a considerable increase in the number of calls received through the hotline. Unfortunately, some callers mistakenly thought they were contacting their transplant centers directly using the UNOS patient services toll-free number. Staff members have estimated that 10-15% of current calls are from individuals who believe they are actually calling their centers for information related to routine matters such as appointment scheduling.

In an attempt to resolve this problem, the patient services voicemail recording was changed approximately to explain the type of information that can be accessed through the patient services line and to clarify that the staff do not have access to confidential patient information. The voicemail recording also specifically directs callers to contact their centers if they are calling about their medical needs or treatment or if they are trying to reach their coordinator, social worker, or other transplant center staff.

The MPSC discussed and supported the PAC's proposal to develop a separate letter or brochure that could be distributed with the listing letters. Suggestions were made that the description of the patient services hotline displayed on the websites include the use of the line to report concerns or grievances as indicated in the bylaw.

33. Additional Concerns Noted during Peer Site Visit: The MPSC discussed an issue discovered during a peer visit conducted at a transplant center whose kidney transplant program was experiencing lower than expected outcomes. The team members relayed their concerns to the Data Subcommittee, which discussed the issue during its meeting on May 5, 2008.

During the course of its review, the peer team noted concerns relating to a single surgeon being involved in the declaration of death in organ donors, procurement of the organs, and in the transplant surgery. The team informed the center at the end of the visit of the potential conflict this practice presents and was aware of conversations between the OPO and the center regarding this practice.

The MPSC discussed the issue at length on May 7, 2008, and referenced the Uniform Anatomical Gift Act (UAGA), Section 14, Part I, which states:

Neither the physician who attends the decedent at death nor the physician who determines the time of the decedent's death may participate in the procedures for removing or transplanting a part from the decedent.

Based upon existing state laws, and Policy 2.2.1, the MPSC agreed that it would consider making an adverse recommendation of Member Not in Standing against the OPO, based upon a violation of Policy 2.2.1, which requires the Host OPO to verify that death has been pronounced according to applicable laws. The CEO of the transplant center will be notified of the conflict of interest and inconsistent practice with state laws and asked to respond to the MPSC Chair on or before May 16, 2008. Additionally, the Committee agreed that the Bylaws and/or Policies should be amended to include language that addresses the UAGA and requires surgeons within a transplant program involved in declaration of donor death not be involved in organ procurement and transplantation.

34. Transplant Center Summary (TCS) Reports: During the January 2008 MPSC meeting, MPSC members noted the need for a quick reference for a Center that provides an overview of all MPSC related activities. It was suggested that the MPSC adopt an APPGAAR score or report that would list for any Center reporting to the MPSC: policy compliance reviews, data subcommittee reviews, pending and historical personnel changes, wait list and transplant data, organ acceptance rates, and reports of adverse events in living donors. Staff prepared a sample APPGAAR Report for a special case and MPSC members recommended these Reports be prepared for all members participating in an informal discussion, interview, or hearing during the May 2008 meeting, to further test the project. In preparation for the May meeting, Staff suggested modifications to the report, including changing the name to "TCS Reports" or Transplant Center Summary Reports. Nine TCS Reports were prepared for the May 2008 meeting, and MPSC members reported gaining additional insight into the Center. Staff and MPSC members will continue to refine the project/reports, particularly as technology facilitates the creation of the reports for all Members reporting to the MPSC, rather than limiting the reports to the programs pending due process rights.
35. UNOS Actions: During the January/February meeting, the Committee members agreed 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 vote was unanimous.

During its May meeting, the Committee unanimously approved a motion to accept the program specific decisions made during the OPTN/UNOS meeting as UNOS recommendations and 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 vote was unanimous.

**Attendance at the Membership and Professional Standards Committee Meeting
January 31–February 1, 2008 and May 6-7, 2008**

NAME	POSITION	Attended Aug 1-2, 2007	Attended Nov 13- 14, 2007	Attended Jan 31 – Feb 1, 2008	Attended May 6-7, 2008
Robert S Higgins MD,MSHA	Chair	X	X	X	X
Carl Berg MD	Vice Chair	X	X		X
Paul Morrissey MD	Regional Rep.	X	X	X	X
Lynt Johnson MD	Regional Rep.	X	X	X	X
George Loss Jr., MD, PhD	Regional Rep.	X	X	X	X
John Goss MD	Regional Rep.				
Chris Freise MD	Regional Rep.	X	X	X	X
Jorge Reyes MD	Regional Rep.	X		X	
Yolanda Becker MD, FACS	Regional Rep.	X	X	X	X
Michael Voigt MD	Regional Rep.	X	X	X	X
Patricia Sheiner MD	Regional Rep.	X		X	
Lynn Driver CPTC	Regional Rep.	X	X	X	X
Tim Brown	At Large	X	X	X*	X
Jonathan Chen MD	At Large		X	X	X
Niloo Edwards MD	At Large	X	X	X	X
James Gleason	At Large	X	X	X	X
Julie Heimbach MD	At Large	X	X	X	X
John Herre MD	At Large	X	X	X	X
Donald Hricik MD	At Large	X	X	X	X
John Lake MD	At Large	X	X	X	X
Geoffrey Land PhD	At Large	X	X	X	X
Richard Luskin MPA	At Large	X	X	X	X
Jill Maxfield RN, CPTC	At Large	X			X
Patricia McDonough RN, CPTC, CCTC	At Large	X	X	X	X
Brendan McGuire MD	At Large	X	X	X	X
Jennie Perryman RN, PhD	At Large	X	X	X	X
Fuad Shihab MD	At Large		X	X	X
Randall Starling MD, MPH	At Large	X	X	X	X
Randolph Steadman M.D.	At Large	X	X	X	X
David Weill MD	At Large		X	X	X
James Burdick MD	Ex Officio				
Christopher McLaughlin	Ex Officio	X	X	X	X
Robert Walsh	Ex Officio				X
Charlotte Arrington MPH	SRTR Liaison	X	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	Attended May 6-7, 2008
Sally Harris Aungier	Committee Liaison	X	X	X	X
David Kappus MAS	Committee Liaison	X	X	X	X
Doug Heiney	Support Staff	X			
Terri Bessom	Support Staff		X	X	X
Heather Bowman	Support Staff		X	X	X
Elizabeth Coleburn	Support Staff	X	X	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	X
Shelia Foster	Support Staff			X	X
Alex Garza	Support Staff	X	X	X	X
Suzanne Gellner JD, CHC	Support Staff	X	X	X	
Walter K. Graham	Support Staff	X			
Jason Livingston, Esq.	Support Staff				X
Karl McCleary Ph.D., M.P.H.	Support Staff	X	X	X	X
Joel Newman	Support Staff	X		X	
Jacqueline O'Keefe MBA	Support Staff	X	X	X	X
Anne Paschke	Support Staff		X		X
John Persons, Esq.	Support Staff	X			
John Rosendale	Support Staff		X	X	X
Leah Slife	Support Staff	X	X		X
Donna Whelan	Support Staff		X	X	X

* Participated by conference call

BRIEFING PAPER

Proposal to the OPTN and UNOS Bylaws: Restoration of Membership Privileges Following an Adverse Action (Proposed Changes to Appendix A, Section 3.01A Paragraphs (1) and (3) and Section 5.05A, Addition of Section 5.07A.)

Sponsoring Committee: Membership and Professional Standards Committee (MPSC)

This bylaw defines how a member may be considered for restoration for full membership privileges, and provides the expectations for a member to move from an adverse action to a lesser action or status.

Affected groups: OPTN/UNOS members.

Summary and Goals of the Proposal:

The OPTN/UNOS has taken adverse actions against several members including the action of “Member Not in Good Standing.” The bylaws do not presently provide a clear mechanism or pathway to restore full membership privileges to a member that has received an adverse action such as “Member Not in Good Standing” or “Probation.” These proposed modifications to Section 5.05A “Restoration of Unrestricted Membership” will further describe the circumstances under which the MPSC can consider restoring a member’s full privileges. These modifications will also provide OPTN members with clear expectations for time periods before restoration of full membership privileges may be requested.

Background and Significance of Proposal:

This proposed OPTN/UNOS bylaw is sponsored by the Membership and Professional Standards Committee (MPSC). The MPSC obtained input and feedback from the OPTN Executive Committee. That feedback was incorporated into this proposal.

The proposed modifications to the bylaws will better define how a Member may be considered for restoration of full membership privileges, and provide a way for a member to move from an adverse action such as “Member Not in Good Standing” to a lesser action or status, such as “Probation.”

There may be times when a member has demonstrated substantial improvements in the area that led to the initial adverse action, but a complete restoration of privileges may not be appropriate because continued monitoring is warranted. The proposed modifications will provide some minimum requirements that the member demonstrate improvement. At the same time, the proposed bylaw will provide the MPSC or Board of Directors the latitude to assess the level of improvement achieved under the circumstances. The proposed addition to the bylaws of a new Section 5.07A “Changes in Membership Adverse Action Status” will provide a framework for the MPSC and the Board of Directors to use in making decisions about moving a member from an adverse action such as “Member Not in Good Standing” to the lesser action or status.

In August 2007, the Membership and Professional Standards Committee reviewed the draft proposal that would better define how a Member may be considered for restoration for full membership privileges, and provide a way for a member to move from an adverse action to a lesser action or status. The committee asked that the concept of “trial reinstatement” be added and that the proposal be re-circulated to the committee members for further review.

The MPSC reviewed the draft and provided the following comments:

- One committee member asked to see a section (iv) added to 5.07A “Demonstrated reversal of cause” for why they were on Probation/Member Not in Good Standing.
- One committee member asked whether this change would provide a 3 month loophole under which everyone would apply.
- One committee member asked for clarification regarding which types of restricted status to which this subsection applies.
- One committee member suggested that three months may be too soon for a member to demonstrate substantial and sustained change. A longer timeframe for reconsideration (e.g., four to six months) would be warranted.
- One committee member offered that trial reinstatement is fine but it should only happen at least six months after Member Not in Good Standing or Probation.
- One member sought clarification of the statement about “downgrade of status” not entitling the member to due process. The member always has the right of due process. What we should say is that if they apply for reinstatement and a lesser status is recommended (i.e., Member Not in Good Standing to Probation) that the member forfeits the right to request a Hearing in this circumstance.

Based on these comments, the three month period for “Changes in Membership Adverse Action Status” was modified to six months.

In September 2007, the Executive Committee reviewed the draft proposal and made the following comments:

- The MPSC did not discuss status reductions for those already on Probation. This was resolved by making trial reinstatement the next step down from Probation in 5.07A.
- Six months may not be long enough in lower than expected outcomes cases. Specifically, six months may not be long enough when only one more cohort of SRTR data will be available. There may need to be a 12-month minimum (two cohorts) for low outcome situations, but this should be discussed by the MPSC.

The MPSC considered the Executive Committee’s comments and decided to change the time periods from six to twelve months. This addition would require that the member would not be eligible to request movement from one status to a lesser status until at least twelve months have elapsed.

Supporting Evidence and/or Modeling:

This proposed modification to the bylaws was deemed to be necessary by the MPSC because there had not been any predetermined path or timeline for restoring privileges to a member that had an adverse action. This proposed modification will provide minimum timelines under which the adverse actions will apply.

Additional data collection:

Additional data collection is not required by this bylaw proposal.

Expected Implementation Plan:

This bylaw proposal will require programming in UNetSM.

Communication/Education Plan:

This bylaw would be communicated via the policy notice process and through a summary update at each regional meeting.

Monitoring and Evaluation:

Not applicable.

Policy Performance Measures

Pending

Bylaw Proposal:

**APPENDIX A TO UNOS BYLAWS
Interviews and Hearings**

3.01A Definition of “Adverse”

- (1) **Recommendations or Actions:** Subject to Section 3.01A (4) below, the following recommendations or actions shall, if deemed adverse pursuant to Section 3.01A (2) below, entitle the applicant or member affected thereby to a hearing:
 - (a) Rejection of initial membership or rejection of designation as a transplant program;
 - (b) Probation;
 - (c) Initial declaration of “Member Not in Good Standing” and subsequent determinations by the Board of Directors or Executive Committee not to restore the Member to unrestricted membership status;
 - (d) Suspension of membership privileges either directly or after a period of probation;
 - (e) Termination of membership, either directly or after a period of probation or suspension; and

- (f) Any other action specified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c) including, by way of example and not limitation, removal of designation as a transplant program.
- (2) **When Deemed Adverse:** A recommendation or action listed in Section 3.01A (1) above shall be deemed adverse only when it has been:
- (a) Recommended by the MPSC or, in the case of: (i) rejection of initial membership, (ii) rejection of designation as a transplant program, or (iii) findings with respect to Category I potential violations, recommended by a Subcommittee of the MPSC; or
 - (b) Taken by the Board of Directors or the Executive Committee contrary to a favorable recommendation by the MPSC or subcommittee of the MPSC under circumstances where no right to a hearing existed; or
 - (c) Taken by the Board of Directors or the Executive Committee on its own initiative without benefit of a prior recommendation by the MPSC.
- (3) **Interviews:** Except in the case of Category I potential violations, when the MPSC or MPSC-PCSC is considering making an adverse recommendation concerning an applicant or a Member or issuing a letter of reprimand, or when an organ-specific committee refers a matter to the MPSC/MPSC-PCSC with a recommendation that the MPSC consider such an action under Section 2.05A above, the applicant or Member shall be entitled to an interview before the MPSC or the MPSC-PCSC. The interview shall not constitute a hearing, shall be preliminary in nature, and shall not be conducted according to the procedural rules provided with respect to hearings. The applicant or Member shall be informed of the general nature of the circumstances and may present information relevant thereto. A summary record of such interview shall promptly be made by the MPSC and a copy promptly provided to the applicant or Member who was granted the interview.

Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for an interview and/or other procedural rights described below.

Members shall not be entitled to an interview in the case of Category I potential violations; or if action is being considered pursuant to 5.05A or 5.07A of these Bylaws.

- (a) An applicant or Member shall have the right to one hearing proceeding, and subsequent appellate review unless the Board of Directors conducts the hearing, with respect to any application for membership, application for designation as a transplant program, and request for corrective action to enforce membership requirements in which an adverse recommendation or action is taken. The hearing may be requested upon the first to occur of the adverse recommendations or actions listed in section 3.01A(1) above or, if waived at such time by the applicant's or member's failure to request a hearing within the time and in the manner specified in section 3.02A below, upon any subsequent adverse recommendation or action arising out of the same application for membership, application for designation as a transplant program, or request for corrective action to enforce membership requirements.
- (b) **Category I Potential Violations.** In the case of a determination of time sensitive threat to patient health or public safety in connection with Category I potential violations, the hearing and any subsequent appellate review will commence together with or follow rather than precede the Executive Committee's or the Board's decision regarding and action upon the MPSC subcommittee's recommendation, as set forth below:
 - (i) The MPSC subcommittee recommendation will be referred immediately to the Executive Committee. At the same time, notice will be given to the Member by

registered or certified mail, return receipt requested, as well as facsimile transmission. Where the finding continues to be a Category I potential violation with time sensitive threat to patient health or public safety, the MPSC subcommittee action shall include a recommendation for designation of the Member to be Member Not in Good Standing and that the offending transplant program or institution voluntarily inactivate, and, failing acceptance of this recommendation to voluntarily inactivate with immediate action to so inactivate (including notice to and assistance for patients pursuant to UNOS requirements);

- (ii) Following receipt of the MPSC subcommittee recommendation, the Executive Committee shall determine whether it or the Board of Directors shall consider the matter and the Executive Committee or the Board, as the case may be, shall consider the same and affirm, modify, or reverse the recommendation or action in the matter. A concise statement of the result and the reasons therefore, and all documentation considered, shall be transmitted to the Executive Director;
- (iii) The Executive Director, or his/her designee, shall promptly send a copy of the result to the Member by registered or certified mail, return receipt requested (as well as facsimile transmission) if the decision continues to be adverse to the Member. A copy of the result also shall be forwarded to the MPSC or to the Board of Directors, as determined by the Executive Committee, in the event the Member exercises its rights to a hearing under Section 3.02A of the Bylaws. The Member may request that a copy of the supporting documentation be furnished at the Member's expense;
- (iv) Notice of a decision by the Executive Committee or Board that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members; and
- (v) In the event the Member exercises its right to a hearing, the process described in Section 3.02A will be initiated or continued, as applicable, consistent with the timing of delivery and receipt of notices. The hearing will be before the MPSC, the Board or the Executive Committee as determined by the Executive Committee.

Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take other appropriate action using other appropriate process even if the steps noted above for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for a hearing and/or subsequent appellate review.

Members will not be entitled to a Hearing in the case that action is being considered pursuant to 5.05A or 5.07A of these Bylaws, except as provided in those sections.

3.02 A - no changes

3.03 A - no changes

4.01A – no changes

Effect of Board Actions

5.01A – no changes

5.02A – no changes

5.03A – no changes

5.04A [RESERVED]

5.05A Restoration of Unrestricted Membership

Upon presentation of evidence to the satisfaction of the MPSC that a probationary Member, Member declared Not in Good Standing, or a suspended Member has fully complied with UNOS requirements, including completion of actions prescribed as a result of the imposition of sanctions, the MPSC shall recommend that the Board of Directors restore unrestricted membership privileges, in the case of a Member placed on probation or declared Not in Good Standing, or recommend restoration of unrestricted membership privileges, in the case of suspension of the Member’s membership privileges.

The Member must demonstrate to the satisfaction of the MPSC that:

- (i) The Member is in substantial compliance with UNOS requirements;
- (ii) The Member has fully implemented any corrective action plan or action plan previously required by the MPSC; and
- (iii) The Member has demonstrated that the underlying cause for the adverse action has been corrected, or eliminated.

For the purposes of this section, “substantial compliance” means that there are no pending compliance issues that might lead to a Category I violation, and that the type of violation that resulted in the adverse action is not likely to occur again.

There is no timeline for consideration of requests for unrestricted membership, in that time passed does not demonstrate compliance or remedy. The burden is on the member to demonstrate that restoration of membership privileges is appropriate. However, the MPSC may consider requests during its regularly scheduled meetings beginning:

- a) twelve months after the approval of a corrective action plan; or
- b) twelve months after the approval of an action plan subsequent to the Board of Director’s or Secretary’s adverse action.

In its discretion, the MPSC may require an unannounced site survey and/or peer conducted site visit prior to consideration of the request.

The Member shall be entitled to a Hearing regarding restoration of unrestricted membership only if the MPSC denies the request by the Member and the Member alleges that the MPSC acted arbitrarily and capriciously.

5.06A Restoration of Privileges after Violation of Mandatory Policies under Section 121.10(c) of the OPTN Final Rule

Upon presentation of evidence to the satisfaction of the MPSC that a Member ~~penalized~~ sanctioned for violation of a mandatory policy under Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), has fully complied with requirements for the restoration of membership privileges, including completion of actions prescribed as a result of the imposition of sanctions, the MPSC shall recommend to the Board of Directors that the ~~penalty~~ sanction be removed.

5.07A – Lesser Adverse Actions

If a Member requests restoration of unrestricted membership pursuant to Section 5.05A of Appendix A to the Bylaws, the MPSC may recommend to the Board of Directors the lesser adverse actions of “Probation”

or, if the existing status is Probation, a trial reinstatement period. The recommendation may be considered if the Member has demonstrated to the MPSC's satisfaction that it is:

- i) in substantial compliance with UNOS requirements;
- ii) the underlying cause for the adverse action is substantially corrected; and
- iii) the corrective action plan or action plan are in the process of being implemented.

For the purposes of this section, "substantial compliance" means that there are no pending compliance issues that might lead to a Category I violation, and that the type of violation that resulted in the adverse action is not likely to occur again.

There is no timeline for consideration of requests for a modification of adverse actions, in that time passed does not demonstrate substantial compliance or correction. The burden is on the member to demonstrate that restoration of membership privileges is appropriate. However, the MPSC may consider requests at its regularly scheduled meetings beginning:

- a) twelve months after the approval of a corrective action plan; or
- b) twelve months after the approval of an action plan subsequent to the Board of Director's adverse action.

In its discretion, the MPSC may require an unannounced site survey and/or peer conducted site visit prior to consideration of the request.

The consideration of lesser adverse actions pursuant to this section shall not entitle the Member to an Interview or Hearing under these bylaws. The Member shall be entitled to a Hearing regarding the recommendation for the action of "Probation" or trial reinstatement only if the MPSC denies the request by the Member and the Member alleges that the MPSC acted arbitrarily and capriciously.

No further changes to Appendix A

APPENDIX A TO OPTN BYLAWS Interviews and Hearings

3.01A - Definition of "Adverse"

- (1) **Recommendations or Actions:** Subject to Section 3.01a (4) below, the following recommendations or actions shall, if deemed adverse pursuant to Section 3.01a (2) below, entitle the applicant or Member affected thereby to a hearing:
 - (a) Rejection of initial membership or rejection of designation as a transplant program;
 - (b) Probation;
 - (c) Initial declaration of Member Not in Good Standing and subsequent determinations by the Board of Directors or Executive Committee not to restore the Member to unrestricted membership status;
 - (d) Suspension of membership privileges either directly or after a period of probation;
 - (e) Termination of membership, either directly or after a period of probation or suspension.
 - (f) Any other action specified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), including, by way of example and not limitation, removal of designation as a transplant program.
- (2) **When Deemed Adverse:** A recommendation or action listed in section 3.01a (1) above shall be deemed adverse only when it has been:
 - (a) Recommended by the MPSC or, in the case of: (i) rejection of initial membership, (ii) rejection of designation as a transplant program, or (iii) findings with respect to Category I potential violations, recommended by a Subcommittee of the MPSC; or

- (b) Taken by the Board of Directors or the Executive Committee contrary to a favorable recommendation by the MPSC or subcommittee of the MPSC under circumstances where no right to a hearing existed; or
 - (c) Taken by the Board of Directors or the Executive Committee on its own initiative without benefit of a prior recommendation by the MPSC.
- (3) **Interviews:** Except in the case of Category I potential violations, when the MPSC or MPSC-PCSC is considering making an adverse recommendation concerning an applicant or a Member or issuing a letter of reprimand, or when an organ-specific committee refers a matter to the MPSC/MPSC-PCSC with a recommendation that the MPSC consider such an action under Section 2.05A above, the applicant or Member shall be entitled to an interview before the MPSC or the MPSC-PCSC. The interview shall not constitute a hearing, shall be preliminary in nature, and shall not be conducted according to the procedural rules provided with respect to hearings. The applicant or Member shall be informed of the general nature of the circumstances and may present information relevant thereto. A summary record of such interview shall promptly be made by the MPSC and a copy promptly provided to the applicant or Member who was granted the interview. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for an interview and/or other procedural rights described below.

Members shall not be entitled to an interview in the case of Category I potential violations; or if action is being considered pursuant to 5.05A or 5.07A of these bylaws.

(4) **Right to a Hearing:**

- (a) An applicant or Member shall have the right to one hearing proceeding, and subsequent appellate review unless the Board of Directors conducts the hearing, with respect to any application for membership, application for designation as a transplant program, and request for corrective action to enforce membership requirements in which an adverse recommendation or action is taken. The hearing may be requested upon the first to occur of the adverse recommendations or actions listed in section 3.01A(1) above or, if waived at such time by the applicant's or member's failure to request a hearing within the time and in the manner specified in section 3.02A below, upon any subsequent adverse recommendation or action arising out of the same application for membership, application for designation as a transplant program, or request for corrective action to enforce membership requirements.

- (b) **Category I Potential Violations.** In the case of a determination of time sensitive threat to patient health or public safety in connection with Category I potential violations, the hearing and any subsequent appellate review will commence together with or follow rather than precede the Executive Committee's or the Board's decision regarding and action upon the MPSC subcommittee's recommendation, as set forth below:

- (i) The MPSC subcommittee recommendation will be referred immediately to the Executive Committee. At the same time, notice will be given to the Member by registered or certified mail, return receipt requested, as well as facsimile transmission. Where the finding continues to be a Category I potential violation with time sensitive threat to patient health or public safety, the MPSC subcommittee action shall include a recommendation for designation of the Member to be Member Not in Good Standing and that the offending transplant program or institution voluntarily inactivate, and, failing acceptance of this recommendation to voluntarily inactivate with immediate action to so inactivate (including notice to and assistance for patients pursuant to OPTN requirements), the MPSC subcommittee shall further recommend approval from the Secretary

to suspend member privileges, terminate membership or designated transplant program status, and/or take action specified in the OPTN Final Rule.

- (ii) Following receipt of the MPSC subcommittee recommendation, the Executive Committee shall determine whether it or the Board of Directors shall consider the matter and the Executive Committee or the Board, as the case may be, shall consider the same and affirm, modify, or reverse the recommendation or action in the matter. A concise statement of the result and the reasons therefore, and all documentation considered, shall be transmitted to the Executive Director.
- (iii) The Executive Director, or his/her designee, shall promptly send a copy of the result to the Member by registered or certified mail, return receipt requested (as well as facsimile transmission), and to the Secretary of HHS within three business days or such longer period as may be necessitated for good cause, as determined by the Secretary, if the decision continues to be adverse to the Member. A copy of the result also shall be forwarded to the MPSC or to the Board of Directors, as determined by the Executive Committee, in the event the Member exercises its rights to a hearing under Section 3.02A of the Bylaws. The Member may request that a copy of the supporting documentation be furnished at the Member's expense.
- (iv) Notice of a decision by the Executive Committee or Board that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members. The membership shall be notified of decisions by the Executive Committee or Board to recommend to the Secretary of HHS suspension of membership privileges or termination of membership only upon approval of such recommendation by the Secretary.
- (v) In the event the Member exercises its right to a hearing, the process described in Section 3.02A will be initiated or continued, as applicable, consistent with the timing of delivery and receipt of notices. The hearing will be before the MPSC, the Board or the Executive Committee as determined by the Executive Committee.

Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take other appropriate action using other appropriate process even if the steps noted above for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for a hearing and/or subsequent appellate review.

Members shall not be entitled to a Hearing in the case that action pursuant to 5.05A or 5.07A of these bylaws is being considered, except as provided in those sections.

- (5) **Right of Appeal to the Secretary.** An applicant for membership or designation as a transplant program shall have the right to appeal decisions of the MPSC, MPSC subcommittees, or the Board of Directors regarding these applications to the Secretary of HHS in accordance with the OPTN Final Rule, 42 CFR Part 121. In the event an applicant exercises this right of appeal prior to exhaustion of the applicant's other procedural rights as described in these Bylaws, the applicant shall notify the OPTN Contractor of this exercise by registered or certified mail, return receipt requested. Upon receiving such notification, the OPTN Contractor shall notify the Secretary of the status of the matter with respect to these procedures within three business days or such longer period as may be necessitated for good cause, as determined by the Secretary. Pending a decision on the appeal, the process defined by these procedures shall continue unless the Secretary directs otherwise. In the event the appeal is denied, the process shall be further continued or reinitiated,

as applicable. Any other decision on the appeal by the Secretary shall be submitted to the MPSC or Board of Directors as appropriate for action consistent with the Secretary's decision.

4.01A No changes

Effect of Board Actions

5.01A – no changes

5.02A – no changes

5.03A – no changes

5.04A – no changes

5.05A - Restoration of Unrestricted Membership

Upon presentation of evidence to the satisfaction of the MPSC that a probationary Member, Member declared Not in Good Standing, or suspended Member has fully complied with OPTN requirements, including completion of actions prescribed as a result of the imposition of sanctions, the MPSC shall recommend that the Board of Directors restore unrestricted membership privileges, in the case of a Member placed on probation or declared Not in Good Standing, or recommend restoration of unrestricted membership privileges to the Secretary of HHS, in the case of suspension of the Member's membership privileges.

The Member must demonstrate to the satisfaction of the MPSC that:

- (i) the Member is in substantial compliance with OPTN requirements;
- (ii) the Member has fully implemented any corrective action plan or action plan previously required by the MPSC; and
- (iii) the Member has demonstrated that the underlying cause for the adverse action has been corrected, or eliminated.

For the purposes of this section, "substantial compliance" means that there are no pending compliance issues that might lead to a Category I violation, and that the type of violation that resulted in the adverse action is not likely to occur again.

There is no timeline for consideration of requests for unrestricted membership, in that time passed does not demonstrate compliance or remedy. The burden is on the member to demonstrate that restoration of membership privileges is appropriate. However, the MPSC may consider requests during its regularly scheduled meetings beginning:

- a) twelve months after the approval of a corrective action plan; or
- b) twelve months after the approval of an action plan subsequent to the Board of Director's or Secretary's adverse action.

In its discretion, the MPSC may require an unannounced site survey and/or peer conducted site visit prior to consideration of the request.

The Member shall be entitled to a Hearing regarding restoration of unrestricted membership only if the MPSC denies the request by the Member and the Member alleges that the MPSC acted arbitrarily and capriciously.

5.06A - Restoration of Privileges after Violation of Mandatory Policies under Section 121.10(c) of the OPTN Final Rule

Upon presentation of evidence to the satisfaction of the MPSC that a Member ~~penalized~~ sanctioned for violation of a mandatory policy under Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), has fully complied with OPTN requirements for the restoration of membership privileges, including completion of actions prescribed as a result of the imposition of sanctions, the MPSC shall recommend that the Board of Directors recommend to the Secretary of HHS that the ~~penalty~~ sanction be removed.

5.07A – Lesser Adverse Actions

If a member requests restoration of unrestricted membership pursuant to Section 5.05 A of Appendix A to the Bylaws, the MPSC may recommend to the Board of Directors the lesser adverse actions of “Probation” or, if the existing status is Probation, a trial reinstatement period. The recommendation may be considered if the Member has demonstrated to the MPSC’s satisfaction that it is:

- i) in substantial compliance with the OPTN requirements;
- ii) the underlying cause for the adverse action is substantially corrected; and
- iii) the corrective action plan or action plan are in the process of being implemented.

For the purposes of this section, “substantial compliance” means that there are no pending compliance issues that might lead to a Category I violation, and that the type of violation that resulted in the adverse action is not likely to occur again.

There is no timeline for consideration of requests for a modification of adverse actions, in that time passed does not demonstrate substantial compliance or correction. The burden is on the member to demonstrate that restoration of membership privileges is appropriate. However, the MPSC may consider requests at its regularly scheduled meetings beginning:

- a) twelve months after that approval of a corrective action plan; or
- b) twelve months after the approval of an action plan subsequent to the Board of Director’s or Secretary’s adverse action.

In its discretion, the MPSC may require an unannounced site survey and/or peer conducted site visit prior to consideration of the request.

The consideration of lesser adverse actions pursuant to this section shall not entitle the Member to an Interview or Hearing under these bylaws. The Member shall be entitled to a Hearing regarding the recommendation for the action of “Probation” or trial reinstatement only if the MPSC denies the request by the Member and the Member alleges that the MPSC acted arbitrarily and capriciously.

No further changes to Appendix A

Summary of Public Comments

1. Individual Comments

As of 4/30/2008, 28 responses have been submitted to UNOS regarding this policy proposal. Of these, 22 (78.57%) supported the proposal, 1 (3.57%) opposed the proposal, and 5 (17.86%) had no opinion. Of the 23 who responded with an opinion, 22 (95.65%) supported the proposal and 1 (4.35%) opposed the proposal. Comments on the proposal received to date are as follows:

I: Individuals Comments:

Comment 1:

vote: Support

Date Posted: 04/15/2008

The verbage is still a bit confusing as it appears that no matter what there will be 12 months before an adverse action will be reconsidered, not 3 or 6 months.

Committee Response: The Committee amended the proposal to clarify the timelines.

Comment 2:

vote: No Opinion

Date Posted: 02/11/2008

I am not sure they should be reinstated at all but this may be unduly harsh.

Committee Response: The Committee considered this response but did not remove the option for reinstatement.

Comment 3:

vote: Oppose

Date Posted: 04/30/2008

Excerpt from letter dated 4 /28/08 from the American Liver Foundation

Secondly, the Membership and Professional Standards Committee has recommended that a policy be established to permit transplant centers, organ procurement organizations, and other UNOS members who fall into the "member not in good standing" category a pathway to restoration of full membership privileges. UNOS members who have been placed on probation and receive the "member not in good standing" classification have been guilty of significant

violations of UNOS policies. ALF would urge that such organizations be readmitted to full privileges only after appropriate personnel and have demonstrated policy and operational changes which necessitated the action taken, and then only upon agreement of a program of rigorous follow up on-site audits.

Committee Response: The Committee agrees that members must demonstrate that substantial changes have been made and sustained.

II. Regional Comments

REGIONAL COMMENT SUMMARY

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Did Not Consider
1	3/31/2008	15 yes, 0 no, 0 abstentions		
2	4/18/2008	21 yes, 0 no, 0 abstentions		
3	5/2/2008	16 yes, 1 no, 0 abstentions		
4	5/2/2008	18 yes, 0 no, 1 abstention		
5	5/1/2008	25 yes, 0 no, 0 abstentions		
6	3/7/2008	39 yes, 0 no, 0 abstentions		
7	4/18/2008	16 yes, 1 no, 0 abstentions		
8	4/25/2008	20 yes, 0 no, 0 abstentions		
9	3/26/2008	14 yes, 1 no, 0 abstentions		
10	3/28/2008	16 yes, 0 no, 0 abstentions		
11	3/20/2008	15 yes, 0 no, 0 abstentions		

III. Comments from Other Committees:

AD HOC INTERNATIONAL RELATIONS COMMITTEE

No Comment

HISTOCOMPATIBILITY COMMITTEE

Support with no comment

KIDNEY TRANSPLANTATION COMMITTEE

The Kidney Transplantation Committee reviewed the requirements during its March 2008 meeting and agrees that they are necessary additions to the OPTN/UNOS Bylaws.

15 in favor, 0 opposed, 0 abstentions

LIVING DONOR COMMITTEE

The Living Donor Committee supports this proposed change to the OPTN/UNOS Bylaws. Since transplant centers may be cited for violation of living donation Bylaws or policies, it is important that those centers have defined timelines for corrective actions and improvement plans to help ensure protection of living donors.

18 in favor, 0 opposed, 0 abstentions

MINORITY AFFAIRS COMMITTEE

The committee determined that there was no minority impact from the proposed policy.

OPERATIONS COMMITTEE

No Comment

ORGAN AVAILABILITY COMMITTEE

The Committee discussed this proposal on their April 14th conference call and neither supports or opposes it and offers no comment.

PANCREAS TRANSPLANTATION COMMITTEE

The Pancreas Committee considered this proposal during its March 14, 2008 meeting. The Committee voted to support this proposal. (14-Support, 0-Oppose, 0-Abstain)

PATIENT AFFAIRS COMMITTEE

The Pancreas Committee considered this proposal during its March 14, 2008 meeting. The Committee voted to support this proposal. (14-Support, 0-Oppose, 0-Abstain)

PEDIATRIC TRANSPLANTATION COMMITTEE

After discussion, the Committee agreed that the additions outlined in the proposal were reasonable. The Committee voted unanimously to support this proposal (Committee vote: 16-0-0).

POLICY OVERSIGHT COMMITTEE

Cedric Sheffield, M.D., reviewed this proposal from the Membership and Professional Standards Committee (MPSC). Due to the nature of the proposal, goals and metrics are not easy to define. UNOS staff will develop a list of review questions that will be more applicable to the development of Bylaw proposals.

One Committee member expressed concern about the use of the word 'may' in: "the MPSC may consider requests during its regularly scheduled meetings." The questions raised are: Can the MPSC refuse a center's request for review after 12 months? Is the burden on the center to make sure the process is moving along? Is there a limit to how long this process can linger on (beyond 12 months)? UNOS staff explained that the intent was that the process cannot begin earlier than 12 months, after substantial demonstration of compliance with the corrective action plan. Committee members asked whether there any circumstances under which a plan of action may not require 12 months? In general, Committee members felt that the policy language is confusing.

Committee Response

The MPSC amended the proposal in response to the questions raised by the Policy Oversight Committee.

THORACIC ORGAN TRANSPLANTATION COMMITTEE

The Committee supported this proposal: 17-Supported; 0-Opposed; 1-Abstention.

TRANSPLANT ADMINISTRATORS COMMITTEE

The TAC supported this proposal with no further comment.

TRANSPLANT COORDINATORS COMMITTEE

The TCC supported this proposal by a vote of 13-0-0.

Proposal Status:

During its May 2008 meeting, the Committee discussed the responses to the proposal that were received during the public comment period. The Committee specifically responded to the recommendation and questions raised by the Policy Oversight Committee and amendments were made to improve the readability of the bylaws thereby making it easier for members to interpret the requirements and under the process.

Changes included

- 5.05A – the content of this section was divided into four subsections with headers including 1) Request for Restoration of Membership Privileges, 2) Time Limits, 3) Additional Requirements, 4) Hearing.
 - 1) Request for Restoration of Membership Privileges: Language was added that clarifies when
 - a member can request restoration of privileges; and
 - that the burden is on the member to demonstrate that restoration of privileges is appropriate.
 - 2) Time Limits: Language was added to address when a member can make an initially or subsequent request.
 - 3) Additional Requirements: Section header was the only change.
 - 4) Hearing: New language clarifies that if requested a hearing will be scheduled at the next regularly scheduled meeting of the MPSC after the request is submitted and at the member’s expense. Costs of participating in a hearing are already addressed in Appendix A, Section 6 (Costs and Expenses).
- 5.07A – Lesser Adverse Actions: Changes were made consistent with Section 5.05A as described above

The Committee recommends the following resolution for consideration by the Board of Director:

**** RESOLVED, that the modifications to the Bylaws, Appendix A, Sections 3.01A Paragraphs (1) and (3) and 5.05A, and new Section 5.07A, as set forth in the [Briefing Paper as amended], are hereby approved, effective June 20, 2008.**

The Committee voted 19 For, 0 Against, 0 Abstentions.

IV. Final Proposal

Note: Double underline/Double Strikeouts are changes recommended by the MPSC post public comment.

Proposed Modifications to the Appendix A of the UNOS and OPTN Bylaws

Bylaw Proposal:

APPENDIX A TO UNOS BYLAWS Interviews and Hearings

3.01A Definition of “Adverse”

- (1) **Recommendations or Actions:** Subject to Section 3.01A (4) below, the following recommendations or actions shall, if deemed adverse pursuant to Section 3.01A (2) below, entitle the applicant or member affected thereby to a hearing:
 - (a) Rejection of initial membership or rejection of designation as a transplant program;
 - (b) Probation;
 - (c) Initial declaration of “Member Not in Good Standing” and subsequent determinations by the Board of Directors or Executive Committee not to restore the Member to unrestricted membership status;
 - (d) Suspension of membership privileges either directly or after a period of probation;
 - (e) Termination of membership, either directly or after a period of probation or suspension; and
 - (f) Any other action specified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c) including, by way of example and not limitation, removal of designation as a transplant program.
- (2) **When Deemed Adverse:** A recommendation or action listed in Section 3.01A (1) above shall be deemed adverse only when it has been:
 - (a) Recommended by the MPSC or, in the case of: (i) rejection of initial membership, (ii) rejection of designation as a transplant program, or (iii) findings with respect to Category I potential violations, recommended by a Subcommittee of the MPSC; or
 - (b) Taken by the Board of Directors or the Executive Committee contrary to a favorable recommendation by the MPSC or subcommittee of the MPSC under circumstances where no right to a hearing existed; or
 - (c) Taken by the Board of Directors or the Executive Committee on its own initiative without benefit of a prior recommendation by the MPSC.
- (3) **Interviews:** Except in the case of Category I potential violations, when the MPSC or MPSC-PCSC is considering making an adverse recommendation concerning an applicant or a Member or issuing a letter of reprimand, or when an organ-specific committee refers a matter to the MPSC/MPSC-PCSC with a recommendation that the MPSC consider such an action under Section 2.05A above, the applicant or Member shall be entitled to an interview before the MPSC or the MPSC-PCSC. The interview shall not constitute a hearing, shall be preliminary in nature, and shall not be conducted according to the procedural rules provided with respect to hearings.

The applicant or Member shall be informed of the general nature of the circumstances and may present information relevant thereto. A summary record of such interview shall promptly be made by the MPSC and a copy promptly provided to the applicant or Member who was granted the interview.

Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for an interview and/or other procedural rights described below.

Members shall not be entitled to an interview in the case of Category I potential violations; or if action is being considered pursuant to 5.05A or 5.07A of these Bylaws.

- (a) An applicant or Member shall have the right to one hearing proceeding, and subsequent appellate review unless the Board of Directors conducts the hearing, with respect to any application for membership, application for designation as a transplant program, and request for corrective action to enforce membership requirements in which an adverse recommendation or action is taken. The hearing may be requested upon the first to occur of the adverse recommendations or actions listed in section 3.01A(1) above or, if waived at such time by the applicant's or member's failure to request a hearing within the time and in the manner specified in section 3.02A below, upon any subsequent adverse recommendation or action arising out of the same application for membership, application for designation as a transplant program, or request for corrective action to enforce membership requirements.
- (b) **Category I Potential Violations.** In the case of a determination of time sensitive threat to patient health or public safety in connection with Category I potential violations, the hearing and any subsequent appellate review will commence together with or follow rather than precede the Executive Committee's or the Board's decision regarding and action upon the MPSC subcommittee's recommendation, as set forth below:
 - (i) The MPSC subcommittee recommendation will be referred immediately to the Executive Committee. At the same time, notice will be given to the Member by registered or certified mail, return receipt requested, as well as facsimile transmission. Where the finding continues to be a Category I potential violation with time sensitive threat to patient health or public safety, the MPSC subcommittee action shall include a recommendation for designation of the Member to be Member Not in Good Standing and that the offending transplant program or institution voluntarily inactivate, and, failing acceptance of this recommendation to voluntarily inactivate with immediate action to so inactivate (including notice to and assistance for patients pursuant to UNOS requirements);
 - (ii) Following receipt of the MPSC subcommittee recommendation, the Executive Committee shall determine whether it or the Board of Directors shall consider the matter and the Executive Committee or the Board, as the case may be, shall consider the same and affirm, modify, or reverse the recommendation or action in the matter. A concise statement of the result and the reasons therefore, and all documentation considered, shall be transmitted to the Executive Director;
 - (iii) The Executive Director, or his/her designee, shall promptly send a copy of the result to the Member by registered or certified mail, return receipt requested (as well as facsimile transmission) if the decision continues to be adverse to the Member. A copy of the result also shall be forwarded to the MPSC or to the Board of Directors, as determined by the Executive Committee, in the event the Member exercises its rights to a hearing under Section 3.02A of the Bylaws.

The Member may request that a copy of the supporting documentation be furnished at the Member's expense;

- (iv) Notice of a decision by the Executive Committee or Board that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members; and
- (v) In the event the Member exercises its right to a hearing, the process described in Section 3.02A will be initiated or continued, as applicable, consistent with the timing of delivery and receipt of notices. The hearing will be before the MPSC, the Board or the Executive Committee as determined by the Executive Committee.

Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take other appropriate action using other appropriate process even if the steps noted above for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for a hearing and/or subsequent appellate review.

Members will not be entitled to a Hearing in the case that action is being considered pursuant to 5.05A or 5.07A of these Bylaws, except as provided in those sections.

3.02 A - no changes

3.03 A - no changes

4.01A – no changes

Effect of Board Actions

5.01A – no changes

5.02A – no changes

5.03A – no changes

5.04A [RESERVED]

5.05A Restoration of Unrestricted Membership

Upon presentation of evidence to the satisfaction of the MPSC that a probationary Member, Member declared Not in or a suspended Member has fully complied with UNOS Good Standing requirements, including completion of actions prescribed as a result of the imposition of sanctions, the MPSC shall recommend that the Board of Directors restore unrestricted membership privileges, in the case of a Member placed on probation or declared Not in Good Standing, or recommend restoration of unrestricted membership privileges, in the case of suspension of the Member's membership privileges.

1) Request for Restoration of Membership Privileges. A Member may request restoration of membership privileges after demonstration of substantial compliance with the corrective action plan. The Member must demonstrate to the satisfaction of the MPSC that:

- (iv) the Member is in substantial compliance with OPTN requirements;
- (v) the Member has fully implemented any corrective action plan or action plan previously required by the MPSC; and

(vi) the Member has demonstrated that the underlying cause for the adverse action has been corrected, or eliminated.

For the purposes of this section, “substantial compliance” means that there are no pending compliance issues that might lead to a Category I violation, and that the type of violation that resulted in the adverse action is not likely to occur again.

There is no presumption in favor of granting requests for restoration of unrestricted membership, in that time passed does not demonstrate compliance or remedy. The burden is on the Member at all times to demonstrate that restoration of membership privileges is appropriate.

2) **Time Limits.** The burden is on the member to demonstrate that restoration of membership privileges is appropriate. However, the MPSC will only consider requests during its regularly scheduled meetings. The Member may not request restoration of membership privileges until on or after:

- a) twelve months after the approval of a corrective action plan, or
- b) twelve months after the approval of an action plan subsequent to the Board of Director’s or Secretary’s adverse action.

In the event that the MPSC denies the Member’s request for restoration of membership privileges, the Member may renew its request six months from the date of the MPSC denial of its prior request.

3) **Additional Requirements.** In its discretion, the MPSC may require an unannounced site survey and/or peer conducted site visit prior to consideration of the request.

4) **Hearing.** If the MPSC denies the Member’s request for restoration of privileges under this section, then the Member shall be entitled to a Hearing with the MPSC at the next regularly scheduled meeting of the MPSC after the Member submits such request and at the Member’s expense consistent with these bylaws. ~~regarding restoration of unrestricted membership only if the MPSC denies the request by the Member and the Member alleges that the MPSC acted arbitrarily and capriciously.~~

5.06A Restoration of Privileges after Violation of Mandatory Policies under Section 121.10(c) of the OPTN Final Rule

Upon presentation of evidence to the satisfaction of the MPSC that a Member ~~penalized~~ sanctioned for violation of a mandatory policy under Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), has fully complied with requirements for the restoration of membership privileges, including completion of actions prescribed as a result of the imposition of sanctions, the MPSC shall recommend to the Board of Directors that the ~~penalty~~ sanction be removed.

5.07A – Lesser Adverse Actions

If a Member requests restoration of unrestricted membership pursuant to Section 5.05A of Appendix A to the Bylaws, the MPSC may recommend to the Board of Directors the lesser adverse actions of “Probation” or, if the existing status is Probation, a trial reinstatement period. The recommendation may be considered if the Member has demonstrated to the MPSC’s satisfaction that it is:

- i) in substantial compliance with OPTN requirements;
- ii) the underlying cause for the adverse action is substantially corrected; and
- iii) the corrective action plan or action plan are in the process of being implemented.

For the purposes of this section, “substantial compliance” means that there are no pending compliance issues that might lead to a Category I violation, and that the type of violation that resulted in the adverse action is not likely to occur again.

There is no timeline for consideration of requests for a modification of adverse actions, in that time passed does not demonstrate substantial compliance or correction. There is no presumption in favor of granting requests for unrestricted membership, in that time passed does not demonstrate compliance or remedy. The burden is on the member at all times to demonstrate that restoration of membership privileges is appropriate. However, the MPSC ~~may~~ will only consider requests during its regularly scheduled meetings, beginning: The Member may not request restoration of membership privileges under this section until on or after:

- a) twelve months after the approval of a corrective action plan, or
- b) twelve months after the approval of an action plan subsequent to the Board of Director’s or Secretary’s adverse action.

In its discretion, the MPSC may require an unannounced site survey and/or peer conducted site visit prior to consideration of the request.

The consideration of lesser adverse actions pursuant to this section shall not entitle the Member to an Interview or Hearing under these bylaws. The Member shall be entitled to a Hearing at the Member’s expense consistent with these bylaws regarding the recommendation for the action of “Probation” or trial reinstatement only if the MPSC denies the request by the Member and the Member alleges that the MPSC acted arbitrarily and capriciously. In the event that the MPSC denies the Member’s request for restoration of membership privileges under this section, the Member may renew its request six months from the date of the MPSC denial of its prior request.

No further changes to Appendix A

APPENDIX A TO OPTN BYLAWS
Interviews and Hearings

3.01A - Definition of "Adverse"

- (1) **Recommendations or Actions:** Subject to Section 3.01a (4) below, the following recommendations or actions shall, if deemed adverse pursuant to Section 3.01a (2) below, entitle the applicant or Member affected thereby to a hearing:
 - (a) Rejection of initial membership or rejection of designation as a transplant program;
 - (b) Probation;
 - (c) Initial declaration of Member Not in Good Standing and subsequent determinations by the Board of Directors or Executive Committee not to restore the Member to unrestricted membership status;
 - (d) Suspension of membership privileges either directly or after a period of probation;
 - (e) Termination of membership, either directly or after a period of probation or suspension.
 - (f) Any other action specified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), including, by way of example and not limitation, removal of designation as a transplant program.

- (2) **When Deemed Adverse:** A recommendation or action listed in section 3.01a (1) above shall be deemed adverse only when it has been:
 - (a) Recommended by the MPSC or, in the case of: (i) rejection of initial membership, (ii) rejection of designation as a transplant program, or (iii) findings with respect to Category I potential violations, recommended by a Subcommittee of the MPSC; or
 - (b) Taken by the Board of Directors or the Executive Committee contrary to a favorable recommendation by the MPSC or subcommittee of the MPSC under circumstances where no right to a hearing existed; or
 - (c) Taken by the Board of Directors or the Executive Committee on its own initiative without benefit of a prior recommendation by the MPSC.

- (3) **Interviews:** Except in the case of Category I potential violations, when the MPSC or MPSC-PCSC is considering making an adverse recommendation concerning an applicant or a Member or issuing a letter of reprimand, or when an organ-specific committee refers a matter to the MPSC/MPSC-PCSC with a recommendation that the MPSC consider such an action under Section 2.05A above, the applicant or Member shall be entitled to an interview before the MPSC or the MPSC-PCSC. The interview shall not constitute a hearing, shall be preliminary in nature, and shall not be conducted according to the procedural rules provided with respect to hearings. The applicant or Member shall be informed of the general nature of the circumstances and may present information relevant thereto. A summary record of such interview shall promptly be made by the MPSC and a copy promptly provided to the applicant or Member who was granted the interview. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for an interview and/or other procedural rights described below.

Members shall not be entitled to an interview in the case of Category I potential violations; or if action is being considered pursuant to 5.05A or 5.07A of these bylaws.

- (4) **Right to a Hearing:**
 - (a) An applicant or Member shall have the right to one hearing proceeding, and subsequent appellate review unless the Board of Directors conducts the hearing, with respect to any

application for membership, application for designation as a transplant program, and request for corrective action to enforce membership requirements in which an adverse recommendation or action is taken. The hearing may be requested upon the first to occur of the adverse recommendations or actions listed in section 3.01A(1) above or, if waived at such time by the applicant's or member's failure to request a hearing within the time and in the manner specified in section 3.02A below, upon any subsequent adverse recommendation or action arising out of the same application for membership, application for designation as a transplant program, or request for corrective action to enforce membership requirements.

- (b) **Category I Potential Violations.** In the case of a determination of time sensitive threat to patient health or public safety in connection with Category I potential violations, the hearing and any subsequent appellate review will commence together with or follow rather than precede the Executive Committee's or the Board's decision regarding and action upon the MPSC subcommittee's recommendation, as set forth below:
- (i) The MPSC subcommittee recommendation will be referred immediately to the Executive Committee. At the same time, notice will be given to the Member by registered or certified mail, return receipt requested, as well as facsimile transmission. Where the finding continues to be a Category I potential violation with time sensitive threat to patient health or public safety, the MPSC subcommittee action shall include a recommendation for designation of the Member to be Member Not in Good Standing and that the offending transplant program or institution voluntarily inactivate, and, failing acceptance of this recommendation to voluntarily inactivate with immediate action to so inactivate (including notice to and assistance for patients pursuant to OPTN requirements), the MPSC subcommittee shall further recommend approval from the Secretary to suspend member privileges, terminate membership or designated transplant program status, and/or take action specified in the OPTN Final Rule.
 - (ii) Following receipt of the MPSC subcommittee recommendation, the Executive Committee shall determine whether it or the Board of Directors shall consider the matter and the Executive Committee or the Board, as the case may be, shall consider the same and affirm, modify, or reverse the recommendation or action in the matter. A concise statement of the result and the reasons therefore, and all documentation considered, shall be transmitted to the Executive Director.
 - (iii) The Executive Director, or his/her designee, shall promptly send a copy of the result to the Member by registered or certified mail, return receipt requested (as well as facsimile transmission), and to the Secretary of HHS within three business days or such longer period as may be necessitated for good cause, as determined by the Secretary, if the decision continues to be adverse to the Member. A copy of the result also shall be forwarded to the MPSC or to the Board of Directors, as determined by the Executive Committee, in the event the Member exercises its rights to a hearing under Section 3.02A of the Bylaws. The Member may request that a copy of the supporting documentation be furnished at the Member's expense.
 - (iv) Notice of a decision by the Executive Committee or Board that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members. The membership shall be notified of decisions by the Executive Committee or Board to recommend to the Secretary of HHS suspension of membership privileges or termination of membership only upon approval of such recommendation by the Secretary.

- (v) In the event the Member exercises its right to a hearing, the process described in Section 3.02A will be initiated or continued, as applicable, consistent with the timing of delivery and receipt of notices. The hearing will be before the MPSC, the Board or the Executive Committee as determined by the Executive Committee.

Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take other appropriate action using other appropriate process even if the steps noted above for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for a hearing and/or subsequent appellate review.

Members shall not be entitled to a Hearing in the case that action pursuant to 5.05A or 5.07A of these bylaws is being considered, except as provided in those sections.

- (5) **Right of Appeal to the Secretary.** An applicant for membership or designation as a transplant program shall have the right to appeal decisions of the MPSC, MPSC subcommittees, or the Board of Directors regarding these applications to the Secretary of HHS in accordance with the OPTN Final Rule, 42 CFR Part 121. In the event an applicant exercises this right of appeal prior to exhaustion of the applicant's other procedural rights as described in these Bylaws, the applicant shall notify the OPTN Contractor of this exercise by registered or certified mail, return receipt requested. Upon receiving such notification, the OPTN Contractor shall notify the Secretary of the status of the matter with respect to these procedures within three business days or such longer period as may be necessitated for good cause, as determined by the Secretary. Pending a decision on the appeal, the process defined by these procedures shall continue unless the Secretary directs otherwise. In the event the appeal is denied, the process shall be further continued or reinitiated, as applicable. Any other decision on the appeal by the Secretary shall be submitted to the MPSC or Board of Directors as appropriate for action consistent with the Secretary's decision.

4.01A No changes

Effect of Board Actions

5.01A – no changes

5.02A – no changes

5.03A – no changes

5.04A – no changes

5.05A - Restoration of Unrestricted Membership

Upon presentation of evidence to the satisfaction of the MPSC that a probationary Member, Member declared Not in Good Standing, or suspended Member has fully complied with OPTN requirements, including completion of actions prescribed as a result of the imposition of sanctions, the MPSC shall recommend that the Board of Directors restore unrestricted membership privileges, in the case of a Member placed on probation or declared Not in Good Standing, or recommend restoration of unrestricted membership privileges to the Secretary of HHS, in the case of suspension of the Member's membership privileges.

- 1) **Request for Restoration of Membership Privileges.** A Member may request restoration of membership privileges after demonstration of substantial compliance with the corrective action plan. The Member must demonstrate to the satisfaction of the MPSC that:

- a) the Member is in substantial compliance with OPTN requirements;
- b) the Member has fully implemented any corrective action plan or action plan previously required by the MPSC; and
- c) the Member has demonstrated that the underlying cause for the adverse action has been corrected, or eliminated.

For the purposes of this section, “substantial compliance” means that there are no pending compliance issues that might lead to a Category I violation, and that the type of violation that resulted in the adverse action is not likely to occur again.

There is no presumption in favor of granting ~~timeline for consideration of~~ requests for unrestricted membership, in that time passed does not demonstrate compliance or remedy. The burden is on the Member at all times to demonstrate that restoration of membership privileges is appropriate.

- 2) **Time Limits.** ~~The burden is on the member to demonstrate that restoration of membership privileges is appropriate. However, the~~ The MPSC ~~may~~ will only consider requests during its regularly scheduled meetings. ~~beginning;~~ The Member may not request restoration of membership privileges until on or after:

- a) twelve months after the approval of a corrective action plan, or
- b) twelve months after the approval of an action plan subsequent to the Board of Director’s or Secretary’s adverse action.

In the event that the MPSC denies the Member’s request for restoration of membership privileges, the Member may renew its request six months from the date of the MPSC denial of its prior request.

- 3) **Additional Requirements.** In its discretion, the MPSC may require an unannounced site survey and/or peer conducted site visit prior to consideration of the request.
- 4) **Hearing.** If the MPSC denies the Member’s request for restoration of privileges under this section, then ~~the~~ The Member shall be entitled to a Hearing with the MPSC at the next regularly scheduled meeting of the MPSC after the Member submits such request and at the Member’s expense consistent with these bylaws. ~~regarding restoration of unrestricted membership only if the MPSC denies the request by the Member and the Member alleges that the MPSC acted arbitrarily and capriciously.~~

5.06A - Restoration of Privileges after Violation of Mandatory Policies under Section 121.10(c) of the OPTN Final Rule

Upon presentation of evidence to the satisfaction of the MPSC that a Member ~~penalized~~ sanctioned for violation of a mandatory policy under Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), has fully complied with OPTN requirements for the restoration of membership privileges, including completion of actions prescribed as a result of the imposition of sanctions, the MPSC shall recommend that the Board of Directors recommend to the Secretary of HHS that the ~~penalty~~ sanction be removed.

5.07A – Lesser Adverse Actions

If a member requests restoration of unrestricted membership pursuant to Section 5.05 A of Appendix A to the Bylaws, the MPSC may recommend to the Board of Directors the lesser adverse actions of “Probation” or, if the existing status is Probation, a trial reinstatement period. The recommendation may be considered if the Member has demonstrated to the MPSC’s satisfaction that it is:

- i) in substantial compliance with the OPTN requirements;
- ii) the underlying cause for the adverse action is substantially corrected; and
- iii) the corrective action plan or action plan are in the process of being implemented.

For the purposes of this section, “substantial compliance” means that there are no pending compliance issues that might lead to a Category I violation, and that the type of violation that resulted in the adverse action is not likely to occur again.

There is no timeline for consideration of requests for a modification of adverse actions, in that time passed does not demonstrate substantial compliance or correction. The burden is on the member at all times to demonstrate that restoration of membership privileges is appropriate. However, the MPSC ~~may~~ will only consider requests during its regularly scheduled meetings. ~~beginning~~. The Member may not request restoration of membership privileges under this section until on or after:

- a) twelve months after the approval of a corrective action plan, or
- b) twelve months after the approval of an action plan subsequent to the Board of Director’s or Secretary’s adverse action.

In its discretion, the MPSC may require an unannounced site survey and/or peer conducted site visit prior to consideration of the request.

The consideration of lesser adverse actions pursuant to this section shall not entitle the Member to an Interview or Hearing under these bylaws. The Member shall be entitled to a Hearing at the Member’s expense consistent with these bylaws, regarding the recommendation for the action of “Probation” or trial reinstatement only if the MPSC denies the request by the Member and the Member alleges that the MPSC acted arbitrarily and capriciously. In the event that the MPSC denies the Member’s request for restoration of membership privileges under this section, the Member may renew its request six months from the date of the MPSC denial of its prior request.

No further changes to Appendix A

BRIEFING PAPER

Proposal to Change the Elector System for Histocompatibility Lab Members and Medical/Scientific Members: OPTN and UNOS Bylaws, Article I, (Members); Article II (Board of Directors), Article VI (Officers).

Sponsoring Committee: Membership and Professional Standards Committee (MPSC)

This proposal eliminates the current elector system for voting privileges and responsibilities for Histocompatibility Laboratory Members and Medical/Scientific Organizations. This proposal permits each histocompatibility laboratory and each medical/scientific member a single vote in the affairs of the OPTN/UNOS and removes the need for separate national elections for both the histocompatibility member and medical/scientific member electors.

Affected groups:

Histocompatibility Laboratory Members
Medical/Scientific Organization Members
All OPTN members

Summary and Goals of the Proposal:

This bylaw proposal eliminates the current elector system for voting privileges and responsibilities for histocompatibility laboratory members and medical/scientific organizations. This bylaw proposal permits each histocompatibility laboratory and each medical/scientific member a single vote in the affairs of the OPTN/UNOS and removes the need for separate national elections for both the histocompatibility member and medical/scientific member electors.

Background and Significance of Proposal:

In November 2003, the OPTN/UNOS Board of Directors adopted the OPTN charter and bylaws and related modifications to the UNOS bylaws. These changes created a need for member histocompatibility laboratories to nominate and elect both regional and national electors. According to Article I (Members) Section 1.9(c) (Voting Privileges and Responsibilities – Histocompatibility Laboratory Members) as a class, were to be represented by 33 separate histocompatibility laboratory member electors. Each histocompatibility laboratory member elector was to be entitled to one vote on OPTN or UNOS affairs and the electors would be elected by the histocompatibility laboratory members. Presently, there are 58 independent histocompatibility laboratories. Under the former bylaws, each histocompatibility laboratory received a single vote in the affairs of the OPTN/UNOS.

In November 2003, the Board of Directors also adopted changes to the bylaws that created a need for member medical/scientific organizations to elect national electors. According to Article I (Members) Section 1.9(d) (Voting Privileges and Responsibilities-Medical/Scientific Members) of the OPTN/UNOS bylaws, the medical/scientific members that provide services and/or are involved in activities on an interregional or national basis, as a class, would be

represented by 24 separate national medical/scientific member electors. Each medical/scientific member elector would be entitled to one vote on OPTN/UNOS affairs requiring a vote of the membership. Medical/scientific member electors were to be elected by and from among the medical/scientific members. Presently, there are 21 medical/scientific members. Under the former bylaws, each medical/scientific member received a single vote in the affairs of the OPTN/UNOS.

Each of the separate elections required under the electors system creates unnecessary complexity in the OPTN, adds additional burden to OPTN contractor staff, and adds costs to OPTN operations. Moreover, there is no evidence to support that allowing each independent histocompatibility laboratory or each medical/scientific member to have voting eligibility would increase the voting potential of the membership group substantially. Thus, voting eligibility would remain fair among the voting classes absent the elector system for these classes of member. Therefore, the Membership and Professional Standards Committee is proposing bylaw modifications that would permit each histocompatibility laboratory and medical/scientific member to receive one vote in OPTN/UNOS and remove the need for separate national elections for both the histocompatibility member and medical/scientific member electors.

Plan for Evaluating the Proposal:

This bylaw proposal does not require monitoring.

Additional data collection:

Additional data collection will not be required as a result of this bylaw change.

Expected Implementation Plan:

This proposed bylaw requires programming to accurately reflect the voting types in the member database. Programming should not delay implementation.

Communication/Education Plan:

This bylaw would be communicated via the policy notice process and through a summary update at each regional meeting.

Monitoring and Evaluation:

This bylaw proposal does not require monitoring.

Bylaw Proposal:

Changes made following public comment are shown as double underline, double ~~strikeout~~.

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

BYLAWS

ARTICLE I

MEMBERS

- 1.1 **Membership Categories.** No Changes
- 1.2 **Institutional Members.** No Change.
- 1.3 **Medical/Scientific Members.** No Changes.
- 1.4 **Public Organization Members.** No Changes
- 1.5 **Business Members.** No changes
- 1.6 **Individual Members.** No Changes
- 1.7 **Application Process and Requirements/Appeal Protocol.** No Changes
- 1.8 **Terms.** No Changes.
- 1.9 **Voting Privileges and Responsibilities.** There shall be six classes of voting Members: (i) Transplant Hospital Members, (ii) OPO Members, (iii) Histocompatibility Laboratory Members, (iv) Medical/Scientific Members, (v) Public Organization Members, and (vi) Individual Members. OPTN Members designated “OPTN Members Not in Good Standing” shall not have voting or other OPTN Member privileges until such designation has been removed; provided, however, that all OPTN Members, including Members designated “OPTN Members Not in Good Standing” shall be obligated to comply with OPTN Member responsibilities. Business Members shall not be entitled to voting privileges in OPTN affairs.
 - a. **Transplant Hospital Members.** Each Transplant Hospital Member shall be entitled to one vote on OPTN affairs requiring a vote of the Membership; provided, however, that a Transplant Hospital must have received approval as a designated transplant program for at least one organ before it is entitled to vote on affairs of the OPTN.
 - b. **OPO Members.** Each OPO Member shall be entitled to one vote on OPTN affairs requiring a vote of the Membership; provided, however, that an OPO must be independent of the Transplant Hospital(s) it serves, which may include a single Transplant Hospital, before it is entitled to vote on affairs of the OPTN. For purposes of the OPTN Charter and Bylaws, independence from Transplant Hospital(s) served shall be defined by demonstration of a distinct governing body for the OPO that is separate and not under the direct or indirect control of the governing body of any of the OPO’s Transplant Hospitals or of the governing body of a commonly controlled group of the OPO’s Transplant Hospitals.

- c. Histocompatibility Laboratory Members.** ~~Histocompatibility Laboratories, as a class, shall be represented by 33 separate Histocompatibility Laboratory Member Electors. Each Histocompatibility Laboratory Member Elector shall be entitled to one vote on OPTN affairs requiring a vote of the Membership. Histocompatibility Laboratory Member Electors shall be elected by and from among the Histocompatibility Laboratory Members as follows:~~
- ~~(i) Histocompatibility Laboratory Members residing within each of the 11 Regions (as defined in Article 2.4 of these Bylaws) shall elect two Histocompatibility Laboratory Member Electors from their respective region. If there are no Histocompatibility Laboratory Members residing within a Region, then the number of national Histocompatibility Laboratory Member Electors described in (ii) below shall be increased by two for every such Region without Histocompatibility Laboratory Members.~~
 - ~~(ii) All Histocompatibility Laboratory Members, collectively, shall elect eleven national Histocompatibility Laboratory Member Electors or, if there are no Histocompatibility Laboratory Members residing in one or more regions, as many national Histocompatibility Laboratory Member Electors as necessary so that there are no more than and no fewer than 33 Histocompatibility Laboratory Member Electors.~~
 - ~~(iii) Any person serving as or designated by the named OPTN Representative for a Histocompatibility Laboratory Member may serve as a Histocompatibility Laboratory Member Elector upon nomination for and election to this office. OPTN Representatives for Histocompatibility Laboratory Members may submit their own names as candidates for Histocompatibility Laboratory Member Elector, representing Histocompatibility Laboratory Members at the regional or national level. For the number of Histocompatibility Laboratory Member Electors to be elected regionally or nationally, those receiving the highest number of votes among eligible candidates shall be elected.~~
 - ~~(iv) The term of a Histocompatibility Laboratory Member Elector shall be two years. Histocompatibility Laboratory Member Electors may serve successive terms.~~
 - ~~(v) Nominations and elections for Histocompatibility Laboratory Member Elector shall be conducted through the Internet using the OPTN web site, www.optn.org, and/or the United States mail. The number of Histocompatibility Laboratory Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 9% and 11% of the then current total number of Institutional Members.~~

Notwithstanding the foregoing, in the event the total number of Histocompatibility Laboratory Members at any time at which a vote of the OPTN membership is to take place is equal to or fewer than the then current number of Histocompatibility Laboratory Member Electors, the process for voting through Member Electors described above shall be suspended and each such Histocompatibility Laboratory Member shall be entitled to one vote on any OPTN matter requiring a vote of the Membership.

- d. Medical/Scientific Members.** ~~Medical/Scientific Members that provide services and/or are involved in activities on an interregional or national basis, as a class, shall be represented by 24 separate national Medical/Scientific Member Electors. Each Medical/Scientific Member Elector shall be entitled to one vote on OPTN affairs requiring a vote of the Membership. Medical/Scientific Member Electors shall be elected by and from among the Medical/Scientific Members as follows:~~

- ~~(i) All Medical/Scientific Members, collectively, shall elect the 24 national Medical/Scientific Member Electors.~~
- ~~(ii) Any person serving as or designated by the named OPTN Representative for a Medical/Scientific Member may serve as a Medical/Scientific Member Elector upon nomination for and election to this office. OPTN Representatives for Medical/Scientific Members may submit their own names as candidates for Medical/Scientific Member Elector, representing Medical/Scientific Members at the national level. For the number of Medical/Scientific Member Electors to be elected nationally, those receiving the highest number of votes among eligible candidates shall be elected.~~

- ~~(iii) — The term of a Medical/Scientific member Elector shall be two years or the remaining OPTN Membership term of the Medical/Scientific member with whom the Medical/Scientific Member Elector is affiliated, whichever is shorter. Medical/Scientific Member Electors may serve successive terms.~~
- ~~(iv) — Nominations and elections for Medical/Scientific Member Elector shall be conducted through the Internet using the OPTN web site, www.optn.org, and/or the United States mail.~~

~~The number of Medical/Scientific Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 6% and 8% of the then current total number of Institutional members.~~

~~Medical/Scientific Members must provide services and/or be involved in activities on an interregional or national basis to participate in the election of Medical/Scientific Member Electors.~~

~~Notwithstanding the foregoing, in the event the total number of Medical/Scientific Members in good standing at any time at which a vote of the OPTN membership is to take place is equal to or fewer than the then current number of Medical/Scientific Member Electors, the process for voting through Member Electors described above shall be suspended and each such Medical/Scientific Member shall be entitled to one vote on any OPTN matter requiring a vote of the Membership.~~

e. Public Organization Members. No Changes.

f. Individual Members. Individual Members, as a class, shall be represented by 12 separate Individual Member Electors. Each Individual Member Elector shall be entitled to one vote on OPTN affairs requiring a vote of the Membership. Individual Member Electors shall be elected by and from among the Individual Members as follows:

- (i) Individual Members residing within each of the 11 Regions (as defined in Article 2.4 of these Bylaws) shall elect one Individual Member Elector from their respective region. If there are no Individual Members residing within a Region, then the number of national Individual Member Electors described in (ii) below shall be increased by one for every such Region without Individual Members.
- (ii) All Individual Members, collectively, shall elect a twelfth national Individual Member Elector or, if there are no Individual Members residing in one or more regions, as many national Individual Member Electors as necessary so that there are no more than and no fewer than 12 Individual Member Electors.
- (iii) With the exception of employees currently employed by or independent contractors currently working with OPOs, Transplant Hospitals, or Histocompatibility Laboratories, any Individual Member may serve as an Individual Member Elector upon nomination for and election to this office. Individual Members may submit their own names as candidates for Individual Member Elector, representing Individual Members at the regional or national level. For the number of Individual Member Electors to be elected nationally, those receiving the highest number of votes among eligible candidates shall be elected.
- (iv) The term of an Individual Member Elector shall be two years or the remaining OPTN Membership term of the Individual Member elected to the office of Individual Member Elector, whichever is shorter. Individual Member Electors may serve successive terms.
- (v) Nominations and elections for Individual Member Elector shall be conducted through the Internet using the OPTN web site, www.optn.org, and/or the United States mail.

The number of Individual Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 3% and 5% of the then current total number of Institutional Members.

Notwithstanding the foregoing, in the event the total number of Individual Members at any time at which a vote of the OPTN membership is to take place is equal to or fewer than the then current number of Individual Member Electors, the process for voting through Member Electors described above shall be suspended and each such Individual Member shall be entitled to one vote on any OPTN matter requiring a vote of the Membership.

Affairs of the OPTN involving a vote of the Membership include, for example, election of the Board of Directors (see Article II of these Bylaws), election of the Principal Officers (see Article VI of these Bylaws), and amendment of these Bylaws (see Article X of these Bylaws).

Cumulative voting on affairs of the OPTN is not allowed.

Upon being elected to Membership in the OPTN, each Institutional Member, Medical/Scientific Member and Public Organization Member shall indicate its acceptance by appointing a representative with authority to vote and act for the Member in all affairs of the OPTN and an alternate representative who shall have such authority if the representative is unable to vote or act. Additionally, each Institutional Member, Medical/Scientific Member and Public Organization Member shall notify the Executive Director in writing of the name and address of its representative, to whom all notices may be sent, and of its alternate representative. Upon being elected to Membership in the OPTN, each Business Member shall indicate its acceptance by designating in writing the name of a representative and address to which notices may be sent. Upon his or her election, each Individual Member shall notify the Executive Director in writing of his or her name and address to which notices may be sent.

A majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Medical/Scientific Members ~~Electors~~, Public Organization Member Electors, and Individual Member Electors, eligible to vote represented in person or by proxy, shall constitute a quorum for the transaction of business at any meeting. A vote of a majority of those present and eligible to vote shall be sufficient to transact any business that might come before the meeting, except where a greater or lesser vote is provided for in the Bylaws.

1.10 Member Obligations. No Changes

1.11 Removal of Non-Qualifying Members. No Changes

1.12 Meetings. The annual meeting of the Members to elect a Board of Directors pursuant to Article 2.1 of these Bylaws, to elect Principal Officers pursuant to Section 6.1 of these Bylaws and to address such other matters as may be appropriate shall be held in February or March of each calendar year and may be held in conjunction with the annual meeting of the Board of Directors. Special meetings of the Members may be called at any time by the President, Executive Director, or a majority of the Board of Directors, or by written application of a majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors stating the time, place, and purpose of the meeting. Members attending meetings shall do so at no cost to the OPTN. Meetings of the OPTN membership typically shall be open to the public; however, discussions involving confidential matters including, OPTN member admission, credentialing, monitoring, or disciplinary matters and matters involving individuals' privacy where disclosure would constitute a clearly unwarranted invasion of personal privacy, shall be reserved for closed sessions as appropriate and consistent with the OPTN Contract. Representatives from the Federal government serving on the Board of Directors, or their designees, shall not be precluded from attending such closed sessions of OPTN meetings.

Written notice of any regular or special meeting of the Members shall state the date, time, and place of the meeting and the purpose for which the meeting is called, and shall be mailed to each Member not fewer than 25 or more than 60 days before the date of the meeting. Giving notice of a meeting of Members to a

Member or Member Elector who is not eligible to vote does not imply that the Member or Member Elector may vote.

A written waiver of notice signed at any time by a Member or Member Elector shall be the equivalent of any notice required herein. A Member or Member Elector who attends a meeting shall be deemed to have had timely and proper notice of the meeting unless the Member or Member Elector attends for the express purpose of objecting that the meeting is not lawfully called or convened.

1.13 Registration Fees. No changes

1.14 Expenses Incurred on Behalf of Members. No Changes.

1.15 Affiliated Organizations. No Changes.

ARTICLE II

BOARD OF DIRECTORS

2.1 Authority. The OPTN Board of Directors governs the OPTN and is responsible for developing policies and criteria within the mission of the OPTN.

2.2 Election/Terms. Members of the OPTN Board of Directors shall be elected by majority vote of Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors represented in person or by proxy at each annual meeting of the Members at which a quorum is present. Directors may also be elected at any special meeting of the Members if the Board of Directors is being expanded. Directors shall serve for a term of two years, with exceptions as noted below, which shall begin immediately following the conclusion of the last regular meeting of the Board of Directors prior to July 1 of each calendar year. Members of the Board who are transplant candidates, transplant recipients, organ donors, or family members, or representatives of voluntary health organizations or the general public shall serve for a term of three years. Board members who also hold positions as Officers serve one year terms, with the exception of the Treasurer and Secretary who shall have staggered terms with one another and shall serve two year terms and the Vice President of Patient & Donor Affairs who shall serve for a term of two years. Each voting Transplant Hospital Member, OPO Member, Histocompatibility Laboratory Member ~~Elector~~, Public Organization Member Elector, Medical/Scientific Member ~~Elector~~, and Individual Member Elector is entitled to one vote for each Director position to be elected. There shall be no cumulative voting.

2.3 Number. [No changes].

2.4 Regions. There shall be eleven (11) geographic regions in the United States. The current composition of these regions is set forth in Article IX. Changes to this composition shall require approval of the Board of Directors. The Board shall maintain procedures for the election of one "Councillor" and one "Associate Councillor" from each region by vote of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, and Individual Member Electors for the Region and individuals who both reside in the region and have voting privileges at regional meetings as set forth in this section. The Councillor will serve as the representative of these Members and individuals. The Associate Councillor shall represent the region on the Membership and Professional Standards Committee and act in place of the Councillor during his absence or disability. Unless otherwise directed by the Board of Directors or the President, regional elections shall be completed on or before December 31 of each year and shall be held in accordance with one of the following protocols selected by the incumbent Councillor after consultation with or vote of his region's Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member

Electors, and Individual Member Electors and individuals residing in the region who have voting privileges at Regional meetings as set forth in this section:

- a. There shall be a single slate of nominees for Councillor submitted by Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members, ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, or individuals with voting privileges at regional meetings. The person who receives the second highest number of votes in the election shall be the Associate Councillor; or
- b. There shall be a slate of nominees for Councillor and a separate slate for the Associate Councillor, chosen in either case from nominations submitted by Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members, ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, or persons with voting privileges at regional meetings; or
- c. There shall be a separate slate for Councillor and another slate for Associate Councillor/Councillor-Elect. After one such election, there shall be a slate for a new Associate Councillor/Councillor-Elect, with the incumbent in that position becoming the Councillor automatically. In each case, the slate shall be composed of nominations submitted by Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members, ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, or persons with voting privileges at regional meetings.

The Councillor and Associate Councillor of each region shall be elected for the same term, which shall be either one year or two years, beginning in each case on the date of the annual meeting of the Members following his or her election. The Councillors or Associate Councillors shall not succeed themselves in office. The Councillor from each region shall be responsible, along with the President and the Executive Director, for organizing and coordinating regional activities to carry out purposes of the OPTN. The Nominating Committee in preparing its slate of nominees for election as Director at each annual meeting of Members, shall include as a Director nominee each Councillor who has been elected by the region's Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members, ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, and persons residing in the regions who have voting privileges at regional meetings to serve for a term that includes the year following the upcoming annual meeting of Members, with the goal of assuring to the greatest extent possible that at least one representative of each region will serve on the Board of Directors at all times. A Councillor may be removed from office with or without cause by majority vote of all the region's Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members, ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, and persons residing in the region who have voting privileges at regional meetings, as evidenced by signed ballots presented to the President or the Board of Directors.

Each Transplant Hospital Member, OPO Member, Regional Histocompatibility Laboratory Member, ~~Elector~~, the Regional Public Organization Member Elector, and the Regional Individual Member Elector (other than an Institutional Member or Public Organization Member from a category that is not named in the Charter as amended or restated) who resides in a region shall have one vote on any matter before the region for a vote, including the election of Councillor and Associate Councillor. Any person currently serving on an OPTN standing committee who is a representative of the general public (including, for example, patients and their families, donors, donor families, and individuals drawn from the fields of law, theology, ethics, health care financing, the social and behavioral sciences, and labor and management unrelated to the field of health care) and who is not employed by or on the medical staff of an Institutional Member, Medical/Scientific Member or Public Organization Member also may vote on all regional business. Additionally, one or more representatives of Medical/Scientific Members with principal offices located in a Region may vote on regional business, as determined by and pursuant to such protocols as developed by the respective Regions.

2.5 Meetings. No Changes.

2.6 Notice of Meetings. No Changes.

- 2.7 **Quorum.** No Changes.
- 2.8 **Committees.** No Changes.
- 2.9 **Conflicts of Interest.** No Changes.
- 2.10 **Removal from Office.** A Director may be removed from office with or without cause, but only by the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors at a meeting called and noticed expressly for the purpose of voting to remove him/her.
- 2.11 **Relationship of OPTN Board and OPTN Contractor's Board.** No Changes.

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

BYLAWS

These Bylaws govern the structure and operation of the Organ Procurement and Transplantation Network (OPTN). By accepting membership in the OPTN, each Member agrees to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies as in effect from time to time. The OPTN will conduct ongoing and periodic reviews and evaluations of each Member OPO and Transplant Hospital for compliance with the OPTN Final Rule and OPTN policies. All OPTN Members are subject to review and evaluation for compliance with OPTN policies. All such compliance monitoring is performed using processes and protocols developed by the OPTN Contractor in accordance with the contract with the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), to operate the OPTN (OPTN Contract).

ARTICLE VI

OFFICERS

- 6.1 **Officers.** The Principal Officers of the OPTN shall be a President, Vice President, Vice President of Patient and Donor Affairs, Treasurer, and Secretary. They shall be elected by the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors at the annual meeting of Members and shall assume the duties of their respective positions immediately following the conclusion of the last regular meeting of the Board of Directors prior to July 1 of each calendar year. The Assistant Officers shall be one or more Assistant Treasurers and one or more Assistant Secretaries, who shall be elected from time to time by the Board of Directors upon nomination by the President. The Principal Officers shall serve for a term of one year, except for the Secretary and Treasurer, who shall have staggered terms with one another and shall serve for a term of two years, and except for the Vice President of Patient and Donor Affairs who shall serve for a term of two years. No person may hold more than one position at the same time, except that the Treasurer shall also serve as an Assistant Secretary. All Principal Officers shall serve without compensation.

[No Further changes to this section]

UNOS Bylaws

ARTICLE I

MEMBERS

- 1.1 [No changes]
- 1.2 **Institutional Members** [No changes]
- 1.3 **Medical/Scientific Members.** [No changes]
- 1.4 **Public Organization Members.** [No changes]
- 1.5 **Business Members.** [No changes]
- 1.6 **Individual Members.** [No changes]
- 1.7 **Application Process and Requirements/Appeal Protocol.** [No changes].
- 1.8 **Terms.** [No changes].
- 1.9 **Voting Privileges and Responsibilities.** There shall be six classes of voting Members: (i) Transplant Hospital Members, (ii) OPO Members, (iii) Histocompatibility Laboratory Members, (iv) Medical/Scientific Members, (v) Public Organization Members, and (vi) Individual Members. Members designated “Members Not in Good Standing” shall not have voting or other Member privileges until such designation has been removed; provided, however, that all UNOS Members, including Members designated “Members Not in Good Standing” shall be obligated to comply with Member responsibilities. Business Members shall not be entitled to voting privileges in UNOS corporate affairs. All voting members of the Organ Procurement and Transplantation Network (OPTN) shall be entitled to voting privileges in UNOS Board of Directors and Officer elections.
- a. Transplant Hospital Members. [No changes]
- b. OPO Members. [No changes]
- c. Histocompatibility Laboratory Members. ~~Histocompatibility Laboratories, as a class, shall be represented by 33 separate Histocompatibility Laboratory Member Electors. Each Histocompatibility Laboratory Member Elector shall be entitled to one vote on UNOS affairs requiring a vote of the Membership. Histocompatibility Laboratory Member Electors shall be elected by and from among the Histocompatibility Laboratory Members as follows:~~
- (i) ~~Histocompatibility Laboratory Members residing within each of the 11 Regions (as defined in Article 2.4 of these Bylaws) shall elect two Histocompatibility Laboratory Member Electors from their respective region. If there are no Histocompatibility Laboratory Members residing within a Region, then the number of national Histocompatibility Laboratory Member Electors described in (ii) below shall be increased by two for every such Region without Histocompatibility Laboratory Members.~~
- (ii) ~~All Histocompatibility Laboratory Members, collectively, shall elect eleven national Histocompatibility Laboratory Member Electors or, if there are no Histocompatibility Laboratory Members residing in one or more regions, as many national Histocompatibility Laboratory Member Electors as necessary so that there are no more than and no fewer than 33 Histocompatibility Laboratory Member Electors.~~

- (iii) — Any person serving as or designated by the named UNOS Representative for a Histocompatibility Laboratory Member may serve as a Histocompatibility Laboratory Member-Elector upon nomination for and election to this office. UNOS Representatives for Histocompatibility Laboratory Members may submit their own names as candidates for Histocompatibility Laboratory Member-Elector, representing Histocompatibility Laboratory Members at the regional or national level. For the number of Histocompatibility Laboratory Member-Electors to be elected regionally or nationally, those receiving the highest number of votes among eligible candidates shall be elected.
- (iv) — The term of a Histocompatibility Laboratory Member-Elector shall be two years. Histocompatibility Laboratory Member-Electors may serve successive terms.
- (v) — Nominations and elections for Histocompatibility Laboratory Member-Elector shall be conducted through the Internet using the UNOS web site, www.unos.org, and/or the United States mail.

The number of Histocompatibility Laboratory Member-Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 9% and 11% of the then current total number of Institutional Members.

Notwithstanding the foregoing, in the event the total number of Histocompatibility Laboratory Members at any time at which a vote of the UNOS membership is to take place is equal to or fewer than the then current number of Histocompatibility Laboratory Member-Electors, the process for voting through Member-Electors described above shall be suspended and each such Histocompatibility Laboratory Member shall be entitled to one vote on any UNOS matter requiring a vote of the Membership.

d. **Medical/Scientific Members.** Medical/Scientific Members that provide services and/or are involved in activities on an interregional or national basis, as a class, shall be represented by 24 separate national Medical/Scientific Member-Electors. Each Medical/Scientific Member-Elector shall be entitled to one vote on UNOS affairs requiring a vote of the Membership. Medical/Scientific Member-Electors shall be elected by and from among the Medical/Scientific Members as follows:

- (i) — All Medical/Scientific Members, collectively, shall elect the 24 national Medical/Scientific Member-Electors.
- (ii) — Any person serving as or designated by the named UNOS Representative for a Medical/Scientific Member may serve as a Medical/Scientific Member-Elector upon nomination for and election to this office. UNOS Representatives for Medical/Scientific Members may submit their own names as candidates for Medical/Scientific Member-Elector, representing Medical/Scientific Members at the national level. For the number of Medical/Scientific Member-Electors to be elected nationally, those receiving the highest number of votes among eligible candidates shall be elected.
- (iii) — The term of a Medical/Scientific member-Elector shall be two years or the remaining UNOS Membership term of the Medical/Scientific member with whom the Medical/Scientific Member-Elector is affiliated, whichever is shorter. Medical/Scientific Member-Electors may serve successive terms.
- (iv) — Nominations and elections for Medical/Scientific Member-Elector shall be conducted through the Internet using the UNOS web site, www.unos.org, and/or the United States mail.

The number of Medical/Scientific Member-Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 6% and 8% of the then current total number of Institutional members.

~~Medical/Scientific Members must provide services and/or be involved in activities on an interregional or national basis to participate in the election of Medical/Scientific Member Electors.~~

~~Notwithstanding the foregoing, in the event the total number of Medical/Scientific Members in good standing at any time at which a vote of the UNOS membership is to take place is equal to or fewer than the then current number of Medical/Scientific Member Electors, the process for voting through Member Electors described above shall be suspended and each such Medical/Scientific Member shall be entitled to one vote on any UNOS matter requiring a vote of the Membership.~~

e. Public Organization Members. [No changes]

f. **Individual Members.** Individual Members, as a class, shall be represented by 12 separate Individual Member Electors. Each Individual Member Elector shall be entitled to one vote on UNOS affairs requiring a vote of the Membership. Individual Member Electors shall be elected by and from among the Individual Members as follows:

- (i) Individual Members residing within each of the 11 Regions (as defined in Article 2.4 of these Bylaws) shall elect one Individual Member Elector from their respective region. If there are no Individual Members residing within a Region, then the number of national Individual Member Electors described in (ii) below shall be increased by one for every such Region without Individual Members.
- (ii) All Individual Members, collectively, shall elect a twelfth national Individual Member Elector or, if there are no Individual Members residing in one or more regions, as many national Individual Member Electors as necessary so that there are no more than and no fewer than 12 Individual Member Electors.
- (iii) With the exception of employees currently employed by or independent contractors currently working with OPOs, Transplant Hospitals, or Histocompatibility Laboratories, any Individual Member may serve as an Individual Member Elector upon nomination for and election to this office. Individual Members may submit their own names as candidates for Individual Member Elector, representing Individual Members at the regional or national level. For the number of Individual Member Electors to be elected nationally, those receiving the highest number of votes among eligible candidates shall be elected.
- (iv) The term of an Individual Member Elector shall be two years or the remaining UNOS Membership term of the Individual Member elected to the office of Individual Member Elector, whichever is shorter. Individual Member Electors may serve successive terms.
- (v) Nominations and elections for Individual Member Elector shall be conducted through the Internet using the UNOS web site, www.unos.org, and/or the United States mail.

The number of Individual Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 3% and 5% of the then current total number of Institutional Members.

Notwithstanding the foregoing, in the event the total number of Individual Members at any time at which a vote of the UNOS membership is to take place is equal to or fewer than the then current number of Individual Member Electors, the process for voting through Member Electors described above shall be suspended and each such Individual Member shall be entitled to one vote on any UNOS matter requiring a vote of the Membership.

Affairs of the UNOS involving a vote of the Membership include, for example, election of the Board of Directors (see Article II of these Bylaws), election of the Principal Officers (see Article VI of these Bylaws), and amendment of these Bylaws (see Article X of these Bylaws).

Cumulative voting on affairs of the UNOS is not allowed.

Upon being elected to Membership in the UNOS, each Institutional Member, Medical/Scientific Member and Public Organization Member shall indicate its acceptance by appointing a representative with authority to vote and act for the Member in all affairs of the UNOS and an alternate representative who shall have such authority if the representative is unable to vote or act. Additionally, each Institutional Member, Medical/Scientific Member and Public Organization Member shall notify the Executive Director in writing of the name and address of its representative, to whom all notices may be sent, and of its alternate representative. Upon being elected to Membership in UNOS, each Business Member shall indicate its acceptance by designating in writing the name of a representative and address to which notices may be sent. Upon his or her election, each Individual Member shall notify the Executive Director in writing of his or her name and address to which notices may be sent.

A majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Medical/Scientific Members ~~Electors~~, Public Organization Member Electors, and Individual Member Electors, eligible to vote represented in person or by proxy, shall constitute a quorum for the transaction of business at any meeting. A vote of a majority of those present and eligible to vote shall be sufficient to transact any business that might come before the meeting, except where a greater or lesser vote is provided for in the Bylaws.

1.10 Member Obligations. [No changes]

1.11 Removal of Non-Qualifying Members. [No changes]

1.12 Meetings. The annual meeting of the Members to elect a Board of Directors pursuant to Article 2.1 of these Bylaws, to elect Principal Officers pursuant to Section 6.1 of these Bylaws and to address such other matters as may be appropriate shall be held in February or March of each calendar year and may be held in conjunction with the annual meeting of the Board of Directors. Special meetings of the Members may be called at any time by the President, Executive Director, or a majority of the Board of Directors, or by written application of a majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors stating the time, place, and purpose of the meeting. Members attending meetings shall do so at no cost to UNOS. Meetings of the UNOS membership typically shall be open to the public; however, discussions involving confidential matters including, UNOS member admission, credentialing, monitoring, or disciplinary matters and matters involving individuals' privacy where disclosure would constitute a clearly unwarranted invasion of personal privacy, shall be reserved for closed sessions as appropriate and consistent with the OPTN Contract.

Written notice of any regular or special meeting of the Members shall state the date, time, and place of the meeting and the purpose for which the meeting is called, and shall be mailed to each Member not fewer than 25 or more than 60 days before the date of the meeting. Giving notice of a meeting of Members to a Member or Member Elector who is not eligible to vote does not imply that the Member or Member Elector may vote.

A written waiver of notice signed at any time by a Member or Member Elector shall be the equivalent of any notice required herein. A Member or Member Elector who attends a meeting shall be deemed to have had timely and proper notice of the meeting unless the Member or Member Elector attends for the express purpose of objecting that the meeting is not lawfully called or convened.

[No further changes to this section]

ARTICLE II
BOARD OF DIRECTORS

2.1 Authority. [No changes].

2.2 Election/Terms. Members of the Board of Directors shall be elected by majority vote of Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors represented in person or by proxy at each annual meeting of the Members at which a quorum is present. Directors may also be elected at any special meeting of the Members if the Board of Directors is being expanded. Directors shall serve for a term of two years, with the exceptions noted below, which shall begin immediately following the conclusion of the last regular meeting of the Board of Directors prior to July 1 of each calendar year. Members of the Board who are transplant candidates, transplant recipients, organ donors, or family members, or representatives of voluntary health organizations or the general public shall serve for a term of three years. Board members who also hold positions as Officers serve one year terms, with the exception of the Treasurer and Secretary who shall have staggered terms with one another and shall serve two year terms and the Vice President of Patient & Donor Affairs, who shall serve for a term of two years. Each voting Transplant Hospital Member, OPO Member, Histocompatibility Laboratory Member ~~Elector~~, Public Organization Member Elector, Medical/Scientific Member ~~Elector~~, and Individual Member Elector is entitled to one vote for as many persons as there are Directors to be elected. There shall be no cumulative voting.

2.3 Number. [No changes]

2.4 Regions. There shall be eleven (11) geographic regions in the United States. The current composition of these regions is set forth in Article IX. Changes to this composition shall require approval of the Board of Directors. The Board shall maintain procedures for the election of one "Councillor" and one "Associate Councillor" from each region by vote of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, and Individual Member Electors for the Region and individuals who both reside in the region and have voting privileges at Regional meetings as set forth in this section. The Councillor will serve as the representative of these Members and individuals. The Associate Councillor shall represent the region on the Membership and Professional Standards Committee and act in place of the Councillor during his or her absence or disability. Unless otherwise directed by the Board of Directors or the President, regional elections shall be completed on or before December 31 of each year and shall be held in accordance with one of the following protocols selected by the incumbent Councillor after consultation with or vote of his region's Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, and Individual Member Electors and individuals residing in the region who have voting privileges at Regional meetings as set forth in this section:

- a. There shall be a single slate of nominees for Councillor submitted by Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, the Public Organization Member Elector, or individuals with voting privileges at Regional meetings. The person who receives the second highest number of votes in the election shall be the Associate Councillor; or
- b. There shall be a slate of nominees for Councillor and a separate slate for the Associate Councillor, chosen in either case from nominations submitted by Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, or persons with voting privileges at Regional meetings; or
- c. There shall be a separate slate for Councillor and another slate for Associate Councillor/Councillor-Elect. After one such election, there shall be a slate for a new Associate

Councillor/Councillor-Elect, with the incumbent in that position becoming the Councillor automatically. In each case, the slate shall be composed of nominations submitted by Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, or persons with voting privileges at Regional meetings.

The Councillor and Associate Councillor of each region shall be elected for the same term, which shall be either one year or two years, beginning in each case on the date of the annual meeting of the Members following his or her election. The Councillors or Associate Councillors shall not succeed themselves in office. The Councillor from each region shall be responsible, along with the President and the Executive Director, for organizing and coordinating regional activities to carry out the purposes of the Corporation. The Nominating Committee in preparing its slate of nominees for election as Director at each annual meeting of Members, shall include as a Director nominee each Councillor who has been elected by the region's Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, and persons residing in the region who have voting privileges at regional meetings to serve for a term that includes the year following the upcoming annual meeting of Members, with the goal of assuring to the greatest extent possible that at least one representative of each region will serve on the Board of Directors at all times. A Councillor may be removed from office with or without cause by majority vote of all the region's Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, and persons residing in the region who have voting privileges at Regional meetings, as evidenced by signed ballots presented to the President or the Board of Directors.

Each Transplant Hospital Member, OPO Member, Regional Histocompatibility Laboratory Member ~~Elector~~, the Regional Public Organization Member Elector, and the Regional Individual Member Elector (other than an Institutional Member or Public Organization Member from a category that is not named in the Articles of Incorporation as amended or restated) who resides in a region shall have one vote on any matter before the region for a vote, including the election of Councillor and Associate Councillor. Any person currently serving on a UNOS standing committee who is a representative of the general public (including, for example, patients and their families, donors, donor families, and individuals drawn from the fields of law, theology, ethics, health care financing, the social and behavioral sciences, and labor and management unrelated to the field of health care) and who is not employed by or on the medical staff of an Institutional Member, Medical/Scientific Member or Public Organization Member also may vote on all regional business. Additionally, one or more representatives of Medical/Scientific Members with principal offices located in a Region may vote on regional business, as determined by and pursuant to such protocols as developed by the respective Regions.

- 2.5 **Meetings.** [No changes].
- 2.6 **Notice of Meetings.** [No changes].
- 2.7 **Quorum.** [No changes].
- 2.8 **Committees.** [No changes].
- 2.9 **Conflicts of Interest.** [No changes].
- 2.10 **Removal from Office.** A Director may be removed from office with or without cause, but only by the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors at a meeting called and noticed expressly for the purpose of voting to remove him/her.
- 2.11 **Relationship of UNOS Board of Directors and OPTN Board of Directors.** [No changes].

ARTICLE VI

OFFICERS

- 6.1 Officers.** The principal Officers of the Corporation shall be a President, Vice President, Vice President of Patient and Donor Affairs, Treasurer, and Secretary. Such principal Officers shall be elected by the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors at the annual meeting of Members and shall assume the duties of their respective offices immediately following the conclusion of the last regular meeting of the Board of Directors prior to July 1 of each calendar year. The assistant Officers shall be one or more Assistant Treasurers and one or more Assistant Secretaries, who shall be elected from time to time by the Board of Directors upon nomination by the President. The Principal Officers shall serve for a term of one year, except for the Treasurer and Secretary, who shall have staggered terms with one another and shall serve for a term of two years and except for the Vice President of Patient and Donor Affairs who shall serve for a term of two years. No person may hold more than one office at the same time, except that the Treasurer shall also serve as an Assistant Secretary. Election as President shall constitute appointments as Chairman of the Board of Directors. All principal Officers shall serve without compensation.

[No further changes to this section]

Summary of Public Comments

1. Individual Comments

As of 4/30/2008, 30 responses have been submitted to UNOS regarding this policy proposal. Of these, 22 (73.33%) supported the proposal, 2 (6.67%) opposed the proposal, and 6 (20.00%) had no opinion. Of the 24 who responded with an opinion, 22 (91.67%) supported the proposal and 2 (8.33%) opposed the proposal. Comments on the proposal received to date are as follows:

Comment 1:

vote: Oppose

Date Posted: 02/11/2008

An election is a good system

Committee Response: No response required

Comment 2:

vote: Support

Date Posted: 04/04/2008

ASHI approves of this change in the UNOS Bylaws.

Committee Response: No response required

II. Regional Comments

REGIONAL COMMENT SUMMARY

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Did Not Consider
1	3/31/2008	14 yes, 0 no, 0 abstentions		
2	4/18/2008	19 yes, 2 no, 0 abstentions		
3	5/2/2008	13 yes, 0 no, 4 abstentions		
4	5/2/2008	14 yes, 3 no, 2 abstentions		
5	5/1/2008	25 yes, 0 no, 0 abstentions		
6	3/7/2008	34 yes, 0 no, 5 abstentions		
7	4/18/2008	16 yes, 1 no, 0 abstentions		
8	4/25/2008	20 yes, 0 no, 0 abstentions		
9	3/26/2008	17 yes, 0 no, 0 abstentions		
10	3/28/08	15 yes, 1 no, 0 abstentions		
11	3/20/2008	15 yes, 0 no, 0 abstentions		

Region 4: Several members in the region do not think it is fair that the hospital based laboratories will not receive a vote in the affairs of the OPTN/UNOS.

Committee Response: This Comment was not received prior to the MPSC meeting, however, consideration of voting rights for in-house labs, in-house OPOs, and organ transplant programs who shared under a single institutional membership. This element of the bylaws was not specifically under consideration at this time.

III. Comments from Other Committees:

AD HOC INTERNATIONAL RELATIONS COMMITTEE

No Comment

HISTOCOMPATIBILITY COMMITTEE

Approve.

The elimination of the vote for Independent Histocompatibility laboratories was punitive as it reduced the overall representation of laboratories in the OPTN. This proposal is fairer than the original system in that it provides a voice for all labs, not just the independent ones. It will also improve OPTN operations and reduce operating costs by eliminating separate national elections.

Committee Response: The Committee agrees.

KIDNEY TRANSPLANTATION COMMITTEE

No Comment

LIVER AND INTESTINAL ORGAN TRANSPLANTATION COMMITTEE

No Comment

MINORITY AFFAIRS COMMITTEE

The committee determined that there was no minority impact from the proposed policy.

OPERATIONS COMMITTEE

No Comment

OPO COMMITTEE

The OPO Committee chose not to discuss this proposal.

ORGAN AVAILABILITY COMMITTEE

The Committee reviewed this proposal on a conference call April 14th and chose not to discuss.

PANCREAS TRANSPLANTATION COMMITTEE

No comment.

PATIENT AFFAIRS COMMITTEE

The Patient Affairs Committee supported the proposal with a vote of 14-0-0.

PEDIATRIC TRANSPLANTATION COMMITTEE

After discussion, the Committee determined there was no specific pediatric issue requiring further comment.

POLICY OVERSIGHT COMMITTEE

Dr. Orlowski reviewed this proposal from the MPSC, which will permit each histocompatibility laboratory and each medical/scientific member a single vote in the affairs of the OPTN/UNOS and removes the need for separate national elections for both the histocompatibility member and medical/scientific member electors. This proposal simplifies a complicated system. The Committee was generally in support of the proposal, but would like to know the total number of electors and the percentage change this proposal would bring about.

Committee Response: There are 81 Electors, and 373 votes total. 33 are Histocompatibility Laboratory Member Electors, 12 are Individual Member Electors, 12 are Public Organization Member Electors, and 24 are Medical/Scientific Member Electors.

THORACIC ORGAN TRANSPLANTATION COMMITTEE

The Committee supported this proposal: 14-Supported; 0-Opposed; 4-Abstention. The Committee inquired whether this bylaw change would impact future Committee membership.

Committee Response: This change will not impact future Committee membership.

TRANSPLANT ADMINISTRATORS COMMITTEE

No Comment.

TRANSPLANT COORDINATORS COMMITTEE

No comment.

Post Public Comment Consideration:

The Committee met on May 6-7, 2008, to discuss feedback to this public comment proposal. The Committee decided to make not to make any changes to the bylaw language that was sent out for public comment. The Committee voted to send the proposal to the Board of Directors for approval in June 2008.

**** RESOLVED, that the modifications to the OPTN Bylaws, Article I, (Members); Article II (Board of Directors), Article VI (Officers), as set forth in Exhibit M-2, and corresponding modifications to the UNOS Articles of Incorporation, are hereby approved, effective June 20, 2008.**

The Committee voted 26 For, 0 Against, 0 Abstentions.