

OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE REPORT
March 23, 2007
SUMMARY

I. Action Items for Board Consideration:

- The Board of Directors is asked to approve for designated program status one new transplant center, two new programs in an existing member centers, and nine existing live donor liver programs. (Item 1, Page 5).
- The Board of Directors is asked to approve the continued membership of five medical/scientific member organizations and one public organization member for a two-year term. (Item 1, Page 5).
- The Board of Directors is asked to grant full approval to one existing program that now meets the full requirements for that organ. (Item 1, Page 5).
- The Board of Directors is asked to approve proposed revisions to the Bylaws, Appendix B, Attachment I, Section VI “Transplant Surgeon & Physician,” and Section XII(C) “Transplant Programs.” These modifications further define what “on site” means with relation to availability of transplant surgeons and physicians to provide service to their patients in need of organ transplantation. The objective is to make existing criteria regarding physician and surgeon availability more clear and specific. (Item 4, Pages 8-15).
- The Board of Directors is asked to approve proposed revisions to the Bylaws, Appendix B, Section II, “Transplant Hospitals,” “Investigation of Personnel”; Appendix B, Attachment 1, Section IV “Investigation of Personnel,” Section VII “Transplant Surgeon and Physician”; and Appendix B, Attachment I, Section XII (C). These modifications to the Bylaws are expected to enhance oversight of individual physicians and surgeons. (Item 5, Pages 15-25).

II. Other Significant Items:

- Committee Goals: During its January/February meeting the Committee was presented with the Goals that had been approved for the next year and the progress that had been made on each. (Item 2, Pages 5-6)
- Update on the Efforts of the Joint Work Group for MPSC Process Improvement. The Committee was updated on the reports and discussion that took place during the December 2006 Board of Directors meeting. The Joint Subcommittee was divided into three Work Groups to review and develop suggested improvements and then propose changes to the membership review process and standards. Staff will continue to work with the Joint Subcommittee to develop bylaw modifications to allow the OPTN to enhance its processes. (Item 3, Pages 6-8).
- Offer/Organ Acceptance Rate Modeling: The Committee was updated on the Process Improvement Work Group’s progress in the development of an agreeable methodology for collecting and analyzing organ acceptance/turndown rates and deaths on the waiting list, which can be used to evaluate program performance. (Item 6, Pages 25-26).

- Program Related Actions and Personnel Changes: The Committee reviewed 51 key personnel change applications during its January/February meeting (Item 7, Page 26).
- Due Process Proceedings: The Committee conducted five interviews and held five informal discussions with member organizations. Two transplant hospitals made presentations before the Committee. (Item 8, Page 26).
- Update on Inclusion of Donation after Cardiac Death (DCD) protocols in Transplant Center Membership: The MPSC was updated on the progress of the DCD Policy Working Group that was established for the purpose of developing policy as it pertains to the oversight of DCD protocols. (Item 9, Pages 26-27).
- Update on Live Donor Liver Transplant Program Application Process: Staff provided the Committee with an update on the number of live donor liver programs that had been processed and their status (Item 10, Pages 27-28).
- Live Donor Liver Transplant Program Requirements: The Committee discussed the requirements for living donor programs and provided guidance to the Living Donor Policy Work Group on the development of oversight requirements and the content of the live donor kidney program application (Item 11, Pages 28-31).
- Update on Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data). A Subcommittee of the MPSC initially reviewed two cases of a death of a live donor that occurred prior to the January/February meeting. They concluded that no further action was required as there was not any evidence of a policy violation and patient safety issues at the center were not exposed. The Committee reviewed the findings of the Subcommittee during its January/February meeting and agreed that no further action was required (Item 12, Page 32).
- Pancreas Outcome Analysis Model: The Committee was updated on the ongoing issue of pancreas (including kidney/pancreas and pancreas after kidney) program outcome monitoring. The SRTR was asked to evaluate potential models and possibilities available for increasing the sample size so the analytical model could be applied to pancreas programs. During the October 11, 2006, MPSC meeting, the Committee was informed that the SRTR was prepared to begin work to create the model. However, the Committee agreed that the Pancreas Transplantation Committee needed to review the variables, including recipient and donor risk factors, before development of the model. The MPSC was informed that the Pancreas Transplantation Committee will be considering this issue during their next meeting. (Item 13, Page 32).
- Proposed Modifications to Data Elements on UNetSM Transplant Recipient Follow-up (TRF) Form. The proposal would significantly reduce the number of data elements that transplant centers will be required to submit on the Transplant Recipient Follow-up (TRF) form after 5 years post-transplant. The Committee voted to support the proposal. (Item 15, Page 33).
- Proposed Modifications to OPTN/UNOS Policy 3.1 (Organ Distribution: Definitions). The aim of the proposed policy modifications is to improve patient safety by requiring verification of UNOS Donor ID number of all organs prior to transplant. The Committee voted to support the proposal and made further recommendations for refinement. (Item 16, Page 33).

- Number of days a program has its waitlist inactive (but not membership): Staff presented the Committee with an overview of the programs that during had periods when the Waitlist Program Status field was set to temporarily inactive during 2006, but the program had not inactivated its membership status. 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. (Item 18, Page 34-35).
- UNOS Actions: During the January/February meeting, 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 20, page 35).

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**REPORT OF THE
OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE
TO THE
BOARD OF DIRECTORS
St. Louis, MO
March 23, 2007**

**Timothy L. Pruett, M.D., Chair
Niloo M. Edwards, M.D., Vice Chair**

- I. Regular Committee Meetings. The following report presents the Membership and Professional Standards Committee's (MPSC) deliberations and recommendations on matters considered by the Committee during its January 30 – February 1, 2007, meeting.
1. Membership Application Issues: The Committee recommends that the Board of Directors approve one new transplant center, two new programs in existing member centers, and nine live donor liver programs.

In addition to considering applications for institutional membership, the Committee reviewed applications for continued medical/scientific and public organization membership (two-year term), and recommends continued membership for these members.

Reports from Conditionally Approved Programs: During its January 2007 meeting, the Committee approved a change in status of a lung transplant program from 24-month conditional approval to full approval. The program had previously been conditionally approval pending full certification of the primary surgeon by the American Board of Thoracic Surgery.

Report on Application for Designated Transplant Program Status of a Registered Pancreas Islet Program: During its October 2006 meeting, the Committee made a unanimous determination that a Center's application for designated transplant program status of its registered pancreas islet transplant program should be closed as incomplete because the application remained incomplete over a year after it was submitted, and that the four patients on the Center's waitlist should be removed. The Center was notified in writing of the Committee's determination, and the Center submitted a written response withdrawing its registered pancreas islet transplant program effective November 16, 2006. The Center also removed the patients from its pancreas islet waitlist.

2. Overview of Committee Goals: During its January/February meeting, the Committee reviewed the goals that had been approved for the year and the progress that had been made on each. A summary of the goals and the progress made on each is described below:
- Goal: Develop the process for action on referral made to MPSC as a result of the new policy requiring notification of death or listing for transplant of a living donor.
Progress: Members were informed of the requirement and have begun to use the new online reporting option in the Patient Safety System that was activated on January 3, 2007. (See Section 14 of this report for additional details).
 - Goal: Partner with Living Donor Committee to determine what policies are needed to provide oversight of living donor programs (donor safety and patient outcomes).

Progress: A Work Group has been formed and has been reviewing information distributed electronically. Members of the Work Group also met briefly on January 31, 2007, during the MPSC meeting to further define their specific goals and plans to further involve representatives from the Living Donor Committee. (See Section 13 of this report for additional details).

- Goal: Participate in the working group to be established by the OPO Committee to develop the required elements of the mandated DCD protocols.
Progress: MPSC members participated in the DCD Working Group developing protocol guidelines. The Board approved the modification to the Bylaws that establishes model elements to be included in DCD protocols during its December 2006 meeting.
- Goal: Consider any policy or procedures that need to be put in place to support violations of the newly passed policy that requires all DCD procurements to be done in accordance with an established protocol.
Progress: During the October Meeting of the MPSC, a DCD Policy Subcommittee was established and charged with developing policy and methods for monitoring and enforcing compliance as it pertains to the oversight of approved DCD protocols. The MPSC was given a progress updated during its January/February meeting. (See Section 11 below for additional details).
- Goal: Continue work with SRTR to develop organ specific acceptance rate metrics of center performance.
Progress: The SRTR provided acceptance rate data factoring in a couple of newly identified variables. The MPSC Process Improvement Work Group 1 met by conference call on January 18, 2007, to discuss this issue and has recommended a pilot study through the Data Subcommittee. The MPSC was given a progress updated during its January/February meeting. (See Section 7 below for additional details).
- Goal: Provide a 6-month update to Board on progress or changes made in implementing the 2006 MPSC improvement project
Progress: A report was included in the December 2006 report to the Board of Directors as well as this document.
- Goal: Provide to the Finance Committee prior to the March 2007 Board meeting, an update on budgetary needs for next financial year.
Progress: Developed budgetary needs for presentation to the Finance Committee by March 2007.

The Committee also discussed their work in terms of the HHS Program Goals and the Strategic Plan Goals. While the goals are not necessarily specific to the work of the Committee, it was agreed that it has a role with increasing DCD.

3. Update on the Efforts of the Joint Work Group for MPSC Process Improvement: At the November 2005 Board meeting, the Executive Committee and the Board of Directors directed the Membership and Professional Services Committee (MPSC) to form a work group composed of members of the MPSC and the Board of Directors to identify improvements for, and propose changes to, the membership review processes and standards. The Board called for a special report from the Joint Work Group for MPSC Process Improvements to be presented at the March

2006 Board meeting. This report was to include recommendations on how the OPTN might change existing bylaws and enhance its processes.

The initiative was prompted, in large part, by reviews of situations involving non-compliance with OPTN requirements, which highlighted certain aspects of the MPSC's work that could benefit from reassessment. This included, for example, methods for expediting the detection of such situations as well as addressing them once detected, further definition of concepts addressing need for physicians and surgeons to be on hand at transplant programs to provide transplant services, and methods to prevent individuals from repeating inappropriate behavior engaged in at one institution, upon moving to a second institution. The initiative was further prompted by the need generally to take advantage of opportunities for self reflection and improvement.

Given the short time frame (March 2006) for the Group to report its recommendations, the issues were divided among three smaller working groups. Each group met at least twice by conference call; once face to face on February 1, 2006; and then collectively on January 11 and February 2, 2006, to discuss their assigned tasks and form recommendations. The MPSC Chair presented these recommendations along with estimated implementation costs to the Board of Directors at the March 2006 Meeting. The Board reviewed the recommendations and requested that the Work Group continue refining and developing them into specific Bylaw and policy proposals for the June 2006 Board Meeting.

During its July 2006 meeting, the Committee was updated on the discussion that took place during the June 2006 Board of Directors meeting regarding the review and development of suggested process improvements, and then proposed changes to the membership review process and standards.

Understanding that further efforts for process improvements were still underway, the Board requested that the proposals be distributed for Public Comment immediately. These recommendations were distributed for public comment on August 28, 2006, for a period of 30 days. The MPSC recommended that the Board approve the proposals that are now complete after the period of public comment. The two proposals that are being recommended for approval in this report and the one that remains under development will be further discussed below.

The goals are listed below by their current status:

Completed Goals:

- The establishment of a confidential communication line directly to UNOS for individuals wishing to divulge sensitive information;
- Consideration of procedures that would improve the timeliness of required compliance with corrective action, site visit action plans, and MPSC review, along with requirements that failure of a center to meet timelines would prompt immediate consideration of adverse action; and the same would apply to instances of dishonesty in the provision of information or failure to adhere to representations in documents submitted;
- A Bylaw requiring members to notify the OPTN of reviews and adverse actions taken against them by other organizations.

Goals Recommended to the Board for Final Action:

- A Bylaw requirement specifically defining what constitutes onsite availability of transplant surgeon and physician coverage (see Item 4 below);
- Consideration of a bylaw that would prohibit a physician or surgeon who has been a primary focus in assessing activity leading to an adverse action which involves loss of membership of a program or a center to not be permitted to be primary physician or surgeon at another UNOS approved program (see Item 5 below);

Goals – Still under Development:

- Bylaws that enable the MPSC to determine how organ acceptance/turndown rates and deaths on the waiting list will be evaluated and incorporated into the standard elements of center performance in addition to patient and graft survival (work on this proposal continues in development and an update is provided in Item 6 below.

4. Proposed Modifications to Bylaws, Appendix B, Attachment I, Section VI “Transplant Surgeon & Physician,” and Section XII(C) “Transplant Programs” (Proposal 2): This proposal further defines what “on site” means with relation to availability of transplant surgeons and physicians to provide service to their patients in need of organ transplantation. The objective is to make existing criteria regarding physician and surgeon availability clearer and more specific.

Background: During its meeting in May 2006, the MPSC reviewed recommendations that had been provided by the Process Improvement Work Group, which was tasked by the Executive Committee and the Board of Directors with developing a Bylaw requirement specifically defining what constitutes onsite availability of transplant surgeon and physician coverage. Presently, the Bylaws require that qualified physicians and surgeons be “on site” at the transplant center, and that “100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service.”

The concepts addressed in the proposed Bylaws changes were initially intended to better define the terms “on site” and “100% coverage.”

In discussing the revisions, it was suggested that the provision addressing single-physician or surgeon programs be clarified. The intent is not to prohibit programs from operating with a single transplant surgeon and/or transplant physician plan. Instead, the intent is to ensure that the program’s patients are fully informed and understand that there may be times that a transplant surgeon and/or transplant physician is not available and therefore may not be able to accept an organ offer.

The Committee provided a copy of the proposal to the Board of Directors when it met on June 29-30, 2006, and the Board endorsed the proposal for distribution for public comment (Exhibit M-1).

Public Comment Process: During its October 2006 meeting, the Committee discussed the responses to the proposal received during the public comment period. Thirty-two individual responses were submitted regarding this policy proposal. Of these, 22 (68.75%) supported the proposal, 9 (28.13%) opposed the proposal, and 1 (3.13%) had no opinion. Additionally, all of the Regions considered the proposal. Two supported the proposal without comment. Four regions voted against the proposal. Nine of the regions, including those that supported the spirit of the proposal, submitted comments asking that it be amended. Representatives from the Ad Hoc International Relations, Kidney Transplantation, Liver and Intestinal Organ Transplantation,

Minority Affairs, Pancreas Transplantation, Pediatric Transplantation, and Thoracic Organ Transplantation Committees met by teleconference on September 26, 2006, and considered the proposal. The group voted to support the proposal but had questions and recommendations for additional language.

In summary, the comments provided by individuals and the Regions included, but were not limited to, the following:

- This proposal does not take into consideration the volume of any given transplant program.
- The proposal does not account for single surgeon programs that share staff with affiliated pediatric or VA medical centers.
- One hour driving time was considered restrictive and could prohibit surgeons from performing their own procurements.
- Definition of “additional transplant physician” is not adequate.
- The proposal does not address availability of other staff such as clinical coordinators.

Based on the number of comments received and suggestions for amending the proposal, the Committee voted to refer the issue back to the Process Improvement Work Group for further review and development. The Committee also noted that no current members of the MPSC served on the Joint Work Group, therefore, Drs. Julie Heimbach, John Goss, and Geof Land were appointed.

Update from Work Group Meetings on January 3 and 10, 2007: Work Group 2, chaired by Dr. Frederick Grover, met by conference call on January 3, 2007, in order to discuss the proposals. The Work Group met again on January 10, 2007, and continued to refine the proposal.

The Work Group discussed comments received from individuals, Regions, and committees; further modifications to the Proposal; and implementation of the proposed changes.

Defining Coverage: The Work Group discussed the language regarding one-hour availability of the surgeon and physician and agreed to make further amendments to the proposal that would more clearly define its intent.

It was agreed that a goal was to ensure timely organ acceptance and to prevent unnecessary delays in organ procurement following acceptance. It was noted that DonorNet[®] should help with timely acceptance but may not prevent delays after acceptance so the Work Group recommended modifying the proposal to define more clearly the expectation that the whole process of acceptance, procurement, and implantation needs to take place in a timely manner.

The Work Group agreed that the proposed requirements for defining additional transplant surgeons and transplant physicians should be applied to existing programs and that a member staff audit should be conducted after the criteria are approved by the Board. Centers could make additions, changes, or deletions to the staff at this time. This audit would involve sending a letter to all program directors with a list of the individuals currently listed in the database as surgeons and physicians for specific organ transplant programs. The directors would be asked to verify which of these individuals meet the new definition of “additional” transplant surgeon or “additional” transplant physician and the Membership Database would be updated accordingly. The Work Group discussed various ways of establishing a schedule to create the annual audit due dates, including using the initial date of approval, but realized that method would create a heavy workload on certain months since most dates will correlate to the months that the Board of

Directors met. Additionally, the Work Group agreed that it would be simpler to mail the audit to all programs within a given center at the same time rather than on different schedules based on approval dates. Once the initial survey is conducted future verification of the “additional” surgeons and physicians may be performed during the existing annual member staff audit, when key personnel change applications are submitted, or by specific written notification.

Program Coverage Plan: A Program Coverage Plan must be submitted in writing to UNOS and describe how 100% medical and surgical coverage will be provided in the program by individuals who are credentialed by the hospital to provide transplant service for the programs. After further consideration, the Work Group made the following suggestions to refine this proposal:

- The proposed bylaw calls for the program to provide a copy of the Program Coverage Plan to the OPTN/UNOS. The Work Group suggested modifying the language so that all programs, not just those that are single surgeon or single physician, would have to notify their patients of their coverage plan...
- The Work Group also agreed that the program should update UNOS and the patients if there are substantive changes in the program or personnel.

The above recommendation was further modified after consideration by the MPSC.

Implementation - Program Coverage Plan: The Work Group made the recommendations below regarding implementation of the proposal but agreed that the MPSC should have the final say in the implementation plan. While the Work Group did discuss the number of programs that would be reporting (over 900) and the fact that it would be difficult for the MPSC to review all of the Program Coverage Plans, it did not discuss in detail the specific financial or staffing resources needed by UNOS or the members to carry out this process. The suggestions from the Work Group include the following:

- That staff review the individual Program Coverage Plans and then provide the MPSC with a list of programs that returned their Plans. If the program appears to be fully covered (i.e. provides 365/24/7 coverage) staff could report receipt of the Plan to the Committee and further Committee review would not be necessary at that time. Staff would also provide the Committee with a list of any programs that did not return their Plan by the assigned due date.
- If the program is covered by a single surgeon and/or single physician, the MPSC or an MPSC Subcommittee should automatically review it. Staff could also forward to the Committee any Plans that raise questions during their review.
- MPSC should automatically review programs that do not have 365/24/7 coverage. The MPSC may also want to consider reviewing programs that have inactivate waitlist time during the year (but who did not formally inactivate their membership status).
- The audit of the Program Coverage Plan and initial staff review would be implemented immediately, on a rotating basis (such as by region) in order for staff and the Committee to effectively manage a process of this magnitude.
- Process for notifying patients of the Program Coverage Plan: The Work Group agreed that it would recommend that the Programs must send a written notice out to patients within 3 months of the Bylaw being implemented. The Work Group did not discuss the (financial) resources for the hospitals to perform this task. The Work Group also discussed developing standard language for inclusion in patient acceptance letters. Such language should convey the sense that “...If this transplant center’s availability of surgeons and physicians is not

acceptable to you, you have the right to seek another transplant center...” This concept was modified by the MPSC and is further discussed below.

Update from January/February MPSC Meeting. The Committee reconsidered the proposal when it met on February 1, 2007. Dr. Stuart Sweet, a member of the Process Improvement Work Group, led the discussion (by conference call). It considered the modifications suggested by the Work Group as a result of the comments received during the public comment process. Their discussion was focused on the whether or not the language conveyed the intent of the proposal as well as concerns about the enforceability of the requirements. It was suggested that the language be recast to make it clearer that the Committee is trying to identify a pattern of behavior rather than monitoring events on a case-by-case basis (e.g. monitoring the ability to be on site within one hour ground transportation time.)

Program Coverage Plan Concerns: The Committee discussed the implementation of the proposed Program Coverage Plan and specifically its scope. It was concerned that the originally proposed language might be confusing and cause programs to send out a notice to patients each time there is an instance when the program could not accept organs due to coverage issues. It was not the Committee’s intent for this to happen. Members suggested that changes in coverage can occur in any program, so even programs with 365/24/7 coverage provided by multiple transplant surgeons and transplant physicians are susceptible and should send an initial letter to their patients letting them know that they did not expect any periods of staff unavailability that would lead to the center not being able to accept organs. The program should provide their patients with a written summary of the Program Coverage Plan at the time they are listed, and when there are any substantial changes in program or personnel. The Committee recommended that the proposed modification to the Bylaws be amended to incorporate the follow recommendation.

** RESOLVED, that the proposal be amended to incorporate the following language into Appendix B, Attachment I, Section VI “Transplant Surgeon and Physician” and Attachment I, Section XII to Appendix B of the UNOS Bylaws “Designated Transplant Program Criteria”: *“All programs should provide patients with a written summary of the Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel.”*

The Committee Voted 19 For, 3 Against, 0 Abstentions.

The Committee agreed that in addition to these modifications to the Bylaws, that efforts to develop a system for monitoring organ acceptance rates should be continued. This developing methodology for collecting and analyzing organ acceptance/turndown rates and deaths on the waiting list will be used to evaluate program performance and could identify programs that are inappropriately inactive and may pose a risk to patient safety.

On Site Availability of Surgeons and Physicians: The Committee considered the comments regarding the originally proposed language, which specified *“When “on call” a surgeon/physician must be available and able to be on the hospital premises within one-hour ground transportation time.”* ...

The Committee discussed the comments suggesting that the proposed language could potentially impact transplant surgeons and transplant physicians that are designated as the primary transplant surgeon/transplant physician in two facilities such as adult and pediatric (or V.A.) hospitals on the same campus or in close proximity. The proposal prohibits the primary transplant surgeon or primary transplant physician from being designated as the primary transplant surgeon/primary

transplant physician at more than one transplant center unless there are additional transplant surgeons/transplant physicians at each of those facilities. The Committee agreed that it was important that these programs also have additional transplant surgeons and transplant physicians in order to provide 365/24/7 coverage and it was not inclined to rescind or further modify this proposal.

The Committee agreed that at the most basic level, a transplant surgeon/transplant physician needs to be available to take care of the patients and there needs to be someone available to accept organs. They do not have to be the same individual. They pointed out that organs can be accepted based on phone conversations and that a transplant surgeon/transplant physician's physical presence is not required for organ acceptance. After further discussion and the review of the comments, the Committee agreed that the one-hour driving time was restrictive and could prevent surgeons from performing their own procurements. It would also be difficult to monitor compliance with this requirement.

The Committee's discussion returned to the intention of the requirement - to minimize the instances that an organ is turned down because of staff unavailability; and to prevent situations where a transplant surgeon/transplant physician is not available to respond quickly to emergent situations. The Committee agreed to the following language, as proposed by the Work Group:

“A transplant surgeon or transplant physician must be readily available in a timely manner to facilitate organ acceptance, procurement, and implantation, and to address urgent patient issues.”

The Committee also supported the following resolution:

**** RESOLVED**, that the proposed modifications to Appendix B, Attachment I, Section VI “Transplant Surgeon and Physician” and Attachment I, Section XII to Appendix B of the UNOS Bylaws “Designated Transplant Program Criteria” be amended to incorporate the following language: *When on call the transplant surgeon and transplant physician may not be on call for two transplant programs more than 30 miles apart unless the circumstances have been reviewed and approved by the Membership and Professional Standards Committee.*

The Committee voted 16 For, 6 Against, 0 Abstentions.

The pairing of the two newly proposed requirements (above) makes it possible to remove the reference to one hour transportation times, while at the same time addressing timely availability of a transplant surgeon or transplant physician to respond to organ offers and emergent situations; as well as these individuals being designated a primary transplant surgeon or primary transplant physician at more than one center unless there are additional surgeons/physicians at each of those facilities.

The Committee discussed the remaining language, such as the improved definitions of additional transplant surgeon and additional transplant physician, in the proposal as modified by the Work Group and recommends the following resolution for consideration by the Board of Director:

**** RESOLVED**, that the following modifications to Appendix B, Attachment I, Section VI “Transplant Surgeon and Physician” and Attachment I, Section XII to Appendix B of the UNOS Bylaws “Designated Transplant Program Criteria” having been distributed for public comment and subsequent reconsideration by

the Committee, are approved effective pending notice and programming in UNetsm, if and as applicable.

The Committee voted: 19 For, 3 Against, 0 Abstentions.

Proposed Modifications to the Appendix B, Attachment 1 of the UNOS and OPTN Bylaws

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

Appendix B, Attachment 1 of the OPTN Bylaws

VI. Transplant Surgeon and Physician. The transplant program must identify a qualified primary surgeon and primary physician, the requirements for whom are specified below, as well as the program director.

A. The program director, in conjunction with the primary transplant surgeon and primary transplant physician, must submit to the OPTN Contractor in writing ~~written~~ a Program Coverage Plan, which documents ~~ation how that~~ 100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The Program Coverage Plan must address the following requirements:

- (1) All transplant programs should have transplant surgeon(s) and transplant physician(s) available 365 days a year, 24 hours a day, 7 days a week, to provide program coverage. If such coverage cannot be provided, a written explanation must be provided that justifies the current level of coverage to the satisfaction of the Membership and Professional Standards Committee (MPSC). All ~~transplant programs~~ should provide patients with a written summary of the Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel. ~~served by a single transplant surgeon or transplant physician or unable to provide transplant surgeon/physician coverage 365 days a year, 24 hours a day, 7 days a week shall inform its patients of this fact in writing and explain the potential unavailability of one or both of these individuals, as applicable, during the year.~~
- (2) When “on call” a ~~surgeon/physician must be available and able to be on the hospital premises within one hour ground transportation time.~~ transplant surgeon and transplant physician may not be on call at two transplant programs more than 30 miles apart unless the specific circumstances of that coverage have been reviewed and approved by the Membership and Professional Standards Committee.
- (3) A transplant surgeon or transplant physician must be readily available in a timely manner to facilitate organ acceptance, procurement, and implantation, and to address urgent patient issues.
- (~~3~~ 4) The primary transplant surgeon or ~~primary~~ transplant physician cannot be designated as the primary transplant surgeon/primary transplant physician at more than one transplant center unless there are “additional” transplant surgeons/transplant physicians at each of those facilities.
 - (i) Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.

(ii) Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of the transplant patients immunosuppression.

- B. The primary surgeon and primary physician, collectively, are further responsible for ensuring the ongoing operation of the program in compliance with the criteria set forth in this Appendix B, Attachment I, and notification to the OPTN Contractor if at any time the program deviates from such criteria.

~~A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year. (relocated to Section (1) above)~~

Sections VII – XI - No Changes

Attachment I, Section XII to Appendix B of the UNOS Bylaws -Designated Transplant Program Criteria

XII. Transplant Programs.

- A. No Change
- B. No Change.
- C. To qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria. Each transplant program must identify a UNOS qualified primary surgeon and physician, the requirements for whom are described below, as well as the program director.

The program director, in conjunction with the primary transplant surgeon and primary transplant physician, must submit to UNOS in writing provide written a Program Coverage Plan, which documents ation how that 100% medical and surgical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The Program Coverage Plan must address the following requirements:

- (1) All transplant programs should have transplant surgeon(s) and physician(s) available 365 days a year, 24 hours a day, 7 days a week, to provide program coverage. If such coverage cannot be provided, a written explanation must be provided that justifies the current level of coverage to the satisfaction of the MPSC. All ~~A~~ transplant programs should provide patients with a written summary of the Program Coverage Plan, at the time of listing or when there are any substantial changes in program or personnel. ~~served by a single surgeon or physician or unable to provide transplant surgeon/physician coverage 365 days a year, 24 hours a day, 7 days a week shall inform its patients of this fact in writing and explain the potential unavailability of one or both of these individuals, as applicable, during the year.~~
- (2) When “on call” a A surgeon/physician must be available and able to be on the hospital premises within one-hour ground transportation time to address urgent patient issues.
- (3) A transplant surgeon must be readily available in a timely manner to facilitate organ acceptance, procurement, and implantation.
- (4) ~~(3)~~ The primary transplant surgeon/primary transplant physician cannot be designated as the primary surgeon/primary transplant physician at more than one transplant center unless there are “additional” transplant surgeons/transplant physicians at each of those facilities.

- (i) Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.
- (ii) Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients ~~immunosuppression.~~

A transplant center applying as a new member or for a key personnel change must include for the proposed primary transplant surgeon and/or physician a report from their hospital credentialing committee that the committee has reviewed the said individual's state licensing, board certification, training, and transplant CME's and affirm that they are "currently" a member in good standing.

Implementation issues – Program Coverage Plan: The Committee also discussed the Work Group's suggestion of developing standard language for inclusion in patient acceptance letters. The Committee did not fully agree with the Work Group's suggestion that language be added to the candidate acceptance letter, indicating that they have the "right to seek another transplant center..." The Committee thought that a better alternative would be for the OPTN to provide a letter that is directed to the patients, but require the center to provide this letter to each patient when they are listed. It could accompany the acceptance letter, be on OPTN letterhead, and signed by the current OPTN president. The acceptance letter should refer to the OPTN letter, so that if it is not enclosed, the patient will be aware that they need to make an inquiry of the center.

The Committee also had concerns about the burden that would be placed on centers with large waiting lists if a letter regarding program coverage had to be sent annually, and agreed that they would recommend that this information be provided in the acceptance letter and when there were substantial changes in the program or personnel. At the conclusion of the discussion, the Committee agreed to support the following concepts:

- ** RESOLVED, that the Committee explore the feasibility of implementing the oversight component relating to program coverage by having the OPTN provide a letter for the transplant patients, that the center will in turn provide to each patient when the patient is listed, along with the acceptance letter. This letter would touch on the listing and behavior issues we have with the centers, and include the patient hotline number and information about patient rights. It was determined that the letter should come from the OPTN/UNOS as an oversight organization rather than the center itself. The acceptance letter must reference the OPTN letter as an enclosure.

The Committee voted 23 For, 0 Against, 0 Abstentions.

The Committee agreed that this project should be referred to the Patient Affairs Committee for further development since it parallels a similar Committee project regarding patient notification.

5. Proposed Modifications to Bylaws, Appendix B, Section II, "Transplant Hospitals," "Investigation of Personnel;" Appendix B, Attachment 1, Section IV "Investigation of Personnel;" Section VII "Transplant Surgeon and Physician;" and Appendix B, Attachment I, Section XII (C) (Proposal 4). The aim is to prevent an individual physician or surgeon who has been involved in non-compliant activity at one institution from continuing that or similar activity at the same or another institution. The proposed modifications to the Bylaws would enhance oversight of individual physicians and surgeons by requiring:

- Transplant hospitals to conduct investigations, upon request, according to their peer review protocols and report to the OPTN,
- Applicants for primary physician or surgeon to submit assessments of prior non-compliant behavior with which they or other individuals proposed as part of the transplant team have been involved, as well as plans to ensure that the improper conduct is not continued, and
- Applicants for primary physician or surgeon to submit letters of recommendation attesting to their overall qualifications to act as primary physician or surgeon, as applicable, and addressing matters such as the individual's personal integrity, honesty, and familiarity with and experience in adhering to OPTN requirements and compliance protocols.

Background: Transplant hospitals may apply to be members of the OPTN/UNOS, and transplant programs within hospital members may apply to be designated by OPTN/UNOS to receive organs for transplantation. Once approved, the hospital becomes a Member of OPTN/UNOS and the program is designated to receive organs. Individual physicians and surgeons associated with these institutions and programs may be reviewed as part of the member/designated program application, but are not approved independently from the member/designated program application. There presently are no criteria for physicians and surgeons distinct from requirements associated with training and experience to serve as the primary physician or surgeon for a particular transplant program.

Certain data banks, e.g., the National Practitioner Data Bank (NPDB) and Healthcare Integrity and Protection Data Bank (HIPDB), collect and report information about various adverse actions that are taken against individual physicians and surgeons. The OPTN does not presently participate in these data banks; it appears that so long as the OPTN continues to approve institutions and programs, without independently approving individual physicians and surgeons, there is no expectation that OPTN would participate in these data banks.

OPTN Bylaws do not exist in a vacuum. To the contrary, the bylaws presently rely upon state licensure, as well as hospital credentialing and privileging processes, to ensure that individual physicians and surgeons are qualified to provide patient care services in accordance with jurisdictional and other relevant requirements. OPTN primary physician and surgeon criteria then supplement these processes by requiring minimum levels of competence and currency in the care of organ transplant candidates and recipients specifically.

Policy Proposal: In evaluating its charge to address misconduct for which an individual physician or surgeon appears uniquely responsible, the MPSC Process Improvement Work Group and MPSC worked within a framework consistent with existing Bylaws emphasizing institutional responsibility, and without embarking upon new processes to approve individual physicians and surgeons. The Work Group developed a two-pronged approach. New or revised activities would be incorporated: (1) at the time a policy compliance inquiry is underway, and (2) during the application process.

1. Policy Compliance Inquiry Underway.

- The proposal incorporates a requirement that, at the request of the MPSC, transplant programs must investigate an individual physician or surgeon's role in a matter under investigation by the MPSC where the MPSC made a final determination of "Probation" or "Member Not in Good Standing." The investigation would conduct its review

pursuant to the institution's standard peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process.

- If, during a MPSC inquiry, it appears that a physician or surgeon is substantially responsible for non-compliant behavior at the institution, the MPSC could request the program to perform such a peer review investigation. The institution would be asked to report to the MPSC whether it had initiated, conducted, and concluded the inquiry according to its standard processes and pursuant to the OPTN Bylaws provision.

2. Application Process.

- OPTN Bylaws already define Primary Physician and Surgeon responsibility to include *“ensuring the ongoing operation of the program in compliance with the criteria set forth in ...Appendix B, Attachment I, and notification to the OPTN Contractor if at any time the program deviates from such criteria.”* This provides authority to hold the primary physician and surgeon accountable for transgressions of their existing programs and avoidance of transgressions in any new program to which the physician or surgeon moves.
- The proposal would incorporate within the application to be named primary physician or surgeon requirements for self-assessment of all physicians and surgeons participating in the transplant program regarding their involvement in prior transgressions and plans to ensure that the improper activity is not continued. Additionally, a question will be added to the application(s) requiring that each named individual submit their individual self-query response from the National Practitioners Data Bank as a part of the application.
- A Plan for Continuing Policy Compliance (PCPC) also would be incorporated as a new application requirement and used for self-reporting and updating information on some periodic timetable. Questions developed to form the basis of the PCPC would be designed to:
 - Disclose involvement in prior inappropriate behavior;
 - Report to the satisfaction of MPSC that safeguards are (or will be) in place to assure similar transgressions will not be repeated; and
 - Report a plan for educating all physicians and surgeons providing transplant services about OPTN policies and processes.

Bylaws cannot impede a person from serving as a primary transplant surgeon or physician unless the plan for the new center is inadequate or would put the program and patients at risk.

The PCPC would define the trigger for reporting prior misconduct as affiliation at any point in time with a transplant program that received a final determination of Probation or Member not in Good Standing. The questions forming the basis of the PCPC would be developed to understand the physician or surgeon's role and assure that the new program has considered how it will prevent same or similar activity from recurring.

The Work Group acknowledged that oversight is more difficult when a physician or surgeon who participates in inappropriate activity leaves the institution where the misconduct occurred prior to an MPSC inquiry that results in a final determination of

Probation or Member not in Good Standing. A requirement for submission of letters of recommendation, described below, is proposed to discern such information. Additionally, several of the PCPC questions would be designed specifically in an attempt to reveal these situations.

- Finally, the proposal would further incorporate within the application to be named primary physician or surgeon requirements for letters of recommendation attesting to the individual's overall qualifications, personal integrity, familiarity with OPTN requirements, etc. The source of the letters would be persons of authority affiliated with transplants programs previously served by the individual.

In developing the proposal, the Work Group summarized the following potential advantages:

- Transplant hospitals would continue to be responsible for credentialing individual physicians and surgeons and monitoring their professional conduct. The proposal would emphasize situations that require particular oversight as well as processes to ensure that such oversight occurs. It also would reinforce responsibility for policy compliance in general.
- The proposal would avoid costs and exposure to legal liability associated with processes to approve (or credential) individual physicians and surgeons independently of their institutions. This would include, for example, establishing, monitoring, investigating, and enforcing (with appropriate due process provided) criteria for which the physicians and surgeons would be accountable individually.
- The proposal may be tested as an initial step, for study and subsequent modification as determined appropriate, before embarking upon more resource intensive proposals.

The Work Group also noted the following potential disadvantages:

- The proposal would not prohibit a physician or surgeon involved in prior non-compliant activity from later being approved as a primary physician or surgeon or being accepted as part of a transplant team.
- The proposal's oversight for a physician or surgeon who leaves an institution before a MPSC inquiry resulting in a final determination for an adverse action is initiated and moves to another institution may appear weak. Questions would be developed as part of the primary physician/surgeon application process and letters of recommendation would be required in an attempt to address this concern. Ensuring appropriate due process protections for these individuals is challenging since they are no longer affiliated with the institutional transgressor and were not present at the time of the MPSC investigation. Occurrences of this nature involving a physician or surgeon believed to be substantially responsible for the inappropriate behavior have been non-existent or at least not frequent in the past; it is expected that they would not be frequent in the future.

The Joint Work Group determined that the proposal would accomplish the intended objective without excessive financial and other resource demands and should be approved for public comment consideration. The proposal was presented to and endorsed by the Board of Directors for distribution for public comment during their June 2006 meeting.

October 2006 Update: When the Committee met in October 2006, it reviewed comments received from individuals, the Regions, and other Committees (Exhibit M-2). The Committee received 25 individual responses regarding this policy proposal. Of these, 20 (80.00%) supported

the proposal, 1 (4.00%) opposed the proposal, and 4 (16.00%) had no opinion. Of the 21 who responded with an opinion, 20 (95.24%) supported the proposal and 1 (4.76%) opposed the proposal. All of the regions voted in support of the proposal and several submitted comments even if in support. Additionally, the Committee received comments from several committees who also voted in support of the proposal. In summary, the Committee considered comments expressing concern about the following issues:

Comments received during Regional Meetings:

- Information gathered in a peer review investigation should not be disclosed to the public.
- It is not clear who would be responsible for submitting an assessment of all physicians and surgeons participating in the program regarding their involvement in prior transgressions of OPTN requirements and plans to ensure that the improper conduct is not continued.
- There should be a way to identify individuals who have been affiliated with a program's adverse action even if the individuals have left the program prior to the action being initiated.
- These policies should also apply to OPOs and Histocompatibility Labs.
- UNOS should move into a more active role of credentialing physicians.

Comments received from other Committees:

- Concerns were raised about relying on the community to be honest about prior violations.
- A transplant hospital may be somewhat reluctant to provide this kind of reference that could ultimately lead to a candidate for another position not receiving an offer for a job.
- Many institutions have policies in terms of staff recommendations to limit information to term of employment and will not discuss any disciplinary issues that may have occurred.
- Concern was raised about moving the credentialing away from the hospitals and whether any feedback had been received from institutions.

Summary of MPSC Comments and Concerns – October 2006:

The Committee emphasized that the proposal places the burden on the program to conduct investigations and inquiries of individual physicians and surgeons. The intent is for the institution to have a discussion with the individual to ensure that an inappropriate activity is not continued.

The Committee considered the event that would trigger a reporting requirement for an individual and initially suggested that it could be a hearing before the MPSC. During its January/February meeting, the Committee reconsidered this suggestion and based upon the recommendation from the Work Group, agreed that the trigger for reporting should be a final determination of Probation or Member Not in Good Standing, which includes a requirement for public notification. This would be clarified in the application as part of the directions for completing the Plan for Continuing Policy Compliance. The Committee also discussed how this proposed bylaw might be implemented and agreed that it should be effective prospectively after Board approval; it would not be applied retroactively. In October, the Committee made the following observations about the proposal:

- MPSC needs to become very specific in its recommendations by indicating a particular person who is responsible for specific inappropriate behavior. Defining responsibility for wrongdoing at an individual level is very difficult
- How can an individual find out if they have been identified as the responsible person for such inappropriate behavior or appeal to have this identification reversed?

- Does there need to be a forum for talking to individuals who may have left the institution prior to an action being initiated with the program resulting in possible adverse action?
- Other Databases, such as the National Practitioners Data Bank, have very specific criteria about who might be identified in connection with wrongdoing, whereas this proposal does not.
- UNOS' role is to approve programs. Approving individuals, as suggested by one of the regions, would imply a different philosophy for the OPTN. Additional resources would be required to take this approach.
- The comments and MPSC discussion suggest that there is disagreement about what level of oversight of individual physicians and surgeons by the OPTN is either practical in terms of yielding results that are productive or advisable in terms of new activity for the OPTN.

Based on the comments received during the public comment period as well as the issues raised by the Committee, the MPSC referred the issue back to the Process Improvement Work Group for further review and development.

Work Group Update - January 2007:

The Work Group met by conference call on January 3 and 10, 2007, and reviewed the responses received during the public comment period as well as the observations from the MPSC. Minor modifications were made to the proposal to further refine its scope and to respond to the public comments as appropriate.

A key change included adding language to the Bylaws that would specify that institutions that are placed on probation or determined to be a "Member not in Good Standing" would be responsible for an investigation of their personnel.

MPSC January/February 2007 Meeting Update: The MPSC reviewed the recommendations of the Process Improvement Work Group 1 when it met in January 30- February 1, 2007. The discussion was led by Dr. Stuart Sweet, a member of the Work Group, who participated by conference call. The MPSC continued to discuss its concerns regarding the scope and implementation of the proposed requirements.

The Committee also discussed the following concerns that were made by a member of the Work Group after its call on January 10:

- 1) The MPSC should have the authority to request that a center investigate the role played by any member of the transplant program identified during an MPSC investigation (not just primary physician and surgeon).

The MPSC agreed, but clarified that it can only ask the center if it conducted its own peer review investigation and to certify that it was done according to its due process procedures; it cannot ask for its corrective action plan itself because it would have been developed in response to the institutions peer review process. General information may be communicated to the Committee, but the actual details of the compliance plan may not. The subject of the peer review, the "errant actor," would have to rely on the center's due process procedures to contest its findings and the OPTN/UNOS would not have access to the information gathered during this process. The individual does not have the ability to waive this privilege. The privilege is that of the peer review body.

It is up to the hiring institution to conduct its mandatory inquiries before it gives a surgeon or physician privileges. Databanks are only intended to supplement the usual credentialing process.

- 2) Each physician or surgeon included in an application, whether as primary physician or surgeon or playing a role in the 100% coverage plan, should submit an attestation of their lack of involvement in any prior program during a period of concern that led to Probation, "Member Not in Good Standing," etc. If there is prior involvement, the physician/surgeon should explain their role, and if they were responsible for policy violations, steps taken to prevent future occurrence. These explanations would also need to be submitted with a personnel change application.

When a center submits an application for a new program or a change in key personnel, it will need to provide this information. Each person named in an application would have to answer the question such as "were you on staff or associated with a member center that received a final determination of Probation or Member not in Good Standing, and were you there during the period the violation occurred?" "If yes, were you a part of any policy violations?" If yes, they would need to explain what they plan to do to prevent this behavior from occurring at the new center.

Based on the information on file and submitted by the center, the Committee will need to interpret who was involved in the program during the period that was investigated. UNOS can ask for a Plan for Continuing Policy Compliance as a part of the application. This plan would be protected under the Committee's peer review process.

- 3) Include in a program application a requirement for a policy compliance plan that describes processes for monitoring/education, etc. Submission of a Plan for Continuing Policy Compliance might be considered regardless of whether there are prior transgressions. It could refer to the specific issues and plans identified in the physician/surgeon application.

The Committee can request a plan from each program.

The Committee also addressed the following issues:

- The Committee addressed the concerns regarding how long an individual would have to report on their involvement or lack thereof in the behavior that led to a final determination of probation or Member Not in Good Standing. The Committee agreed that the reporting period would be indefinite. This response was based on the reporting mechanisms in place for state board licensing and other similar regulatory bodies.
- Probation and "Member Not in Good Standing" are determined at the center level. It is possible that an applicant from one organ transplant program may not be aware of the issues in another program at the same center, and may not be able to answer specific questions. The MPSC agreed that the answer could be that just that – the issue was in another program that the individual was not involved in the behavior that led to the final determination of Probation or Member Not in Good Standing. The MPSC can decide if the information they provide is relevant.

- It is the responsibility of the surgeon/physician named in an application to be as open about their involvement as they can be. If data from the OPTN/UNOS database differs from what individual provides, the MPSC can review the records from its own peer review process and determine if the individual has provided appropriate information.

The Committee asked if the Membership Database could provide a mechanism for keeping track of individuals known to be involved in “transgressions.” Staff acknowledged that the database could be updated to reflect this information, which in turn could be provided to the MPSC during its review of an application or upon request for other types of reviews. This information would both supplement and validate the information submitted by the transplant center. It is believed that this process will respond to the public comments regarding a method to ensure honest responses. This tracking system could be developed without the addition of new bylaw language because it is a mechanism for implementing the bylaw changes that have already been proposed. The Committee further discussed the collection information regarding past “transgressors” but noted that it had previously agreed that it would not apply the bylaws to an action that occurred prior to the Board of Directors approval of the new requirements.

- The Committee further discussed the nature of peer review by the Committee and within the member institutions. The Committee was reminded that documents or statements that are initiated, created, or generated by or at the request of the peer review entity are confidential. This may include the details of the review process prior to the final determination. For example, the Board of Directors or Committee would not be entitled to a Corrective Action Plan that resulted from an institution’s peer review of an individual. The OPTN/UNOS however, could obtain a certification from the institution that they conducted the review in accordance with the institution’s peer review bylaws. It was agreed that the Bylaws proposal would need to be amended to make sure that individual investigation does not violate peer review.

The Committee was unable to resolve all its concerns during the course of the meeting and a motion to approve the proposed requirements as amended by the Work Group was not supported.

** RESOLVED, that the Committee supports the proposal as amended by the Work Group and with further clarifying language to be provided by legal staff.

The Committee voted 7 For, 16 Against, 0 Abstentions.

Subsequent to the MPSC meeting, staff continued to work on the language and process for implementing the proposed Bylaws in a manner that would not conflict with the institutional peer review process. The attached modifications would clarify that the institution and/or program’s investigation must be conducted pursuant to the “standard peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process.” Modifications to the following sections of the Bylaws were suggested by staff and required review and approval by the MPSC in order to advance the proposal to the Board of Directors.

The remaining concerns of the MPSC were related to the implementation of the proposals and included an individual surgeon or physician having to declare themselves as involved in an adverse action or not, for an indefinite period; and the broadness of the proposal such that an individual would have to declare themselves if they were employed at the center when an event occurred that resulted in probation or “Member not in Good Standing” regardless of their position in the specific program that that initiated the review.

The Committee suggested that one approach for refining the scope of review might be for the Committee to consider whether the behavior/event was attributed to a systemic or programmatic problem. It was suggested that the MPSC declare the type at the time the final determination is made and then records could be flagged accordingly. The MPSC will then know the level of evaluation that may need to be performed on the staff from that member institution in the future. This process would seem to accomplish the goal of further refining who has to submit to this additional process.

Subsequent to the meeting, and through talks with the National Practitioners Data Bank (NPDB), staff has also developed a method for collecting information regarding individuals in a manner that would not violate the institution’s peer review process. A requirement for an additional supporting document is being added to the application forms so that each named individual must submit their individual self query response from the NPDB as a part of the application. This requirement places the burden of making the inquiry on the individual and the program and would avoid the problem of UNOS not having the ability to make inquiries of the NPDB directly. The current Bylaws (Appendix A) already give the Committee the leeway to ask for this information without a specific change in the bylaws.

Summary of Changes:

These changes can be found in the following sections of the Bylaws. Changes in the OPTN Bylaws will be carried over in the UNOS Bylaws.

1) Appendix A to the Bylaws – OPTN, 2.06A - *Membership and Professional Standards Committee Action*

The modifications to this section add to the list of actions the MPSC might require of a center that is placed under probation or determined to be a “Member not in Good Standing” (MNGS) the option of requiring a center to conduct an investigation of its personnel. This would not apply to Section (6) *Termination of Membership or Designated Program Status* because once the center has been removed from membership; we can no longer impose such requirements. Although it was thought that the likelihood of an a center being referred to the Secretary for suspension of privileges without first being placed on probation or made a MNGS was extremely low, the Work Group asked that the option for an investigation be added under Section (5) *Suspension of Member Privileges*.

2) Appendix A to the Bylaws – OPTN, Application and Hearing Procedures for Members and Designated Transplant Programs, 1.03A - *Procedures upon Application for Membership*

The proposed modification puts in place a “Plan for Continuing Policy Compliance” under the application process. This requirement specifies that the named primary surgeon and/or primary physician must conduct an assessment of the program’s surgeons or physicians regarding prior transgressions, and if they have been involved in prior transgressions, to submit a plan that ensures the improper conduct is not continued.

3) Appendix B to Bylaws – Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership, I. Transplant Hospitals, D. Investigation of Personnel

This modification gives the MPSC the latitude to request that a transplant hospital conduct an investigation of its personnel at the Committee’s request and report its final determination to the Committee in a way that is consistent with and protects the institution’s own peer review process. This proposed Bylaw provides a mechanism for having the hospital examine an individual’s role in a matter that the MPSC has under investigation and report to the MPSC. If a center fails to comply, then the MPSC is empowered to take further action.

4) Attachment I to Appendix B of the Bylaws, IV. Investigation of Personnel and VII. Transplant Surgeon and Physician

Section IV of this proposed revision is essentially the same as #3 above except that it places the emphasis on a “transplant program” being responsible for the investigation. The focus in #3 is the “transplant hospital.”

The proposed language under Section VII incorporates a new requirement into the membership application process that follows along the line of #1 above. The named primary transplant surgeon or primary transplant physician in each application must submit an assessment of all physicians and surgeons participating in the program regarding their involvement in prior transgressions of OPTN requirements and plans to ensure that the improper conduct is not continued. In response to a request made by the Committee during our last meeting, we have included modifications to this proposal to recognize the confidential nature of the institution’s peer review process.

5) Appendix B, Attachment I, Section XII(C), of the Bylaws.

A requirement for an additional letter of reference has been added under each organ program and each of the surgeon and physician pathways for meeting the requirements. This letter would be different from the other letters of reference, which in essence verify that the individual has met the training and/or experience requirements. This new letter would need to attest to the individual’s personal integrity, honesty, familiarity with and experience in adhering to the OPTN requirements and compliance protocols. A single letter could address both the experience and training of an individual as well as these new elements.

The Committee considered the final revisions to the proposal on the Committee Management System and supported the recommended language as shown in Exhibit M-2.

**** RESOLVED, that the modifications to the following sections of the OPTN and UNOS Bylaws:**

- **Appendix A to the Bylaws – OPTN and UNOS, Section 1.03A Application and Hearing Procedures for Members and Designated Transplant Programs, 1.03A - Procedures upon Application for Membership;**
- **Appendix A to the Bylaws – OPTN and UNOS, Section 2.06A - Membership and Professional Standards Committee Action;**
- **Appendix B to OPTN and UNOS Bylaws – Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership, I. Transplant Hospitals, D. Investigation of Personnel;**

- **Attachment I to OPTN and UNOS Appendix B of the Bylaws, IV. Investigation of Personnel, and VII. Transplant Surgeon and Physician; and**

- **Appendix B, Attachment I, Section XII(C), of the UNOS Bylaws,**

as fully set forth in Exhibit M-2, are hereby approved effective pending notice and programming in UNetsm, if and as applicable.

The Committee vote 17 For, 1 Against, 0 Abstentions.

6. Offer/Organ Acceptance Rate Modeling: The Committee was updated on the Process Improvement Work Group's progress in the development of an agreeable methodology for collecting and analyzing organ acceptance/turn-down rates and deaths on the waiting list, which can be used to evaluate program performance.

Background: The primary purpose of the metric is to identify programs that are inappropriately inactive and may pose a risk to patient safety. The Work Group agreed that each analysis will have to be organ specific to account for unique clinical and logistical characteristics, and requested that the Scientific Registry of Transplant Recipients (SRTR) create multi-variable models comparing actual to expected acceptance rates (looking at both offers and organs offered) for each organ starting with kidney, liver, and then the other organs.

Work Group 1, which was tasked with this effort, has met numerous times either in person or via conference call to review the proposed analysis models.

Progress Report: On January 31, 2007, Dr. David Mulligan updated the Committee on the Process Improvement Work Group's progress in the development of an agreeable methodology for collecting and analyzing organ acceptance/turn-down rates and deaths on the waiting list, which can be used as a flag to evaluate program performance.

A timeline was presented, which provided a chronology of the work beginning in January 2006 to this point. The "good organ" criterion was presented by Dr. Mulligan and SRTR staff. Good organ criteria are defined as kidney or livers transplanted within 50 offers and/or by one of the first 3 centers receiving an offer. The acceptance rate information for kidney and liver programs had been placed by SRTR on the programs' private sites for review. A couple of criteria for data inclusion in the analysis were discussed between the Working Group and SRTR. The SRTR was scheduled to publicly release this center specific data to the public on January 11, 2007 when a decision was made by SRTR and HRSA to delay its release because some questions were raised regarding the data considered as good organ turn-downs. The Committee members were apprised of a discussion regarding this issue that the Working Group had with the SRTR and its resulting decision to continue with piloting program reviews flagged with the current methodology for both kidney and liver. Dr. Mulligan explained the acceptance rate model has been developed with the knowledge that it is probably not perfect, but it is a tool that has identified four programs that subsequently closed, so it deserves a chance to be evaluated. Some discussion occurred regarding delaying any acceptance rate model until "better" turn down data is collected with DonorNet 2007.

The Working Group expressed confidence in the current model so they were recommending that this spring, kidney and liver programs identified as having observed acceptance rates for both offers and organs below the expected levels with statistical significance, should be contacted and asked to provide information that will help the Working Group understand what this measure is

actually determining. These programs will be told that this methodology is under testing and it is not being used as a performance determinant by the MPSC at this time. After seeing the data regarding identification of the four closed programs that were identified as having less than expected acceptance rates, the Committee agreed that this was reasonable thing to do. The Working Group intends to report its findings at a future Committee meeting.

7. Program and Personnel Changes: During its January/February meeting, the Committee reviewed and accepted programs changing status by voluntarily inactivating, withdrawing from designated program status, or reactivating. Additionally, the Committee reviewed 51 Key Personnel Changes and approved 45 of these applications. The remaining applications remain in process.

The Committee specifically discussed one center that had closed its lung transplant program but had not sent out written notification to its patients with a copy to UNOS. The Bylaws require that the center provide the patient with a notice that is copied to UNOS. The *Inactive Transplant Center Transfer of Waitlisted Transplant Candidates Protocol*, which was approved by this Committee, further specifies that the center must provide the following:

- (i) *written notice to candidates (with a copy to UNOS) to be distributed within 5 business days of inactivation date, explaining: (1) the program's reasons to inactivate (2) that while still on the waiting list of the inactive program the candidate cannot receive an organ offer and (3) options for candidates to transfer with the phone number of the administrative office of the inactivating center to help with patient transfers,*

The Committee determined that this center should receive a letter from the Committee requesting a copy of their Action Plan for taking care of their patients (facilitating care and transfer) and for complying with the Bylaws and the Protocol. [Copies of the patient notification letters were received subsequent to the meeting].

8. Due Process Proceedings: The Committee conducted five interviews and held five informal discussions with member organizations related to changes in Key Personnel and policy compliance issues.
9. Update on the Inclusion of Donation after Cardiac Death (DCD) protocols in Transplant Center Membership (OPO Committee): The Committee continued its discussion regarding requirements for DCD protocols as a condition of transplant center and Organ Procurement Organization (OPO) membership.

Background: This issue was first discussed by the Committee during its February 2006, meeting and it has continued to participate through the its representatives in the efforts of the DCD Working Group. During the October 2006, meeting of the MPSC, a DCD Policy Subcommittee/working group was established and charged with developing policy as it pertains to the oversight of DCD protocols.

Update: During its January/February 2007 meeting, the Committee learned that the Board approved during its December 2006 meeting, the following DCD related proposal and bylaw modifications:

The following model elements shall be incorporated for OPO and transplant hospital DCD recovery protocols: Candidate Selection, Consent, Patient Management, Withdrawal of Life Sustaining Measures, Pronouncement of Death, Organ Recovery and Financial Considerations. (Attachment III).

Appendix B to OPTN Bylaws

I. Organ Procurement Organizations Donation after Cardiac Death: *OPOs must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. OPO DCD recovery protocols must address the required model elements set forth in Attachment III.*

II. Transplant Hospitals Donation after Cardiac Death. *Transplant hospitals must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. Transplant Hospital DCD recovery protocols must address the required model elements set forth in Attachment III.*

The Committee was informed that the DCD model elements, which were approved, are not considered all-inclusive and complete. The OPO Working Group is currently preparing proposed enhancements to these elements. The DCD Policy Working Group established and charged with developing policy as it pertains to the oversight of DCD protocols has been contacted and will meet once agreed upon enhanced DCD model elements are complete. These enhanced DCD model elements were completed and distributed for public comment on February 16, 2007. The DCD Policy Subcommittee will meet as soon as possible and discuss procedures as well as potential bylaw changes that would be needed in order to monitor and enforce the requirements. Members of the DCD Policy Working Group are Rob Linderer and Charlie Alexander, co-chairs; Susan Gunderson; Drs. Alan Reed, Jorge Reyes, Juan Arenas, Cosme Manzarbeitia, Randolph Steadman, and Chris Freise. The Subcommittee was given the latitude to involve others as needed.

The goal is to provide the Board of Directors with proposals on how to ensure the DCD model elements are included and followed by the OPOs and transplant centers when pursuing DCD donations and what actions the OPTN/UNOS can take if they are not for consideration at their March 2007 meeting. In addition, the intention is for donor hospitals, which are not transplant centers to adopt DCD protocols from the OPOs, which incorporate the model elements.

10. Update on Live Donor Liver Transplant Program Application Process: On March 1, 2005, UNOS notified all liver transplant programs of the new live donor liver program criteria for designated transplant program status. In accordance with Appendix B, Section II, Attachment I of the OPTN Bylaws, and Appendix B, Attachment I, Section XIII of the UNOS Bylaws, each existing live donor liver transplant program was asked to complete an application demonstrating its ability to comply with the Criteria for Institutional Membership. The application submission deadline was June 1, 2005.

During the July meeting the Committee was informed that the June 16, 2006, issue of the Federal Register contained a response by the Health Resources and Services Administration (HRSA) to public comments regarding the enforceability of OPTN policies regarding living donor transplantation, including equitable allocation of living donor organs. HRSA determined that OPTN living donor guidelines should be given the same status as other OPTN policies under the OPTN Final Rule and that the OPTN is directed to develop such policies in the same manner used for policies on deceased donor organs and recipients. OPTN member non-compliance with living donor policies is subject to the same consequences as other policies established by the OPTN under the terms of the Final Rule. Based on the ruling, staff was directed to send letters out to all live donor liver programs regarding the change in authority, and how it impacted applications that were in process or programs that had not submitted an application.

When it met on January 30 - February 1, the Committee was given an update on the status of all live donor liver applications that had been received (see table below). The Committee was also informed that to date, all of the transplant centers that had initially been sent applications for live donor liver transplant programs had responded by either submitting an application or opting out.

Summary Report of Live Donor Liver Applications Received (as of February 1, 2007)

Completed:

48 Approved by Board – Full Approval
10 Approved by Board – Conditional Approval

Pending Final Recommendation to the Board in March 2007:

5 Recommended by MPSC for Full Approval
5 Recommended by MPSC for Conditional Approval

Applications in Process:

3 Applications Ruled Incomplete by MPSC
4 Applications Pending Review

Other:

3 Applications closed as incomplete after 1 year (2 reapplied)
9 Applications withdrawn during review process
2 Programs Voluntarily Inactivated

Total applications Received: 87

All Liver programs responded by applying or opting out.

Subsequent to the January/February 2007 meeting, one of the applications still pending review was closed as incomplete because it remained incomplete for over one year from the date of submission.

During its January/February meeting, the MPSC also discussed a center that submitted an opt-out form in place of a live donor liver application on May 27, 2005. The center subsequently submitted an application on May 15, 2006, but began performing live donor liver transplants before the application was approved. The Committee decided during its discussion that no action would be taken against the center. A formal vote was not taken.

11. Live Donor Transplant Program Requirements: During the October 2006 meeting, a Committee member asked if the criteria for live donor liver programs is realistic and not too prohibitive. Concern was expressed that a well established hepatobiliary surgeon with thousands of resections may not meet the requirements to serve as a primary transplant surgeon, and that there could be previously active programs that did not apply because they could not fulfill the new or revised requirements.

Background: The Committee had previously reviewed a detailed report of the application deficiencies when it was developing the conditional pathway for live donor liver programs; however, it was suggested that a subcommittee of the MPSC should look at historical aspects of the live donor liver programs. This review should include the centers that applied and have not completed the application process, as well as those that had been previously active but had not applied. The review should assess whether or not the requirements are appropriate based on the available data. Committee members suggested that the Subcommittee review the work of the

NIH Study of Adult to Adult Living Donor Liver Transplantation (AALDLT or A2ALL) and data from the SRTR. Dr. Gruessner agreed to Chair this subcommittee. The Committee agreed that a subcommittee should be appointed to reassess the live donor liver requirements. This Subcommittee would report its finding to the Committee, which would then ask the Liver/Intestinal Organ Transplantation Committee and the Living Donor Committee to review the findings, if needed. Dr. Gruessner explained a proposal for another pathway in the live donor liver criteria to the Committee when it met in January/February. This proposal will be taken under consideration as the Live Donor Policy Work Group continues to explore changes and oversight issues related to living donation.

Live Donor Kidney Transplant Program Application Process: The staff provided the Committee with an initial draft of the live donor kidney program application form for their input. The Committee was informed that once it finalizes a draft of the document it will be forwarded to the Office of Management and Budget (OMB) for approval. The time taken to complete the OMB process varies. The Committee also reviewed the requirements for live donor kidney programs, which were approved in 2004. It was concerned that the requirements that were developed seemed to have a focus on the recipient surgery rather than the safety of the live donor. The Committee viewed the necessary requirements as having two elements:

- Safety for the living donor to make sure the appropriate personnel are taking care of the donor. The current requirements establish the minimum number of transplants and live donor procurement operations that must have been performed by surgeons at centers wishing to apply for UNOS certification. The Committee agreed that this criteria should be expanded upon to ensure that the surgery is being done safely and that the potential living donors are being worked up appropriately.
- The living donor is more than just the donor operation. A potential donor needs to be educated regarding the potential risks and benefits of donation. They should have access to a variety of specialists who are unique to the living donor program, so there are no conflicts of interest. Separation should be maintained between the deceased and living donor programs.

The Committee agreed that prior to sending out the live donor kidney program applications that the oversight elements need to be further developed. The Committee believes that it has an obligation to describe the model elements that a living donor program must have in place to ensure donor safety. It also noted that there are OPO's involved in anonymous living donor programs and that model elements should also address these arrangements. This effort has been tasked to the Living Donor Policy Advisory Work Group and their report appears below. The Committee emphasized the need for the MPSC and the Living Donor Committee to be working in partnership on these requirements rather than developing similar criteria in a separate process. The MPSC needs to be involved in the development of living donor requirements that it will ultimately be responsible for enforcing. The Committee also wanted to review related work product from the Living Donor Committee to see which issues have already been addressed, especially those that may be critical to this discussion.

The Committee weighed two options:

- Amend the application form as appropriate following the development of additional requirements, if that process can be done in a projected three months; or

- Send out an initial application that focuses on the experience and training of the transplant surgeons; and a second application form that focuses on the programmatic elements of the program.

At the conclusion of its discussion, the Committee agreed that it would be better to take the time to develop these requirements for inclusion in a single comprehensive application form. This method would be more effective than a multi-phased application process and would ultimately place less of a burden on the members, the Committee, and staff, provided that it could be done within a reasonable period of time. The Committee supported the following resolution.

- ** RESOLVED, that a final draft of the application be prepared after a meeting of the MPSC Working Group and representatives from the Living Donor Committee with a goal of having the application complete within 3 months.

The Committee voted 17 For, 1 Against, 3 Abstentions.

The goal is to have a proposal for the next MPSC meeting that can then be sent to OMB for approval. Following the discussion, Ginny McBride, HRSA OPTN Project Officer, agreed to consult with HHS Counsel regarding the OPTNs jurisdiction in area of living donation.

Living Donor Policy Advisory Work Group: During the October 2006 meeting, a new Living Donor Policy Advisory Work Group was formed to develop the methods for assessing non-compliance with the policy and determining what sanctions can be applied and under what circumstances. This Workgroup is chaired by Julie Heimbach, M.D. Other members include Drs. Don Hricik, Rainer Gruessner, Tom Gonwa, Cosme Manzarbeitia, Juan Arenas, and Jennie Perryman. The Living Donor Committee has also been asked to appoint three individuals. It was agreed that the Group should address all organs and that as it develops the proposal they should highlight the definitions of what would be considered in each Category (I-III) as described in the Appendix A of the Bylaws. Patient safety and significant process issues should be clearly identified in the policy.

During the January/February meeting, this group led a discussion on these issues in order to clarify their objectives. Additionally, they held an impromptu meeting on January 31, following the adjournment of the MPSC meeting, to continue to refine their goals. During that meeting Drs. Randy Steadman and Geof Land were asked to participate on the Work Group. Appointment of the Living Donor Committee members is still pending. The Work Group laid out the following rationale and goals for their work.

Rationale: MPSC is now charged with review of adverse live donor outcomes per Policy 7.3.3, which requires transplant centers to report a live donor death or failure of a live donor's organ function within 72 hours of the event to UNOS for review by the MPSC. However, thus far there are no bylaws or guidelines to determine whether any violations of OPTN policy occurred. In the absence of policy to guide us, reviews are currently conducted by the MPSC to determine whether the center acted within accepted standard of care and without negligence. Additionally, the OPTN/UNOS has been charged with oversight of living donor organ transplantation, and therefore guidelines and/or bylaws must be developed. Ensuring compliance of such bylaws and policies will be a responsibility of the MPSC. When reviewing adverse outcomes under Policy 7.3.3, members of the MPSC could use newly developed guidelines/bylaws to determine if a violation of OPTN policy occurred. The Committee can also use these guidelines as part of our

review of programs with lower than expected outcomes, accreditation of new programs, or other issues requiring MPSC oversight.

Goals:

1. Develop a minimum set of criteria for granting designated program status to centers performing living donor transplants (completed for liver, pending for other organs)
 - Bylaws have been completed and enacted for live donor liver transplant programs.
 - What is the status for kidney, lung, pancreas, and small bowel living donor program credentialing?
 - How many live donor transplant procedures are being performed annually?
 - How should MPSC members be involved with this process?
2. Monitor outcomes for all living donors, including mandatory reporting of donor death or loss of organ function per Policy 7.3.3.
 - What data is available currently from UNOS regarding live donors subsequently listed for kidney, liver, pancreas, or lung transplant?
 - Do we plan for OPTN/UNOS auditing of social security death master files or USRDS database to ensure compliance with this?
 - Will we mandate a period of donor follow-up?
 - Define actions MPSC may consider if a program is found to have an adverse event, which may have been due to negligent or inadequate care.
 - Should data regarding all known adverse outcomes be collected and analyzed, and used to develop guidelines for donor work-up? Should this same information be used to consider providing to centers minimum recommendations for peri-operative care (i.e. DVT prophylaxis) if the review of an adverse event reveals something which could likely prevent the adverse outcome?
3. Ensure adequate donor education/informed consent.
 - Consider developing a brief educational document (organ specific) that is published by the OPTN/UNOS, which all centers would distribute. Such a publication would include information, including potential adverse outcomes, related the specific procedure. Advantages of such a document would be helping centers to comply in a uniform way with informed consent.
 - Should we require evaluation of potential donors by mental health professionals (social worker, psychologist, or psychiatrist)?
 - Do we describe a role for a “donor advocate?” Work with the Living Donor Committee on this issue.
 - It was agreed that the Work Group needs to review the white papers and other published documents on this subject.
4. Work-up of potential donors:
 - Should there be guidelines or a minimum set of required elements?

It was agreed that the Work Group needs to have more input from the Living Donor Committee on this issue, including background on the discussions that had already taken place on these issues.

The Work Group also discussed monitoring live donor recipient outcomes and agreed that it is not necessary to review recipient outcomes separately.

12. Update on Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data): The Committee was updated by staff on the status of events surrounding the two live donor deaths that were 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 to be 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 the cases involving the death of a live donor (kidney) at Center 04565A in October 2006, and a live donor (liver) at Center 24530A in November 2005. They concluded that no further action was required in either case as there was not any evidence of policy violations and patient safety issues were not exposed. The Committee reviewed the findings of the Subcommittee during its January/February meeting and agreed that no further action was required in either instance. The Committee approved the following recommendation:

** RESOLVED, that the Committee accepts the report of the Subcommittee in response to the deaths of live donors at Centers 04565A and 24530A.

The Committee vote was unanimous.

The report will also be disseminated to the Living Donor Committee and to the centers where the events occurred.

Immediately prior to the MPSC meeting, two new Living Donor Adverse Outcome cases were electronically reported through the new Patient Safety System in UNet Secure Enterprisesm. Both cases involved native kidney failure in the live donor. They are currently being processed and will be put out for subcommittee review on the Committee Management System in February 2007.

13. 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) program outcome monitoring. A number of committee members suggested that the Committee consider implementation of pancreas outcome monitoring. In turn, the SRTR was asked 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. It is 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 requested the Pancreas Transplantation Committee discuss the variables to be included in an outcome analysis model for pancreas alone, pancreas after kidney, and simultaneous kidney/pancreas transplantation.

During the January 2007 meeting, the Committee was informed that the Pancreas Transplantation Committee will report back to the MPSC for discussion during the May 2007 meeting.

14. Special Presentation Scientific Registry of Transplant Recipients (SRTR): The SRTR staff made a presentation on the Center-Specific Reporting Tools: The presentation covered the following topics: Data sources used by the SRTR; what are Center-Specific Reports, and for whom are they intended; risk adjustment; dealing with lost patients: censoring and extra ascertainment; comparison points: norms versus targets; and interpretation of survival statistics. Committee members had an opportunity to ask questions and provide input to the SRTR during the presentation. This discussion did not result in any action items
15. Proposed Modifications to Data Elements on UNetSM Transplant Recipient Follow-up (TRF) Form (Policy Oversight Committee): The proposal would significantly reduce the number of data elements that transplant centers will be required to submit on the Transplant Recipient Follow-up (TRF) form after 5 years post-transplant. The Committee initially reviewed this proposal on the Committee Management System where it was supported as written. During the January/February meeting the Committee voted to support the proposal.

** RESOLVED, that the Committee supports the changes to the Data Elements on UNetSM Transplant Recipient Follow-up (TRF) Form, which were proposed by the Policy Oversight Committee.

The Committee vote 20 For, 0 Against, 0 Abstentions

16. Proposed Modifications to Policy 3.1 (Organ Distribution: Definitions) (Operations Committee). The aim of the proposed policy modifications is to improve patient safety by requiring verification of UNOS Donor ID number of all organs prior to transplant. The genesis for this proposal was a request by the MPSC to the Operations Committee in 2005 for it to review information regarding an incorrect, but ABO-identical organ placement error situation. The Committee initially reviewed this proposal on the Committee Management System and it was supported as written but a quorum was not achieved. During its January/February meeting, the Committee voted to support the proposal as written.

** RESOLVED, that the Committee supports the proposed changes to Policy 3.1 (Organ Distribution: Definitions).

The Committee voted 22 For, 1 Against, 0 Abstentions.

The Committee appreciates that this is a complicated issue and agreed to refer the issue back to the Operations Committee for the purpose of further exploring ways to ensure that the correct donor organ goes to the intended recipient. The Committee requested that the Operations Committee consider the following suggestions: color coded blood type labels; consistent nomenclature for verbal for naming of ABO blood type; mechanisms to verify between the organ and the intended recipient, a numbering system that is less at risk for confusion; and a label on exterior surface on last sterile barrier (Donor ID and blood type).

** RESOLVED, that the Committee asks the Operations Committee to explore additional further mechanisms to confirm ABO validation, including such items as color coded blood type labels; consistent nomenclature for verbal for naming of ABO blood type; mechanisms to verify between the organ and the intended recipient, a numbering system that is less at risk for confusion; and a label on exterior surface on last sterile barrier (Donor ID and blood type).

The Committee voted 23 For, 0 Against, 0 Abstentions.

17. Providing Information to Patients Regarding Center Reviews and Results: MPSC was informed of the Patient Affairs Committee's (PAC) discussion and draft proposal regarding patient notification. The PAC has been examining ways to improve candidate/patient information regarding the results of transplant center reviews and the results of those reviews with an eye towards recommending improvements. The Patient Affairs Committee raised the following questions: What is our responsibility to keep patients informed? How much information should be provided regarding the center review process/results so that centers are being treated fairly but patients are kept informed? How can we make educational material and data easier to understand?

Additionally, the MPSC was shown the newly developed center profile which will reside on the OPTN website and provide center specific information in a format that is easy for the public to understand. The Committee reviewed the elements included in the dashboard and suggested incorporating local waiting times within DSAs. Additionally, they discussed displaying the surgical depth of the program by displaying information about the number of surgeons available to the program as listed in the Membership database; and the need to provide outcomes data for small volume transplant programs. Feedback from HHS was still pending for this project at the time the Committee met.

18. Number of days a program has its waitlist inactive (but not membership): Staff presented the Committee with an overview of the programs that during had periods when the Waitlist 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, and further 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 seek information on the status of the program and its future plans.

19. Committee Charge: In light of the discussion of its Committee Goals and Process Improvement Initiatives the Committee also reviewed its charge (below) for currency. The Committee discussed how it would continue to carry out its current charge as well as absorb the new work that is being set forth through the Committee Goals and the MPSC Process Improvement Initiatives. During the next few months, committee members were encouraged to identify the essential components of its work and contemplate a possible reorganization into more than one committee where the workload can be further distributed.

MPSC Charge

The Membership and Professional Standards Committee (MPSC) is charged with insuring that OPTN/UNOS member clinical transplant centers, independent organ procurement agencies and independent tissue typing laboratories meet and remain in compliance with OPTN/UNOS Criteria for Institutional Membership. To accomplish this, the MPSC:

- *Develops and recommends membership criteria for each class of membership to the Board;*
- *Recommends additions and revisions to membership criteria as needed;*

- *Reviews each membership application for Institutional Membership and adopts recommendations to be presented to the Board;*
- *Monitors members for compliance with membership criteria and policies including transplant center outcomes and activity levels; and*
- *Reviews reported policy violations and makes recommendations to the Board.*

20. UNOS Actions: During the January/February meeting, 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.

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

The Committee voted 21 For, 0 Against, 0 Abstentions.

**Attendance at the Membership and Professional Standards Committee Meeting
January 30 – February 1, 2007**

Committee Members Attending

Timothy L. Pruett, M.D.	Chair
Niloo M. Edwards, M.D.	Vice Chair & At Large
Craig Lellehei, M.D.	Region 1
Cosme Manzarbeitia, M.D.	Region 2
Alan I. Reed, M.D.	Region 3
Chris E. Freise, M.D.	Region 5
Jorge D. Reyes, M.D.	Region 6
Rainer W. G. Gruessner, M.D., Ph.D.	Region 7
Rob J. Linderer, RN, BSN	Region 8
Patricia A. Sheiner, M.D.	Region 9
Jeffrey D. Punch, M.D.	Region 10
Santiago R. Vera, M.D.	Region 11
Juan D. Arenas, M.D.	At Large
Bonita Balkcom Guilford	At Large
Terry D. Box, M.D.	At Large
Susan Gunderson, MHA	At Large
Julie K. Heimbach, M.D.	At Large
Donald E. Hricik, M.D.	At Large
Geoffrey A. Land, Ph.D.	At Large
Jennie P. Perryman, RN, Ph.D.	At Large
Randall C. Starling, M.D.	At Large
Randolph H. Steadman, M.D.	At Large
Debra L. Sudan, M.D.	At Large
David Weill, M.D.	At Large
Ginny McBride, RN, MPH, CPTC	Ex Officio

Committee Members Unable to Attend

John A. Goss, M.D.	Region 4
Thomas A. Gonwa, M.D.	At Large
Jill M. Maxfield, RN, CPTC	At Large
Dale G. Renlund, M.D.	At Large
Renee Dupee, Esq.	Ex Officio
Richard Durbin, MBA	Ex Officio

SRTR Staff in Attendance

Doug Schaubel, Ph.D.
Charlotte Arrington, MPH

UNOS Staff

Sally H. Aungier, Administrator, Membership Services
Betsy Coleburn, Review Board Coordinator
Rosey Edmunds, Membership Coordinator
Mary D. Ellison, Ph.D., MSHA, Assistant Executive Director for Federal Affairs
Suzanne Gellner, Assistant Director of Analysis & Due Process
Douglas A. Heiney, Deputy AED for Administration
Dave Kappus, Assistant Director, Membership & Policy
Karl McCleary, Ph.D., MPH, Director, Policy, Membership, and Regional Administration

Jacqui O'Keefe, Membership Coordinator
John Persons, Esq., UNOS General Counsel (Attended by phone on 2/1/07)
John Rosendale, Biostatistician
Deanna Sampson, Director, Evaluation and Quality
Leah Slife, Membership Coordinator

EXHIBIT M-1

BRIEFING PAPER

Proposal 2: Proposed Modifications to Bylaws, Appendix B, Attachment I, Section VI “Transplant Surgeon & Physician,” and Section XII(C) “Transplant Programs” (Membership and Professional Standards Committee)

Summary/Performance Objective-Aim

This proposal further defines what “on site” means with relation to availability of transplant surgeons and physicians to provide service to their patients in need of organ transplantation. The objective is to make existing criteria regarding physician and surgeon availability clearer and more specific.

Background and Significance

During its meeting in May 2006, the Membership and Professional Standards Committee (MPSC) reviewed recommendations that had been provided by the Process Improvement Work Group, which was tasked by the Executive Committee and the Board of Directors with developing a Bylaw requirement specifically defining what constitutes onsite availability of transplant surgeon and physician coverage. Presently, the Bylaws require that qualified physicians and surgeons be “on site” at the transplant center, and that “100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service.”

The concepts addressed in the proposed Bylaws changes were intended to better define the terms “on site” and “100% coverage,” as described below:

- That when on call a surgeon/physician must be available and be able to be on the hospital premises within 1-hour ground transportation time.
- The surgeon/physician cannot be designated a primary at more than one center unless there are additional surgeons/physicians at each of those facilities.
- The intent is that all transplant programs should have transplant surgeons and physicians available 365/24/7 to provide program coverage.
 - Transplant programs served by a single physician or surgeon or unable to provide 365/24/7 coverage would be required to notify their patients in writing.
- The Group further discussed its proposed definitions for “additional” staff and concluded the following definitions should be forwarded to the MPSC for their consideration as a possible refinement to the Bylaws:
 - Additional Transplant Surgeons must be able to independently perform the transplant operation and procurement procedures.
 - Additional Transplant Physicians must be able to independently manage immunosuppression.

In discussing these revisions, it was suggested that the provision addressing single physician or surgeon programs be clarified. The intent is not to prohibit programs from operating with a single surgeon and/or physician plan to provide coverage. Instead, the intent is to ensure that the program’s patients are fully informed and understand that there may be times that the surgeon and/or physician is not available and may not be able to accept an organ offer. Furthermore, the Committee clarified that one hour transportation times pertain to being available to transplant an organ, and for the surgeon/physician “on call” for the transplant service to respond to an emergent situation, which can occur with respect to the ongoing care of any transplanted patient and may require the surgeon/physician be present in that hospital quickly.

The Committee made the following recommendation to the Board of Directors when it met on June 29-30, 2006, and the Board endorsed the proposal.

- ** RESOLVED, that the modifications to the OPTN and UNOS Bylaws, Appendix B, Attachment I, Section VI; and the UNOS Bylaws, Section XII(C), as set forth below, are hereby endorsed by the Board of Directors for distribution for public comment, effective June 30, 2006.

Policy Proposal:

Appendix B, Attachment 1 of the UNOS and OPTN Bylaws

VI. Transplant Surgeon and Physician. The transplant program must identify a qualified primary surgeon and primary physician, the requirements for whom are specified below, as well as the program director.

A. The program director, in conjunction with the primary surgeon and primary physician, must submit in writing ~~written~~ a Program Coverage Plan, which documents ~~how that~~ 100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. ~~The Program Coverage Plan must address the following requirements:~~

(1) All transplant programs should have transplant surgeon(s) and physician(s) available 365 days a year, 24 hours a day, 7 days a week, to provide program coverage. If such coverage cannot be provided, ~~a~~ written explanation must be provided that justifies the current level of coverage to the satisfaction of the MPSC. A transplant program served by a single surgeon or physician or unable to provide transplant surgeon/physician coverage 365 days a year, 24 hours a day, 7 days a week shall inform its patients of this fact in writing and explain the potential unavailability of one or both of these individuals, as applicable, during the year.

(2) When “on call” a surgeon/physician must be available and able to be on the hospital premises within one-hour ground transportation time.

(3) The primary transplant surgeon/physician cannot be designated as the primary surgeon/physician at more than one transplant center unless there are “additional” surgeons/physicians at each of those facilities.

(i) Additional Transplant Surgeons must be able to independently perform the transplant operation and procurement procedures.

(ii) Additional Transplant Physicians must be able to independently manage immunosuppression.

B. The primary surgeon and primary physician, collectively, are further responsible for ensuring the ongoing operation of the program in compliance with the criteria set forth in this Appendix B, Attachment I, and notification to the OPTN Contractor if at any time the program deviates from such criteria.

~~A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year. (relocated to Section (1) above)~~

Sections VII – XI - No Changes

Attachment I, Section XII to Appendix B of the UNOS Bylaws -Designated Transplant Program Criteria

XII. Transplant Programs.

A. No Change

C. No Change.

- C. To qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria. Each transplant program must identify a UNOS qualified primary surgeon and physician, the requirements for whom are described below, as well as the program director.

The program director, in conjunction with the primary surgeon and physician, must submit in writing provide written a Program Coverage Plan, which documents ~~ation~~ how that 100% medical and surgical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The Program Coverage Plan must address the following requirements:

- (1) All transplant programs should have transplant surgeon(s) and physician(s) available 365 days a year, 24 hours a day, 7 days a week, to provide program coverage. If such coverage cannot be provided, a written explanation must be provided that justifies the current level of coverage to the satisfaction of the MPSC. A transplant program served by a single surgeon or physician or unable to provide transplant surgeon/physician coverage 365 days a year, 24 hours a day, 7 days a week shall inform its patients of this fact in writing and explain the potential unavailability of one or both of these individuals, as applicable, during the year.
- (2) When “on call” a surgeon/physician must be available and able to be on the hospital premises within one-hour ground transportation time.
- (3) The primary transplant surgeon/physician cannot be designated as the primary surgeon/physician at more than one transplant center unless there are “additional” surgeons/physicians at each of those facilities.
 - (i) Additional Transplant Surgeons must be able to independently perform the transplant operation and procurement procedures.
 - (ii) Additional Transplant Physicians must be able to independently manage immunosuppression.

A transplant center applying as a new member or for a key personnel change must include for the proposed primary transplant surgeon and/or physician a report from their hospital credentialing committee that the committee has reviewed the said individual’s state licensing, board certification, training, and transplant CME’s and affirm that they are “currently” a member in good standing.

Resource Analysis:

The proposed modification will impact transplant centers. Centers that do not presently have a program coverage plan will need to develop a plan, which will enable the programs to demonstrate compliance with the new requirements.

These changes are refinements to criteria presently used to review program and key personnel applications for membership in the OPTN, as well as the surveys utilized by the Data Subcommittee to evaluate program performance. This process is carried out routinely by Membership staff in conjunction with the MPSC, and they will continue to do so with or without the adoption of these changes. Communications can apprise the transplant community of these changes in the course of their normal activities. As additional resources are available, the staff may carry out a comprehensive review of all programs to collect Program Coverage Plans and information regarding who is designated by a program as an “additional” surgeon or physician.

Monitoring:

The questions in the existing applications and surveys (e.g. applications for new programs, reactivation, and key personnel changes, staffing surveys, and Outcomes and Activity Surveys) that are relative to program coverage will

be changed to incorporate the concepts outlined in the modified Bylaws. The responses will be reviewed by staff and the MPSC during the evaluation process.

Summary of Public Comments

The proposal was issued to a mailing list of approximately 11,500 individuals and organizations for a comment period of 30 days beginning August 28, 2006 and ending September 27, 2006.

I. Individual Comments

As of 9/29/2006, 32 responses have been submitted to UNOS regarding this policy proposal. Of these, 22 (68.75%) supported the proposal, 9 (28.13%) opposed the proposal, and 1 (3.13%) had no opinion. Of the 31 who responded with an opinion, 22 (70.97%) supported the proposal and 9 (29.03%) opposed the proposal. Comments on the proposal received to date are as follows:

Comment 1:

vote: Oppose

Appendix B, attachment 1, section VI: A. The "program coverage plan" - who should it be submitted to? The institution or UNOS/OPTN?

A. (2) It is not clear what surgeon/physician means; is it transplant surgeon? Transplant physician? If that is the case, then it contradicts the premise that the program can operate without having the surgeon/physician available but having to give a written notice to the patient explaining potentially unavailability at any given time throughout the year.

A. (3) This proposal does not take into consideration the volume of any given transplant program, that may be a more objective way of looking at the availability issue, and insuring the transplant physician, and especially the surgeon's availability, and at the same time not restricting or effectively shutting down the operation of any given program. It also does not help pediatric patients who are transplanted at separate free-standing children's hospitals that only admit and treat pediatric patients. What is the solution for a pediatric program that shares the transplant surgeon with an adult transplant program?, which is probably the case most of the time due to the relatively low numbers of pediatric transplants done at any given transplant institution. Admitting pediatric patients for such a highly complex specialty as renal transplantation is really not in the best interest of pediatric patients, and I would say not a viable option. A pediatric program is better served by a transplant surgeon who does a large number of transplants, both adult and pediatric, than a dedicated pediatric transplant surgeon who does only 10-15 pediatric transplants per year (an average-sized pediatric transplant program performs 10-15 transplants per year). The center volume effect is well documented in the pediatric literature. In addition, it is very hard, almost impossible, to recruit a pediatric transplant surgeon dedicated to doing pediatric transplants with such small numbers. I suggest that allowing a transplant surgeon to be the primary surgeon at more than one institution should be looked at in terms of the number of transplant done yearly, and taking into consideration pediatric patients.

Committee Response:

Comment A above: The program coverage plan should be developed by the institution and submitted to the OPTN/UNOS.

Comment A(2) above: The Committee clarified the language in the proposal in response to this comment.

Comment A(3) above: The goal of this proposal is not to define staffing ratios based on the number of transplants performed by a transplant program. This information can be addressed in the program's coverage plan.

The Committee reviews program volume and outcomes in other processes. The intent of this proposal is not to address those processes.

This proposal does not limit a primary transplant surgeons/primary transplant physicians participation in programs at multiple facilities. If a person is named at a primary surgeon or physician at more than one center then they must demonstrate how coverage is provided to each program by other transplant surgeons/transplant physicians who qualify as "additional" as described in the proposed bylaw.

Comment 2:

vote: Oppose

DEPARTMENT OF VETERANS AFFAIRS IOWA CITY HEALTH CARE SYSTEM Medical Center 601 Highway 6 West, Iowa City, IA, 52246-2208 September 25, 2006 Dr. Timothy Pruett Chair, MPSC Attn: Betsy

Gans UNOS 700 N 4th Street Richmond, VA 23219 Dear Members of the Board and Committee: Proposed Modifications to Bylaws, Appendix B, Attachment 1, Section IV, "Transplant Surgeon & Physician" and Section XII (C) "Transplant Programs" We are writing during the public comment phase in response to the proposed changes to "Physician and Surgeon Coverage at Transplant Centers." The physical plant of the Iowa City VA Medical Center, which we represent, is located immediately adjacent to the University of Iowa Hospitals and Clinics. Although both the University of Iowa Hospitals and the VA Medical Centers have separate reporting requirements as transplant hospitals, our center identifiers, UIHC as IAIV and the VA as IAIV-VA1, recognizes the close affiliation between these two transplant centers. The program director for the transplant center at each hospital is different, but both centers share the same group of transplant surgeons and transplant nephrologists. The transplant surgeon on call accepts kidneys for both centers, cognizant of the availability of another transplant surgeon. Thus, for purposes of providing additional coverage, scheduling of elective and on-call transplant surgeries, we would suggest that these two transplant centers be considered as a single center when reviewing the requirement to providing primary and "additional" surgeons at each of these facilities. We agree that a transplant program must provide transplant surgeon and physician coverage at all times with additional surgeons and physicians available at each of these facilities. When on-call, our surgeons and physicians can be within the hospital premises within an hour of ground transportation time, except when a surgeon is away from the center traveling, or is indisposed. We are thus able to provide the coverage that UNOS/OPTN envisages and can certainly inform our patients that on occasion the transplant centers may only have a single surgeon. We are currently in the recruiting phase for additional transplant surgeons but we believe that we have the required backup coverage now except as stated above. The proposed changes in the UNOS and OPTN bylaws do not explicitly clarify the intent when two closely affiliated programs work together to provide physician/surgeon coverage. The lack of clarity in these policies would put smaller programs at risk of being in violation of UNOS and OPTN bylaws. We feel that there should be some flexibility in the regulations and further clarification of these bylaws with consideration being given to the requirements for affiliated hospitals that share health care personnel. Sincerely, Christie Thomas, MD Program Director VA Transplant Center Iowa City, IA And John S. Cowdry, MD Chief of Staff VA Iowa City Health Care System Iowa City, IA

Committee Response:

The Committee does not anticipate reviewing VA hospitals that are affiliated with a University separately since they were approved under a single membership, which is described in Appendix B, Attachment 1 of the Bylaws as follows:

Veterans Administration Hospitals that are Dean's Committee Hospitals and share a common university based transplant team, need not make independent application to UNOS, but may be considered members under the university program with which they are affiliated. Independent Veterans Administration Hospitals, or Veterans Administration Hospitals which are not Dean's Committee Hospitals sharing a common university based transplant team, must submit application and be approved for UNOS membership in order to list patients and have access to donor organs shared through the network.

Likewise, a pediatric program that exists under a single membership with the adult program would not be considered separately.

Comment 3:

vote: Oppose

I am providing a comment on policy proposal #2, Bylaws, Appendix B, Attachment 1, Section VI, pdf document number 187. I am specifically concerned about the definitive requirement that the transplant surgeon and transplant physician be 1 hour driving time from the hospital. For many people around the country, including my center in New York City, this is not possible depending on weather, time of day, road accidents, construction, and other variables. To what does the policy refer? Average driving time? Optimal driving time? Slowest driving time? How is that determined? Who will adjudicate these measurements?

Further, the wording of the proposal is ambiguous such that it is not clear if the policy is always referring to the UNOS designated and credentialed surgeon and physician, or if the policy is referring to any surgeon and physician who is assigned to the transplant service (e.g., fellows, residents, other attending physicians providing cross coverage). I strongly urge the committees to reconsider this policy proposal, work on the wording, and then resubmit it for public comment.

Committee Response:

The Committee clarified that the one hour driving time relates to the individual that is on call to ensure that the patient is cared for in a timely and responsible manner. It was pointed out that the person on call does not have to be the same one that is taking calls on organ offers. The Committee has recommended an amendment to the language that recognizes that the one hour requirement should be met "barring unforeseen circumstances." Additionally, language was added that further clarifies the surgeons availability for accepting and implanting an organ within acceptable ischemic time limits.

If a patient has emergency someone needs to be there to take care of them in a timely manner, which is not the same as accepting and transplanting an organ within a reasonable ischemic time. Different timeline.

Comment 4:

vote: Oppose

I do not believe that it is necessary for a transplant program to have the transplant physician available within one hour. I think the language should be amended that the transplant surgeon or physician be available within one hour while on call. That would allow one physician programs that have only one surgeon and/or one physician to still have some flexibility. There should also be some room to allow the NPs or PAs in the transplant program to serve as the designee for the physician (or surgeon). This would seem to be very safe for the patients in this era of cellular technology.

Committee Response:

This proposal does not limit who takes initial call.

The Committee continues to feel that it is important that a transplant surgeon/transplant physician be readily available to the program and able to care for patients in a timely and responsible manner.

Comment 5:

vote: Oppose

In my previous comments, I forgot to also mention the inconsistency in the language concerning the "additional surgeon." In one section the terminology is "additional surgeon" and in the same subsection it defines "additional transplant surgeons." Is this a loophole or an error?

Committee Response:

The Committee intended for this to refer to the transplant surgeon and amended the language to make it clearer.

Comment 6:

vote: Oppose

The background and significance section suggest that the intent of these changes are "...not to prohibit programs from operating with a single surgeon and/or physician..." It seems that the intent is to provide quality of care in a timely manner.

Item (1) says that programs with one surgeon/physician must inform all recipients of this fact. Why? I can understand that if there is no surgeon/physician available (illness, vacation, physician loss) that all recipients must be notified immediately, but why tell the patient initially? If the purpose is to let patients know that only one surgeon/physician is available then we must extend this to include all situations when this occurs; i.e. when one surgeon/physician in a two person practice goes on vacation, to meetings, is ill, retires, or leaves the practice. Otherwise, it would seem that smaller, one surgeon/physician transplant centers are being discriminated against and the proposal could be interpreted as a scare tactic push recipients to larger practices.

Item (2) (having a one hour ground time response time), appears like a reasonable suggestion. However, this may prohibit transplant surgeons from doing their own procurements. Has the board consider this. Item (3), suggest that the primary surgeon/physician cannot be the primary surgeon/physician at more than one transplant center. In certain situations, this may not work to the recipients advantage.

In the paragraphs that follow, I would like to use our situation in Corpus Christi, Texas to demonstrate this point and show how acceptance of item (3) will disadvantage renal failure patients in our city. The hospitals in Corpus Christi, Texas serve the lower 32 counties of the state; a population of about 2.1 million people. Driscoll Children's Hospital and Christi Spohn Hospital are interested in developing renal transplant services. The Childrens Hospital has about 15 patients on dialysis and anticipates doing about 5 to 6 renal transplants per

year. The adult hospital serves over 1000 dialysis patients in the county and could serve as a renal transplant referral center for the lower Rio Grande Valley; dialysis population over 3000 patients. The estimated renal transplant volume for the adult hospital would begin at about 30 transplants per year with a maximum of about 115 per year. Since my arrival in Corpus on August 1, 2005, we have been working to provide renal transplant services to adults and children. Driscoll Children's Hospital received UNOS approval effective June 30th, 2006 and Medicare approval yesterday (9/25/06). Spohn hospital is just beginning the UNOS application process. The hospitals are 1 mile apart. According to the hospital bylaws, the adult hospital cannot admit children and the Childrens Hospital cannot admit adults. The medical community supports both hospitals and the development to both renal transplant programs. Therefore, there is a need for two transplant centers. Both programs are renal only programs with a combined volume that, at the present time, can only support one surgeon.

Again, I need to ask what is the purpose of the proposed change? While I can see the logic for different primary surgeons at each MULTI-ORGAN transplant center, I do not see it in the situation we have in our city. In our situation, we have two specialty hospitals (one adult and one children's hospital), that will be low volume renal only programs. The need to have two transplant centers is only because of the presence of a free standing children's hospital. Having a separate, free-standing Childrens hospital is clearly a benefit to the community and improves the level of pediatric care.

Adoption of item (3) will negate this advantage for our pediatric renal recipients and for no demonstrable benefit. Therefore, I would urge you to reconsider the wording in item (3) for renal only programs, low volume single organ programs, and programs that serve both children and adults.

P. Stephen Almond, M.D., F.A.C.S. Chief, Division of Pediatric Surgery and Transplantation Bruce M. Henderson, Chair in Pediatric Surgery Driscoll Children's Hospital 3533 South Alameda Street Suite 302 Corpus Christi, TX 78411 361-694-4700 Phone 361-694-4701 FAX stephen.almond@dchstx.org

Committee Response:

The Committee appreciates the issues raised in these the comments.

Response to the first issue (above): The intent is to ensure that the program's patients are fully informed and understand that there may be times that the surgeon and/or physician is not available and may not be able to accept an organ offer.

Response to the second issue (above): The proposal does not specify that the primary transplant surgeon must also perform the procurement procedure so this operation may be performed by another individual. The procuring surgeon does not have to be a transplant surgeon.

Additionally, this proposal does not limit a primary transplant surgeon's/primary transplant physician's participation in programs at multiple facilities. If a person is named as a primary transplant surgeon or primary transplant physician at more than one center then they must demonstrate how coverage is provided to each program by other transplant surgeons/transplant physicians who qualify as "additional" as described in the proposed bylaw.

Comment 7:

vote: Oppose

What is so sacrosanct about 60 min by ground? is 30 min by non-ground transportation vs 90 minutes by ground going to be a basis for disciplinary action? from a federal level, it seems to me that a general, 'due diligence' guideline is more appropriate here. favor existing, local processes for dealing with problems if 'red flags' (e.g. turning down an organ because of lack of surgeon or MD availability a problem from standpoint of care delivery in any other way). that said, i would favor a strict reporting requirement on the part of centers if local peer review and other oversight processes identify problems.

Committee Response:

The Committee amended the language to address some of these concerns.

Comment 8:

vote: Support

Discussion from regional meeting: 1) clarify consortium groups, such as VA's and Children's Hospitals with 1 vote, but multiple sites. 2) support the intents, but final language is clear for single transplant group wording
Vote: 18-0-0

Staff Note: *See Regional Comments below.*

Committee Response:

See response to Comment 2 above.

Comment 9:

vote: Support

In favor of policy with revised language as follows: Dear OPTN/UNOS Board of Directors: On behalf of the American Society of Transplant Surgeons (ASTS), thank you for the opportunity to respond to the OPTN solicitation of comments on the proposal further defining what "on site" means with relation to availability of transplant surgeons and physicians to provide service to their patients in need of organ transplantation as set forth in the OPTN Policy Proposals for Public Comment Notice of August 28, 2006. Please note that immunosuppression in transplant programs throughout the United States is managed by the surgeon(s). The ASTS would like the Board to consider further defining the following two points:

A.(3)(ii) Additional Transplant Surgeons/Physicians must be able to independently manage immunosuppression.

B. The primary surgeon and primary physician, collectively, must be capable to evaluate potential donors and recipients with respect to their candidacy, provide the necessary care pre-, peri- and post-transplantation patient management, including immunosuppression, as well as care required for the relevant disease management of the specific patient population. Further, the primary surgeon/physician are responsible for ensuring the ongoing operation of the program in compliance with the criteria set forth in this Appendix B, Attachment I, and notification to the OPTN contractor if at any time the program deviates from such criteria.

We hope that these comments are helpful to OPTN.

Committee Response: The Committee appreciates the comments from the ASTS and has amended the proposal to reflect that the surgeons and physicians must be credentialed by the institution to "provide transplant services." The Committee has also recommended changes to the definitions of additional transplant surgeons and physicians, which should address some of the concerns that were raised.

Comment 10:

vote: Support

No comments

Comment 11:

vote: Support

The American Society of Transplantation (AST) strongly supports proposed modifications to Bylaws, Appendix B, Attachment I, Section VI "Transplant Surgeons & Physicians" and Section XII(C) "Transplant Programs" to further define what constitutes onsite availability of transplant physicians and surgeon to provide coverage and service to the patients in need of organ transplantation. Certified programs must be prepared to provide care to transplant patients every day, all year around. The covering surgeon on-call should be qualified to perform the transplant procedure(s) independently. The covering transplant physician on-call must be qualified and properly trained to provide optimal care to transplant patients. Unfortunately, the exact criteria for the covering transplant physicians has been poorly defined.

The AST looks forward to working with UNOS to further define the criteria and expertise necessary for these physicians to provide optimal care to potential transplant recipients as well as being able to address donor issues. I would be happy to provide further comments upon request. Thank you very much again for allowing us to participate in this important process. Sincerely, Jeffrey S. Crippin, MD

Committee Response: The Committee appreciates the comments from the AST and welcomes additional input on the requirements. The requirements presently address only the qualifications for the primary transplant surgeon and primary transplant physician in detail and do not presently delineate minimum qualifications for additional transplant surgeon and physicians beyond the basic definition that has been proposed. The Committee

has amended the proposed language to specify that the individual must be credentialed by the institution to provide transplant services.

REGIONAL COMMENT SUMMARY

Region	Meeting Date	Motion to Approve as Written	Approved as Amended <i>(see below)</i>	Did Not Consider
1	9/11/06	9 yes, 2 no, 0 abstentions		
2	10/6/06	5 yes, 25 no, 1 abstention		
3	9/29/06	3 yes, 9 no, 0 abstention	<i>7 yes, 3 no, 2 abstentions</i>	
4	10/6/06	8 yes, 7 no, 3 abstentions	<i>15 yes, 0 no, 1 abstention</i>	
5	9/01/06	27 yes, 1 no, 0 abstention		
6	9/15/06	32 yes, 14 no, 6 abstentions		
7	10/6/06	5 yes, 9 no, 0 abstentions		
8	9/8/06	18 yes, 0 no, 0 abstentions		
9	9/27/06	14 yes, 0 no, 0 abstention		
10	9/22/06	19 yes, 0 no, 0 abstention		
11	9/29/06	2 yes, 11 no, 0 abstention	<i>9 yes, 1 no, 3 abstentions</i>	

REGIONAL COMMENTS:

Region 1:

The members noted that the policy should include language regarding the on-call physicians and surgeons specifically that they do not need to be credentialed by the OPTN/UNOS, only credentialed by the hospital.

Committee Response: The OPTN/UNOS does not credential individual surgeons and physicians but it does review the credentials of the individuals proposed as the primary transplant surgeon and primary transplant physician to ensure that they meet the minimum criteria on behalf of the program. Additional transplant surgeons and additional transplant physicians only need to be credentialed by the hospital and are not required to meet the same minimum standards.

Region 2: Overall, the Region 2 Members were in support of the intent of the proposal to improve patient safety and avoid the “itinerant surgeon.” They fully support the necessity for full coverage for transplant centers and full disclosure to patients if there is not. However, members were not in support of the proposal as written. During the discussion, the following concerns were raised:

- Requiring that the on-call surgeon/physician be within an hour drive of the hospital is not realistic and should not be included in this policy. Not only is the driving time sometimes out of an individuals control (i.e. traffic, accidents, weather), but it is often unnecessary for the surgeon/physician to be on site within an hour. The specific time period of one hour time should not be included in this proposal.
- Spirit of the bylaw change is very appropriate, but needs to have improved wording that will protect patients without imposing excessive control or limitations to transplant physicians/surgeons. Need to have greater input and suggested wording from Members.
- Spirit is laudable; but the restrictive numbers are punitive rather than helpful. Placing specific time limits on physician/surgeon could result in noncompliance that would set legal precedence.
- If the goal is to secure adequate patient access, the end point should not be surgeon availability but % of acceptable donors transplanted.
- Intent of proposal is fully supported but many agreed that the Metrics used were wrong. Could use turndown rates, refusal codes.
- Many Members agreed that they could support this proposal with minor wording changes to the “1-hour” criteria (i.e. normally, barring unforeseen circumstances) or onset of time could be related to completion of tests or other procedures that precede needing a presence of a surgeon/physician.
- Language does not address physician extenders in “additional staff”
- Language is too restrictive and does not take into account support staff (i.e. Fellows, NPs, PAs)

Committee Response:

The Committee discussed and amended the language that described the need for the individual on call to be available within one hour.

The Committee agrees that it is important to take acceptance rates into consideration. The MPSC is already developing methodology for collecting and analyzing organ acceptance/turndown rates and deaths on the waiting list, which can be used to evaluate program performance.

It is not the intent of this proposal to address other members of the transplant team.

Regions 3/11:

The members did not approve the proposal as written. During the discussion, the following concerns were brought up:

- This is a hospital credentialing issue. Hospitals define distance/time standards.
- UNOS cannot mandate one standard response time for every center.
- The one hour standard would present logistical issues for single surgeon programs who have to perform the organ recovery prior to the organ transplant.

Regions 3/11 approved the following Amendment to Section VI. Also, there was a concern raised that in post transplant emergent situations, Itinerant Surgeons who are not part of the transplant team would be involved.

VI. Transplant Surgeon and Physician. The transplant program must identify a qualified primary surgeon and primary physician, the requirements for whom are specified below, as well as the program director.

A. The program director, in conjunction with the primary surgeon and primary physician, must submit in writing ~~written~~ a Program Coverage Plan, which documents ~~ation~~ how that 100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The Program Coverage Plan must address the following requirements:

(1) All transplant programs should have transplant surgeon(s) and physician(s) available 365 days a year, 24 hours a day, 7 days a week, to provide program coverage. If such coverage cannot be provided, a written explanation must be provided that justifies the current level of coverage to the satisfaction of the MPSC. A transplant program served by a single surgeon or physician or unable to provide transplant surgeon/physician coverage 365 days a year, 24 hours a day, 7 days a week shall inform its patients of this fact in writing and explain the potential unavailability of one or both of these individuals, as applicable, during the year.

~~(2) When "on call" a surgeon/physician must be available and able to be on the hospital premises within one hour ground transportation time.~~

(2) A surgeon/physician must be readily available for organ acceptance and implantation and able to be on the hospital premises within cold ischemic time limits.

(3) The primary transplant surgeon/physician cannot be designated as the primary surgeon/physician at more than one transplant center unless there are "additional" surgeons/physicians at each of those facilities.

(i) Additional Transplant Surgeons must be able to independently perform the transplant operation and procurement procedures.

(ii) Additional Transplant Physicians must be able to independently manage immunosuppression.

B. The primary surgeon and primary physician, collectively, are further responsible for ensuring the ongoing operation of the program in compliance with the criteria set forth in this Appendix B, Attachment I, and notification to the OPTN Contractor if at any time the program deviates from such criteria.

~~A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year.~~ (relocated to Section (1) above).

Committee Response:

The Committee appreciates the comments from Regions 3 and 11 and agreed to incorporate the suggestion for adding language that defines the surgeon's availability for organ acceptance and implantation as suggested.

With regard to the one hour presenting logistical issues for single surgeon programs who have to perform the organ recovery prior to the organ transplant the Committee believes that the

amendments to proposal address this concern. The Committee also pointed out that the recovery surgeon does not need to be a transplant surgeon.

Region 4: Region 4 approved the following amendment:

- (i) Additional Transplant Surgeons must be able to independently perform the transplant operation and procurement procedures. Transplant Surgeons can also manage immunosuppression.*
- (ii) Additional Transplant Physicians must be able to independently manage immunosuppression.*

Several members voiced the concern that transplant surgeons often manage immunosuppression and the bylaw should reflect this practice.

Several members were also concerned with the proposed language which does not allow a transplant surgeon/physician to be designated as the primary surgeon/physician at more than one transplant center unless there are “additional” surgeons/physicians at each facility. A couple of members were confused by the wording, and were not sure if additional staff needed to specifically be “transplant” surgeons/physicians. One member felt strongly that a surgeon should be able to serve as the primary surgeon at an adult transplant center and a pediatric transplant center without additional transplant surgeons on staff at the pediatric center.

This modification was unacceptable to several members.

Committee Response:

The Committee agreed to amend the proposed language to incorporate the fact that surgeons also manage patient care.

The Committee indicated that the “additional” staff do need to be trained/experienced transplant surgeons and transplant physicians.

The Committee agreed that a surgeon could be the primary transplant surgeon at more than one facility as long as there are additional transplant surgeons involved in the program. This was allowed for in the original proposal.

Region 6: Although the region supported the proposal, the following concerns were voiced:

- 100% coverage at all times is not realistic. There can be exceptions in well covered centers when a surgeon/physician is not available for a very limited amount of time. It should not be necessary for a program to notify patients in writing when an unanticipated situation arises resulting in a temporary lapse in coverage. For example: There may be times when the volume at a program is greater than the number of available transplant surgeons/physicians.
- Proposal should require that ALL candidates get something in writing about center coverage.
- Definition of availability is overly broad and does not lend itself to real life situations.
- Often transplant programs at VA hospitals have the same transplant team as their affiliated hospitals. Policy needs to address this situation.

Committee Response:

The Goal set forth in the Bylaws is for coverage to be provided 365/24/7, and if that is not possible that the patients need to be informed via the patient teaching materials and/or their listing notice letter. This notification could describe, for example, instances when an organ may not be accepted.

The Program Coverage Plan should describe the availability of the transplant surgeons and transplant physicians over the coming year and should be based on the best estimate by the program directors. It is not the intent of this Bylaw that patients be informed of each situation when an organ cannot be accepted.

The Committee responded to the 3rd item above and has amended the proposal to further define “availability.”

The Committee agrees with the 4th comment above and believes that the Bylaws already address VA

Medical Centers, which are in most cases not independent members of the OPTN/UNOS. (See also response to Comment 2 above)

Region 7: Region 7 was concerned about the wording of the “on-call” portion of the policy. It was discussed that many institutions have “systems” that are established to handle transplantation and that this policy does not account for these systems since it assumes that there would be one person on-call. The region also commented that it felt that there needed to be some additional language that there would be oversight to the letter that was sent to patients concerning the single surgeon/physician. They felt that there should be standard verbiage used by all transplant programs.

Committee Response: The Committee amended the language and the phrase “on call” has been further clarified in the proposal. Additionally, the Committee agreed to consider the development of standard language for the patients relative to the program coverage plan. The Plan and patient notice information is subject to review during a routine UNOS staff audit performed by the Department of Evaluation and Quality.

Region 8:

The region supported the proposal with the following comments:

- Language needs to address transplant consortia (i.e. VA programs/children’s programs that are affiliated with a “parent” hospital). Often these centers are in very close proximity and share a common transplant team.
- One hour time frame for response to the hospital is too strict given the unpredictable nature of traffic and weather in many areas of the country.

Committee Response:

The Bylaws already address the criteria for VA Medical Centers (see response to Comment 2 above). The Committee agreed that there may be times when one hour is not possible due to weather or other extenuating circumstances and has amended the proposed language..

Region 9:

The region approved this proposal with the caveat that the MPSC continue to review the bylaws to address underserved patients in terms of inadequate staffing at transplant centers. The members also would like for the committee to identify how many surgeons/physicians/ coordinators each center should have on staff.

Committee Response: The Committee appreciates this comment however, it was not the intent of this proposal to address staffing ratios.

III. Committee Responses:

Representatives from the Ad Hoc International Relations, Kidney Transplantation, Liver and Intestinal Organ Transplantation, Minority Affairs, Pancreas Transplantation, Pediatric Transplantation and Thoracic Organ Transplantation Committees met by teleconference, using Microsoft® Live Meeting® to review the five proposals currently out for public comment by the Membership and Professional Standards Committee. Due to the abbreviated time frame for this public comment, a conference call was scheduled to provide an opportunity for these committees to discuss the proposals and provide feedback to the MPSC. Additional comments were solicited from members who were unable to participate. These comments are *italicized* to indicate that they were not part of discussion by the full group.

This proposal further defines what “on site” means with relation to availability of transplant surgeons and physicians to provide service to their patients in need of organ transplantation. The objective is to make existing criteria regarding physician and surgeon availability clearer and more specific.

A member inquired as to what the endpoint was for the one hour timeframe due to it being highly unlikely a transplant would occur within one hour of the organ offer. It was clarified that the one hour would be relative to distance from the hospital utilizing ground transportation, not necessarily for a

transplant, but for patient care in an emergency situation with a patient that has already been transplanted or a patient awaiting transplant. This timeframe was driven by situations in which a surgeon was the primary surgeon at more than one center separated by more than an hour driving time. It was a mechanism to ensure there was a way to get the surgeon on site when necessary for a transplant or to care for a patient. The one hour timeframe was chosen due to similar requirements set forth for trauma surgeons.

A member inquired if the committee discussed updating the coverage plans and the circumstances required for updating the plans. It was noted the committee did discuss these and will continue to develop them. The items being brought forward at this time were those the committee felt could be implemented with fewer resources when compared to others. The inquiring member felt it might be worth putting something in place requiring the programs to update UNOS when the coverage plans change not so much for proactive evaluation but in retrospect when faced with a situation where the coverage plan changed without notification.

A member stated at the Region 5 meeting when this item was discussed the concept was generally approved, but questions arose concerning the ability to monitor compliance. In large metropolitan areas with dense traffic, driving across town may not be plausible in one hour. Small programs in smaller regions and pediatric programs also may not have a surgeon readily available, especially on weekends. It was noted the committee looked at the number of programs that would be impacted and it was less than 100. If programs are unable to fall within the guidelines for 365/24/7 coverage, it will be necessary to notify patients of these circumstances so that they may make an informed decision on whether that is the correct program for them. The committee anticipates being able to look at program coverage plans as a part of applications submitted for new programs and changes in key personnel, as well as surveys conducted by the Data Subcommittee relative to program outcomes and inactivity.

Vote: 20-1-2

Breakdown of votes by committee:

International Relations:	0-0-1
Kidney*:	1-0-0
Liver:	5-0-0
MAC:	5-0-0
Pancreas*:	5-1-0
Pediatric*:	2-0-0
Thoracic*:	4-0-1

Pediatric Committee Members submitted the following additional comments:

- *"365/24/7 coverage is both laudable, and necessary as a general rule, but may not be possible for all patients in all programs at all times. It appears aimed at assuring that organs for transplantation are not turned down due to physician or surgeon unavailability, thus protecting patient access. While aimed at providing universal access of patients listed for a particular transplant regardless of where they are listed, this may not currently be possible to achieve. This requirement raises very difficult issues to address in special circumstances. For example, a patient requiring an unusual technical variant of a case may require the program director to be present for their case (e.g. cavoportal hemi transposition etc). This person may not be available within one hour, and certainly can not be available 365/24/7. Thus, while it is possible to provide universal access for most patients in most programs, it is impossible to assure that every patient can be provided that assurance. Similarly, some programs offering rare and low volume transplants such as islet cell or multi-visceral may have one surgeon who is present for all such cases to assure safety. These are done in such low volume as not to allow several surgeons to be independently available at all times. Wording to account for the possibility of such intermittent absences as may occur from time to time should be included. An alternative and possibly preferable solution to guarantee access might define what percentage of organ offers can reasonably be considered appropriately declined due to such unavailability. These low volume type circumstances should be infrequent enough as not to exceed a defined measure. This measure*

might be considered a low volume of organs (no more than 5% offers) or some other such appropriately determined volume that could be tracked."

(Same commenter continues) "The one hour rule of surgeon or medical physician availability sets a requirement without a stated objective that is to be met by it. If the objective is availability of care for post-transplant patients within one hour of a call, then this should be specified. This objective should be evaluated, and the appropriateness of UNOS policy determining such a narrow management concern should be discussed. This one hour timeframe is given without consideration of what the "standard of care" would be in differing geographic areas, manpower provisions of hospitals, etc. The use of fellows, hospitalists, or other care providers in transplant programs may make this one hour rule too narrow now or in the near future. Thus, while it may be necessary and sufficient in some areas, it may be insufficient or beyond what is necessary in others. The "one size fits all" approach seems less valuable in protecting safety than actually defining a quantifiable measure of safety that again can be tracked or defining safety within what is considered "standard" in a geographic area such as a UNOS region."

(Same commenter continues) "If the objective is to assure patient access by assuring the ability of physicians to transplant an available organ within an appropriate window, then such should be addressed directly and with wording that states that the availability of the "on call" surgeon should be sufficient that no organs should be declined due to surgeon unavailability. This is virtually never a one hour window, so the specific timeframe seems not to be appropriate to this concern. However, again wording that looks at the actual direct measure of the concern (patient access to organs) would be preferable and more metric driven than the indirect measure of the commute time of the physician. If the intent is to protect some other aspect of patient safety or access then this should be defined and a directly quantifiable endpoint defined."

(Same commenter continues) "These rules are written in such a way that unwanted and unnecessary litigation may derive from them if published in this format. Such would not serve the interests of patient safety, transplant facilities, UNOS or society at large. If a patient becomes ill and an on call attending physician arrives on the scene beyond one hour from an initial call, the present wording would seem to make that physician liable for negligence. Ultimately, the safety of patients is reflected in the survival of those patients and their organ grafts, a clean and quantifiable outcome measure."

- "I am generally happy with the proposals, although a stricter definition of 100% surgical coverage is needed, I think, to cover programs against legal or other actions if unforeseen circumstances occur, such as sickness while the other surgeons are out of town for example. Also I think the expectation for 100% coverage should only apply to adult liver and kidney programs. This being the case, it might be wise to suggest that every program state clearly what coverage they can supply for all of their programs, including a clause regarding unusual and unforeseen circumstances."*
- "The main points I took away from the feedback on this are [1] the one hour rule is too concrete, and does not provide metrics for performance; and [2] the 100% coverage rule sets up some potential for liability if programs do not comply. As I've thought through this it might be better to rewrite clause 1 and 2 in the document to focus on the goals (minimize the number of times organs are turned down because of limited availability of the transplant surgeon or other program resources) and request that ALL programs inform candidates of potential scenarios in which circumstance might occur."*

Committee Response:

See responses to previous comments from Regions 2, and 3/11.

Transplant Coordinators Committee: This proposal clearly defines the meaning of "on site" with relation to availability of transplant surgeons and physicians in order to provide service to their patients

in need of organ transplantation. The objective is to make existing criteria regarding physician and surgeon availability clearer and more specific.

The committee agrees that surgeons must be present 24 hours per day and 365 days per year. They agreed that patients must understand that there may be times when organs are not accepted because of surgeon availability.

The Committee also voiced concerns regarding the availability of clinical transplant coordinators, the potential need to review staffing of transplant centers, and the need for recommendations regarding the availability of the clinical coordinator.

The Committee agreed that the definition of transplant program is vague and that it may be confusing when adult and pediatric centers have the same surgeon. It is essential that patients need to be aware of the fact that a single surgeon program might influence their receiving organ offers.

Motion: The committee agrees with the spirit of the proposed policy change and accepted it by a vote of 10-0-0.

Committee Response: The Committee appreciates the support and concerns of the Transplant Coordinators Committee. It was not the intent of this proposal to address the availability of staff other than surgeons and physicians. The MPSC would be happy to consider a proposal from the Transplant Coordinators Committee that addresses the availability of clinical transplant coordinators.

Patient Affairs Committee: This proposal further defines what “on site” means with relation to availability of transplant surgeons and physicians to provide service to their patients in need of organ transplantation. The objective is to make existing criteria regarding physician and surgeon availability clearer and more specific.

The Committee utilized the Committee management system to vote on this proposal by September 27, 2006. There was not a quorum as only seven of eighteen Committee members voted. There was brief written discussion surrounding the support of required correspondence with candidates regarding lack of staff coverage. All seven members voted unanimously to support the proposed policy.

The Vote was 7 For, 0 Against, 0 Abstentions.

Committee Response: The Committee appreciates the support from the Patient Affairs Committee.

Proposal Status:

Update: During its October 2006 meeting, the Committee discussed the responses to the proposal that were received during the public comment period. Based on the number of comments received and suggestions for amending the proposal, the Committee voted to refer the issue back to the Process Improvement Work Group for further review and development. It was noted that no current members of the MPSC served on the Joint Work Group, therefore, the following members were appointed: Drs. Julie Heimbach, John Goss, and Geof Land.

In summary, the comments provided by individuals and the Regions included, but were not limited to, the following:

- This proposal does not take into consideration the volume of any given transplant program.
- The proposal does not account for single surgeon programs that share staff with affiliated pediatric or VA medical centers.
- One hour driving time was considered restrictive and could prohibit surgeons from performing their own procurements.
- Definition of “additional transplant physician” is not adequate.
- The proposal does not address availability of other staff such as clinical coordinators.

Update from Work Group Meetings on January 3 and 10, 2007: The MPSC Process Improvement Work Group 2, chaired by Dr. Frederick Grover, met by conference call on January 3, 2007, in order to discuss the proposals. The Work Group met again on January 10, 2007, and continued to refine the proposal.

The Work Group discussed comments received from individuals, Regions, and committees; further modifications to the Proposal; and implementation of the proposed changes.

Defining Coverage: The Work Group discussed the language regarding one-hour availability of the surgeon and physician and agreed to make further amendments to the proposal that would more clearly define its intent.

It was agreed that a goal was to ensure timely organ acceptance and to prevent unnecessary delays in organ procurement following acceptance. It was noted that DonorNet® should help with timely acceptance but may not prevent delays after acceptance so the Work Group recommended modifying the proposal to more clearly define the expectation that the whole process of acceptance, procurement, and implantation needs to take place in a timely manner.

The Work Group agreed that the proposed requirements for defining additional transplant surgeons and transplant physicians should be applied to existing programs and that a member staff audit should be conducted after the criteria are approved by the Board. Centers could make additions, changes, or deletions to the staff at this time. This audit would involve sending a letter to all program directors with a list of the individuals currently listed in the database as surgeons and physicians for specific organ transplant programs. The directors would be asked to verify which of these individuals meet the new definition of “additional” transplant surgeon or “additional” transplant physician and the Membership Database would be updated accordingly. The Work Group discussed various ways of establishing a schedule to create the annual audit due dates, including using the initial date of approval, but realized that method would create a heavy workload on certain months since most dates will correlate to the months that the Board of Directors met. Additionally, the Work Group agreed that it would be simpler to mail the audit to all programs within a given center at the same time rather than on different schedules based on approval dates. Once the initial survey is conducted future verification of the “additional” surgeons and physicians may be performed during the existing annual member staff audit, when key personnel change applications are submitted, or by specific written notification.

Program Coverage Plan: A Program Coverage Plan must be submitted in writing to UNOS and describe how 100% medical and surgical coverage will be provided in the program by individuals who are credentialed by the hospital to provide transplant service for the programs. After further consideration, the Work Group made the following suggestions to refine this proposal:

- The proposed bylaw calls for the program to provide a copy of the Program Coverage Plan to the OPTN/UNOS. The Work Group suggested modifying the language so that all programs, not just those that are single surgeon or single physician, would have to notify their patients of their coverage plan..
- The Work Group also agreed that the program should update UNOS and the patients if there are substantive changes in the program or personnel.

The above recommendation was further modified after consideration by the MPSC.

Implementation - Program Coverage Plan: The Work Group made the recommendations below regarding implementation of the proposal but agreed that the MPSC should have the final say in the implementation plan. While the Work Group did discuss the number of programs that would be reporting (over 900) and the fact that it would be difficult for the MPSC to review all of the Program Coverage Plans, it did not discuss in detail the specific financial or staffing resources needed by UNOS or the members to carry out this process. The suggestions from the Work Group include the following:

- That staff review the individual Program Coverage Plans and then provide the MPSC with a list of programs that returned their Plans. If the program appears to be fully covered (i.e. provides 365/24/7 coverage) staff could report receipt of the Plan to the Committee and further Committee review would not be necessary at that time. Staff would also provide the Committee with a list of any programs that did not returned their Plan by the assigned due date.
- If the program is covered by a single surgeon and/or single physician, the MPSC or an MPSC Subcommittee should automatically review it. Staff could also forward to the Committee any Plans that raise questions during their review.
- MPSC should automatically review programs that do not have 365/24/7 coverage. The MPSC may also want to consider reviewing programs that have inactivate waitlist time during the year (but who did not formally inactivate their membership status).
- The audit of the Program Coverage Plan and initial staff review would be implemented immediately, on a rotating basis (such as by region) in order for staff and the Committee to effectively manage a process of this magnitude.
- Process for notifying patients of the Program Coverage Plan: The Work Group agreed that it would recommend that the Programs must send a written notice out to patients within 3 months of the Bylaw being implemented. The Work Group did not discuss the (financial) resources for the hospitals to perform this task. The Work Group also discussed developing standard language for inclusion in patient acceptance letters. Such language should convey the sense that "...If this transplant center's availability of surgeons and physicians is not acceptable to you, you have the right to seek another transplant center..." This concept was modified by the MPSC and is further discussed below.

Update from January/February MPSC Meeting. The Committee reconsidered the proposal when it met on February 1, 2007. Dr. Stuart Sweet, a member of the Process Improvement Work Group, led the discussion (by conference call). It considered the modifications suggested by the Work Group as a result of the comments received during the public comment process. Their discussion was focused on the whether or not the language conveyed the intent of the proposal as well as concerns about the enforceability of the requirements. It was suggested that the language be recast to make it clearer that the Committee is trying to identify a pattern of behavior rather than monitoring events on a case-by-case basis (e.g. monitoring the ability to be on site within one hour ground transportation time.)

Program Coverage Plan Concerns: The Committee discussed the implementation of the proposed Program Coverage Plan and specifically its scope. It was concerned that the originally proposed language might be confusing and cause programs to send out a notice to patients each time there is an instance when the program could not accept organs due to coverage issues. It was not the Committee's intent for this to happen. Members suggested that changes in coverage can occur in any program, so even programs with 365/24/7 coverage provided by multiple transplant surgeons and transplant physicians are susceptible and should send an initial letter to their patients letting them know that they did not expect any periods of staff unavailability that would lead to the center not being able to accept organs. The program should provide their patients with a written summary of the Program Coverage Plan at the time they are listed, and when there are any substantial changes in program or personnel. The Committee recommended that the proposed modification to the Bylaws be amended to incorporate the follow recommendation.

** RESOLVED, that the proposal be amended to incorporate the following language into Appendix B, Attachment I, Section VI "Transplant Surgeon and Physician" and Attachment I, Section XII to Appendix B of the UNOS Bylaws "Designated Transplant Program Criteria": *"All programs should provide patients with a written summary of the Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel."*

The Committee Voted 19 For, 3 Against, 0 Abstentions.

The Committee agreed that in addition to these modifications to the Bylaws, that efforts to develop a system for monitoring organ acceptance rates should be continued. This developing methodology for collecting and analyzing organ acceptance/turndown rates and deaths on the waiting list will be used to evaluate program performance and could identify programs that are inappropriately inactive and may pose a risk to patient safety.

On Site Availability of Surgeons and Physicians: The Committee considered the comments regarding the originally proposed language, which specified that “*When “on call” a surgeon/physician must be available and able to be on the hospital premises within one-hour ground transportation time.*” ...

The Committee discussed the comments suggesting that the proposed language could potentially impact transplant surgeons and transplant physicians that are designated as the primary transplant surgeon/transplant physician in two facilities such as adult and pediatric (or V.A.) hospitals on the same campus or in close proximity. The proposal prohibits the primary transplant surgeon or primary transplant physician from being designated as the primary transplant surgeon/primary transplant physician at more than one transplant center unless there are additional transplant surgeons/transplant physicians at each of those facilities. The Committee agreed that it was important that these programs also have additional transplant surgeons and transplant physicians in order to provide 365/24/7 coverage and it was not inclined to rescind or further modify this proposal.

The Committee agreed that at the most basic level, a transplant surgeon/transplant physician needs to be available to take care of the patients and there needs to be someone available to accept organs. They do not have to be the same individual. They pointed out that organs can be accepted based on phone conversations and that a transplant surgeon/transplant physician’s physical presence is not required for organ acceptance. After further discussion and the review of the comments, the Committee agreed that the one-hour driving time was restrictive and could prevent surgeons from performing their own procurements. It would also be difficult to monitor compliance with this requirement.

The Committee’s discussion returned to the intention of the requirement - to minimize the instances that an organ is turned down because of staff unavailability; and to prevent situations where a transplant surgeon/transplant physician is not available to respond quickly to emergent situations. The Committee agreed to the following language, as proposed by the Work Group:

“A transplant surgeon or transplant physician must be readily available in a timely manner to facilitate organ acceptance, procurement, and implantation, and to address urgent patient issues.”

The Committee also supported the following resolution:

** RESOLVED, that the proposal modifications to Appendix B, Attachment I, Section VI “Transplant Surgeon and Physician” and Attachment I, Section XII to Appendix B of the UNOS Bylaws “Designated Transplant Program Criteria” be amended to incorporate the following language: *When on call the transplant surgeon and transplant physician may not be on call for two transplant programs more than 30 miles apart unless the circumstances have been reviewed and approved by the Membership and Professional Standards Committee.*

The Committee voted 16 For, 6 Against, 0 Abstentions.

The pairing of the two newly proposed requirements (above) makes it possible to remove the reference to one hour transportation times, while at the same time addressing timely availability of a transplant surgeon or transplant physician to respond to organ offers and emergent situations; as well as these individuals being designated a primary transplant surgeon or primary transplant

physician at more than one center unless there are additional surgeons/physicians at each of those facilities.

The Committee discussed the remaining language, such as the improved definitions of additional transplant surgeon and additional transplant physician, in the proposal as modified by the Work Group and recommends the following resolution for consideration by the Board of Director:

**** RESOLVED, that the following modifications to Appendix B, Attachment I, Section VI “Transplant Surgeon and Physician” and Attachment I, Section XII to Appendix B of the UNOS Bylaws “Designated Transplant Program Criteria” having been distributed for public comment and subsequent reconsideration by the Committee, as set forth below are approved effective pending notice and programming in UNetsm, if and as applicable.**

The Committee voted: 19 For, 3 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 B, Attachment 1 of the UNOS and OPTN Bylaws

Appendix B, Attachment 1 of the OPTN Bylaws

VI. Transplant Surgeon and Physician. The transplant program must identify a qualified primary surgeon and primary physician, the requirements for whom are specified below, as well as the program director.

A. The program director, in conjunction with the primary transplant surgeon and primary transplant physician, must submit to the OPTN Contractor in writing ~~written~~ a Program Coverage Plan, which documents ~~ation~~ how that 100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The Program Coverage Plan must address the following requirements:

- (1) All transplant programs should have transplant surgeon(s) and transplant physician(s) available 365 days a year, 24 hours a day, 7 days a week, to provide program coverage. If such coverage cannot be provided, a written explanation must be provided that justifies the current level of coverage to the satisfaction of the Membership and Professional Standards Committee (MPSC). All ~~A~~ transplant programs should provide patients with a written summary of the Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel. ~~served by a single transplant surgeon or transplant physician or unable to provide transplant surgeon/physician coverage 365 days a year, 24 hours a day, 7 days a week shall inform its patients of this fact in writing and explain the potential unavailability of one or both of these individuals, as applicable, during the year.~~
- (2) When “on call” a surgeon/physician must be available and able to be on the hospital premises within one hour ground transportation time. ~~transplant surgeon and transplant physician may not be on call at two transplant programs more than 30 miles apart unless the specific circumstances of that coverage have been reviewed and approved by the Membership and Professional Standards Committee.~~

- (3) A transplant surgeon or transplant physician must be readily available in a timely manner to facilitate organ acceptance, procurement, and implantation and to address urgent patient issues.
- (3 4) The primary transplant surgeon or ~~primary~~ primary transplant physician cannot be designated as the primary transplant surgeon/primary transplant physician at more than one transplant center unless there are ~~additional~~ transplant surgeons/transplant physicians at each of those facilities.
- (i) Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.
- (ii) Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of the transplant patients ~~immunosuppression~~.
- B. The primary surgeon and primary physician, collectively, are further responsible for ensuring the ongoing operation of the program in compliance with the criteria set forth in this Appendix B, Attachment I, and notification to the OPTN Contractor if at any time the program deviates from such criteria.

~~A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year.~~ (relocated to Section (1) above)

Sections VII – XI - No Changes

Attachment I, Section XII to Appendix B of the UNOS Bylaws -Designated Transplant Program Criteria

XII. Transplant Programs.

- A. No Change
- B. No Change.
- C. To qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria. Each transplant program must identify a UNOS qualified primary surgeon and physician, the requirements for whom are described below, as well as the program director.

The program director, in conjunction with the primary transplant surgeon and primary transplant physician, must submit to UNOS in writing provide written a Program Coverage Plan, which documents ~~ation~~ how that 100% medical and surgical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The Program Coverage Plan must address the following requirements:

- (1) All transplant programs should have transplant surgeon(s) and physician(s) available 365 days a year, 24 hours a day, 7 days a week, to provide program coverage. If such coverage cannot be provided, ~~an~~ written explanation must be provided that justifies the current level of coverage to the satisfaction of the MPSC. ~~All~~ ~~A~~ transplant programs should provide patients with a written summary of the Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel. ~~served by a single surgeon or physician or unable to provide~~

~~transplant surgeon/physician coverage 365 days a year, 24 hours a day, 7 days a week shall inform its patients of this fact in writing and explain the potential unavailability of one or both of these individuals, as applicable, during the year.~~

- (2) When “on call” a A surgeon/physician must be available and able to be on the hospital premises within one-hour ground transportation time to address urgent patient issues.
- (3) A transplant surgeon must be readily available in a timely manner to facilitate organ acceptance, procurement, and implantation.
- (4) ~~(2)~~ The primary transplant surgeon/primary transplant physician cannot be designated as the primary surgeon/primary transplant physician at more than one transplant center unless there are “additional” transplant surgeons/transplant physicians at each of those facilities.
 - (i) Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.
 - (ii) Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients immunosuppression.

A transplant center applying as a new member or for a key personnel change must include for the proposed primary transplant surgeon and/or physician a report from their hospital credentialing committee that the committee has reviewed the said individual’s state licensing, board certification, training, and transplant CME’s and affirm that they are “currently” a member in good standing.

Implementation issues – Program Coverage Plan: The Committee also discussed the Work Group’s suggestion of developing standard language for inclusion in patient acceptance letters. The Committee did not fully agree with the Work Group’s suggestion that language be added to the candidate acceptance letter, indicating that they have the “right to seek another transplant center...” The Committee thought that a better alternative would be for the OPTN to provide a letter that is directed to the patients, but require the center to provide this letter to each patient when they are listed. It could accompany the acceptance letter, be on OPTN letterhead, and signed by the current OPTN president. The acceptance letter should refer to the OPTN letter, so that if it is not enclosed, the patient will be aware that they need to make an inquiry of the center.

The Committee also had concerns about the burden that would be placed on centers with large waiting lists if a letter regarding program coverage had to be sent annually, and agreed that they would recommend that this information be provided in the acceptance letter and when there were substantial changes in the program or personnel. At the conclusion of the discussion, the Committee agreed to support the following concepts:

- ** RESOLVED, that the Committee explore the feasibility of implementing the oversight component relating to program coverage by having the OPTN provide a letter for the transplant patients, that the center will in turn provide to each patient when the patient is listed, along with the acceptance letter. This letter would touch on the listing and behavior issues we have with the centers, and include the patient hotline number and information about patient rights. It was determined that the letter should come from the OPTN/UNOS as an oversight organization rather than the center itself. The acceptance letter must reference the OPTN letter as an enclosure.

The Committee voted 23 For, 0 Against, 0 Abstentions.

The Committee agreed that this project should be referred to the Patient Affairs Committee for further development since it parallels a similar Committee project regarding patient notification.

Executive Summary

Proposal 2: Proposed Modifications to Bylaws, Appendix B, Attachment I, Section VI “Transplant Surgeon & Physician,” and Section XII(C) “Transplant Programs”

OPTN/UNOS Membership and Professional Standards Committee

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Executive Summary

Proposal 2: Proposed Modifications to Bylaws, Appendix B, Attachment I, Section VI “Transplant Surgeon & Physician,” and Section XII(C) “Transplant Programs”

OPTN/UNOS Membership and Professional Standards Committee

Section 1: Information to be provided to the POC

Summary/Background

Proposal Summary	
Subject	Description
Brief summary of proposed Policy	This proposal further defines what “on site” means with relation to availability of transplant surgeons and physicians to provide service to their patients in need of organ transplantation.
Primary goal(s) of Policy as set forth by sponsoring Committee	The objective is to make existing criteria regarding physician and surgeon availability clearer and more specific.
Assessment of policy	1. Program Coverage Plans will be collected from centers to ensure that they have a plan for providing appropriate coverage as described in the proposed bylaws. 2. Transplant centers will be asked to indicate which surgeons and physicians in their program meet the new definition of “additional” transplant surgeon/physician.

Checklist for Analytic Modeling

5-Point Checklist for Analytic Modeling	
Component	Assessed by Committee?
Statement of the Objectives of the Proposed Policy	Not applicable
Building the Models	Not applicable
Testing the Models	Not applicable
Testing the Consequences of the Formulated Proposed Policy Prior to Implementation (Simulation Modeling)	Not applicable
Evaluation of the Effectiveness of the Policy	Not applicable

Executive Summary

Proposal 2: Proposed Modifications to Bylaws, Appendix B, Attachment I, Section VI “Transplant Surgeon & Physician,” and Section XII(C) “Transplant Programs”

OPTN/UNOS Membership and Professional Standards Committee

Additional supporting data/analyses

See Attached Briefing Paper from March 2007 MPSC Report to the Board of Directors.

Program Goals, Strategic Plan and Relationship to OPTN Final Rule

Goals	
Program Goal	Impact
Increase number of deceased donor transplants	Not applicable
Increase number of DCD donors	Not applicable
Increase number of non-DCD donors	Not applicable
Increase life years gained	Not applicable
Increase organs transplanted/donor - non-DCD	Not applicable
Increase organs transplanted/donor - DCD	Not applicable
Strategic Plan	Impact
Increase donors and transplants in support of HHS Program Goals	Not applicable
Refine allocation policies, incorporating concepts of: <ul style="list-style-type: none">• donor risk• recipient benefit, and• net benefit	Not applicable
Reduce variation of death on the waiting list across the country	Not applicable
Optimize a safe environment for living donor transplantation	Will occur, but as a consequence to these changes.
Improve compliance with policies to protect patient safety and preserve public trust	Will occur, but as a consequence to these changes.
Improve the OPTN data system	Not applicable

Executive Summary

Proposal 2: Proposed Modifications to Bylaws, Appendix B, Attachment I, Section VI “Transplant Surgeon & Physician,” and Section XII(C) “Transplant Programs”

OPTN/UNOS Membership and Professional Standards Committee

Comportment with the Final Rule

Yes. These changes will help to ensure transplant center compliance with Section §121.9 by further verifying that the transplant programs have the appropriate staff available.

New/Modified Data Collection Requirements

Data Collection Requirements	
Data Collection Principle	Details
Develop transplant, donation, and allocation policies	Not applicable
Determine if institutional members are complying with policies	Not applicable
Determine member-specific performance	Not applicable
Ensure patient safety when no alternative sources of data exist.	Not applicable
Fulfill the requirements of the OPTN Final Rule.	Not applicable
*For specific populations (e.g. Pediatrics, Living Donors) if exceptions to the foregoing principles, have alternative sources of information been explored?	Not applicable

Public Comment Summary

Public Comment Distribution

Has the proposal been distributed for public comment? YES

Date of distribution: 08/28/2006

Public comment end date: 09/27/2006

Thirty-two individual responses were submitted regarding this policy proposal. Of these, 22 (68.75%) supported the proposal, 9 (28.13%) opposed the proposal, and 1 (3.13%) had no opinion.

Public Comment Response Tally				
Type	Response Total	In Favor	Opposed	No Comment
Individual Comments	32	22 /68.75%	9/ 28.13%	1/ 3.13%
Regional Comments	11 Regions	7	4	0

Executive Summary

Proposal 2: Proposed Modifications to Bylaws, Appendix B, Attachment I, Section VI “Transplant Surgeon & Physician,” and Section XII(C) “Transplant Programs”

OPTN/UNOS Membership and Professional Standards Committee

Primary Public Comment Concerns/Questions

In summary, the comments provided by individuals and the Regions included, but were not limited to, the following:

- This proposal does not take into consideration the volume of any given transplant program.
- The proposal does not account for single surgeon programs that share staff with affiliated pediatric or VA medical centers.
- One hour driving time was considered restrictive and could prohibit surgeons from performing their own procurements.
- Definition of “additional transplant physician” is not adequate.
- The proposal does not address availability of other staff such as clinical coordinators.

Estimated UNOS Resource Utilization -

UNOS Resource Estimates for Implementation	
Area	Impact
Resource Impact	<p>Membership Staff:</p> <ol style="list-style-type: none"> 1) Conduct an audit of all programs to verify which individuals in their program meet the new definition of “additional” surgeon/physician. 2) Collect Program Coverage Plans from over 900 transplant programs. Perform staff evaluation and direct Plans to the MPSC that need further review. 3) DEQ staff auditors to verify that program has a Program Coverage Plan when they are on site and that it has conveyed this information to its patients as described in the proposed Bylaws. <p>Department of Evaluation and Quality (DEQ) Staff:</p> <ol style="list-style-type: none"> 1) During site surveys of transplant centers, DEQ staff will verify that each program has a Program Coverage Plan. DEQ staff will also verify that candidates are notified of the Program Coverage Plan at the time of listing. DEQ staff already monitors for compliance with candidate notification during site surveys of transplant centers and will modify current monitoring efforts to incorporate this change. This Bylaw change will require an additional monitoring effort for DEQ, but should not require additional staff.
Estimated FTEs	Membership (520 hours/2080 hours) = .25 FTE

Implementation Strategy

Implementation Plan Status		
Documentation/Plan	Complete?	Status Comments
Functional and Technical Specification Documents	No	In process and being evaluated in conjunction with the System Redesign.
Resource Analysis Assessment	Yes	Budget information submitted to the Finance Committee and Board for consideration at the March 2007

Executive Summary

Proposal 2: Proposed Modifications to Bylaws, Appendix B, Attachment I, Section VI “Transplant Surgeon & Physician,” and Section XII(C) “Transplant Programs”

OPTN/UNOS Membership and Professional Standards Committee

		meeting.
Communications and Education Plan	In process	A policy notice mailing will be sent to the members that describe the changes to the Bylaws and how they will be implemented.
Monitoring Plan	In process	The MPSC Process Improvement Work Group has suggested monitoring methods to the MPSC. Monitoring implementation is subject to the necessary resources being approved in the budget. (See also section Monitoring Effort Summary below).

Section 2: POC RECOMMENDATIONS to Board of Directors

Policy Oversight Committee (POC) Recommendations

Date(s) proposal reviewed by POC: Not Applicable

POC Policy Scorecard

Not Applicable

Summary of Recommendations

Not Applicable

Board of Directors Review

Date(s) proposal submitted to Board of Directors: 3/23/2007

Executive Summary

Proposal 2: Proposed Modifications to Bylaws, Appendix B, Attachment I, Section VI “Transplant Surgeon & Physician,” and Section XII(C) “Transplant Programs”

OPTN/UNOS Membership and Professional Standards Committee

Community and Membership Impact	
Community/Member/Organization	Impact Description
Transplant Centers	<p>1) Each program will need to submit a Program Coverage Plan following approval of the proposed Bylaws. Programs will need to submit updates to the Plans as described in the Bylaws.</p> <p>2) Programs will need to complete an initial Audit to determine which staff are designated as “additional” transplant surgeons/physicians so that the Membership Database can be updated. Changes and additions will need to be reported on an ongoing basis.</p> <p>3) Programs will need to notify their patients of their coverage plan within 3 months of Bylaw approval and send out updates as necessary if there are substantial changes to the program or personnel.</p>

Appendix B: Communication and Education Plan

Communication Responsibilities and Outcomes			
Type of Communication	Audience(s)	Delivery Method(s)	Timeframe
Policy Notice	Transplant Directors, surgeons, physicians and administrators	Electronic	Within 30 days of Board Approval
Staff Audit notice distributed by the Membership Department	Transplant Program Directors with copy to primary transplant administrator.	Mail	Dependent upon budget approval for necessary FTE’s
Coverage Plan notice to be distributed the Membership Department	Transplant Program Directors with copy to primary transplant administrator.	Electronic and/or mail.	Dependent upon budget approval for necessary FTE’s

Education / Training Responsibilities and Outcomes			
Education / Training Description	Audience(s)	Delivery Method(s)	Timeframe
<i>Not Applicable</i>			

Appendix C: Monitoring Plan

Member Expectations

Executive Summary

Proposal 2: Proposed Modifications to Bylaws, Appendix B, Attachment I, Section VI “Transplant Surgeon & Physician,” and Section XII(C) “Transplant Programs”

OPTN/UNOS Membership and Professional Standards Committee

Member Description/Group	Action
Transplant Center	<p>Each program will be required to submit a Program Coverage Plan to the OPTN/UNOS, and share with their patients a summary of the Plan at time of listing and if there are any substantial changes in the program or personnel. Additionally, the Plan must be available for examination upon request</p> <p>2) Programs will be required to complete an initial Audit, distributed by the Membership Department, to determine which staff are designated as “additional” transplant surgeons/physicians so that the Membership Database can be updated. Changes and additions will need to be reported on an ongoing basis.</p> <p>3) Programs must to notify their patients of the Program’s Coverage Plan in writing within 3 months of Bylaw approval and send out updates as necessary if there are substantial changes to the program or personnel</p>

Monitoring Effort Summary

#	Monitoring Action Planned	Plan Detail
1	Staff review the individual Program Coverage Plans	<p>The audit of the Program Coverage Plan and initial staff review would be implemented upon implementation and proper notice, on a rotating basis (such as by region) in order for staff and the Committee to effectively manage a process of this magnitude.</p> <p>That staff review the individual Program Coverage Plans and then provide the MPSC with a list of programs that returned their Plans. If the program appears to be fully covered (i.e. provides 365/24/7 coverage) staff could report receipt of the Plan to the Committee and further Committee review would not be necessary at that time. Staff would also provide the Committee with a list of any programs that did not returned their Plan by the assigned due date.</p>
2	MPSC or an MPSC Subcommittee review of Program Coverage Plans	<p>If the program is covered by a single surgeon and/or single physician, the MPSC or an MPSC Subcommittee should automatically review it. Staff could also forward to the Committee any Plans that raise questions during their review. MPSC should automatically review programs that do not have 365/24/7 coverage. The MPSC may also want to consider reviewing programs that have inactivate waitlist time during the year (but who did not formally inactivate their membership status).</p>
	Patient Notification by program	<p>Process for notifying patients of the Program Coverage Plan: The Work Group agreed that it would recommend that the Programs must send a written notice out to patients within 3 months of the Bylaw being implemented and proper notice.</p>

Executive Summary

Proposal 2: Proposed Modifications to Bylaws, Appendix B, Attachment I, Section VI “Transplant Surgeon & Physician,” and Section XII(C) “Transplant Programs”

OPTN/UNOS Membership and Professional Standards Committee

3	Site Surveys of Transplant Centers Conducted by DEQ Staff	During site surveys of transplant centers, DEQ staff will verify that each program has a Program Coverage Plan. DEQ staff will also verify that candidates are notified of the Program Coverage Plan at the time of listing.
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EXHIBIT M-2

BRIEFING PAPER

Proposal 4: Proposed Modifications to Bylaws, Appendix B, Section II, “Transplant Hospitals,” “Investigation of Personnel;” Appendix B, Attachment 1, Section IV “Investigation of Personnel;” Section VII “Transplant Surgeon and Physician;” and Appendix B, Attachment I, Section XII (C) (Membership and Professional Standards Committee).

Summary/Performance Objective-Aim

The proposed modifications to the Bylaws would enhance oversight of individual physicians and surgeons by requiring:

- Transplant hospitals to conduct investigations, upon request, according to their peer review protocols and report to the OPTN;
- Applicants for primary physician or surgeon to submit assessments of prior non-compliant behavior with which they or other individuals proposed as part of the transplant team have been involved, as well as plans to ensure that the improper conduct is not continued; and
- Applicants for primary physician or surgeon to submit letters of recommendation attesting to their overall qualifications to act as primary physician or surgeon, as applicable, and addressing matters such as the individual’s personal integrity, honesty, and familiarity with and experience in adhering to OPTN requirements and compliance protocols.

The aim is to prevent an individual physician or surgeon who has been involved in non-compliant activity at one institution from continuing that or similar activity at the same or another institution.

Background and Significance

Transplant hospitals may apply to be members of the OPTN/UNOS, and transplant programs within hospital members may apply to be designated by OPTN/UNOS to receive organs for transplantation. Once approved, the hospital becomes a Member of OPTN/UNOS and the program is designated to receive organs. Individual physicians and surgeons associated with these institutions and programs may be reviewed as part of the member/designated program application, but are not approved independently from the member/designated program application. There presently are no criteria for physicians and surgeons distinct from requirements associated with training and experience to serve as the primary physician or surgeon for a particular transplant program.

Certain data banks, e.g., the National Practitioner Data Bank (NPDB) and Healthcare Integrity and Protection Data Bank (HIPDB), collect and report information about various adverse actions that are taken against individual physicians and surgeons. The OPTN does not presently participate in these data banks; it appears that so long as the OPTN continues to approve institutions and programs, without independently approving individual physicians and surgeons, there is no expectation that OPTN would participate in these data banks.

OPTN Bylaws do not exist in a vacuum. To the contrary, the bylaws presently rely upon state licensure, as well as hospital credentialing and privileging processes, to ensure that individual physicians and surgeons are qualified to provide patient care services in accordance with jurisdictional and other relevant requirements. OPTN primary physician and surgeon criteria then supplement these processes by requiring minimum levels of competence and currency in the care of organ transplant candidates and recipients specifically.

Policy Proposal

In evaluating its charge to address misconduct for which an individual physician or surgeon appears uniquely responsible, the MPSC Process Improvement Work Group and the MPSC worked within a framework consistent with existing Bylaws emphasizing institutional responsibility, and without embarking upon new processes to approve individual physicians and surgeons. The Work Group developed a two-pronged approach. New or revised

activities would be incorporated: (1) at the time a policy compliance inquiry is underway, and (2) during the application process.

1. Policy Compliance Inquiry Underway.

- The proposal incorporates a requirement that, at the request of the MPSC, transplant programs must investigate an individual physician or surgeon's role in a matter under investigation by the MPSC where an adverse action against the hospital is being considered, for possible reporting to the NPDB, loss of privileges, suspension, probation, or other appropriate action as determined by the program. The investigation would include peer review pursuant to the institution's standard process for conducting inquiries of potential professional misconduct.
- If during a MPSC inquiry it appears that a physician or surgeon is substantially responsible for non-compliant behavior at the institution, the MPSC could request the program to perform such a peer review investigation. The institution would be asked to report to the MPSC whether it had initiated, conducted, and concluded the inquiry according to its standard processes and pursuant to the OPTN Bylaws provision.

2. Application Process.

- OPTN Bylaws already define Primary Physician and Surgeon responsibility to include: *"ensuring the ongoing operation of the program in compliance with the criteria set forth in ...Appendix B, Attachment I, and notification to the OPTN Contractor if at any time the program deviates from such criteria."* This provides authority to hold the primary physician and surgeon accountable for transgressions of their existing programs and avoidance of transgressions in any new program to which the physician or surgeon moves.
- The proposal would incorporate within the application to be named primary physician or surgeon requirements for self-assessment of all physicians and surgeons participating in the transplant program regarding their involvement in prior transgressions and plans to ensure that the improper activity is not continued.
- A Plan for Continuing Policy Compliance (PCPC) also would be incorporated as a new application requirement and used for self-reporting and updating information on some periodic timetable. Questions developed to form the basis of the PCPC would be designed to:
 - Disclose involvement in prior inappropriate behavior;
 - Report to the satisfaction of MPSC safeguards are (or will be) in place to assure similar transgressions will not be repeated; and
 - Report a plan for educating all physicians and surgeons providing transplant services about OPTN policies and processes.

The PCPC would define the trigger for reporting prior misconduct as affiliation at any point in time with a transplant program that has appeared before the MPSC for a Hearing. The questions forming the basis of the PCPC would be developed to understand the physician or surgeon's role and assure that the new program has considered how it will prevent same or similar activity leading to the Hearing from recurring.

The Work Group acknowledged that oversight is more difficult when a physician or surgeon who participates in inappropriate activity leaves the institution where the misconduct occurred prior to an MPSC inquiry that results in a Hearing. A requirement for submission of letters of recommendation, described below, is proposed to discern such information. Additionally, several of the PCPC questions would be designed specifically in an attempt to reveal these situations.

- Finally, the proposal would further incorporate within the application to be named primary physician or surgeon requirements for letters of recommendation attesting to the individual's overall qualifications, personal integrity, familiarity with OPTN requirements, etc. The source of

the letters would be persons of authority affiliated with transplants programs previously served by the individual.

In developing the proposal, the Work Group summarized the following potential advantages:

- Transplant hospitals would continue to be responsible for credentialing individual physicians and surgeons and monitoring their professional conduct. The proposal would emphasize situations that require particular oversight as well as processes to ensure that such oversight occurs. It also would reinforce responsibility for policy compliance in general.
- The proposal would avoid costs and exposure to legal liability associated with processes to approve (or credential) individual physicians and surgeons independently of their institutions. This would include, for example, establishing, monitoring, investigating, and enforcing (with appropriate due process provided) criteria for which the physicians and surgeons would be accountable individually.
- The proposal may be tested as an initial step, for study and subsequent modification as determined appropriate, before embarking upon more resource intensive proposals.

The Work Group also noted the following potential disadvantages:

- The proposal would not prohibit a physician or surgeon involved in prior non-compliant activity from later being approved as a primary physician or surgeon or being accepted as part of a transplant team.
- The proposal's oversight for a physician or surgeon who leaves an institution before a MPSC inquiry resulting in an adverse action is initiated and moves to another institution may appear weak. Questions would be developed as part of the primary physician/surgeon application process and letters of recommendation would be required in an attempt to address this concern. Ensuring appropriate due process protections for these individuals is challenging since they are no longer affiliated with the institutional transgressor and were not present at the time of the MPSC investigation. Occurrences of this nature involving a physician or surgeon believed to be substantially responsible for the inappropriate behavior have been non-existent or at least not frequent in the past; it is expected that they would not be frequent in the future.

The Joint Work Group determined that the following proposals accomplish the intended objectives without excessive financial and other resource demands and should be approved for public comment consideration. The proposals were presented to and endorsed by the Board of Directors during their June 2006 meeting. They were subsequently circulated for public comment.

Bylaw Proposal:

Appendix A to the Bylaws – OPTN and UNOS Application and Hearing Procedures for Members and Designated Transplant Programs

Section 1

1.01A - Nature of Membership/Designated Transplant Program Status [No Change]

1.02A - Duration of Membership [No Change]

1.03A - Procedures upon Application for Membership

- (1) General Procedure: The Membership and Professional Standards Committee shall investigate and consider under confidential medical peer review each application for membership and designation as a transplant program and shall adopt and transmit recommendations thereon to the Board of Directors.
- (2) Application Form: Each application for membership and designation as a transplant program shall

be in writing, submitted on the prescribed form approved by the Membership and Professional Standards Committee, and signed by the applicant.

(3) Content: The application form shall include:

- (a) Acknowledgment and Agreement: A statement that the applicant has received and read the current Charter, Bylaws, and Policies and that the applicant agrees: (i) to be bound by the terms thereof, as amended, if the applicant is granted membership and/or designated transplant program status and (ii) to be bound by the terms thereof in all matters relating to consideration of the application without regard to whether or not the applicant is granted membership or designated transplant program status.
- (b) Qualifications: Detailed information and supporting documentation, as may be specified by the Membership and Professional Standards Committee (MPSC) from time to time and described in the application form, concerning the applicant's qualifications, including information in satisfaction of the basic qualifications specified in Article 1 of the Bylaws and the Criteria for Membership (Appendix B) regarding applicable membership requirements. This shall include, by way of example and without in any way limiting information that may be required in the application, submission of a:
 - (1) Plan for Continuing Policy Compliance that reports results from an assessment by the named primary physician and/or surgeon for transplant programs designated to perform organ transplants regarding involvement of any of the program's physicians or surgeons in prior transgressions of OPTN requirements and plans to ensure that the improper conduct is not continued.
- (c) Information on Liability Insurance Coverage: For OPO, Transplant Hospital, and Histocompatibility Laboratory Members, information as to whether the applicant has currently in force liability insurance with at least \$1,000,000 limits of coverage per occurrence. Coverage must be provided by an insurer that is either licensed or approved by the insurance regulatory agency of the state in which the applicant's principal office is located. In lieu of insurance coverage, evidence of equivalent coverage through a funded self-insurance arrangement shall suffice. At the request of the organization that operates the OPTN under contract with HHS (OPTN Contractor), the applicant or member shall furnish a current certificate of insurance.
- (d) Administrative Remedies: A statement whereby the Member agrees that, when an adverse ruling is made with respect to membership or designated transplant program status, the Member will exhaust the administrative remedies afforded by these Bylaws and applicable Federal regulations before resorting to formal legal action.
- (e) Release of Information to HHS: A statement whereby the Member authorizes the release of any and all information to HHS (directly or through the OPTN Contractor) regarding applications for membership or designation as a transplant program in the OPTN, and activities for monitoring and enforcing OPTN membership criteria, policies, and Federal regulations as described in these Bylaws.

1.04A - Processing the Application [No Change]

1.05A - Effect of Membership and Professional Standards Committee Action [No Change]

1.06A - Time Periods for Processing [No Change]

1.07A - Reapplication after Adverse Decision [No Change]

Appendix B to Bylaws - OPTN
Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations.

[No Change]

II. Transplant Hospitals.

General. [No Change]

Survival Rates. [No Change]

Inactive Membership Status. [No Change]

Investigation of Personnel. At the request of the MPSC, the Transplant Hospital must conduct an investigation of personnel identified by the MPSC, who are associated with one or more of the Transplant Hospital's designated transplant programs (as defined below) qualified as a transplant program by other than the requirements set forth in Attachment I and sub-attachments to Appendix B, and report to the MPSC upon initiation and conclusion of the inquiry that it has conducted the investigation in accordance with the terms of this provision. The purpose of the investigation would be to examine the individual's or individuals' role(s) in a matter under review by the MPSC and would be explained to the Transplant Hospital. The Hospital's investigation must include peer review pursuant to the institution's standard process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process. Failure to comply with this provision shall result in recommendation to the Board of Directors that the Board so notify the Secretary, and/or take appropriate action in accordance with Appendix A of these Bylaws.

Patient Notification. [No Change]

Clinical Transplant Coordinator. [No Change]

Financial Coordinator. [No Change]

Routine Referral Procedures. [No Change]

Designated Transplant Program Status. [No Change]

III. Histocompatibility Laboratories. [No Change]

Attachment I to Appendix B of the OPTN and UNOS Bylaws

A transplant program that meets the following criteria shall be qualified as a designated transplant program to receive organs for transplantation:

I. Facilities and Resources. [No Change]

II. Inactive Program Status. [No Change]

III. Reporting Changes in Key Personnel. [No Change]

IV. Investigation of Personnel. At the request of the MPSC, the designated transplant program must conduct an investigation of personnel identified by the MPSC, who are associated with the program, and report to the MPSC upon initiation and conclusion of the inquiry that it has conducted the investigation in accordance with the terms of this provision. The purpose of the investigation would be to examine the individual's or individuals' role(s) in a matter under review by the MPSC and would be explained to the designated transplant program. The program's investigation must include peer review pursuant to the program's institutional standard process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process. Failure to comply with this provision shall result in appropriate action in accordance with Appendix A of these Bylaws.

IV. OPO Affiliation. The transplant program must have letters of agreement or contracts with an OPO as defined in Article 1.2 of the Bylaws.

VI. Histocompatibility Laboratory Affiliation. The transplant program must use, for its histocompatibility testing, a laboratory that meets the standards for histocompatibility testing, as described in these Bylaws, Appendix B, Attachment II, and is approved by the Board of Directors as meeting these standards.

VII. Transplant Surgeon and Physician. The transplant program must identify a qualified primary surgeon and primary physician, the requirements for whom are specified below, as well as the program director. The program director, in conjunction with the primary surgeon and primary physician, must submit written documentation that 100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The primary surgeon and primary physician, collectively, are further responsible for ensuring the ongoing operation of the program in compliance with the criteria set forth in this Appendix B, ~~Attachment I~~, and notification to the OPTN Contractor if at any time the program deviates from such criteria. Upon applying to serve as primary surgeon or primary physician, the applicant shall submit an assessment, which follows guidelines provided in the application and is satisfactory to the MPSC, of all physicians and surgeons participating in the program regarding their involvement in prior transgressions of OPTN requirements and plans to ensure that the improper conduct is not continued.

A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year.

A. Renal Transplantation [No Change]

B. Liver Transplantation [No Change]

C. Pancreas Transplantation [No Change]

D. Pancreatic Islet Transplantation [No Change]

E. Heart Transplantation [No Change]

F. Lung Transplantation [No Change]

G. Heart/Lung Transplantation [No Change]

VIII. Collaborative Support. [No Change]

VIXH. Ancillary Services. [No Change]

IX. Blood Bank Support. [No Change]

XI. Transplant Mental Health and Social Support Services. [No Change]

XII. Additional Requirements for Pancreatic Islet Transplantation. [No Change]

Appendix B, Attachment I, Section XII (C)

** RESOLVED, that Appendix B, Attachment I, Section XII(C), of the Bylaws shall be amended, and submitted for public comment, to add the following requirement as a criterion for an individual to be qualified through fellowship training or acquired clinical experience as the primary transplant surgeon or primary transplant physician, as applicable. This provision shall be modified, as appropriate, to accommodate language for each of the organ systems and pathways for qualification through fellowship training or acquired clinical experience and appropriate effective dates provided: [The specific Bylaws text to accompany this resolution, incorporating appropriate provisions for each of the organ systems and pathways for qualification, is attached as Appendix 1.]

That the individual has a letter of recommendation from the person named as primary physician or primary surgeon at the fellowship training program [transplant program last served by the individual] attesting to the individual's overall qualifications to act as primary physician [surgeon], addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

APPENDIX 1

Appendix B, Attachment I, Section XII (C) of the Bylaws Designated Transplant Program Criteria Proposed Changes to Language for Letters of Recommendation

XII. Transplant Programs.

A – B [No Changes]

XII. Transplant Programs.

- C. To qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria. Each transplant program must identify a UNOS qualified primary surgeon and physician, the requirements for whom are described below. The program director, in conjunction with the primary surgeon and physician, must provide written documentation that 100% medical and surgical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year.

A transplant center applying as a new member or for a key personnel change must include for the proposed primary transplant surgeon and/or physician a report from their hospital credentialing committee that the committee has reviewed the said individual's state licensing, board certification status, training and affirm that they are "currently" a member in good standing.

(1) **Kidney Transplantation**

Transplant Surgeon - Each transplant center must have on site a qualified kidney transplant surgeon. A kidney transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital. Such a surgeon must complete a two year formal transplant fellowship at a transplant program meeting UNOS membership criteria in renal transplantation. In lieu of a two year formal transplant fellowship, two years of experience with a transplant program meeting the criteria for acceptance into UNOS will suffice.

The surgeon shall have current certification by either the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or their foreign equivalent. If board certification in Urology is pending (as in the case of one just finished training) conditional approval may be granted for a 12-month period, with the possibility of its being renewed for an additional 12-month period to allow time for the completion of certification. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

A formal training program for kidney transplant surgeons requires that formal training must occur in a training program approved by the Membership and Professional Standards Committee of UNOS. The criteria for approval of such a program are as follows:

(aa) – (bb) [No Changes]

To qualify as a kidney transplant surgeon, the training/experience requirements will be met if the following conditions of either (cc), (dd), or (ee) are met.

- (cc) Training during the applicant's transplant fellowship. For kidney transplantation the training requirements for the transplant surgeon can be met during a two-year transplant fellowship if the following conditions are met:

(i) - (iv) [No Changes]

- (v) The individual has a letter, sent directly to UNOS from the director of that training program and chairman of the department or credentialing committee, verifying that the fellow has met the above requirements, and that the fellow is qualified to direct a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary surgeon at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) [No Changes]

- (dd) For kidney transplantation, if the transplant surgeon requirements have not been met, as outlined above, in a transplant fellowship, the requirements can be met by acquired clinical experience if the following conditions are met:

(i) – (iii) [No Changes]

- (iv) The surgeon has a letter, sent directly to UNOS, from the director of this transplant program and chairman of the department or credentialing committee, verifying that the surgeon has met the above requirements, and is qualified to direct a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary surgeon at the transplant program last served by the individual, attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

- (ee) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary kidney transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary kidney transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing kidney transplantation is equivalent to that described in the above requirements. Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of all aspects of kidney transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person named as primary physician or primary surgeon at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary kidney transplant surgeon is temporary only and shall cease to exist for applications for primary kidney transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(ff) [No Changes].

- (b) Transplant Physician - Each kidney transplant program must have on site a qualified transplant physician. A kidney transplant physician shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The kidney transplant physician shall have current board certification in nephrology by the American Board of Internal Medicine, the American

Board of Pediatrics, or the foreign equivalent. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

A formal training program for kidney transplant physicians requires that formal training must occur in a training program approved by the MPSC of UNOS. The criteria for approval of such a program follows:

(aa) – (bb) [No Changes]

To qualify as a kidney transplant physician, the training/experience requirement will be met if the following conditions of either (cc), (dd), (ee), (ii), or (jj) are met. For a pediatrician to qualify as a kidney transplant physician, the training/experience requirements will be met if the following conditions of either (ee), (ff), (gg), (hh), (ii), or (jj) are met:

(cc) The training requirements for the kidney transplant physician can be met during the applicant's nephrology fellowship if the following conditions are met:

(i) – (v) [No Changes]

(vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified kidney transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii) – (ix) [No Changes]

(dd) The training requirements for the kidney transplant physician can be met during a separate 12-month transplant nephrology fellowship if the following conditions are met

(i) – (v) [No Changes]

(vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified kidney transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (vii) [No Changes]
- (ee) If a board certified or eligible nephrologist has not met the above requirements in a nephrology fellowship or transplantation medicine fellowship the training/experience requirements for the kidney transplant physician can be met by acquired clinical experience if the following conditions are met:
 - (i) – (iv) [No Changes]
 - (v) That the individual has written a detailed letter to UNOS outlining his/her experience in a kidney transplant program and in addition that supporting letters documenting the experience and competence of the individual from the qualified transplant physician and/or the kidney transplant surgeon who has been directly involved with the individual, have been sent to UNOS.
- (ff) The training/experience requirements for a kidney transplant physician can be met by completion of 3 years of pediatric nephrology as mandated by the American Board of Pediatrics in a training program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the ACGME, if during that 3 year program, there has been an aggregate of 6 months of clinical care for transplant patients and the following conditions are met:
 - (i) – (iii) [No Changes]
 - (iv) The individual must have had a letter sent directly to UNOS from the program director of the pediatric nephrology training program, as well as from the qualified kidney transplant physician and the qualified kidney transplant surgeon verifying that the fellow has met the above requirements, that he/she is qualified to become a kidney transplant physician, and a medical director of a renal transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed

appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) – (vi) [No Changes]

(gg) The training/experience requirements for the kidney transplant physician can be met during a separate transplantation fellowship if the following conditions are met, and the individual is a certified pediatric nephrologist, or is approved by the American Board of Pediatrics to take the certifying examination.

(i) – (iii) [No Changes]

(iv) The individual must have had a letter sent directly to UNOS from the program director of the pediatric nephrology training program, as well as from the qualified kidney transplant physician and the qualified kidney transplant surgeon verifying that the fellow has met the above requirements, that he/she is qualified to become a kidney transplant physician, and a medical director of a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

(hh) If a certified pediatric nephrologist, or a pediatric nephrologist approved by the American Board of Pediatrics to take the certifying examination, has not met requirements (ff)(i) - (ff) (iv) or (gg)(i) – (gg)(iv), he/she can meet the training/ experience requirements to qualify as a kidney transplant physician if the following conditions are met:

(i) [No Changes]

(ii) That supporting letters documenting the experience and competence of the individual from the qualified kidney transplant physician and the qualified kidney transplant surgeon who has been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with

and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(iii) - (vi) [No Changes]

- (ii) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary kidney transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary kidney transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of kidney transplant patients is equivalent to that described in the above requirements. Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of all aspects of kidney transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person named as primary physician or primary physician at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary kidney transplant physician is temporary only and shall cease to exist for applications for primary kidney transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

- (jj) In the case of a change in the primary kidney transplant physician at a UNOS approved kidney transplant program, if items (cc) iii or (ee) i-ii are not met, the replacement physician, a nephrologist, can function as a kidney transplant physician for a maximum period of twelve months if the following conditions are met:

(i) – (vi) [No Changes]

(kk) [No Changes]

(2). **Live Donor Kidney Transplant Programs.** [No Changes]

(3) **Liver Transplantation**

- (a) Transplant Surgeon - Each transplant center must have on site a qualified liver transplant surgeon. A liver transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The surgeon shall have current certification by either the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or their foreign equivalent. If board certification in Urology is pending (as in the case of one just finished training) conditional approval may be granted for a 12-month period, with the possibility of its being renewed for an additional 12-month period to allow time for the completion of certification. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

A formal training program for transplant surgeons requires that formal training must occur in a training program approved by the Membership and Professional Standards Committee of UNOS. The criteria for approval of such a program are as follows:

(aa) - (bb) [No Changes]

- (cc) Training during the applicant's transplant fellowship. For liver transplantation the training requirements for the transplant surgeon can be met during a two-year transplant fellowship if the following conditions are met:

(i) - (iv) [No Changes]

- (v) The individual has a letter, sent directly to UNOS from the director of that training program verifying that the fellow has met the above requirements, and that the fellow is qualified to direct a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary surgeon at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) [No Changes]

(dd) For liver transplantation, if the transplant surgeon requirements have not been met, as outlined above, in a transplant fellowship, the requirements can be met by acquired clinical experience if the following conditions are met.

(i) - (iii) [No Changes]

(iv) The surgeon has a letter, sent directly to UNOS, from the director of this transplant program and chairman of the department or credentialing committee, verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary surgeon at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

(ee) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary liver transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary liver transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing liver transplantation is equivalent to that described in the above requirements.

Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in liver transplant patient care within the last two years) of all aspects of liver transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person named as primary physician or primary surgeon at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon,

director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary liver transplant surgeon is temporary only and shall cease to exist for applications for primary liver transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these Bylaws and implemented.

The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process

(ff) [No Changes]

- (b) Transplant Physician - Each liver transplant program must have on site a qualified transplant physician. A liver transplant physician shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The liver transplant physician shall have current board certification in gastroenterology by the American Board of Internal Medicine, American Board of Pediatrics, or the foreign equivalent.

In general, pediatric liver transplant programs should have a board certified pediatrician (or foreign equivalent) who meets the criteria for liver transplant physician. In the absence of such an individual, a physician meeting the criteria as a liver transplant physician for adults, can function as a liver transplant physician for the pediatric program if a pediatric gastroenterologist is involved in the care of the pediatric liver transplant recipients.

The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

To qualify as a liver transplant physician, the training/experience requirement will be met if the following conditions of either (aa), (bb), (cc), (dd), (ee) (ff), (gg), (hh), or (ii) are met:

- (aa) The training requirements for the liver transplant physician can be met during the applicant's gastroenterology fellowship if the following conditions are met:

(i) – (iv) [No Changes]

- (v) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified liver transplant physician

verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) – (viii) [No Changes]

(bb) The training requirements for the liver transplant physician can be met during a separate 12 month transplant hepatology fellowship if the following conditions are met.

(i) – (v) [No Changes]

(vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified liver transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii) [No Changes]

(cc) If a board certified gastroenterologist has not met the above requirements in a gastroenterology, or transplant hepatology, fellowship the training/experience requirements for the liver transplant physician can be met by acquired clinical experience if the following conditions are met:

(i) – (iv) [No Changes]

(v) That the individual has written a detailed letter to UNOS outlining his/her experience in a liver transplant program and in addition that supporting letters documenting the experience

and competence of the individual from the qualified transplant physician and/or liver transplant surgeon who has been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (dd) The training/experience requirements for a liver transplant physician can be met by completion of 3 years of pediatric gastroenterology fellowship training as mandated by the American Board of Pediatrics and accredited by the ACGME RRC-Ped, if during that 3 year program there has been an aggregate of 6 months of clinical care for transplant patients and the following conditions are met:

(i) – (iii) [No Changes]

- (iv) The individual must have had a letter sent directly to UNOS from the program director of the pediatric gastroenterology training program, as well as from the qualified liver transplant physician and the qualified liver transplant surgeon verifying that the fellow has met the above requirements, that he/she is qualified to become a liver transplant physician, and a medical director of a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

- (ee) The training requirements for the liver transplant physician can be met during a separate transplantation fellowship if the following conditions are met, and the individual is a board certified pediatric gastroenterologist, or is approved by the American Board of Pediatrics to take the certifying examination.

(i) – (iii) [No Changes]

- (iv) The individual must have had a letter sent directly to UNOS from the program director of the pediatric gastroenterology training program, as well as from the qualified liver transplant physician and the qualified liver transplant surgeon verifying that the fellow has met the above requirements, that he/she is qualified to become a liver transplant physician, and a medical director of a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

- (ff) If a board certified pediatric gastroenterologist, or a pediatric gastroenterologist approved by the American Board of Pediatrics to take the certifying examination, has not met requirements (dd) or (ee), he/she can meet the training/ experience requirements to qualify as a liver transplant physician if the following conditions are met:

(i) [No Changes]

- (ii) That the physician has written a detailed letter to UNOS outlining his/her experience in a liver transplant program and in addition that supporting letters documenting the experience and competence of the individual from the qualified transplant physician and the qualified transplant surgeon who have been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(iii) - (v) [No Changes]

- (gg) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary liver transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards

Committee for and receive approval of the physician to function as the primary liver transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of liver transplant patients is equivalent to that described in the above requirements.

Furthermore, the individual has a letter of recommendation from the person named as primary physician or primary physician at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary liver transplant physician is temporary only and shall cease to exist for applications for primary liver transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in liver transplant patient care within the last two years) of all aspects of liver transplantation and patient care.

The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(hh) In the case of a change in the primary liver transplant physician at a UNOS approved transplant program, if items (aa) iii or (cc) i-ii are not met, the replacement physician, must be a gastroenterologist/hepatologist, and can function as a liver transplant physician for a maximum period of twelve months if the following conditions are met:

(i) - (vi) [No Changes]

(ii) [No Changes]

(4). Live Donor Liver Transplant Programs.

[No Changes]

(5) Pancreas Transplantation

- (a) Transplant Surgeon - Each transplant center must have on site a qualified transplant pancreas surgeon. A pancreas transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital. Such a surgeon must complete a minimum of one year formal transplant fellowship training and one year of experience or complete a two year formal transplant fellowship at a transplant program meeting UNOS membership criteria in pancreas transplantation. In lieu of a two year formal transplant fellowship, two years of experience with a transplant program meeting the criteria for acceptance into UNOS will suffice.

The surgeon shall have and current certification by either the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or their foreign equivalent. If board certification in Urology is pending (as in the case of one just finished training) conditional approval may be granted for a 12-month period, with the possibility of its being renewed for an additional 12-month period to allow time for the completion of certification. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

A formal training program for transplant pancreas surgeons requires that formal training must occur in a training program approved by the Membership and Professional Standards Committee of UNOS. The criteria for approval of such a program are as follows:

(aa) - (bb) [No Changes]

To qualify as a pancreas transplant surgeon, the training/experience requirements will be met if the following conditions of either (cc), (dd), or (ee) are met.

(cc) Training during the applicant's transplant fellowship. For pancreas requirements for the transplant surgeon can be met during a two-year transplant fellowship if the following conditions are met:

(i) – (iv) [No Changes]

(v) The individual has a letter, sent directly to UNOS from the director of that training program and chairman of the department or credentialing committee, verifying that the fellow has met the above requirements, and that the fellow is qualified to direct a pancreas transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary surgeon at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) [No Changes]

(dd) For pancreas transplantation, if the transplant surgeon requirements have not been met, as outlined above in options-(cc), the requirements can be met by acquired clinical experience if the following conditions are met.

(i) – (iii) [No Changes]

(iv) The surgeon has a letter, sent directly to UNOS, from the director of this transplant program and chairman of the department or credentialing committee, verifying that the surgeon has met the above requirements, and is qualified to direct a pancreas transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary surgeon at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

(ee) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary pancreas transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary pancreas transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing pancreas transplantation is equivalent to that described in the above requirements. Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in pancreas transplant patient care within the last two years) of all aspects of pancreas transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person named as primary physician or primary surgeon at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary pancreas transplant surgeon is temporary only and shall cease to exist for applications for primary pancreas transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(ff) [No Changes]

- (b) Transplant Physician - Each pancreas transplant program must have on site a qualified transplant physician. A pancreas transplant physician shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The transplant physician shall have current certification by either the American Board of Internal Medicine, the American Board of Pediatrics, or their foreign equivalent. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

The transplant physician shall have at least one year of specialized formal training in transplantation medicine or, with some exceptions as set forth in item (ee), a minimum of two years documented experience in transplantation medicine with a transplant program that meets the qualifications for membership in UNOS.

To qualify as a pancreas transplant physician, the training/experience requirements will be met if the following conditions of either (aa), (bb), (cc) (dd), or (ee) are met.

- (aa) The training/experience requirements for the pancreas transplant physician can be met during the applicant's nephrology (endocrinology, diabetology) fellowship if the following conditions are met:

(i) – (v) [No Changes]

- (vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified pancreas transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a pancreas transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician

at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii) – (ix) [No Changes]

(bb) The training requirements for the pancreas transplant physician can be met during a separate 12-month transplant medicine fellowship if the following conditions are met.

(i) – (v) [No Changes]

(vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified pancreas transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a pancreas transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii)- (viii) [No Changes]

(cc) If a board certified or eligible nephrologist, (endocrinologist, or diabetologist) has not met the above requirements in a nephrology fellowship or transplantation medicine fellowship the training/experience requirements for the pancreas transplant physician can be met by acquired clinical experience if the following conditions are met:

(i) – (iv) [No Changes]

(v) That the individual has written a detailed letter to UNOS outlining his/her experience in a pancreas transplant program and in addition that supporting letters documenting the experience and competence of the individual from the qualified transplant physician and/or the pancreas transplant surgeon who has been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (dd) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary pancreas transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary pancreas transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of pancreas transplant patients is equivalent to that described in the above requirements. Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in pancreas transplant patient care within the last two years) of all aspects of pancreas transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person named as primary physician or primary physician at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary pancreas transplant physician is temporary only and shall cease to exist for applications for primary pancreas transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

- (ee) [No Changes]

(ff) [No Changes]

(6) Pancreatic Islet Transplantation [No Changes]

(7) Heart Transplantation

- (a) Transplant Surgeon - Each heart transplant program must have on site a qualified transplant surgeon. A heart transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

Such surgeon shall have current certification by the American Board of Thoracic Surgery or its foreign equivalent. If board certification in thoracic surgery is pending (as in the case of one just finished training) conditional approval may be granted for a 24-month period, with the possibility of its being renewed for an additional 24-month period to allow time for the completion of certification.

The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

If an individual is certified by the American Board of Thoracic Surgery or its foreign equivalent, then the individual must maintain their certification in the American Board or its foreign equivalent..

To qualify as a heart transplant surgeon, the training/experience requirements will be met if the following conditions of either (aa), (bb), (cc), or (dd) are met.

- (aa) The training requirements for the heart transplant surgeon can be met during the applicant's cardiothoracic surgery residency if the following conditions are met:**

(i)- (iii) [No Changes]

- (iv) The individual has a letter, sent directly to UNOS from the director of that training program verifying that the resident has met the above requirements, and that the resident is qualified to direct a heart transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary surgeon at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) – (vi) [No Changes]

(bb) For heart transplantation, when the training requirements for transplant surgeon have not been met during one's cardiothoracic surgery residency, they can be met during a subsequent 12-month heart transplant fellowship if all the following conditions are met:

(i) – (iii) [No Changes]

(iv) The fellow has a letter, sent directly to UNOS from the director of that training program verifying that the fellow has met the above requirements, and that the fellow is qualified to direct a heart transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary surgeon at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) – (vi) [No Changes]

(cc) For heart transplantation, if the transplant surgeon requirements have not been met, as outlined above, in a cardiothoracic residency or heart transplant fellowship, the requirement can be met by experience if the following conditions are met.

(i) – (iii) [No Changes]

(iv) That the surgeon has a detailed letter sent directly to UNOS from the director of the program at which this experience is acquired, which verifies that the surgeon has met the above requirements, and is qualified to direct a heart transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary surgeon at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

(dd) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary heart transplant surgeon, transplant

programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary heart transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing heart transplantation is equivalent to that described in the above requirements. Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in heart transplant patient care within the last two years) of all aspects of heart transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person named as primary physician or primary surgeon at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary heart transplant surgeon is temporary only and shall cease to exist for applications for primary heart transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

- (b) **Transplant Physician** - Each heart transplant program must have on site a qualified transplant physician. A transplant physician for heart transplantation shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital. If an individual is certified by the American Board and its foreign equivalent, the individual must maintain currency in the American Board.

The heart transplant physician shall maintain current board certification or have achieved eligibility in adult or pediatric cardiology by the American Board of Internal Medicine or American Board of Pediatrics or their foreign equivalent.

The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

To qualify as a heart transplant physician, the training/experience requirement will be met if the following conditions of either (aa), (bb), (cc), (ee), (ff), or (gg) are met:

- (aa) The training requirements for the heart transplant physician can be met with the applicant's cardiology fellowship if the following conditions are met:

- (i) – (vi) [No Changes]

- (iv) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified heart transplant physician verifying the fellow has met the above requirements and that he or she has qualified to become a medical director of a heart transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (v) - (vii) [No Changes]

- (bb) When the training requirements for the heart transplant physician have not been met during a cardiology fellowship, they can be met by completing a separate 12-month transplant cardiology fellowship if all of the following conditions are met, and the individual is a board certified or eligible cardiologist.

- (i) – (iii) [No Changes]

- (iv) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified heart transplant physician verifying that the fellow has met the above requirements and that he or she has qualified to become a medical director of a cardiac transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician,

primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) –(vi) [No Changes]

(cc) If the cardiologist has not met the above requirements in a cardiology fellowship or specific cardiac transplant fellowship, the requirements can be met by acquired clinical experience if the following conditions are met, and the individual is a board certified cardiologist.

(i) - (iv) [No Changes]

(v) There should be a supporting letter from either the cardiac transplant physician or the cardiac transplant surgeon at the cardiologist's institution who has been directly involved with the individual and can certify his or her competence.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) [No Changes]

(dd) [No Changes]

(ee) [No Changes]

(ff) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary heart transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary heart transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of heart transplant patients is equivalent to that described in the above requirements. Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in patient care within the last two years) of all aspects of heart transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person named as primary physician or primary physician at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician, addressing the individual's personal integrity,

honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary heart transplant physician is temporary only and shall cease to exist for applications for primary heart transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(gg) [No Changes]

(8) Lung Transplantation

- (a) Transplant Surgeon - Each lung transplant center must have on site a qualified lung transplant surgeon. A lung transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

Such a surgeon shall have current certification by the American Board of Thoracic Surgery or its foreign equivalent. If board certification in thoracic surgery is pending (as in the case of where the surgeon has just completed training) conditional approval may be granted for a 24-month period, with the possibility of its being renewed for an additional 24-month period to allow time for completion of certification.

The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

If an individual is certified by the American Board of Thoracic Surgery or its foreign equivalent, then the individual must maintain their certification in the American Board or its foreign equivalent.

To qualify as a lung transplant surgeon, the training/experience requirements will be met if the following conditions of either (aa), (bb), (cc), or (dd) are met:

- (aa) The training requirements for lung transplant surgeon can be met during the applicant's cardiothoracic surgery residency if the following conditions are met:

(i) – (iii) [No Changes]

(iv) That the resident has a letter sent directly to UNOS from the director of that training program verifying that the resident has met the above requirements and that he/she is qualified to direct a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary surgeon at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

(bb) For lung transplantation, when the training requirements for transplant surgeon have not been met during the applicant's cardiothoracic surgery residency, the requirements may be fulfilled during a subsequent 12-month transplant fellowship if all the following conditions are met:

(i) – (iii)

(iv) That the fellow has a letter sent directly to UNOS from the director of that training program verifying that the fellow is qualified to direct a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary surgeon at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

(cc) For lung transplantation, if the transplant surgeon requirements have not been met as specified above, in a thoracic surgery residency or lung transplant fellowship, the requirements may be met by acquired clinical experience if the following conditions are met:

(i) – (iii) [No Changes]

(iv) That the surgeon has a detailed letter sent directly to UNOS from the director of the program at which this experience is acquired which verifies that the surgeon has met the above

requirements, and is qualified to direct a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary surgeon at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

- (dd) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary lung transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary lung transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing lung transplantation is equivalent to that described in the above requirements.

Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in patient care within the last two years) of all aspects of lung transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person named as primary physician or primary surgeon at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary lung transplant surgeon is temporary only and shall cease to exist for applications for primary lung transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body

responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

- (b) Transplant Physician - Each lung transplant center must have on site a qualified lung transplant physician. A lung transplant physician shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The lung transplant physician shall maintain current board certification or have achieved eligibility in adult or pediatric pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics or the foreign equivalent. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

To qualify as a lung transplant physician, the training/experience requirements will be fulfilled if the following conditions of either (aa), (bb), (cc), (dd), (ee), or (ff) are met:

- (aa) The training requirements for the primary lung transplant physician can be met during the applicant's pulmonary medicine fellowship if the following conditions are met:

(i) - (iii) [No Changes]

- (iv) That the fellow has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified lung transplant physician verifying the fellow has met the above requirements and that/she is qualified to be the medical director of a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vii) [No Changes]

- (bb) For lung transplantation, when the training requirements for lung transplant physician have not been fulfilled during a pulmonary medicine fellowship, the requirements can be met during a separate 12-month transplant pulmonology fellowship if all of the following conditions are met:

(i) - (iii) [No Changes]

- (iv) That the fellow has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified lung transplant physician verifying that the fellow has met the above requirements and that he/she is qualified to be a medical director of a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (v) - (vi) [No Changes]

- (cc) If the physician has not met the above requirements in a pulmonary fellowship or specific transplant pulmonology fellowship, the requirements can be met by acquired clinical experience if the following conditions are met and the individual is a board certified pulmonologist:

- (i) - (iv) [No Changes]

- (v) There should be a supporting letter from either the lung transplant physician or the lung transplant surgeon at the pulmonologist's institution who has been directly involved with the individual and certify his/her competence.

Additionally, that the individual has a letter of recommendation from the person named as primary physician at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (vi) [No Changes]

- (dd) [No Changes]

- (ee) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary lung transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary lung transplant physician provided that the physician can

demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of lung transplant patients is equivalent to that described in the above requirements.

Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in lung transplant patient care within the last two years) of all aspects of lung transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person named as primary physician or primary physician at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary lung transplant physician is temporary only and shall cease to exist for applications for primary lung transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(ff) [No Changes]

(9) Heart/lung Transplantation [No Changes]

(10) –(22) [No Changes]

D. [No Changes]

E. [No Changes]

Resource Analysis

As noted above, the proposal is designed to avoid excessive cost. Still, however, it likely will result in additional time required to complete key personnel (i.e., primary physician and surgeon) applications and may result in additional time required to respond to policy compliance inquiries. In considering this policy proposal, we, therefore, request your input specifically with respect to your expectations for resource impact upon yourself or institution. This information will be used in preparing a resource assessment presented to the Membership and Professional Committee, Policy Oversight Committee, and Board of Directors.

Summary of Public Comments

I. Individual Comments:

The proposal was issued to a mailing list of approximately 11,500 individuals and organizations for a comment period of 30 days beginning August 28, 2006 and ending September 27, 2006.

As of 9/27/2006, 25 responses have been submitted to UNOS regarding this policy proposal. Of these, 20 (80.00%) supported the proposal, 1 (4.00%) opposed the proposal, and 4 (16.00%) had no opinion. Of the 21 who responded with an opinion, 20 (95.24%) supported the proposal and 1 (4.76%) opposed the proposal. Comments on the proposal received to date are as follows:

Comment 1:

vote: Oppose

I could be wrong, but seems that existing processes already address the concerns implicit in this proposal.

Committee Response: The Committee disagrees and believes that this proposal will more clearly define the centers responsibility to investigate the individuals they are hiring to determine the need to submit as Plan for Continuing Policy Compliance.

II. Regional Comment Summary

PROPOSAL 4: Proposed Modifications to Bylaws, Appendix B, Section II, “Transplant Hospitals,” “Investigation of Personnel”; Appendix B, Attachment 1, Section IV “Investigation of Personnel,” Section VII “Transplant Surgeon and Physician”; and Appendix B, Attachment I, Section XII (C) (Membership and Professional Standards Committee)

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Did Not Consider
1	9/11/06	8 yes, 0 no, 1 abstention		
2	10/6/06	29 yes, 0 no, 2 abstentions		
3	9/29/06	7 yes, 2 no, 3 abstentions		
4	10/6/06	18 yes, 1 no, 0 abstentions		
5	9/01/06	28 yes, 0 no, 0 abstention		
6	9/15/06	48 yes, 0 no, 4 abstentions		
7	10/6/06	10 yes, 3 no, 0 abstentions		
8	9/08/06	19 yes, 0 no, 0 abstentions		
9	9/27/06	11 yes, 0 no, 1 abstention		
10	9/22/06	19 yes, 0 no, 0 abstention		
11	9/29/06	10 yes, 0 no, 1 abstention		

COMMENTS:

Region 1: The members are concerned about information gathered in a peer review investigation; they do not think it should be disclosed to the public. The members also felt it was not clear who will be responsible for submitting an assessment of all physicians and surgeons participating in the program regarding their involvement in prior transgressions of OPTN requirements and plans to ensure that the improper conduct is not continued.

Committee Response: The Committee believes that the suggested changes in the proposal, which will define the triggers for review as those that are public (probation or member not in good standing) will resolved these concerns. They further clarified that it is the responsibility of the hospital submitting the application to conduct their reviews of the proposed primary transplant surgeon and proposed primary transplant physician.

Region 10: The members felt that there should be a way to identify individuals whom have been affiliated with a program adverse action even if they have left the program prior to the action being initiated. The region also commented that these policies should to apply to OPOs and Histocompatibility Labs.

Committee Response: See response to Region 1. The Committee agreed that there should be a way to identify individuals. It did not consider the addition of language to incorporate OPO's and histocompatibility laboratories at this time since this proposal was specific to the oversight of surgeons and physicians.

Region 7: Region 7, at length, discussed that they felt UNOS should move into a more active role of credentialing physicians. MPSC, a reporting body, should be able to provide to transplant hospitals a report of a physicians institutional history. They also expressed that a transplant program director SHOULD be held accountable for the actions under his/her watch and that sanctions should follow that individual regardless if they have left the institution under investigation. There was also concern that situations arise where a surgeon or a physician leaves an institution and that, due to the circumstances around their departure, there may be some harsh sentiments expressed in the MPSC letter. The region felt that there should be additional letters of inquiry sent in cases were such a letter was received to ensure that there was a legitimate concern and not just ill feelings.

Committee Response:

The OPTN/UNOS role is to review programs. As a part of that responsibility, UNOS reviews the training and experience of individuals who are proposed as the primary transplant surgeon and primary transplant physician. The Committee agreed that the program directors and administration are accountable for the program's actions. The Committee's review process would be utilized to discover the facts regarding the individual's responsibility in an event that led to a center being placed on probation or Member Not in Good Standing.

III. Comments from Committees

Representatives from the International Relations, Kidney Transplantation, Liver and Intestinal Transplantation, Minority Affairs, Pancreas Transplantation, Pediatric Transplantation and Thoracic Transplantation Committees met by teleconference, using Microsoft® Live Meeting® to review the five proposals currently out for public comment by the Membership and Professional Standards Committee. Due to the abbreviated time frame for this public comment, a conference call was scheduled to provide an opportunity for these committees to discuss the proposals and provide feedback to the MPSC. Additional comments were solicited from members who were unable to participate.

The proposed modifications to the Bylaws would enhance oversight of individual physicians and surgeons by requiring:

- (1) Transplant hospitals to conduct investigations, upon request, according to their peer review protocols and report to the OPTN,
- (2) Applicants for primary physician or surgeon to submit assessments of prior non-compliant behavior with which they or other individuals proposed as part of the transplant team have been involved, as well as plans to ensure that the improper conduct is not continued, and

- (3) Applicants for primary physician or surgeon to submit letters of recommendation attesting to their overall qualifications to act as primary physician or surgeon, as applicable, and addressing matters such as the individual's personal integrity, honesty, and familiarity with and experience in adhering to OPTN requirements and compliance protocols.

The aim is to prevent an individual physician or surgeon who has been involved in non-compliant activity at one institution from continuing that or similar activity at the same or another institution.

A member noted that a transplant hospital might be somewhat reluctant to provide this kind of reference that could ultimately lead to a candidate for another position not receiving an offer for a job. He also noted that many institutions have policies in terms of staff recommendations to limit information to term of employment and not discuss any disciplinary issues that may have occurred. Concern also was raised about shifting the credentialing away from the hospitals and whether any feedback had been received from institutions. At the time of the meeting, no feedback had been received regarding the hospital credentialing. It was questioned whether the public comment document had ever been distributed to hospital credentialing offices. Members were encouraged to re-look at the documents and pass them along internally to anyone they felt would be appropriate.

It was noted that the intent was not to interfere with the hospitals' own peer review process and the committee was aware and sensitive to the fact that hospitals themselves would be limited in the information that could be shared. The proposal would only ask hospitals to follow its own processes through to the end and inform the OPTN that it does so, not necessarily report the results of their investigations, and intrude on the hospitals' processes. The changes made to the bylaws were more concerned with the addition of a plan for following policy compliance and the disclosure of past violations, not changing what the credentialing offices do.

Concerns were raised regarding relying on the community to be honest about prior violations. It was noted that the OPTN will have records of cases that have gone to a hearing and will know who came up during review and whether those individuals moved on to another institution, so some cross-checking will be available. There may not be the ability to catch everything, but a good amount will be known in the background, and if it is not disclosed the proper questions can be asked.

Vote: 11-4-3

Breakdown of votes by committee:

International Relations:	0-0-0
Kidney*:	1-0-0
Liver:	1-1-1
MAC:	3-0-2
Pancreas*:	3-2-0
Pediatric*:	2-0-0
Thoracic*:	3-1-0

Committee Response:

The MPSC appreciates the input of these committees.

Patients Affairs Committee:

This proposed Bylaw change is intended to improve the comprehensiveness of the OPTN member review process and to provide more complete and timely information to the OPTN regarding member reviews by other organizations and agencies.

The Committee utilized the Committee management system to vote on this proposal by September 27, 2006. There was not a quorum as only seven of eighteen Committee members voted. All seven members voted unanimously to support the proposed policy.

Committee Response: The MPSC appreciates the support of the Patient Affairs Committee.

Transplant Coordinators Committee: The proposed modifications to the Bylaws would enhance oversight of individual physicians and surgeons by requiring: (1) Transplant hospitals to conduct investigations, upon request, according to their peer review protocols and report to the OPTN, (2) Applicants for primary physician or surgeon to submit assessments of prior non-compliant behavior with which they or other individuals proposed as part of the transplant team have been involved, as well as plans to ensure that the improper conduct is not continued, and (3) Applicants for primary physician or surgeon to submit letters of recommendation attesting to their overall qualifications to act as primary physician or surgeon, as applicable, and addressing matters such as the individual's personal integrity, honesty, and familiarity with and experience in adhering to OPTN requirements and compliance protocols. The aim is to prevent an individual physician or surgeon who has been involved in non-compliant activity at one institution from continuing that or similar activity at the same or another institution.

The committee agrees that there must be accountability for those surgeons who might move from center to center and UNOS must have an established methodology for tracking specific problems. The proposed change was approved by a vote of 9-0-0.

Committee Response: The Committee believes this proposal will provide for accountability. The Membership Database can be used for tracking specific problems.

IV. Final Proposal

October 2006 Update: When the Committee met in October 2006, it reviewed comments received from individuals, the Regions, and other Committees. All of the regions voted in support of the proposal and several submitted comments even if in support. Additionally, the Committee received comments from several committees who also voted in support of the proposal. In summary, the Committee considered comments expressing concern about the following issues:

Comments received during Regional Meetings:

- Information gathered in a peer review investigation should not be disclosed to the public.
- It is not clear who would be responsible for submitting an assessment of all physicians and surgeons participating in the program regarding their involvement in prior transgressions of OPTN requirements and plans to ensure that the improper conduct is not continued.
- There should be a way to identify individuals who have been affiliated with a program's adverse action even if the individuals have left the program prior to the action being initiated.
- These policies should also apply to OPOs and Histocompatibility Labs.
- UNOS should move into a more active role of credentialing physicians.

Comments received from other Committees:

- Concerns were raised about relying on the community to be honest about prior violations.
- A transplant hospital may be somewhat reluctant to provide this kind of reference that could ultimately lead to a candidate for another position not receiving an offer for a job.
- Many institutions have policies in terms of staff recommendations to limit information to term of employment and will not discuss any disciplinary issues that may have occurred.
- Concern was raised about moving the credentialing away from the hospitals and whether any feedback had been received from institutions.

Summary of MPSC Comments and Concerns – October 2006:

The Committee emphasized that the proposal places the burden on the program to conduct investigations and inquiries of individual physicians and surgeons. The intent is for the institution to have a discussion with the individual to ensure that an inappropriate activity is not continued.

The Committee considered the event that would trigger a reporting requirement for an individual and initially suggested that it could be a hearing before the MPSC. During its January/February meeting, the Committee reconsidered this suggestion and based upon the recommendation from the Work Group, agreed that the trigger for reporting should be a final determination of “Probation” or “Member Not in Good Standing,” which include a requirement for public notification. This would be clarified in the application as part of the directions for completing the Plan for Continuing Policy Compliance. The Committee also discussed how this proposed bylaw might be implemented and agreed that it should be effective prospectively after Board approval; it would not be applied retroactively. In October the Committee made the following observations about the proposal:

- MPSC needs to become very specific in its recommendations by indicating a particular person who is responsible for specific inappropriate behavior. Defining responsibility for wrongdoing at an individual level is very difficult
- How can an individual find out if they have been identified as the responsible person for such inappropriate behavior or appeal to have this identification reversed?
- Does there need to be a forum for talking to individuals who may have left the institution prior to an action being initiated with the program resulting in possible adverse action?
- Other Databases, such as the National Practitioners Data Bank, have very specific criteria about who might be identified in connection with wrongdoing, whereas this proposal does not.
- UNOS’ role is to approve programs. Approving individuals, as suggested by one of the regions, would imply a different philosophy for the OPTN. Additional resources would be required to take this approach.
- The comments and MPSC discussion suggest that there is disagreement about what level of oversight of individual physicians and surgeons by the OPTN is either practical in terms of yielding results that are productive or advisable in terms of new activity for the OPTN.

Based on the comments received during the public comment period as well as the issues raised by the Committee, the MPSC referred the issue back to the Process Improvement Work Group for further review and development.

MPSC Process Improvement Work Group Update - January 2007:

The Work Group met by conference call on January 3 and 10, 2007, and reviewed the responses received during the public comment period as well as the observations from the MPSC. Minor modifications were made to the proposal to further refine its scope and to respond to the public comments as appropriate.

A key change included adding language to the Bylaws that would specify that institutions that are placed on probation or determined to be a “Member not in Good Standing” would be responsible for an investigation of their personnel.

MPSC January/February 2007 Meeting Update: The MPSC reviewed the recommendations of the Process Improvement Work Group 1 when it met in January 30 - February 1, 2007. The discussion was led by Dr. Stuart Sweet, a member of the Work Group, who participated by conference call. The MPSC continued to discuss its concerns regarding the scope and implementation of the proposed requirements.

The Committee also discussed the following concerns that were made by a member of the Work Group after its call on January 10:

- 1) The MPSC should have the authority to request that a center investigate the role played by any member of the transplant program identified during an MPSC investigation (not just primary physician and surgeon).

The MPSC agreed, but clarified that it can only ask the center if it conducted its own peer review investigation and to certify that it was done according to its due process procedures; it cannot ask for its corrective action plan itself because it would have been developed in response to the institutions peer review process. General information may be communicated to the Committee,

but the actual details of the compliance plan may not. The subject of the peer review, the “errant actor,” would have to rely on the center’s due process procedures to contest its findings and the OPTN/UNOS would not have access to the information gathered during this process. The individual does not have the ability to waive this privilege. The privilege is that of the peer review body.

It is up to the hiring institution to conduct its mandatory inquiries before it gives a surgeon or physician privileges. Databanks are only intended to supplement the usual credentialing process.

- 2) Each physician or surgeon included in an application, whether as primary physician or surgeon or playing a role in the 100% coverage plan, should submit an attestation of their lack of involvement in any prior program during a period of concern that led to Probation, “Member Not in Good Standing,” etc. If there is prior involvement, the physician/surgeon should explain their role and if they were responsible for policy violations, steps taken to prevent future occurrence. These explanations would also need to be submitted with a personnel change application.

When a center submits an application for a new program or a change in key personnel, it will need to provide this information. Each person named in an application would have to answer the question such as “were you on staff or associated with a member center that received a final determination of “Probation” or “Member not in Good Standing,” and were you there during the period the violation occurred?” “If yes, were you a part of any policy violations?” If yes, they would need to explain what they plan to do to prevent this behavior from occurring at the new center.

Based on the information on file and submitted by the center, the Committee will need to interpret who was involved in the program during the period that was investigated.

UNOS can ask for a Plan for Continuing Policy Compliance as a part of the application. This plan would be protected under the Committee’s peer review process.

- 3) Include in a program application a requirement for a policy compliance plan that describes processes for monitoring/education, etc. Submission of a Plan for Continuing Policy Compliance might be considered regardless of whether there are prior transgressions. It could refer to the specific issues and plans identified in the physician/surgeon application.

The Committee can request a plan from each program.

The Committee also addressed the following issues:

- The Committee addressed the concerns regarding how long an individual would have to report on their involvement or lack thereof in the behavior that led to a final determination of “Probation” or “Member Not in Good Standing.” The Committee agreed that the reporting period would be indefinite. This response was based on the reporting mechanisms in place for state board licensing and other similar regulatory bodies.
- Probation and “Member Not in Good Standing” are determined at the center level. It is possible that an applicant from one organ transplant program may not be aware of the issues in another program at the same center, and may not be able to answer specific questions. The MPSC agreed that the answer could be that just that – the issue was in another program that the individual was not involved in the behavior that led to the final determination of “Probation” or “Member Not in Good Standing.” The MPSC can decide if the information they provide is relevant.
- It is the responsibility of the surgeon/physician named in an application to be as open about their involvement as they can be. If data from the OPTN/UNOS database differs from what individual provides, the MPSC can review the records from its own peer review process and determine if the individual has provided appropriate information.

The Committee asked if the Membership Database could provide a mechanism for keeping track of individuals known to be involved in “transgressions”? Staff acknowledged that the database could be updated to reflect this information, which in turn could be provided to the MPSC during its review of an application or upon request for other types of reviews. This information would both supplement and validate the information submitted by the transplant center. It is believed that this process will respond to the public comments regarding a method to ensure honest responses. This tracking system could be developed without the addition of new bylaw language because it is a mechanism for implementing the bylaw changes that have already been proposed. The Committee further discussed the collection information regarding past “transgressors” but noted that it had previously agreed that it would not apply the bylaws to an action that occurred prior to the Board of Directors approval of the new requirements.

- The Committee further discussed the nature of peer review by the Committee and within the member institutions. The Committee was reminded that documents or statements that are initiated, created, or generated by or at the request of the peer review entity are confidential. This may include the details of the review process prior to the final determination. For example, the Board of Directors or Committee would not be entitled to a Corrective Action Plan that resulted from an institution’s peer review of an individual. The OPTN/UNOS could, however, obtain a certification from the institution that they conducted the review in accordance with the institution’s peer review bylaws. It was agreed that the Bylaws proposal would need to be amended to make sure that individual investigation does not violate peer review.

The Committee was unable to resolve all its concerns during the course of the meeting and a motion to approve the proposed requirements as amended by the Work Group was not supported.

** RESOLVED, that the Committee supports the proposal as amended by the Work Group and with further clarifying language to be provided by legal staff.

The Committee voted 7 For, 16 Against, 0 Abstentions.

February 26, 2007, Update

Subsequent to the MPSC meeting, staff continued to work with the Work Group and the MPSC on the language and process for implementing the proposed Bylaws in a manner that would not conflict with the institutional peer review process. The attached modifications would clarify that the institution and/or program’s investigation must be conducted pursuant to the “standard peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process.” Modifications to the following sections of the Bylaws were suggested by staff and approved by the MPSC (electronically) in order to advance the proposal to the Board of Directors for consideration at its March meeting.

The concerns of the MPSC were related to the implementation of the proposals and included an individual surgeon or physician having to declare themselves as involved in an adverse action or not, for an indefinite period; and the broadness of the proposal such that an individual would have to declare themselves if they were employed at the center when an event occurred that resulted in probation or “Member not in Good Standing” regardless of their position in the specific program that that initiated the review.

The Committee suggested that one approach for refining the scope of review might be for the Committee to consider whether the behavior/event was attributed to a systemic or programmatic problem. It was suggested that the MPSC declare the type at the time the final determination is made and then records could be flagged accordingly. The MPSC will then know the level of evaluation that may need to be performed on the staff from that member institution in the future. This process would seem to accomplish the goal of further refining who has to submit to this additional process.

Subsequent to the meeting, and through talks with the National Practitioners Data Bank (NPDB), a method for collecting information regarding individuals in a manner that would not violate the institution's peer review process was developed. A requirement for an additional supporting document is being added to the application forms so that each named individual must submit their individual self query response from the NPDB as a part of the application. This requirement places the burden of making the inquiry on the individual and the program and would avoid the problem of UNOS not having the ability to make inquiries of the NPDB directly. The current Bylaws (Appendix A) already give the Committee the leeway to ask for this information without a specific change in the bylaws.

Final Modifications - Summary of Changes:

These changes can be found in the following sections of the Bylaws. Changes in the OPTN Bylaws will be carried over in the UNOS Bylaws.

1) Appendix A to the Bylaws – OPTN, 2.06A - Membership and Professional Standards Committee

Action

The modifications to this section add to the list of actions the MPSC might require of a center that is placed under probation or determined to be a "Member not in Good Standing" (MNGS) the option of requiring a center to conduct an investigation of its personnel. This would not apply to Section (6) *Termination of Membership or Designated Program Status* because once the center has been removed from membership; we can no longer impose such requirements. Although it was thought that the likelihood of an a center being referred to the Secretary for suspension of privileges without first being placed on probation or made a MNGS was extremely low, the Work Group asked that the option for an investigation be added under Section (5) *Suspension of Member Privileges*.

2) Appendix A to the Bylaws – OPTN, Application and Hearing Procedures for Members and Designated Transplant Programs, 1.03A - Procedures upon Application for Membership

The proposed modification puts in place a "Plan for Continuing Policy Compliance" under the application process. This requirement specifies that the named primary surgeon and/or primary physician must conduct an assessment of the program's surgeons or physicians regarding prior transgressions, and if they have been involved in prior transgressions, to submit a plan that ensures the improper conduct is not continued.

3) Appendix B to Bylaws – Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership, I. Transplant Hospitals. D. Investigation of Personnel

This modification gives the MPSC the latitude to request that a transplant hospital conduct an investigation of its personnel at the Committee's request and report its final determination to the Committee in a way that is consistent with and protects the institution's own peer review process. This proposed Bylaw provides a mechanism for having the hospital examine an individual's role in a matter that the MPSC has under investigation and report back to the MPSC. If a center fails to comply, then the MPSC is empowered to take further action.

4) Attachment I to Appendix B of the Bylaws, IV. Investigation of Personnel and VII. Transplant Surgeon and Physician

Section IV of this proposed revision is essentially the same as #3 above except that it places the emphasis on a "transplant program" being responsible for the investigation. The focus in #3 is the "transplant hospital."

The proposed language under Section VII incorporates a new requirement into the membership application process that follows along the line of #1 above. The named primary transplant surgeon or primary transplant physician in each application must submit an assessment of all physicians and surgeons participating in the program regarding their involvement in prior transgressions of OPTN requirements and plans to ensure that the improper conduct is not continued. In response to a request made by the Committee during our last meeting, we have included modifications to this proposal to recognize the confidential nature of the institution's peer review process.

- 5) Appendix B, Attachment I, Section XII(C), of the Bylaws.
A requirement for an additional letter of reference has been added under each organ program and each of the surgeon and physician pathways for meeting the requirements. This letter would be different from the other letters of reference which in essence verify that the individual has met the training and/or experience requirements. This new letter would need to attest to the individual's personal integrity, honesty, familiarity with and experience in adhering to the OPTN requirements and compliance protocols. A single letter could address both the experience and training of an individual as well as these new elements.

The Committee considered the final revisions to the proposal on the Committee Management System and supported the recommended language as shown in Exhibit M-2.

**** RESOLVED, that the modifications to the following sections of the OPTN and UNOS Bylaws:**

- **Appendix A to the Bylaws – OPTN and UNOS, Section 1.03A Application and Hearing Procedures for Members and Designated Transplant Programs, 1.03A - Procedures upon Application for Membership;**
- **Appendix A to the Bylaws – OPTN and UNOS, Section 2.06A - Membership and Professional Standards Committee Action;**
- **Appendix B to OPTN and UNOS Bylaws – Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership, I. Transplant Hospitals. D. Investigation of Personnel**
- **Attachment I to OPTN and UNOS Appendix B of the Bylaws, IV. Investigation of Personnel and VII. Transplant Surgeon and Physician; and**
- **Appendix B, Attachment I, Section XII(C), of the UNOS Bylaws,**

as fully set forth in Exhibit M-2, are hereby approved effective pending notice and programming in UNetsm, if and as applicable.

The Committee vote 17, For, 1 Against, 0 Abstentions.

Final Proposal

Appendix A to the OPTN and UNOS Bylaws

Application and Hearing Procedures for Members and Designated Transplant Programs

1.01A Nature of Membership/Designated Transplant Program Status [No changes]

1.02A Duration of Membership [No changes]

1.03A Procedures upon Application for Membership

- (1) **General Procedure:** The Membership and Professional Standards Committee shall investigate and consider under confidential medical peer review each application for membership and designation as a transplant program and shall adopt and transmit recommendations thereon to the Board of Directors.
- (2) **Application Form :** Each application for membership and designation as a transplant program shall be in writing, submitted on the prescribed form approved by the Membership and Professional Standards Committee, signed by the applicant.

- (3) **Content:** The application form shall include:
- (a) **Acknowledgment and Agreement:** A statement that the applicant has received and read the current Articles of Incorporation, Bylaws, and Policies and that the applicant agrees:
(i) to be bound by the terms thereof, as amended, if the applicant is granted membership and/or designated transplant program status and (ii) to be bound by the terms thereof in all matters relating to consideration of the application without regard to whether or not the applicant is granted membership or designated transplant program status.
 - (b) **Qualifications:** Detailed information and supporting documentation, as may be specified by the Membership and Professional Standards Committee (MPSC) from time to time and described in the application form, concerning the applicant's qualifications, including information in satisfaction of the basic qualifications specified in Article 1 of the Bylaws and the Criteria for Membership (Appendix B) regarding applicable membership requirements. This shall include, by way of example and without in any way limiting information that may be required in the application, submission of a:
 - (1) Plan for Continuing Policy Compliance that reports results from an assessment by the named primary physician and/or surgeon for transplant programs designated to perform organ transplants regarding involvement of any of the program's physicians or surgeons in prior transgressions of UNOS requirements and plans to ensure that the improper conduct is not continued.
 - (c) **Information on Liability Insurance Coverage:** [No Change]
 - (d) **Administrative Remedies:** [No Change]
 - (e) **Release of Information to HHS:** [No Change]

1.04A - Processing the Application [No Change]

1.05A - Effect of Membership and Professional Standards Committee Action [No Change]

1.06A - Time Periods for Processing [No Change]

1.07A - Reapplication after Adverse Decision [No Change]

Appendix A of the OPTN Bylaws

Application and Hearing Procedures for Members and Designated Transplant Programs

2.01A - 2.05A [No changes]

2.06A - Membership and Professional Standards Committee Action

- (a) **Category I, II, and III Potential Violations.** Matters referred to the MPSC, MPSC-PCSC, or a MPSC ad hoc subcommittee will be defined initially by decision of the MPSC Chairperson (with advice from the Executive Director and President) as Category I potential violations according to the process outlined in Section 2.05 above, or by the MPSC, MPSC-PCSC, or MPSC ad hoc subcommittee as either Category II or Category III potential violations. For Category I potential violations, the MPSC-PCSC or ad hoc subcommittee shall report its determination in writing to the Executive Committee and full MPSC.

Category II potential violations generally are of the type described in Section 2.05(2)(c) above, while Category III potential violations generally are of the type described in Section 2.05(2)(a-b) above. Category II and III potential violations are further distinguished by the expectation that Category II potential violations will proceed to formal Hearings and, perhaps, Appellate Reviews. Upon determination of a Category II potential violation, the MPSC shall consider a timeline for review and action to assist in timely resolution of the matter.

- (b) For Category II and III potential violations, the MPSC-PCSC shall report its action in writing to the full MPSC. The MPSC shall report its action in writing to the Board of Directors.

Category I, II, and III potential violations are generally defined as follows. Individual cases may vary depending upon the unique circumstances, and cases may move among the categories as circumstances may change.

- Category I = potential violation of OPTN requirements posing substantial, time sensitive threat to patient health or public safety,
- Category II = material breach of OPTN requirements, and
- Category III = dialogue with MPSC expected to correct any noncompliant behavior and lead to ongoing future compliance.

Actions available for all categories of potential violations may include, without limitation (see Figures A-2a and A2b for a general overview of these actions), the following. Sanctions listed under numbers (1) and (2) below may be imposed directly by action of either the MPSC-PCSC or MPSC. Sanctions listed under numbers (3) – (7) below must be recommended by the MPSC to the Board of Directors and imposed by the Board, or may be imposed by the Executive Committee or the Board without recommendation of the MSPC. Unless specifically noted, the sanctions listed below may be taken in cases of : (i) noncompliance with policies or behavior posing risk to patient health or public safety covered by Section 1138 of the Social Security Act, 42 U.S.C. § 1320-b8, by virtue of (a) recommendation by the OPTN to be mandatory and designation by the Secretary of HHS for coverage, (b) determination by the Secretary of HHS to be mandatory under the OPTN Final Rule, or (c) determination of risk to the health of patients or to the public safety, which is confirmed by the Secretary of HHS, and (ii) noncompliance with all other OPTN requirements. Policies and behavior posing risk to patient health or public safety described under category (i) above are hereinafter referred to collectively as “policies covered by Section 1138 of the Social Security Act,” or individually as “policy covered by Section 1138 of the Social Security Act.”

The MPSC-PCSC or the MPSC may impose the following sanctions without referral to the Board of Directors for approval:

- (1) **Reject Request for Corrective Action.** The MPSC-PCSC or the MPSC may reject the request for corrective action, notice of which shall be provided to the Board of Directors;
- (2) **Notice of Uncontested Violation, Letter of Warning or Letter of Reprimand.** The MPSC-PCSC or the MPSC may issue a Notice of Uncontested Violation, Letter of Warning or a Letter of Reprimand, any of which is not an adverse action under the Bylaws but is meant to inform the Member of the need for the Member to ensure continuing compliance with OPTN requirements. The Board of Directors and the Secretary of HHS shall be notified of final decisions to issue a Notice of Uncontested Violation, Letter of Warning or a Letter of Reprimand. These categories of non-adverse actions are appropriate under the following circumstances:
 - (a) **Notice of Uncontested Violation** – There has been a violation of OPTN requirements with no substantial evidence of mitigating factors based on

medical judgment, and there is believed to be no likelihood of recurrence. The Member is not entitled to an interview.

- (b) **Letter of Warning** – There has been an apparent violation of OPTN requirements under circumstances in which medical judgment is credibly put forth as a partial mitigating factor and there is believed to be no likelihood of recurrence. The Member is not entitled to an interview.
- (c) **Letter of Reprimand** – There has been an apparent violation of OPTN requirements under circumstances where medical judgment is not a credible mitigating factor and there is believed to be no likelihood of recurrence. The Member shall be entitled to an interview under the procedures described in Section 3.01A prior to any issuance of a Letter of Reprimand by the MPSC/PCSC or the MPSC.

The MPSC may make recommendations to the Board of Directors for the imposition of the following adverse sanctions or the Board of Directors or the Executive Committee may take such action without recommendation by the MPSC:

- (3) **Probation.** The MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord may place the Member on probation, which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed, in the case of initial recommendation by the MPSC, by a final recommendation by the MPSC to and, in any event, final action by the Board of Directors or the Executive Committee and notice to the Secretary of HHS of the final decision to place the Member on probation. Probation may include one or more of the following or other actions deemed appropriate by the MPSC-PCSC/MPSC, Executive Committee, or the Board of Directors and will include notice to all Members.
 - (a) Required submission of a compliance action plan or plan of correction developed to specifications as may be defined by the MPSC-PCSC/MPSC, with demonstration to the MPSC-PCSC/MPSC of adherence to the plan and correction of any non-compliant activity within some period of time.
 - (b) Unscheduled on-site audit(s) throughout the period of probation, to be performed by OPTN Contractor audit staff at the sole reasonable cost and expense of the Member. Such costs and expenses shall include, but not be limited to, travel and lodging expenses of OPTN Contractor staff.
 - (c) Required submission of reports, data, or other evidence to the OPTN Contractor documenting correction of the non-compliant activity throughout the period of probation.
 - (d) Required investigation of personnel as provided for in Section 1.03A of Appendix A of the Bylaws and Sections IV and VII of Attachment I to Appendix B of the Bylaws.
- (4) **Member Not in Good Standing.** The MPSC may recommend that the Board of Directors or Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may declare the Member a Member Not in Good Standing, which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed in the case of an initial recommendation by the MPSC by a final recommendation to, and in any event, final action by the Board of Directors or Executive Committee and notice to the Secretary of HHS of the final decisions to declare the Member a Member Not in Good Standing. Member Not in Good Standing includes all of the following plus any other action deemed

appropriate by the Board of Directors, unless specifically limited to one or more of such actions by the Board of Directors or Executive Committee:

- (a) Withdrawal of voting privileges in OPTN affairs.
- (b) Suspension of the ability for any personnel named in the OPTN Contractor Membership database as associated with the Member - who are not otherwise eligible to serve by virtue of their association with a member in Good Standing - to sit on any Committee, hold office, and sit on the Board of Directors.
- (c) Formal notification, along with subsequent changes in such status, to the entire OPTN Membership as well as to the Chief Executive Officer of Institutional Members
- (d) Formal notification, along with subsequent changes in such status, to the Member's Chief Executive Officer or Administrator and to the state health commissioner or other appropriate state representative with oversight of health care institutions doing business in the Member's state.
- (e) Notice, within reasonable limits and means, to patients and the general public in the area of the Member. Such notice may include, but is not limited to, communication using the OPTN website and/or as prescribed by the Board of Directors for distribution by the Member.
- (f) Required investigation of personnel as provided for in Section 1.03A of Appendix A of the Bylaws and Sections IV and VII Attachment I to Appendix B of the Bylaws.

~~(g)~~ The actions listed for a Member on probation.

- (5) **Suspension of Member Privileges.** Only in the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may request approval from the Secretary to suspend the Member's ability to list patients on the waiting list, the Member's eligibility to receive organ offers for transplants and related services, and other membership privileges, any of which would be an adverse action under the Bylaws which would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed in the case of an initial recommendation by the MSPC by a final recommendation to and, in any event, final action by the Board of Directors or the Executive Committee and, if the decision is to move the request forward, submission of the recommendation to the Secretary of HHS for consideration. Suspension of membership privileges may include one or more of the following or other actions deemed appropriate by the MPSC-PCSC/MPSC, the Executive Committee, or the Board of Directors:

- (a) Suspension of the privilege to hold office and/or sit on OPTN Board of Directors or Committees.
- (b) Suspension of voting privileges in OPTN affairs.
- (c) Suspension of the privilege to receive all organ offers or offers of particular organ types for transplantation and related services.

- (d) Suspension of the privilege to list all patients or patients in need of particular organ types on the Patient Waiting List.
 - (e) Required investigation of personnel as provided for in Section 1.03A of Appendix A of the Bylaws and Sections IV and VII Attachment I to Appendix B of the Bylaws.
 - (f) ~~(e)~~ The actions listed for a Member on probation and the actions listed for a Member Not in Good Standing.
- (6) **Termination of Membership or Designated Transplant Program Status.** Only in the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may request approval from the Secretary to terminate membership or designated transplant program status for one or more organs, which are adverse actions under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed in the case of an initial recommendation by the MPSC, by a final recommendation to and in any event, final action by the Board of Directors or the Executive Committee and, if the decision is to move the request forward, submission of the recommendation to the Secretary of HHS for consideration; and
- (7) **Action Specified in OPTN Final Rule.** Only in the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may recommend to the Secretary of HHS any action specifically identified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed in the case of initial recommendation by the MPSC, by a final recommendation to and in any event, final action by the Board of Directors or the Executive Committee and, if the decision is to move the recommendation forward, submission of the recommendation to the Secretary of HHS for consideration.

Appendix A to the UNOS Bylaws

Corrective Action and Enforcement of UNOS Requirements OPO, Transplant Hospital, and Histocompatibility Laboratory Members

2.01A - 2.05A [No changes]

2.06A Membership And Professional Standards Committee Action

- (a) **Category I, II, and III Potential Violations.** Matters referred to the MPSC, MPSC-PCSC, or a MPSC ad hoc subcommittee will be defined initially by decision of the MPSC Chairperson (with advice from the Executive Director and President) as Category I potential violations according to the process outlined in Section 2.05 above, or by the MPSC, MPSC-PCSC, or MPSC ad hoc subcommittee as either Category II or Category III potential violations. For Category I potential violations, the MPSC-PCSC or ad hoc subcommittee shall report its determination in writing to the Executive Committee and full MPSC.

Category II potential violations generally are of the type described in Section 2.05(2)(c) above, while Category III potential violations generally are of the type described in Section 2.05(2)(a-b) above. Category II and III potential violations are further distinguished by the expectation that Category II potential violations will proceed to formal Hearings and, perhaps, Appellate Reviews. Upon determination of a Category II potential violation, the MPSC shall consider a timeline for review and action to assist in timely resolution of the matter; and

- (b) For Category II and III potential violations, the MPSC-PCSC shall report its action in writing to the full MPSC. The MPSC shall report its action in writing to the Board of Directors.

Category I, II, and III potential violations are generally defined as follows. Individual cases may vary depending upon the unique circumstances, and cases may move among the categories as circumstances may change.

- Category I = potential violation of UNOS requirements posing substantial, time sensitive threat to patient health or public safety,
- Category II = material breach of UNOS requirements, and
- Category III = dialogue with MPSC expected to correct any noncompliant behavior and lead to ongoing future compliance.

Actions available for all categories of potential violations may include, without limitation (see Figures A-2a and A2b for a general overview of these actions), the following. Sanctions listed under numbers (1) and (2) below may be imposed directly by action of either the MPSC-PCSC or MPSC. Sanctions listed under numbers (3) – (7) below must be recommended by the MPSC to the Board of Directors and imposed by the Board, or may be imposed by the Executive Committee or the Board without recommendation of the MSPC. Unless specifically noted, the sanctions listed below may be taken in cases of : (i) noncompliance with policies or behavior posing risk to patient health or public safety covered by Section 1138 of the Social Security Act, 42 U.S.C. § 1320-b8, by virtue of (a) recommendation by the OPTN to be mandatory and designation by the Secretary of HHS for coverage, (b) determination by the Secretary of HHS to be mandatory under the OPTN Final Rule, or (c) determination of risk to the health of patients or to the public safety, which is confirmed by the Secretary of HHS, and (ii) noncompliance with all other UNOS requirements. Policies and behavior posing risk to patient health or public safety described under category (i) above are hereinafter referred to collectively as “policies covered by Section 1138 of the Social Security Act,” or individually as “policy covered by Section 1138 of the Social Security Act.”

The MPSC-PCSC or the MPSC may impose the following sanctions without referral to the Board of Directors for approval:

- (1) **Reject Request for Corrective Action.** The MPSC-PCSC or the MPSC may reject the request for corrective action notice of which shall be provided to the Board of Directors; and
- (2) **Notice of Uncontested Violation, Letter of Warning or Letter of Reprimand.** The MPSC-PCSC or the MPSC may issue a Notice of Uncontested Violation, Letter of Warning or a Letter of Reprimand, any of which is not an adverse action under the Bylaws but is meant to inform the Member of the need for the Member to ensure continuing compliance with UNOS requirements. These categories of non-adverse actions are appropriate under the following circumstance.
 - (a) **Notice of Uncontested Violation** –There has been a violation of UNOS requirements with no substantial evidence of mitigating factors based on medical judgment, and there is believed to be no likelihood of recurrence. The Member is not entitled to an interview;
 - (b) **Letter of Warning** – There has been an apparent violation of UNOS requirements under circumstances in which medical judgment is credibly put forth as a partial mitigating factor and there is believed to be no likelihood of recurrence. The Member is not entitled to an interview; and
 - (c) **Letter of Reprimand** – There has been an apparent violation of UNOS requirements under circumstances where medical judgment is not a credible mitigating factor and there is believed to be no likelihood of recurrence. The Member shall be entitled to an interview under the procedures described in Section 3.01A prior to any issuance of a Letter of Reprimand by the MPSC/PCSC or the MPSC.

The MPSC may make recommendations to the Board of Directors for the imposition of the following adverse sanctions or the Board of Directors or the Executive Committee may take such action without recommendation by the MSPC:

- (3) **Probation.** The MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord may place the Member on probation, which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed, in the case of initial recommendation by the MPSC, by a final recommendation by the MPSC to and, in any event, final action by the Board of Directors or the Executive Committee of the final decision to place the Member on probation. Probation may include one or more of the following or other actions deemed appropriate by the MPSC-PCSC/MPSC, Executive Committee, or the Board of Directors and will include notice to all Members.
 - (a) Required submission of a compliance action plan or plan of correction developed to specifications as may be defined by the MPSC-PCSC/MPSC, with demonstration to the MPSC-PCSC/MPSC of adherence to the plan and correction of any non-compliant activity within some period of time;
 - (b) Unscheduled on-site audit(s) throughout the period of probation, to be performed by UNOS audit staff at the sole reasonable cost and expense of the Member. Such costs and expenses shall include, but not be limited to, travel and lodging expenses of UNOS staff; and
 - (c) Required submission of reports, data, or other evidence to UNOS documenting correction of the non-compliant activity throughout the period of probation.

(d) Required investigation of personnel as provided for in Section 1.03A of Appendix A of the Bylaws and Sections IV and VII of Attachment I to Appendix B of the Bylaws.

(4) **Member Not in Good Standing.** The MPSC may recommend that the Board of Directors or Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may declare the Member a Member “Not in Good Standing” which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed in the case of an initial recommendation by the MSPC by a final recommendation to, and in any event, final action by the Board of Directors or Executive Committee of the Final decision to declare the Member a Member Not in Good Standing. Member Not in Good Standing includes all of the following plus any other action deemed appropriate by the Board of Directors, unless specifically limited to one or more of such actions by the Board of Directors or the Executive Committee:

- (a) Withdrawal of voting privileges in UNOS affairs;
- (b) Suspension of the ability for any personnel named in the UNOS Membership database as associated with the Member - who are not otherwise eligible to serve by virtue of their association with a member in Good Standing - to sit on any Committee, hold office, and sit on the Board of Directors;
- (c) Formal notification, along with subsequent changes in such status, to the entire UNOS Membership as well as to the Chief Executive Officer of Institution Members;
- (d) Formal notification, along with subsequent changes in such status, to the Member’s Chief Executive Officer or Administrator and to the state health commissioner or other appropriate state representative with oversight of health care institutions doing business in the Member’s state;
- (e) Notice, within reasonable limits and means, to patients and the general public in the area of the Member. Such notice may include, but is not limited to, communication using the UNOS website and/or as prescribed by the Board of Directors for distribution by the Member; and

(f) Required investigation of personnel as provided for in Section 1.03A of Appendix A of the Bylaws and Sections IV and VII Attachment I to Appendix B of the Bylaws.

~~(g)(e)~~ The actions listed for a Member on probation.

(5) **Suspension of Member Privileges.** Only in the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may request approval from the Secretary to suspend the Member’s ability to list patients on the waiting list, the Member’s eligibility to receive organ offers for transplant and related services, and other membership privileges, any of which would be an adverse action under the Bylaws which would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed the case of an initial recommendation by the MPSC by a final recommendation to and, in any event, final action by the Board of Directors or the Executive Committee. Suspension of membership privileges

may include one or more of the following or other actions deemed appropriate by the MPSC-PCSC/MPSC, the Executive Committee, or the Board of Directors:

- (a) Suspension of the privilege to hold office and/or sit on the UNOS Board of Directors or Committees;
- (b) Suspension of voting privileges in UNOS affairs;
- (c) Suspension of the privilege to receive all organ offers or offers of particular organ types for transplantation and related services;
- (d) Suspension of the privilege to list all patients or patients in need of particular organ types on the Waiting List; and
- (e) Required investigation of personnel as provided for in Section 1.03A of Appendix A of the Bylaws and Sections IV and VII Attachment I to Appendix B of the Bylaws.
- (f) ~~(e)~~ The actions listed for a Member on probation and the actions listed for a Member Not in Good Standing.

- (6) **Termination of Membership or Designated Transplant Program Status.** Only in the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may terminate membership or designated transplant program status for one or more organs, which are adverse actions under the Bylaws and would first entitle the Member procedural rights as provided in Section 3.01A – 3.03A followed in the case of an initial recommendation by the MPSC, by a final recommendation to and in any event, final action by the Board of Directors or the Executive Committee.
- (7) **Action Specified in OPTN Final Rule.** Only in the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may recommend to the any action specifically identified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed in the case of initial recommendation by the MPSC, by a final recommendation to and in any event, final action by the Board of Directors or the Executive Committee.

- 2.07A **Medical Peer Review** [No changes]
- 2.08A **Enforcement Period** [No changes]
- 2.09A **Restoration of Membership Privileges** [No changes]
- 2.10A **Notice** [No changes]
- 2.11A **Procedural Rights** [No changes]
- 2.12A **Time Period For Action** [No changes]

**Appendix B to Bylaws - OPTN
Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership**

I. Organ Procurement Organizations.

[No Change]

II. Transplant Hospitals.

A. General. [No further changes]

B. Survival Rates. [No further changes]

C. Inactive Membership Status. [No further changes]

D. Investigation of Personnel. At the request of the MPSC, the Transplant Hospital must conduct an investigation, including, of personnel identified by the MPSC, who are associated with one or more of the Transplant Hospital's designated transplant programs (as defined below) qualified as a transplant program by other than the requirements set forth in Attachment I and sub-attachments to Appendix B, and report to the MPSC upon initiation and conclusion of the inquiry that it has conducted the investigation in accordance with the terms of this provision. The purpose of the investigation would be to examine the individual's or individuals' role(s) in a matter under review or reviewed by the MPSC and would be explained to the Transplant Hospital. The Hospital's investigation must be conducted include peer review pursuant to the institution's standard peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process. Failure to comply with this provision shall result in recommendation to the Board of Directors that the Board so notify the Secretary, and/or take appropriate action in accordance with Appendix A of these Bylaws.

E. Patient Notification. [No further changes]

F. Clinical Transplant Coordinator. [No further changes]

G. Financial Coordinator. [No further changes]

H. Routine Referral Procedures. [No further changes]

I. Designated Transplant Program Status. [No further changes]

III. Histocompatibility Laboratories. [No Change]

Appendix B to the UNOS Bylaws

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

IV. Organ Procurement Organizations.

V. Transplant Hospitals.

A. General. [No further changes]

B. Survival Rates. [No further changes]

C. Inactive Membership Status.

D. Investigation of Personnel. At the request of the MPSC, the Transplant Hospital must conduct an investigation, including of personnel identified by the MPSC, who are associated with one or more of the Transplant Hospital's designated transplant programs (as defined below) qualified as a transplant program by other than the requirements set forth in Attachment I and sub-attachments to Appendix B, and report to the MPSC upon initiation and conclusion of the inquiry that it has conducted the investigation in accordance with the terms of this provision. The purpose of the investigation would be to examine the individual's or individuals' role(s) in a matter under review or reviewed by the MPSC and would be explained to the Transplant Hospital. The Hospital's investigation must be conducted include peer review pursuant to the institution's standard peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process. Failure to comply with this provision shall result in recommendation to the Board of Directors that the Board take appropriate action in accordance with Appendix A of these Bylaws.

E. Key Personnel. [No further changes]

F. Patient Notification. [No further changes]

G. Clinical Transplant Coordinator. [No further changes]

H. Financial Coordinator. [No further changes]

I. Routine Referral Procedures. [No further changes]

J. Designated Transplant Program Status. [No further changes]

Attachment I to Appendix B of the OPTN Bylaws

IV. **Facilities and Resources.** [No Change]

V. **Inactive Program Status.** [No Change]

VI. **Reporting Changes in Key Personnel.** [No Change]

IV. Investigation of Personnel. At the request of the MPSC, the designated transplant program must conduct an investigation of personnel identified by the MPSC, who are associated with the program, and report to the MPSC upon initiation and conclusion of the inquiry that it has conducted the investigation in accordance with the terms of this provision. The purpose of the investigation would be to examine the individual's or individuals' role(s) in a matter under review or reviewed by the MPSC and would be explained to the designated transplant program. The program's investigation must be conducted ~~include peer review~~ pursuant to the program's institutional standard peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process. Failure to comply with this provision shall result in appropriate action in accordance with Appendix A of these Bylaws.

IV. OPO Affiliation. The transplant program must have letters of agreement or contracts with an OPO as defined in Article 1.2 of the Bylaws.

VI. Histocompatibility Laboratory Affiliation. The transplant program must use, for its histocompatibility testing, a laboratory that meets the standards for histocompatibility testing, as described in these Bylaws, Appendix B, Attachment II, and is approved by the Board of Directors as meeting these standards.

VII. Transplant Surgeon and Physician. The transplant program must identify a qualified primary surgeon and primary physician, the requirements for whom are specified below, as well as the program director. The program director, in conjunction with the primary surgeon and primary physician, must submit written documentation that 100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The primary surgeon and primary physician, collectively, are further responsible for ensuring the ongoing operation of the program in compliance with the criteria set forth in this Appendix B, ~~Attachment I~~, and notification to the OPTN Contractor if at any time the program deviates from such criteria.

~~Upon applying to serve as~~ Each primary surgeon or primary physician, listed on the application, as a part of the plan for continuing policy compliance, shall submit an assessment, subject to medical peer review confidentiality requirements and which follows guidelines provided in the application and is satisfactory to the MPSC, of all physicians and surgeons participating in the program regarding their involvement in prior transgressions of OPTN requirements and plans to ensure that the improper conduct is not continued. A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year.

H. Renal Transplantation [No Change]

I. Liver Transplantation [No Change]

J. Pancreas Transplantation [No Change]

K. Pancreatic Islet Transplantation [No Change]

L. Heart Transplantation [No Change]

M. Lung Transplantation [No Change]

N. Heart/Lung Transplantation [No Change]

VIII. Collaborative Support. [No further Change]

VIXH. Ancillary Services. [No further Change]

IX. Blood Bank Support. [No further Change]

XI. Transplant Mental Health and Social Support Services. [No further Change]

XII. Additional Requirements for Pancreatic Islet Transplantation. [No further Change]

Attachment I, to Appendix B of the UNOS Bylaws Designated Transplant Program Criteria

A transplant program that meets the following criteria shall be qualified as a designated transplant program to receive organs for transplantation:

VII. Facilities and Resources. [No changes]

II. Inactive Program Status. [No changes]

III. Reporting Changes in Key Personnel. . [No changes]

IV. Investigation of Personnel: At the request of the MPSC, the designated transplant program must conduct an investigation of personnel identified by the MPSC, who are associated with the program, and report to the MPSC upon initiation and conclusion of the inquiry that it has conducted the investigation in accordance with the terms of this provision. The purpose of the investigation would be to examine the individual's or individuals' role(s) in a matter under review or reviewed by the MPSC and would be explained to the designated transplant program. The program's investigation must be conducted ~~include peer review~~ pursuant to the program's institutional standard peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process. Failure to comply with this provision shall result in appropriate action in accordance with Appendix A of these Bylaws.

IV. OPO Affiliation. [No further changes].

VI. Histocompatibility Laboratory Affiliation. [No further changes]

VII. Transplant Surgeon and Physician. The transplant program must identify a qualified primary surgeon and primary physician, the requirements for whom are specified below, as well as the program director. The program director, in conjunction with the primary surgeon and primary physician, must submit written documentation that 100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The primary surgeon and primary physician, collectively, are further responsible for ensuring the ongoing operation of the program in compliance with the criteria set forth in this Appendix B, ~~Attachment I~~, and notification to the OPTN Contractor if at any time the program deviates from such criteria. Each primary surgeon or primary physician, listed on the application ~~ent~~ as a part of the plan for who shares coverage responsibility, shall submit an assessment, subject to medical peer review confidentiality

requirements and which follows guidelines provided in the application and is satisfactory to the MPSC, of all physicians and surgeons participating in the program regarding their involvement in prior transgressions of UNOS requirements and plans to ensure that the improper conduct is not continued. A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year.

O. Renal Transplantation [No Change]

P. Liver Transplantation [No Change]

Q. Pancreas Transplantation [No Change]

R. Pancreatic Islet Transplantation [No Change]

S. Heart Transplantation [No Change]

T. Lung Transplantation [No Change]

U. Heart/Lung Transplantation [No Change]

VIII. Collaborative Support. [No Change]

~~VIX~~ H. Ancillary Services. [No Change]

IX. Blood Bank Support. [No Change]

XI. Transplant Mental Health and Social Support Services. [No Change]

XII. Additional Requirements for Pancreatic Islet Transplantation. [No Change]

**Proposed Changes to Language for Letters of Recommendation
Appendix B, Attachment I, Section XII (C) of the UNOS Bylaws
Designated Transplant Program Criteria,**

XII. Transplant Programs.

A – B [No Changes]

XII. Transplant Programs.

- C. To qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria. Each transplant program must identify a UNOS qualified primary surgeon and physician, the requirements for whom are described below. The program director, in conjunction with the primary surgeon and physician, must provide written documentation that 100% medical and surgical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year.

A transplant center applying as a new member or for a key personnel change must include for the proposed primary transplant surgeon and/or physician a report from their hospital credentialing committee that the committee has reviewed the said individual's state licensing, board certification status, training and affirm that they are "currently" a member in good standing.

(1) **Kidney Transplantation**

Transplant Surgeon - Each transplant center must have on site a qualified kidney transplant surgeon. A kidney transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital. Such a surgeon must complete a two year formal transplant fellowship at a transplant program meeting UNOS membership criteria in renal transplantation. In lieu of a two year formal transplant fellowship, two years of experience with a transplant program meeting the criteria for acceptance into UNOS will suffice.

The surgeon shall have current certification by either the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or their foreign equivalent. If board certification in Urology is pending (as in the case of one just finished training) conditional approval may be granted for a 12-month period, with the possibility of its being renewed for an additional 12-month period to allow time for the completion of certification. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

A formal training program for kidney transplant surgeons requires that formal training must occur in a training program approved by the Membership and Professional Standards Committee of UNOS. The criteria for approval of such a program are as follows:

(aa) – (bb) **[No Changes]**

To qualify as a kidney transplant surgeon, the training/experience requirements will be met if the following conditions of either (cc), (dd), or (ee) are met.

(cc) Training during the applicant's transplant fellowship. For kidney transplantation the training requirements for the transplant surgeon can be met during a two-year transplant fellowship if the following conditions are met:

(i) - (iv) **[No Changes]**

(v) The individual has a letter, sent directly to UNOS from the director of that training program and chairman of the department or credentialing committee, verifying that the fellow has met the above requirements, and that the fellow is qualified to direct a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary

surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) [No Changes]

(dd) For kidney transplantation, if the transplant surgeon requirements have not been met, as outlined above, in a transplant fellowship, the requirements can be met by acquired clinical experience if the following conditions are met:

(i) – (iii) [No Changes]

(iv) The surgeon has a letter, sent directly to UNOS, from the director of this transplant program and chairman of the department or credentialing committee, verifying that the surgeon has met the above requirements, and is qualified to direct a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the transplant program last served by the individual, attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

(ee) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary kidney transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary kidney transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing kidney transplantation is equivalent to that described in the above requirements. Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of all aspects of kidney transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as

deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary kidney transplant surgeon is temporary only and shall cease to exist for applications for primary kidney transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(ff) [No Changes].

- (b) Transplant Physician - Each kidney transplant program must have on site a qualified transplant physician. A kidney transplant physician shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The kidney transplant physician shall have current board certification in nephrology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

A formal training program for kidney transplant physicians requires that formal training must occur in a training program approved by the MPSC of UNOS. The criteria for approval of such a program follows:

(aa) – (bb) [No Changes]

To qualify as a kidney transplant physician, the training/experience requirement will be met if the following conditions of either (cc), (dd), (ee), (ii), or (jj) are met. For a pediatrician to qualify as a kidney transplant physician, the training/experience requirements will be met if the following conditions of either (ee), (ff), (gg), (hh), (ii), or (jj) are met:

- (cc) The training requirements for the kidney transplant physician can be met during the applicant's nephrology fellowship if the following conditions are met:

(i) – (v) [No Changes]

- (vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well

as the supervising qualified kidney transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii) – (ix) [No Changes]

(dd) The training requirements for the kidney transplant physician can be met during a separate 12-month transplant nephrology fellowship if the following conditions are met

(i) – (v) [No Changes]

(vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified kidney transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii) [No Changes]

(ee) If a board certified or eligible nephrologist has not met the above requirements in a nephrology fellowship or transplantation medicine fellowship the training/experience requirements for the kidney transplant physician can be met by acquired clinical experience if the following conditions are met:

(i) – (iv) [No Changes]

- (v) That the individual has written a detailed letter to UNOS outlining his/her experience in a kidney transplant program and in addition that supporting letters documenting the experience and competence of the individual from the qualified transplant physician and/or the kidney transplant surgeon who has been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (ff) The training/experience requirements for a kidney transplant physician can be met by completion of 3 years of pediatric nephrology as mandated by the American Board of Pediatrics in a training program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the ACGME, if during that 3 year program, there has been an aggregate of 6 months of clinical care for transplant patients and the following conditions are met:

(i) – (iii) [No Changes]

- (iv) The individual must have had a letter sent directly to UNOS from the program director of the pediatric nephrology training program, as well as from the qualified kidney transplant physician and the qualified kidney transplant surgeon verifying that the fellow has met the above requirements, that he/she is qualified to become a kidney transplant physician, and a medical director of a renal transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) – (vi) [No Changes]

(gg) The training/experience requirements for the kidney transplant physician can be met during a separate transplantation fellowship if the following conditions are met, and the individual is a certified pediatric nephrologist, or is approved by the American Board of Pediatrics to take the certifying examination.

(i) – (iii) [No Changes]

(iv) The individual must have had a letter sent directly to UNOS from the program director of the pediatric nephrology training program, as well as from the qualified kidney transplant physician and the qualified kidney transplant surgeon verifying that the fellow has met the above requirements, that he/she is qualified to become a kidney transplant physician, and a medical director of a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

(hh) If a certified pediatric nephrologist, or a pediatric nephrologist approved by the American Board of Pediatrics to take the certifying examination, has not met requirements (ff)(i) - (ff) (iv) or (gg)(i) – (gg)(iv), he/she can meet the training/ experience requirements to qualify as a kidney transplant physician if the following conditions are met:

(i) [No Changes]

(ii) That supporting letters documenting the experience and competence of the individual from the qualified kidney transplant physician and the qualified kidney transplant surgeon who has been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician,

primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(iii) - (vi) [No Changes]

- (ii) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary kidney transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary kidney transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of kidney transplant patients is equivalent to that described in the above requirements. Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of all aspects of kidney transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary physician or primary physician, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary kidney transplant physician is temporary only and shall cease to exist for applications for primary kidney transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

- (jj) In the case of a change in the primary kidney transplant physician at a UNOS approved kidney transplant program, if items (cc) iii or (ee) i-ii are not met, the replacement physician, a nephrologist, can function as a kidney transplant physician for a maximum period of twelve months if the following conditions are met:

(i) – (vi) [No Changes]

(kk) [No Changes]

(2) **Live Donor Kidney Transplant Programs.** [No Changes]

(3) **Liver Transplantation**

- (a) Transplant Surgeon - Each transplant center must have on site a qualified liver transplant surgeon. A liver transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The surgeon shall have current certification by either the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or their foreign equivalent. If board certification in Urology is pending (as in the case of one just finished training) conditional approval may be granted for a 12-month period, with the possibility of its being renewed for an additional 12-month period to allow time for the completion of certification. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

A formal training program for transplant surgeons requires that formal training must occur in a training program approved by the Membership and Professional Standards Committee of UNOS. The criteria for approval of such a program are as follows:

(aa) - (bb) [No Changes]

- (cc) Training during the applicant's transplant fellowship. For liver transplantation the training requirements for the transplant surgeon can be met during a two-year transplant fellowship if the following conditions are met:

(i) - (iv) [No Changes]

- (v) The individual has a letter, sent directly to UNOS from the director of that training program verifying that the fellow has met the above requirements, and that the fellow is qualified to direct a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) [No Changes]

(dd) For liver transplantation, if the transplant surgeon requirements have not been met, as outlined above, in a transplant fellowship, the requirements can be met by acquired clinical experience if the following conditions are met.

(i) - (iii) [No Changes]

(iv) The surgeon has a letter, sent directly to UNOS, from the director of this transplant program and chairman of the department or credentialing committee, verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

(ee) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary liver transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary liver transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing liver transplantation is equivalent to that described in the above requirements.

Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in liver transplant patient care within the last two years) of all aspects of liver transplantation and patient care.

Additionally, the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary

surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary liver transplant surgeon is temporary only and shall cease to exist for applications for primary liver transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these Bylaws and implemented.

The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process

(ff) [No Changes]

- (b) Transplant Physician - Each liver transplant program must have on site a qualified transplant physician. A liver transplant physician shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The liver transplant physician shall have current board certification in gastroenterology by the American Board of Internal Medicine, American Board of Pediatrics, or the foreign equivalent.

In general, pediatric liver transplant programs should have a board certified pediatrician (or foreign equivalent) who meets the criteria for liver transplant physician. In the absence of such an individual, a physician meeting the criteria as a liver transplant physician for adults, can function as a liver transplant physician for the pediatric program if a pediatric gastroenterologist is involved in the care of the pediatric liver transplant recipients.

The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

To qualify as a liver transplant physician, the training/experience requirement will be met if the following conditions of either (aa), (bb), (cc), (dd), (ee) (ff), (gg), (hh), or (ii) are met:

- (aa) The training requirements for the liver transplant physician can be met during the applicant's gastroenterology fellowship if the following conditions are met:

(i) – (iv) [No Changes]

- (v) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified liver transplant physician

verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) – (viii) [No Changes]

(bb) The training requirements for the liver transplant physician can be met during a separate 12 month transplant hepatology fellowship if the following conditions are met.

(i) – (v) [No Changes]

(vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified liver transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii) [No Changes]

(cc) If a board certified gastroenterologist has not met the above requirements in a gastroenterology, or transplant hepatology, fellowship the training/experience requirements for the liver transplant physician can be met by acquired clinical experience if the following conditions are met:

(i) – (iv) [No Changes]

- (v) That the individual has written a detailed letter to UNOS outlining his/her experience in a liver transplant program and in addition that supporting letters documenting the experience and competence of the individual from the qualified transplant physician and/or liver transplant surgeon who has been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (dd) The training/experience requirements for a liver transplant physician can be met by completion of 3 years of pediatric gastroenterology fellowship training as mandated by the American Board of Pediatrics and accredited by the ACGME RRC-Ped, if during that 3 year program there has been an aggregate of 6 months of clinical care for transplant patients and the following conditions are met:

(i) – (iii) [No Changes]

- (iv) The individual must have had a letter sent directly to UNOS from the program director of the pediatric gastroenterology training program, as well as from the qualified liver transplant physician and the qualified liver transplant surgeon verifying that the fellow has met the above requirements, that he/she is qualified to become a liver transplant physician, and a medical director of a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

- (ee) The training requirements for the liver transplant physician can be met during a separate transplantation fellowship if the following conditions are met, and the individual is a board certified pediatric

gastroenterologist, or is approved by the American Board of Pediatrics to take the certifying examination.

(i) – (iii) [No Changes]

(iv) The individual must have had a letter sent directly to UNOS from the program director of the pediatric gastroenterology training program, as well as from the qualified liver transplant physician and the qualified liver transplant surgeon verifying that the fellow has met the above requirements, that he/she is qualified to become a liver transplant physician, and a medical director of a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

(ff) If a board certified pediatric gastroenterologist, or a pediatric gastroenterologist approved by the American Board of Pediatrics to take the certifying examination, has not met requirements (dd) or (ee), he/she can meet the training/ experience requirements to qualify as a liver transplant physician if the following conditions are met:

(i) [No Changes]

(ii) That the physician has written a detailed letter to UNOS outlining his/her experience in a liver transplant program and in addition that supporting letters documenting the experience and competence of the individual from the qualified transplant physician and the qualified transplant surgeon who have been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(iii) - (v)[No Changes]

(gg) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary liver transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary liver transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of liver transplant patients is equivalent to that described in the above requirements.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary physician or primary physician, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary liver transplant physician is temporary only and shall cease to exist for applications for primary liver transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in liver transplant patient care within the last two years) of all aspects of liver transplantation and patient care.

The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(hh) In the case of a change in the primary liver transplant physician at a UNOS approved transplant program, if items (aa) iii or (cc) i-ii are not met, the replacement physician, must be a gastroenterologist/hepatologist, and can function as a liver transplant physician for a maximum period of twelve months if the following conditions are met:

(i) - (vi) [No Changes]

(ii) [No Changes]

(4). **Live Donor Liver Transplant Programs.** [No Changes]

(5) **Pancreas Transplantation**

- (a) Transplant Surgeon - Each transplant center must have on site a qualified transplant pancreas surgeon. A pancreas transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital. Such a surgeon must complete a minimum of one year formal transplant fellowship training and one year of experience or complete a two year formal transplant fellowship at a transplant program meeting UNOS membership criteria in pancreas transplantation. In lieu of a two year formal transplant fellowship, two years of experience with a transplant program meeting the criteria for acceptance into UNOS will suffice.

The surgeon shall have and current certification by either the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or their foreign equivalent. If board certification in Urology is pending (as in the case of one just finished training) conditional approval may be granted for a 12-month period, with the possibility of its being renewed for an additional 12-month period to allow time for the completion of certification. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

A formal training program for transplant pancreas surgeons requires that formal training must occur in a training program approved by the Membership and Professional Standards Committee of UNOS. The criteria for approval of such a program are as follows:

(aa) - (bb) [No Changes]

To qualify as a pancreas transplant surgeon, the training/experience requirements will be met if the following conditions of either (cc), (dd), or (ee) are met.

- (cc) Training during the applicant's transplant fellowship. For pancreas requirements for the transplant surgeon can be met during a two-year transplant fellowship if the following conditions are met:

(i) – (iv) [No Changes]

- (v) The individual has a letter, sent directly to UNOS from the director of that training program and chairman of the department or credentialing committee, verifying that the fellow has met the above requirements, and that the fellow is qualified to direct a pancreas transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall

qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) [No Changes]

(dd) For pancreas transplantation, if the transplant surgeon requirements have not been met, as outlined above in options-(cc), the requirements can be met by acquired clinical experience if the following conditions are met.

(i) – (iii) [No Changes]

(iv) The surgeon has a letter, sent directly to UNOS, from the director of this transplant program and chairman of the department or credentialing committee, verifying that the surgeon has met the above requirements, and is qualified to direct a pancreas transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

(ee) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary pancreas transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary pancreas transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing pancreas transplantation is equivalent to that described in the above requirements. Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in pancreas transplant patient care within the last two years) of all aspects of pancreas transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program

director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary pancreas transplant surgeon is temporary only and shall cease to exist for applications for primary pancreas transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(ff) [No Changes]

- (b) Transplant Physician - Each pancreas transplant program must have on site a qualified transplant physician. A pancreas transplant physician shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The transplant physician shall have current certification by either the American Board of Internal Medicine, the American Board of Pediatrics, or their foreign equivalent. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

The transplant physician shall have at least one year of specialized formal training in transplantation medicine or, with some exceptions as set forth in item (ee), a minimum of two years documented experience in transplantation medicine with a transplant program that meets the qualifications for membership in UNOS.

To qualify as a pancreas transplant physician, the training/experience requirements will be met if the following conditions of either (aa), (bb), (cc) (dd), or (ee) are met.

- (aa) The training/experience requirements for the pancreas transplant physician can be met during the applicant's nephrology (endocrinology, diabetology) fellowship if the following conditions are met:

(i) – (v) [No Changes]

- (vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified pancreas transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a pancreas transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii) – (ix) [No Changes]

- (bb) The training requirements for the pancreas transplant physician can be met during a separate 12-month transplant medicine fellowship if the following conditions are met.

(i) – (v) [No Changes]

- (vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified pancreas transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a pancreas transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii)- (viii) [No Changes]

- (cc) If a board certified or eligible nephrologist, (endocrinologist, or diabetologist) has not met the above requirements in a nephrology fellowship or transplantation medicine fellowship the training/experience requirements for the pancreas transplant physician

can be met by acquired clinical experience if the following conditions are met:

(i) – (iv) [No Changes]

- (v) That the individual has written a detailed letter to UNOS outlining his/her experience in a pancreas transplant program and in addition that supporting letters documenting the experience and competence of the individual from the qualified transplant physician and/or the pancreas transplant surgeon who has been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (dd) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary pancreas transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary pancreas transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of pancreas transplant patients is equivalent to that described in the above requirements. Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in pancreas transplant patient care within the last two years) of all aspects of pancreas transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary pancreas transplant physician is temporary only and shall cease to exist for applications for primary

pancreas transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(ee) [No Changes]

(ff) [No Changes]

(6) Pancreatic Islet Transplantation [No Changes]

(7) Heart Transplantation

(a) Transplant Surgeon - Each heart transplant program must have on site a qualified transplant surgeon. A heart transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

Such surgeon shall have current certification by the American Board of Thoracic Surgery or its foreign equivalent. If board certification in thoracic surgery is pending (as in the case of one just finished training) conditional approval may be granted for a 24-month period, with the possibility of its being renewed for an additional 24-month period to allow time for the completion of certification.

The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

If an individual is certified by the American Board of Thoracic Surgery or its foreign equivalent, then the individual must maintain their certification in the American Board or its foreign equivalent..

To qualify as a heart transplant surgeon, the training/experience requirements will be met if the following conditions of either (aa), (bb), (cc), or (dd) are met.

(aa) The training requirements for the heart transplant surgeon can be met during the applicant's cardiothoracic surgery residency if the following conditions are met:

(i)- (iii) [No Changes]

(iv) The individual has a letter, sent directly to UNOS from the director of that training program verifying that the resident has met the above requirements, and that the resident is qualified to direct a heart transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) – (vi) [No Changes]

- (bb) For heart transplantation, when the training requirements for transplant surgeon have not been met during one's cardiothoracic surgery residency, they can be met during a subsequent 12-month heart transplant fellowship if all the following conditions are met:

(i) – (iii) [No Changes]

- (iv) The fellow has a letter, sent directly to UNOS from the director of that training program verifying that the fellow has met the above requirements, and that the fellow is qualified to direct a heart transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) – (vi) [No Changes]

- (cc) For heart transplantation, if the transplant surgeon requirements have not been met, as outlined above, in a cardiothoracic residency or heart transplant fellowship, the requirement can be met by experience if the following conditions are met.

(i) – (iii) [No Changes]

- (iv) That the surgeon has a detailed letter sent directly to UNOS from the director of the program at which this experience is acquired, which verifies that the surgeon has met the above requirements, and is qualified to direct a heart transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

- (dd) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary heart transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary heart transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing heart transplantation is equivalent to that described in the above requirements. Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in heart transplant patient care within the last two years) of all aspects of heart transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary heart transplant surgeon is temporary only and shall cease to exist for applications for primary heart transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim

basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

- (b) **Transplant Physician** - Each heart transplant program must have on site a qualified transplant physician. A transplant physician for heart transplantation shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital. If an individual is certified by the American Board and its foreign equivalent, the individual must maintain currency in the American Board.

The heart transplant physician shall maintain current board certification or have achieved eligibility in adult or pediatric cardiology by the American Board of Internal Medicine or American Board of Pediatrics or their foreign equivalent.

The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

To qualify as a heart transplant physician, the training/experience requirement will be met if the following conditions of either (aa), (bb), (cc), (ee), (ff), or (gg) are met:

- (aa) The training requirements for the heart transplant physician can be met with the applicant's cardiology fellowship if the following conditions are met:

(i) – (vi) [No Changes]

- (iv) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified heart transplant physician verifying the fellow has met the above requirements and that he or she has qualified to become a medical director of a heart transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vii) [No Changes]

- (bb) When the training requirements for the heart transplant physician have not been met during a cardiology fellowship, they can be met by completing a separate 12-month transplant cardiology fellowship if all of the following conditions are met, and the individual is a board certified or eligible cardiologist.

(i) – (iii) [No Changes]

(iv) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified heart transplant physician verifying that the fellow has met the above requirements and that he or she has qualified to become a medical director of a cardiac transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) –(vi) [No Changes]

(cc) If the cardiologist has not met the above requirements in a cardiology fellowship or specific cardiac transplant fellowship, the requirements can be met by acquired clinical experience if the following conditions are met, and the individual is a board certified cardiologist.

(i) - (iv) [No Changes]

(v) There should be a supporting letter from either the cardiac transplant physician or the cardiac transplant surgeon at the cardiologist's institution who has been directly involved with the individual and can certify his or her competence.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) [No Changes]

(dd) [No Changes]

(ee) [No Changes]

- (ff) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary heart transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary heart transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of heart transplant patients is equivalent to that described in the above requirements. Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in patient care within the last two years) of all aspects of heart transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary physician or primary physician, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary heart transplant physician is temporary only and shall cease to exist for applications for primary heart transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(gg) [No Changes]

(8) Lung Transplantation

- (a) Transplant Surgeon - Each lung transplant center must have on site a qualified lung transplant surgeon. A lung transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

Such a surgeon shall have current certification by the American Board of Thoracic Surgery or its foreign equivalent. If board certification in thoracic surgery is pending (as in the case of where the surgeon has just completed training) conditional approval may be granted for a 24-month period, with the possibility of its being renewed for an additional 24-month period to allow time for completion of certification.

The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

If an individual is certified by the American Board of Thoracic Surgery or its foreign equivalent, then the individual must maintain their certification in the American Board or its foreign equivalent.

To qualify as a lung transplant surgeon, the training/experience requirements will be met if the following conditions of either (aa), (bb), (cc), or (dd) are met:

(aa) The training requirements for lung transplant surgeon can be met during the applicant's cardiothoracic surgery residency if the following conditions are met:

(i) – (iii) [No Changes]

(iv) That the resident has a letter sent directly to UNOS from the director of that training program verifying that the resident has met the above requirements and that he/she is qualified to direct a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

(bb) For lung transplantation, when the training requirements for transplant surgeon have not been met during the applicant's cardiothoracic surgery residency, the requirements may be fulfilled during a subsequent 12-month transplant fellowship if all the following conditions are met:

(i) – (iii)

(iv) That the fellow has a letter sent directly to UNOS from the director of that training program verifying that the fellow is qualified to direct a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

(cc) For lung transplantation, if the transplant surgeon requirements have not been met as specified above, in a thoracic surgery residency or lung transplant fellowship, the requirements may be met by acquired clinical experience if the following conditions are met:

(i) – (iii) [No Changes]

(iv) That the surgeon has a detailed letter sent directly to UNOS from the director of the program at which this experience is acquired which verifies that the surgeon has met the above requirements, and is qualified to direct a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

(dd) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary lung transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary lung transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing lung transplantation is equivalent to that described in the above requirements.

Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in patient care within the last two years) of all aspects of lung transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary lung transplant surgeon is temporary only and shall cease to exist for applications for primary lung transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

- (b) Transplant Physician - Each lung transplant center must have on site a qualified lung transplant physician. A lung transplant physician shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The lung transplant physician shall maintain current board certification or have achieved eligibility in adult or pediatric pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics or the foreign equivalent. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

To qualify as a lung transplant physician, the training/experience requirements will be fulfilled if the following conditions of either (aa), (bb), (cc), (dd), (ee), or (ff) are met:

- (aa) The training requirements for the primary lung transplant physician can be met during the applicant's pulmonary medicine fellowship if the following conditions are met:

(i) - (iii) [No Changes]

- (iv) That the fellow has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified lung transplant physician verifying the fellow has met the above requirements and that/she is qualified to be the medical director of a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vii) [No Changes]

- (bb) For lung transplantation, when the training requirements for lung transplant physician have not been fulfilled during a pulmonary medicine fellowship, the requirements can be met during a separate 12-month transplant pulmonology fellowship if all of the following conditions are met:

(i) - (iii) [No Changes]

- (iv) That the fellow has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified lung transplant physician verifying that the fellow has met the above requirements and that he/she is qualified to be a medical director of a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

- (cc) If the physician has not met the above requirements in a pulmonary fellowship or specific transplant pulmonology fellowship, the requirements can be met by acquired clinical experience if the following conditions are met and the individual is a board certified pulmonologist:

(i) - (iv) [No Changes]

(v) There should be a supporting letter from either the lung transplant physician or the lung transplant surgeon at the pulmonologist's institution who has been directly involved with the individual and certify his/her competence.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) [No Changes]

(dd) [No Changes]

(ee) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary lung transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary lung transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of lung transplant patients is equivalent to that described in the above requirements.

Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in lung transplant patient care within the last two years) of all aspects of lung transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary lung transplant physician is temporary only and shall cease to exist for applications for primary

lung transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(ff) [No Changes]

(9) Heart/lung Transplantation [No Changes]

(10)–(22) [No Changes]

D. [No Changes]

E. [No Changes]

Implementation Package

Proposal 4: Proposed Modifications to Bylaws, Appendix B, Section II, "Transplant Hospitals," "Investigation of Personnel"; Appendix B, Attachment 1, Section IV "Investigation of Personnel," Section VII "Transplant Surgeon and Physician"; and Appendix B, Attachment I, Section XII (C) (Membership and Professional Standards Committee).

Proposal Summary

The proposed modifications to the Bylaws would enhance oversight of individual physicians and surgeons by requiring:

- Transplant hospitals to conduct investigations, upon request, according to their peer review protocols and report to the OPTN,
- Applicants for primary physician or surgeon to submit assessments of prior non-compliant behavior with which they or other individuals proposed as part of the transplant team have been involved, as well as plans to ensure that the improper conduct is not continued, and
- Applicants for primary physician or surgeon to submit letters of recommendation attesting to their overall qualifications to act as primary physician or surgeon, as applicable, and addressing matters such as the individual's personal integrity, honesty, and familiarity with and experience in adhering to OPTN requirements and compliance protocols.

The aim is to prevent an individual physician or surgeon who has been involved in non-compliant activity at one institution from continuing that or similar activity at the same or another institution.

For review by: The OPTN/UNOS Board of Directors

Submitted by: The OPTN/UNOS Membership and Professional Standards Committee

Date: February 1, 2007



United Network for Organ Sharing
700 N. 4th Street
Richmond, Virginia 23219

Executive Summary

I. Background/History

Submitted to POC: Not Applicable

Initial POC review: No

Proposed submission to Board of Directors:

Proposal distributed for Public Comment? Yes

Date of distribution: 08/28/2006

End date for Public Comment: 09/27/2006

5-Point Checklist for Analytic Modeling	
Document	Assessed by Committee?
Statement of the Objectives of the Proposed Policy	The proposed modifications to the Bylaws would enhance oversight of individual physicians and surgeons.
Building the Models	Not applicable. No analytic modeling associated with this proposal
Testing the Models	Not applicable
Testing the Consequences of the Formulated Proposed Policy Prior to Implementation (Simulation Modeling)	Not applicable
Evaluation of the Effectiveness of the Policy	The MPSC and UNOS Board of Directors will assess at agreed upon intervals whether the modifications to the Bylaws provide adequate oversight of individual surgeons and physicians.

Accompanying Documentation	
Document	Comments
Policy Development Checklist	Not applicable
Functional and Technical Specification Documents	Not applications
Resource Analysis	The proposed modifications to Appendix B of the Bylaws will impact transplant center members and staff support. New program applicants need to supply a Plan for Continuing Policy Compliance (PCPC) with its application. PCPC submission will also be required periodically as requested by MPSC. Resources impacted by the modifications will depend in part on the number of members that are finally determined to be on probation or "member not in good standing."
Communications and Education Plan	Detailed plan under development. Members will be notified through a policy notice.
Monitoring and Evaluation Plan, Policy Effectiveness Metrics	Membership needs to develop PCPC document which can be used by members to comply with reporting

	requirements. Changes to program and personnel change application forms also required. Department of Evaluation and Quality (DEQ) staff will facilitate MPSC requests of transplant programs when the request is a result of a potential policy violation (i.e. policy compliance subcommittee issue).
Other Supporting Items (List):	Briefing paper outlining the course of progress for this proposal in response to the public comment responses.

II. Impact on Program Goals

* This proposed Bylaw change further defines existing Bylaws.

Program Goal	Impact
Increase number of deceased donor transplants	Not Applicable
Increase number of DCD donors	Not Applicable
Increase number of non-DCD donors	Not Applicable
Increase life years gained	Not Applicable
Increase organs transplanted/donor - non-DCD	Not Applicable
Increase organs transplanted/donor - DCD	Not Applicable

III. Relationship to the Strategic Plan

* This proposed Bylaw change further defines existing Bylaws.

Strategic Plan	Comments
Increase number of deceased donor organs transplanted	Not Applicable
Support live donor transplantation	Not Applicable
Decrease regional variation in opportunity for transplants	Not Applicable
Increase recipient benefit of transplantation	Not Applicable
Improve the OPTN and SRTR data system	Not Applicable

IV. Additional Data Collection

Does proposal require additional data collection? Yes

Reason for Additional Data Collection	Details
Organ Allocation	No
Policy Compliance Monitoring	No
Institutional Performance Evaluation	Yes. Additional information will be collected in the transplant program applications and surveys. This information will be entered in summary format into the application tracking system in Membership Database.
Ongoing Policy Development	No
OPTN Contractual Obligations	No
Patient Care	No

V. Current UNOS Resource Utilization Summary

Board of Directors Approved Policy Modifications	
Title	Estimated Resource Use (FTEs)
Membership Staff	Application Reviews - ensuring completeness of applications prior to review by the MPSC is an ongoing process. The additional documents that will be required may increase the follow up required if they are not appropriately submitted with the initial application. Staff will provide education and instruction to members and physicians regarding Plan for Continuing Policy Compliance and their requirements regarding disclosure. Membership (520 hours/2080 hours) = .25 FTE
Case Reviews	Unknown, volume dependent
Department of Evaluation and Quality Staff	DEQ staff will facilitate MPSC requests of transplant programs when the request is a result of a potential policy violation (i.e. policy compliance subcommittee issue). At this time, the volume of work is unknown. The need for additional staff will be reassessed after implementation.
Other Resource Uses (e.g., UNetSM enhancements, transfer center requests)	
Title	Estimated Resource Use (FTEs)
Enhancements to Membership Database	Appropriate tracking systems will be incorporated into the Membership Database. Some of these changes may be dependent on the System Redesign.
Modification to OPTN Applications	Application changes will need to be drafted by staff in conjunction with the Committee Chair, and submitted to the OMB for approval.