

**OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE REPORT**  
**February 20-21, 2008**  
**SUMMARY**

**I. Action Items for Board Consideration:**

- The Board of Directors is asked to approve two new transplant centers. (Item 1, Page 4).
- The Board of Directors is asked to approve for designated program status one new program in an existing member center. (Item 1, Page 4).
- The Board of Directors is asked to approve continued membership for two medical/scientific organizations and one public organization. (Item 1, Page 4).
- The Board of Directors is asked to grant full approval to one heart transplant program and one liver program that performs living donor transplants. The Board is also asked to grant one-year extensions of conditional status to three programs that perform living donor liver transplants as permitted in the Bylaws. (Item 1, Page 4).
- The Board of Directors is asked to approve the following changes of status for transplant programs: reinstatement of active status for programs that had previously voluntarily inactivated; extensions of conditional status; and full approval for conditionally approved programs. (Item 1, Page 4)
- The Board of Directors is asked to approve modifications to Bylaws Appendix B, Section II, Paragraphs B and C that delineates when “informal discussions” may be held with an Institutional Member. (Item 12, Pages 12 -19).

**II. Other Significant Items:**

- Annual Committee Goals: During its November meeting, the Committee was presented with the Goals that had been approved for the year and the progress that had been made on those are were already underway. (Item 2, Page 5).
- Due Process Proceedings: The Committee conducted one interview with a member organization. (Item 3, Page 5).
- Living Donor Requirements: The Committee provided recommendations on implementing the application process for the transplant programs that perform living donor kidney and liver transplantation. (Item 4, Page 5-6).
- Comment on Proposed Medical Evaluation Resource Document: The Committee considered the proposal that was distributed for public comment. Additional comments will be accepted from the Committee members until December 12, and forwarded to the Living Donor Committee for their consideration. (Item 5, Pages 6-8).

- Living Donor Conditional Approval Bylaws: The Committee will solicit input from the Liver and Intestinal Transplantation Committee regarding the treatment of living donor liver programs that fail to meet the conditional pathway requirements at the end of a second term. (Item 6, Pages 8-9).
- Offer/Organ Acceptance Rate Modeling: The Committee was updated on the Process Improvement Working 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. The current model provides meaningful information, which is relevant, but the Working Group recommended it NOT be used as a standalone measurement of program behavior. A simpler metric is being sought by the Committee, so this charge is being given to the new MPSC Working Group being organized to look at the current use of metrics to evaluate program performance. (Item 8, Pages 9-10).
- Update on enforcement of mandatory Donation after Cardiac Death (DCD) protocols: The Committee was updated on the submission of certification statements from all member OPOs and transplant hospitals, attesting that they have and employ a mandatory DCD organ recovery protocol. Two transplant hospitals stated that they cannot comply with the DCD protocol bylaw and they have been referred to the Advisory Resource Group for assistance. The Committee is recommending to the Board of Directors that any transplant hospital still out of compliance with the mandatory DCD organ recovery protocol requirement after working with the advisory group should be placed into Due Process. The hospital will initially be sent a Letter of Reprimand and until the member is in compliance Due Process will continue until an adverse action up to and including Member Not in Good Standing is taken by the Board. (Item 9, Pages 10-11).
- Program Related Actions and Personnel Changes: The Committee reviewed 62 key personnel change applications during its November meeting. (Item 10, Page 11).
- Evaluation of Approved Programs Relocation to New Physical Sites: The Committee discussed circumstances surrounding the relocation of three transplant centers. They agreed that the CMS certification number could continue to be used as a tool for deciding whether a center may need to apply for a new membership or if the relocation is administrative in nature and that an update to the center description may be required. (Item 11, Pages 11-12).
- Proposal to Modify the OPTN/UNOS Bylaws to Restore Full Membership Privileges Following an Adverse Action (Bylaws Appendix A, Section 3.01A Paragraphs (1) and (3) and Section 5.05A, Addition of Section 5.07A. A draft proposal was considered by the MPSC during its August 1-2, 2007, meeting. The purpose of the proposal is two-fold - to better define how a Member may be considered for restoration of full membership privileges, and to clarify the way to move from "Member Not in Good Standing" to a lesser action, such as probation. The Committee sought input from the Executive Committee on the draft proposal. During the November meeting, the Committee considered the recommendations modified the document accordingly. The proposal will be issued for public comment in February. (Item 13, Pages 19-21).
- Pancreas Outcome Analysis Model: The Committee discussed the issue of pancreas (including kidney/pancreas and pancreas after kidney) transplant program outcome monitoring. At the time of the meeting, the Committee did not yet have requested input from the Kidney and Pancreas Transplantation Committees. (Item 15, Pages 21-22).

- Proposed Modifications to the OPTN/UNOS Bylaws Article I (Members) Section 1.9(c) (Voting Privileges and Responsibilities- Histocompatibility Laboratory Members) and Section 1.9(d) (Voting Privileges and Responsibilities-Medical Scientific Members): The MPSC reviewed and discussed proposed Bylaw modifications that would permit each Histocompatibility Laboratory and Medical/Scientific Member to receive one vote in OPTN/UNOS and remove the need for separate national elections for both the Histocompatibility Member and Medical/Scientific Member electors. This proposed revision will be distributed for public comment. (Item 16, Page 22-23).
- Review of Active Programs with Inactive Wait Lists: The Committee discussed the Data Subcommittee's study of potentially reviewing programs that have an active membership status but have inactive wait lists. The Committee requested that the Bylaws regarding program inactivation be reviewed and that clarifying language be suggested for further Committee review. (Item 17, Pages 23-24).
- Goals for Bylaws Rewrite: Staff updated the Committee on one of the new goals established for the committee by the President: the re-write of the existing Bylaws. The purpose of the revision is to improve clarity regarding member rights and responsibilities, and OPTN/UNOS responsibilities. Clarity will be achieved by the use of plain language and logical organization of the content. (Item 18, Page 24).
- Review of Events under Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data): Staff updated the Committee on the status of events surrounding three live donor deaths that were reviewed under Policy 7.3.3. In all three cases, the Committee determined that no further action was required because there was not any evidence of policy violations and no patient safety issues were indicated. (Item 19, Page 24).
- MPSC Summary Explanation: A summary document that clarifies the MPSC's charge was presented to the Committee for its review and input. This document briefly explains the role and function of the Committee in plain language that is easily understood by the medical professionals and public who are affected by its deliberations and decisions. (Item 20, Pages 24-25).
- Patient Acceptance Letters: The Committee had asked the Patient Affairs Committee to consider the development of a letter the OPTN would provide to transplant patients through the listing center, along with the acceptance letter. This letter would reference the OPTN/UNOS web sites to find center specific data, state the patient's ability to seek care at other centers and include the patient hotline number and information about patient rights. The Committee reviewed and supported a letter drafted by the Patient Affairs Committee, and asked that it move forward with implementation. (Item 21, Page 25).
- Committee Goals: The Committee discussed the goals related to surgeon/physician surveys and program coverage plans and their implementation status. They also discussed the goals related to Bylaws, performance metrics, and network measures and agreed to form two work groups to further these discussions. (Item 22, Pages 26-27).
- UNOS Actions: During the November 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 23, Page 27).

**An Addendum to this report, containing action items, will be distributed following the January 31 – February 1, 2008, meeting of the MPSC.**

**REPORT OF THE  
OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE  
TO THE  
BOARD OF DIRECTORS**

**Orlando, FL**

**February 20-21, 2008**

**Robert S. D. Higgins, M.D., Chair**

**Carl L. Berg, M.D., Vice Chair**

- I. Regular Committee Meetings. The Membership and Professional Standards Committee's (MPSC) met on November 13-14, 2007, in Chicago, Illinois. Its deliberations and recommendations are provided below.
1. Membership Application Issues: The Committee recommends that the Board of Directors approve two new transplant centers and 1 new program in an existing member center. In addition to considering applications for institutional membership, the Committee reviewed applications for continued medical/scientific and public organization membership (two-year terms).

Reports from Conditionally Approved Programs: During its November 2007 meeting, the Committee approved changes in status from conditional to full approval for a liver program that performs living donor transplants and a heart program. The liver program was initially conditionally approved pending performance of seven live donor hepatectomies by the second primary surgeon. The heart program was initially conditionally approved pending acquisition of additional clinical experience on an active heart transplant service by the primary physician; the program resolved the issue by designating a new fully qualified individual as primary heart transplant physician. The Key Personnel Change application was approved by the Committee during the November meeting.

The Committee also reviewed three living donor liver programs that had requested an additional year of conditional status as allowed by the Bylaws, and agreed that the three programs had demonstrated adequate progress to qualify for extensions.

Additionally, the Committee reviewed three transplant programs that had previously voluntarily inactivated and approved reinstatement of the programs active status.

The Committee reviewed bimonthly progress reports for three transplant programs (one kidney, one pancreas, and one heart program) that were conditionally approved for 12 months to provide time for the primary physician to meet the full primary physician criteria or to allow the program to recruit a physician who fully meets primary physician criteria. The Committee also reviewed two progress reports from a kidney program whose primary surgeon was approved under the pediatric pathway with bi-monthly reporting stipulations. The Committee will continue to review these programs to ensure that they are making progress towards meeting the full requirements.

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

Performance Measures

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

Bylaws

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

Network Measures

- Goal 5: Initiate the application process for live donor kidney transplantation, and obtain additional information from programs that perform living donor liver transplants.
- Goal 6: Initiate and complete the audit of transplant surgeons and physicians & update the database accordingly to indicate which individuals meet the new criteria for the program to designate them as “additional” or “other” surgeon/physician.
- Goal 7: Collect and process Program Coverage Plans (primary physician, additional physician, etc.) from all existing transplant programs.
- Goal 8: Review transplant centers and OPOs that are not in compliance with the new Donation after Cardiac Death (DCD) Bylaws requiring that they have protocols to facilitate the recovery of organs from DCD donors.

3. Due Process Proceedings and Informal Discussions: The Committee conducted one interview with a member organization OPO.
4. Living Donor Requirements: The Committee discussed the implementation of the newly passed bylaw modifications that establish additional minimum criteria for granting designated program status to programs that perform living donor kidney and liver transplants. These revised bylaws will further ensure that kidney and liver transplant programs have essential elements in place for the evaluation, consent, and follow-up of living donors.

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

During the November meeting, the staff presented a proposal to the Committee for the review process. The Committee agreed to the plan outlined below and will forward this plan to the Executive Committee for their input:

- Transplant Centers that are currently approved to perform live donor liver transplant (LDL) will need to submit additional information as specified in the bylaws passed by the Board in September. They will be sent a request for this information in January, and given a March due date for submitting the information.
- Programs that provide Living Donor Kidney (LDK) transplants have not previously completed a living donor specific application, so more information will be required from these programs, and staff will need more time to process and prepare these applications.

Once approved by the OMB the LDK applications will be sent to existing kidney transplant programs on a staggered basis by UNOS region. Each kidney transplant program in a specific region will receive the LDK application and be given the same 90-day deadline for completion and submission. Staff hopes to send out all LDK applications by the end of June 2008, with program completion and submission back to UNOS by the end of September 2008. This timeline could be affected by the OMB approval date for the forms.

- Once complete, the LDL and LDK program applications will be assigned to two MPSC reviewers for a detailed review. These reviewers will determine if the applicant meets the criteria for living donor transplantation. If both reviewers agree, they can recommend the application be placed on the MPSC's consent agenda and considered for approval by the full Committee. If the reviewers are not in agreement on the applicant's ability to satisfy the requirements, another MPSC member will be asked to review the application and provide their input. Staff will work with the members to resolve issues raised during the review process. Applications that do not receive a unanimous recommendation for approval will be placed on the Discussion Agenda for consideration during the next scheduled MPSC meeting. The MPSC will present all of its recommendations for application approval to the Board of Directors for its consideration during its November 2008 meeting. This process has been put in place so that regions receiving the applications earlier will not appear to have any advantage over those that are processed later. Applications for new programs will be handled on an "upon receipt" basis and will be eligible for "interim" approval" per the standard application review protocol.

The Committee considered how transplant centers that failed to meet the deadlines for returning their LDK application or an "opt out" form would be addressed. They agreed that failure to comply would be considered under the current Bylaws.

5. Resource Document for the Medical Evaluation of Living Kidney Donors (Sponsored by the Living Donor Committee). The MPSC considered the "Resource Document for the Medical Evaluation of Living Kidney Donors," which was distributed for public comment by the Living Donor Committee. The Committee reviewed the proposed resource document and offered comments. Since it did not receive a copy of the proposal until the meeting, it felt like it needed more time to review the document in detail. A summary of the comments received during the meeting was distributed to the Committee electronically after the meeting, and additional comments were accepted until December 12. A list of the Committee member's comments is provided below:

- An imaging study in addition to an angio is necessary for any live donor. We are not only looking for anatomy, we are looking for pathology. A Committee member suggested that in the last year at their program they had found donors with the following abnormalities that excluded a donor: RCC, Carcinoid of the small bowel, choledoco cyst, and lymphoma. The Committee member observed that if a solitary angio had been done, they would have missed these findings and harmed a donor and a recipient.
- Calculating a donor GFR at the age of 80 is not proven and would not only offer a false sense of safety for some donors, but will exclude many young donors. The creatinine clearance should be >95 corrected for BSA.
- Include smoking cessation in life style choices.

Additional comments received from Committees include the following:

- 2a. The title “Donor typing to determine the risk for acute transplant failure.” should be “...acute transplant rejection.”
- 2b. The family history should not only be about kidney disease, but also diabetes, hypertension, malignancy.
- 2b. “Use of NSAIDs” should be use of “potential nephrotoxic agents, especially NSAIDs”.
- 2e. In the GFR bullet, *recommended minimum GFR (I suggest 80 ml/min) understanding that other centers are more lenient and will base their decision on age of donor. In any case, the sentence “GFR should be within 2 standard deviations .... at age 80” should be removed.*
- 2f. In the bullet regarding cholesterol level, it should all be replaced by simply: “Fasting Lipid Profile.”
- 2f. In the metabolic focused evaluation, last bullet pertaining to the risk of diabetes, a mention of glucose intolerance should be made as follows: “If the risk of diabetes ....but the prospective donor does not meet the definition of diabetes, *or if the patient has glucose intolerance*, they should be...kidney disease.”
- 3b. *My cut-off for BMI in a donor is >30, which is the definition of obese, >35 is severely obese (I understand that other centers feel differently). At least, if BMI>35 is kept, it should be referred to as severely obese.*
- Include language that informs the potential donor and recipient that, through routine tissue typing, it may be discovered the donor does not have the previously assumed relationship to the recipient, i.e. the person that you thought was your parent or child is, in fact, not. The individuals involved may or may not want to know this.

Included below are three comments that arose out of the Region 1 discussion of the live donor document that were submitted by the regional representative on the Committee:

- Concern was raised that this document might exclude donors who might be considered deficient by aspects raised in Section 1, part “1.” Namely, financial debt, or lack of disability and health insurance. That these aspects need to be openly discussed, but are not required had to be emphasized. This is not clear to the transplant community (at least in our Region). The explanation in the preamble that “this resource document is not policy” does not allay these concerns. The document should have a clearer explanation that these are recommendations of best policy, but the final decision on all aspects of the donor evaluation lies with the transplant center.
- The current medical criteria do not spell out concerns for donors meeting any of the CDC defined high-risk behaviors. Since they are well defined and recommended for deceased donor consideration, perhaps they should be included as a group whereby transplant centers will evaluate donors for the presence of risk-factors and provide counseling to the donor and recipient should any be present.

- Perhaps not for this document, but a concern for the Living Donor Committee in the future: what expenses of the donor can the transplant center or the recipient reimburse (travel, lodging, food, gas money, lost wages, etc.). The line between the recipient paying someone's flight to the transplant center and valuable consideration is unclear.
6. Living Donor Liver Conditional Approval Requirements: The MPSC met on November 13-14, 2007, and considered the status of 14 living donor liver transplant centers that presently have conditional approval. This conditional approval was granted to programs that do not have a second surgeon who fully meets the Bylaws.

The Committee noted that 5 of these programs will be concluding their second year in this status in the coming months, and that there are several that may not meet the requirements for full approval at the end of their term. In these cases, it is because the programs have performed few if any living donor liver transplants since conditional approval was granted.

The Bylaws do not provide a clear path forward for programs that reach the end of the two-year conditional approval period (initial year plus a one-year extension) and still do not meet the requirements for full approval. The MPSC considered adding language to the conditional approval pathway clarifying the options for these programs. When the primary surgeon and physician criteria in the Bylaws were last revised in 2006, a 12-month conditional approval pathway available for primary physician key personnel changes for all organs (excluding living donor liver and living donor kidney) was amended to state that programs failing to meet the requirements for full approval at the end of the conditional period must inactivate. When the language for the living donor conditional pathway was proposed to the OPTN/UNOS Board of Directors, the Board was not inclined to support further extensions of conditional approval past the second year.

The MPSC agreed to ask the Liver and Intestinal Organ Transplantation Committee to provide input on the following questions:

- Does the Committee recommend the addition of language to the conditional approval pathway for living donor liver transplant programs indicating that programs unable to meet the criteria for full approval at the end of the 2-year conditional approval period must voluntarily inactivate the living donor liver transplant aspect of their program? If yes, please explain concerns. If not, please consider what the appropriate action and subsequent bylaw modification should be for programs that do not meet criteria for full approval within two years of conditional approval.
- The Bylaws are written such that the conditional approval period applies to the program status rather than the individual primary surgeon. If the program experiences a change in key personnel during the conditional period, and the newly proposed surgeon meets the conditional pathway, would the clock restart at 2 years or would only the remaining balance of time be available? The same question could arise if there is a change in primary physician during this same time period and that proposed individual only qualifies under the conditional pathway as described below in the Bylaws (see page 6).
- Should any limitations be considered for how many times (if any) programs should be allowed to sequentially hold conditional approval based on a series of personnel changes for surgeons who only meet the conditional requirements?

The Liver and Intestinal Organ Transplantation Committee will meet on November 28, 2007, and will consider these questions.

7. Correction to the Bylaws for Living Donor Liver Surgeons: The Committee was updated on the efforts to correct a typographical error in the Bylaws, Appendix B, Attachment I, Section XIII (D)(4)(a)(ii) (Liver Transplant Programs that Perform Living Donor Liver Transplants). The omission of a comma in the live donor liver membership criteria was first observed during the previous Committee meeting. The omission creates the possibility of interpretation of the Bylaw in a manner different from its intended interpretation.

It was the intent of the Committees developing this Bylaw that the 20 resections must be performed within the past 5 years, and of those 20, at least 7 must be live donor procedures. The MPSC has followed this intent in its reviews of live donor liver programs since the beginning of the application process in June 2005 by requiring surgeons to demonstrate that they have performed the required numbers of major hepatic resections and live donor procedures all within the past 5 years. The omission of the comma when the Bylaw was published, however, opens the Bylaw up to interpretation that only the 7 live donor procedures must be done within the past 5 years and other major hepatic resections may be done over a longer and/or more distant period of time. This interpretation arose during an interview at the August 2007 MPSC meeting, where the Member challenged the MPSC's interpretation of the Bylaw based on the missing comma.

The MPSC asked the Executive Committee to approve the insertion of the missing comma to the Bylaw as a housekeeping item. The intent is to clarify the Bylaw and remove the possibility of misinterpretation by members by correcting a typographical error.

The Bylaw currently reads:

*That the center has on site no fewer than two surgeons who qualify as liver transplant surgeons under UNOS Bylaws Appendix B, Attachment I, Section XII(C)(2)(a) and who have demonstrated experience as the primary surgeon or first assistant in 20 major hepatic resectional surgeries (to include living donor operations, splits, reductions, resections, etc.), 7 of which must have been live donor procedures within the prior 5-year period.*

However, there is supposed to be a comma after the word "procedures":

*That the center has on site no fewer than two surgeons who qualify as liver transplant surgeons under UNOS Bylaws Appendix B, Attachment I, Section XII(C)(2)(a) and who have demonstrated experience as the primary surgeon or first assistant in 20 major hepatic resectional surgeries (to include living donor operations, splits, reductions, resections, etc.), 7 of which must have been live donor procedures, within the prior 5-year period.*

This issue will be presented to the Executive Committee for action during its December 18, 2007, meeting. [The Executive Committee approved this change during its December 18, 2008, meeting].

8. Goal 2: Offer/Organ Acceptance Rate Modeling: The Committee was informed that the Process Improvement Working Group decided during its September 12<sup>th</sup> conference call that the current offer/organ acceptance rate modeling was not suitable as a standalone metric for assessing program performance in regards to transplantable organ turn down and offer acceptance practices. The number of variables affecting the behavior are too numerous to control when comparing across DSAs and regions. While the analysis does identify demonstrated extraordinary behaviors

regarding how programs accept organs for transplant, this information appears to be meaningful in combination with other applicable performance data analysis i.e. functional activity and survival rates. With this being the case the Process Improvement Working Group needed guidance from the MPSC regarding what the path forward should be. If the Committee desired, acceptance rate modeling for thoracic organ transplant programs could be initiated, but the Work Group agreed that this too would result in an analysis, which also may not meet the need of providing a definitive stand alone metric for assessing a program's organ acceptance behavior.

The Committee understood the current model's limitations and asked if a broader and simpler metric would be better i.e. organs vs. offer ratios, transplant rate, etc. The Committee recommended ending the current model's development at this time; not moving forward with a thoracic organ model; and finally dissolving the original Process Improvement Work Group. However, the need for evaluating a program's organ acceptance behavior still exists, so the Committee referred this matter to the new MPSC Performance Metrics Working Group that was appointed to review the current use of all metrics in evaluating program performance.

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

All 58 OPOs had certified compliance with the DCD protocol requirement. Of the 261 member transplant hospitals contacted for affirmation of their compliance, only 2 had notified UNOS that they were not in compliance nor were they going to comply with the mandatory DCD organ recovery protocol. These two transplant hospitals were referred to the DCD Advisory Group that is working with non-compliant OPTN members to try and address any issues that they are having. One transplant hospital's medical staff declined to support doing DCD organ recoveries at the hospital and is backing a protocol calling for these cases to be transferred to another facility. The other transplant hospital had a bad experience when it followed its DCD protocol earlier in the year, so a decision was made by the physicians not to do any more DCD cases. The issues appear to be philosophical and ethical. The DCD Advisory Group will report on the success of their intervention at a future meeting.

The DCD Advisory Group requested that the Committee assist them by making recommendations regarding what action(s) will be taken if a transplant hospital absolutely refuses to comply with the mandatory DCD organ recovery protocol. The Committee discussed this issue and agreed that non-compliance should ultimately lead to an adverse action recommendation being made to the Board of Directors. Understanding that the adverse action process should only start after the member is given the time and resources to comply, the Committee agreed to the following process:

- \*\* RESOLVED, that a Letter of Reprimand with the option for an interview with the MPSC be sent to any transplant center that does not comply with the Bylaw requiring that it develop a protocol to facilitate the recovery of organs from DCD donors.

The Committee voted 23 For, 1 Against, 0 Abstentions.

The Committee also discussed what actions would be taken with members who certify they are compliant, but are not actively facilitating DCD donations. A concern was raised regarding who

was certifying compliance for the member institution. A Chief Executive Officer or their designee has signed every Certification of Compliance received. The Committee also discussed a follow up question regarding who was monitoring compliance. Compliance monitoring is complaint-based at this time. If a member is not complying with their certified DCD organ recovery protocol, a complaint would need to be filed and subsequently investigated by UNOS staff. There currently are no complaints or plans to purposely review certified DCD organ recovery protocols. This process may change with more experience.

10. Program Related Actions and Personnel Changes: During its November meeting, the Committee reviewed and accepted programs changing status by voluntarily inactivating or withdrawing from designated program status. Additionally, the Committee reviewed 62 Key Personnel Changes and approved 57. Five applications for change in primary histocompatibility laboratory directors remain in process.

The Committee also reviewed a report of two transplant programs that had not submitted an application for a change in key personnel by the given deadline. Each of these programs had experienced a departure of a primary surgeon or physician. The Committee was notified that one of the individuals decided to continue their involvement with the transplant program, and the personnel change was no longer based on a departure of personnel. The second program, although past due, submitted their application by the meeting date.

11. Evaluation of Approved Programs Relocating to New Physical Sites: The Committee considered several circumstances of transplant hospitals were/are involved in physical relocation efforts. The Bylaws do not specifically address the nuances of these situations. Historically, if a transplant center (hospital) is changing its physical location, but retains all current operational relationships i.e. surgical and nurse staffing, anesthesia, laboratory, etc., and operates in its new location under the same Medicare provider number as before, a letter of explanation from the transplant center would be requested for submission and consideration by the Committee. This letter would describe the new arrangements and include a move date and transition plan.

Staff reported that three transplant centers had recently notified the OPTN/UNOS of their intentions to relocate all of their transplant programs from one physical location to new geographically separate sites. The Bylaws only address those cases where one member program relocates to another member center, and this type of relocation to a new facility, is not addressed.

The staff asked the Committee to provide guidance by answering the following questions about two types of situations:

- An entire transplant center relocates to a totally new physical site, such as when the hospital constructs an entirely new building and the Medicare number transfers with it.

The Committee considered this scenario and agreed that a new application would not be necessary, but that the center would be asked to provide a description of the change, including a relocation timeline, a summary of the anticipated changes, how services will be aligned, and how the move will affect transplantation.

- An entire transplant center or program relocates to a entirely new physical site, and the Medicare number does not transfer with it.

The Committee agreed that a new application should be submitted in this caes. This would include programs relocating and changing to another hospital system affiliation.

The Committee's responses affirmed that the process that is already in place remains appropriate.

12. Proposed Modification to Bylaws Appendix B, Section II, Paragraphs B and C. This proposal was first considered by the MPSC during its August 1-2, 2007 meeting. The purpose of the proposal is to delineate when "informal discussions" may be held with an Institutional Member. The Bylaws provide that a Member is entitled to an interview as part of its due process rights when the MPSC is considering taking specified actions against the members. However, the Committee found that it is useful to engage in discussions with the Member in other circumstances. This proposal clarifies that the Data Subcommittee of the MPSC can use an informal discussion with the Member when conducting its review of survival rates and activity at a program. The intent is to continue fact-finding, and at the same time encourage an open dialogue with the Member about its program. The informal discussion established by the proposal is not an element of due process, nor is it a right of the Member. During its August meeting the Committee agreed to distribute the proposed bylaw change for public comment.

During the November meeting, the Committee reviewed the Public Comments that had been received to date and responded to each. When the Committee met the public comment period was still open but a majority of the comments had been received. After the meeting, additional votes were received but there were no comments that were new in nature. One of the comments received pointed out an error in the Survival Rates section of the Bylaws and the Committee agreed that it should be fixed. The Bylaw presently states that "incomplete follow-up data will be treated as a graft loss or patient deaths in the context of this analysis." Incomplete follow up data is not treated as a graft loss or patient deaths so this language is shown as removed in the final proposal (Exhibit M-2 Briefing Paper).

The Committee agreed to forward this amended proposal to the Board for their consideration.

**\*\* RESOLVED, that the following modifications to Appendix B, Section II, Paragraphs B and C, having been distributed for public comment and subsequent reconsideration by the Committee, are approved effective February 21, 2008.**

The vote was unanimous.

### **Proposed Modifications to Appendix B, Section II, Paragraphs B and C in the UNOS and OPTN Bylaws**

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

#### **OPTN Bylaws, Appendix B**

**B. Survival Rates.** In the distribution of survival rates of all OPTN Members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee ("MPSC") to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality. The MPSC may also require, at its discretion, that the Member participate in a discussion regarding a performance review in the MPSC's quality improvement effort. The

discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the OPTN Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is  $>3$  and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of  $<0.05$ .

Observed events represent deaths or graft losses as reported in UNOS database. Expected events represent deaths or graft losses as calculated utilizing organ specific transplant models. ~~Incomplete follow up data will be treated as a graft loss or patient deaths in the context of this analysis.~~

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality improvement. The Member's failure to do so shall constitute a violation of UNOS requirements.

**C. Inactive Membership Status.** An OPTN Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program (as defined below) may voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC's quality improvement effort. ~~The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.~~

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the OPTN Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

For purposes of these Bylaws, "functionally inactive" is defined as:

- (1) The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or
- (2) No transplant performed for a period of time defined as:
  - (i) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,
  - (ii) No transplant performed in six months in the case of pancreas and lung programs, and
  - (iii) No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals,

with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.

If the Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors notify the Secretary of HHS of the situation in the case of transplant programs approved by the Secretary of HHS for reimbursement under Medicare or transplant programs in Federal hospitals, or take appropriate action in accordance with Appendix A of these Bylaws in all other cases, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients (with a copy to the entity that operates the OPTN under contract with HHS (OPTN Contractor)) of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the patient to the list of another OPTN Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for OPTN membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.

To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.

It is expected that all Transplant Hospitals will duly inform their patients on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify the OPTN Contractor and their patients as described above.

## UNOS Bylaws, Appendix B “Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership”

### II. Transplant Hospitals.

A. No changes

**B. Survival Rates.** In the distribution of survival rates of all UNOS members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee (“MPSC”) to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality improvement. The MPSC may also require, at its discretion, that the Member participate in a discussion regarding a performance review in the MPSC’s quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is  $>3$  and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of  $<0.05$ .

Observed events represent deaths or graft losses as reported in UNOS database. Expected events represent deaths or graft losses as calculated utilizing organ specific transplant models. ~~Incomplete follow up data will be treated as a graft loss or patient deaths in the context of this analysis.~~

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality improvement. The Member’s failure to do so shall constitute a violation of UNOS requirements.

**C. Inactive Membership Status.** A Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program (as defined below) may voluntarily stop transplantation at that transplant program for a period of up to

twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC's quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

For purposes of these Bylaws, "functionally inactive" is defined as:

- (1) The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or
- (2) No transplant performed for a period of time defined as:
  - (i) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,
  - (ii) No transplant performed in six months in the case of pancreas and lung programs, and
  - (iii) No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals,

with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.

If the Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws in all other cases, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the patient to the list of another Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Member be designated as an active member.

To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.

It is expected that all Transplant Hospitals will duly inform their patients on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify UNOS and their patients as described above.

## **ATTACHMENT I TO APPENDIX B OF UNOS BYLAWS**

### **Designated Transplant Program Criteria**

#### **I. Facilities and Resources. No changes**

**II. Inactive Program Status.** Designated transplant programs qualified in accordance with these Attachment I criteria that fail to remain functionally active shall voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. The MPSC may also require, at its discretion, that the Member participate in a discussion regarding a performance review in the MPSC's quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

For purposes of these Bylaws, "functionally inactive" is defined as:

- (1) The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or
- (2) No transplant performed for a period of time defined as:
  - (i) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,

- (ii) No transplant performed in six months in the case of pancreas and lung programs, and
- (iii) No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals, with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.

If the program fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients (with a of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the patient to the list of another Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors take appropriate action.

To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.

It is expected that all designated transplant programs will duly inform their patients on the waiting list if there will be an extended period of time when the program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify UNOS and their patients as described above.

### **XIII. Transplant Programs.**

**A. No changes**

**B. No changes**

C. Sections (1) – (9) No changes

**(10) Survival Rates.** In the distribution of survival rates of all UNOS members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee (“MPSC”) to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality improvement. The MPSC may also require, at its discretion, that the Member participate in a discussion

regarding a performance review in the MPSC's quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is  $>3$  and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of  $<0.05$ .

Observed events represent deaths or graft losses as reported in UNOS database. Expected events represent deaths or graft losses as calculated utilizing organ specific transplant models. ~~Incomplete follow up data will be treated as a graft loss or patient deaths in the context of this analysis.~~

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality improvement. The Member's failure to do so shall constitute a violation of UNOS requirements.

13. Proposal to Change the OPTN and UNOS Bylaws to Restore Full Membership Privileges Following an Adverse Action (Bylaws Appendix A, Section 3.01A Paragraphs (1) and (3) and Section 5.05A, Addition of Section 5.07A. During its August 1-2 meeting, the Membership and Professional Standards Committee (MPSC) reviewed the draft proposal that would better define how a Member may be considered for restoration for full Membership privileges, and provide a way for a Member to move from an adverse action to a lesser action or status. The proposal provides that in order to be released from "Member Not in Good Standing" or "Probation" the Member must demonstrate that it is in (i) substantial compliance with OPTN requirements; (ii) its approved corrective action plan has been fully implemented; and (iii) the root cause of the violation that was the basis for the adverse of action of "Member Not in Good Standing" has been corrected or eliminated. The proposal does not provide a set time period for the adverse action to be in effect. Rather, it provides the flexibility for the MPSC and the Board to consider each Member's specific circumstances. At its August meeting, the Committee asked that the concept of "trial reinstatement" be added and that the proposal be circulated to the Committee Members on the Committee Management system for further review.

The Committee reviewed the draft on Committee Management and in general supported the updated language. Concerns were raised by several committee members that the section 5.07A

*“Changes in Membership Adverse Action Status”* may need further amendment. A summary of the MPSC comments are provided below:

- One Member asked to see a section (iv) added to 5.07A “Demonstrated reversal of cause” for why they were on probation/MNGS.
- One Member asked whether this change would provide a 3 month loophole for which that everyone will apply.
- One Member asked for clarification on which types of restricted status this subsection applies to.
- One Member suggested that three 3 months may be too soon for a member to demonstrate substantial and sustained change. A longer timeframe for reconsideration (e.g. 4-6 months) would be warranted.
- One Member offered that trial reinstatement is fine but it should only happen at least 6 months after MNGS or probation.
- One Member sought clarification of the statement about this “downgrade of status” not entitling member to due process. The member always has the right of due process. What we should say is that if they apply for reinstatement and a lesser status is recommended (i.e., MNGS to probation) that the member forfeits the right to request a hearing in this circumstance.

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

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

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

The MPSC discussed the updated draft document during its November 2007 meeting. The Committee proposed additional changes to the document. These changes included making the time a uniform 12 months for a Member to request each upgrade in status, and clarifying that the member may be required to undergo a peer conducted site visit and/or site survey before the MPSC recommends a change in status. The Committee also asked that the public comment document include a timeline diagram in the briefing paper as an exhibit, to help readers to understand the proposal.

The Committee approved the following resolution by a vote of 21 For, 0 Against, 0 Abstentions:

- \*\* RESOLVED, that the Committee supports the proposal with the suggested modifications and agrees that the proposal should be distributed for public comment.

The MPSC also discussed the patient notification aspects involved when a Member is placed on Probation or declared Member Not in Good Standing.

The Committee approved the following change by a vote of 21 For, 0 Against, 0 Abstentions.

- \*\* RESOLVED, that the Committee supports the proposed addition of the sentence “Patient notification is not required when a Member transitions from Member Not in Good Standing to Probation” to section 5.07A.

The modifications will be incorporated into the draft document and the proposal will be distributed for public comment in February.

14. Questions regarding Policies 6.3 Audit and 6.5 Violations of Policies: Audit of centers where non-resident alien transplant recipients constitute more than 5 percent of recipients of any particular organ type. The MPSC reviewed a proposed memo to the OPTN/UNOS Ad Hoc International Relations Committee. The memo inquired about Policy 6.3 and Policy 6.5 describing the review process for centers performing non-resident alien transplants.

In the spirit of continuous process improvement, the MPSC would like to collaborate with the Ad Hoc International Relations Committee to reevaluate the process for review of non-resident alien transplants in the United States. In order to maintain public trust in the OPTN, it is critical that non-resident alien transplants receive the most thorough and appropriate review possible.

The MPSC has two requests of the Ad Hoc International Relations Committee:

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

The Committee approved the following resolution:

- \*\* RESOLVED, that the Committee endorses moving forward with this request to reevaluate the process for review of non-resident alien transplants to the Ad Hoc International Relations Committee

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

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

During the October 11, 2006, meeting, the Committee was informed that the SRTR was prepared

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

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

**\*\* RESOLVED,** that the MPSC requests that the Pancreas Transplantation, Kidney Transplantation, and UNOS Executive Committees consider the MPSC's use of the current SRTR statistical analysis of one-year post transplant outcomes for programs that perform combined kidney/pancreas transplants until the Pancreas Transplantation Committee and SRTR finish development of the more inclusive pancreas alone, pancreas after kidney, and simultaneous kidney/pancreas outcome model.

Motion passed by a vote of 26 For, 0 Against, 0 Abstentions.

The Kidney Transplantation Committee reviewed the MPSC's request during its December 3, 2007, meeting and deferred the issue to the Pancreas Transplantation Committee.

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

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

16. Proposed Modifications to the OPTN/UNOS Bylaws Article I (Members) Section 1.9(c) (Voting Privileges and Responsibilities- Histocompatibility Laboratory Members) and Section 1.9(d) (Voting Privileges and Responsibilities-Medical Scientific Members): In November 2003, the OPTN/UNOS Board of Directors approved changes to the OPTN Charter and Bylaws and UNOS Bylaws that created a need for member histocompatibility professionals to nominate and elect both regional and national Electors. According to Article I (Members) Section 1.9(c) (Voting Privileges and Responsibilities- Histocompatibility Laboratory Members) of the OPTN/UNOS Bylaws, the 34 Histocompatibility Laboratories, as a class, if they were independent and served at

least one Transplant Hospital that was active in the field of organ transplantation within its service area, were to be represented by 33 separate Histocompatibility Laboratory Member Electors. Each Histocompatibility Laboratory Member Elector was to be entitled to one vote on OPTN or UNOS affairs and the electors would be elected by the Histocompatibility Laboratory Members. Presently, there are 58 independent Histocompatibility Laboratories. Under the bylaws prior to June 2004, each Histocompatibility Laboratory received a single vote in the affairs of the OPTN/UNOS.

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

Each of these separate elections creates unnecessary complexity in the OPTN, adds additional burden on OPTN contractor staff, and adds costs to OPTN operations. Therefore, the MPSC reviewed and discussed proposed Bylaw modifications that would permit each Histocompatibility Laboratory and Medical/Scientific Member to receive one vote in OPTN/UNOS and remove the need for separate national elections for both the Histocompatibility Member and Medical/Scientific Member electors.

The Committee approved the following resolution by a vote of 21 For, 0 Against, 0 Abstentions:

\*\* RESOLVED, that the Committee approves the proposed modifications to the Bylaws and agrees that the proposal should be distributed for public comment.

The draft of the proposal will be distributed for public comment in February.

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

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

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

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

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

Additionally, the MPSC noted concerns with existing Bylaw and Policy language regarding Member responsibilities for notifying candidates of wait list inactivation; specifically, whether the Members are required to notify candidates of a change to inactive status on the wait list and/or the entire wait list was inactivated. At the conclusion of the discussions, the MPSC recommended UNOS Staff review existing bylaw language and if appropriate, provide additional language to clarify Member responsibilities for review during the January 2008 meeting.

18. Goals for Bylaws Rewrite: Staff updated the Committee on one of the new goals established for the Committee by the President: the re-write of the existing Bylaws. The purpose of the revision is to improve clarity regarding member rights and responsibilities, and OPTN/UNOS responsibilities. Clarity will be achieved by the use of plain language and logical organization of the content.
19. Review of Events under Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data): Staff updated the Committee on the status of events surrounding three 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 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 two cases involving the death of living kidney donors, and one case involving native organ failure in a living liver donor. In all three cases, the Subcommittee determined that no further action was required because there was not any evidence of policy violations and no patient safety issues were exposed. These reviews were placed on the consent agenda for the November MPSC meeting and the full Committee unanimously supported the findings of the Subcommittee. The final summary reports were disseminated to the Living Donor Committee and to the respective centers where an event occurred.

20. MPSC Summary Explanation: A summary document that clarifies the MPSC's charge was presented to the Committee for its review and input. This document briefly explains the role and function of the Committee in plain language that is easily understood by the medical professionals and public who are affected by its deliberations and decisions. The MPSC's general areas of responsibility referenced in the document are:

- 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 makes recommendations for Board action.
- Monitors member compliance with OPTN requirements.
- Reviews transplant program performance including outcomes and activity levels.
- Reviews reported policy violations and makes recommendations to the Board.

The desire is to have the document be no longer than three pages. It was agreed that the Committee would review the document further and report any additional suggestions to staff after the meeting. The draft document was reviewed electronically following the meeting and the only change made was to add the staff liaisons contact information. A copy is provided as Exhibit M-1 of this report.

21. Content of Patient Acceptance Letters: During its February 2007 meeting, the Committee recommended that the Board approved changes to the Bylaws that further described program coverage. The Committee agreed to 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 they are wait listed, along with the acceptance letter. The Committee envisioned that this letter would reference the web sites to find center data, state the patient's ability to seek care at other centers, and include the patient hotline number and information about patient rights. It was suggested that the letter should come from the OPTN/UNOS as an oversight organization rather than the center itself and that the acceptance letter must reference the OPTN letter as an enclosure. 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.

Update: During its November meeting, the Committee was informed that the Patient Affairs Committee (PAC) had considered its request and developed a template letter. The Committee agreed to support the letter as written and encourages the PAC to move forward with implementation.

RESOLVED, that the Committee supports the concept and the text in the letter and asks the Patient Affairs Committee to move forward with implementation.

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

Additionally, the Committee recommended that the letter also be made available in Spanish.

In addition to considering the letter itself the Committee responded to the following questions from the PAC:

- Does this letter meet the MPSC's expectations?  
The Committee agreed that this letter meets its expectations.
- Does a requirement for this letter need to be added to the Bylaws?  
The Committee did not believe that the use of this letter mandated in the Bylaws or Policies.
- How will compliance be monitored?  
The Committee did not support compliance monitoring.
- Protocol for updating the letter?

The Committee deferred to the PAC for updating the text and protocol.

22. Other Committee Goals: The following Goals were also addressed by the Committee during its November meeting:

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

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

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

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

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

The completed program transplant surgeons and physicians report is expected in late January 2008. This report supplies the program with what information is currently on file in the UNOS database. This report will be sent with instructions to each transplant program requesting an update regarding the physician staff; their designation with needed documentation as primary, additional or other; and certification by the required primary directors that the surgeons and physicians meet new criteria regarding their moral and ethical standing. This information should be submitted and reviewed by the MPSC no later than June 2008.

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

This goal will be carried out in conjunction with Goal 7 above. A request for a Program Coverage Plan along with instructions and a description will be received with the staffing report. This information should be submitted and reviewed by the MPSC no later than June 2008.

As a result of the discussions regarding the Goals for 2008, the following work groups were formed:

Performance Metrics Work Group: The Committee tasked this work group with reviewing current methods for monitoring transplant program performance as described in Goal 2. This Work Group is also charged with identifying alternative performance metrics, in addition to the current outcome and inactivity measures. Dr. Niloo Edwards will serve as the chair. Other members include the following: Drs. Don Hricik, George Loss, Brendan McGuire, Paul Morrissey, Jennie Perryman, Michael Voigt, Robert Higgins, and Mr. Chris McLaughlin. . Dr. James Wynn, incoming MPSC chair has been asked to participate. This Work Group will meet by conference call on January 18<sup>th</sup> further discuss its charge and path forward.

The Certification Maintenance Work Group is tasked with reviewing the efficiency and effectiveness of the methods that are used for member evaluation on an ongoing basis and making

recommendations on improvements. This work group will be chaired by Drs. Carl Berg and Yolanda Becker. Other members include the following: Drs. John Chen, Niloo Edwards, Julie Heimbach, John Herre, Geof Land, Jack Lake, Jennie Perryman, Fuad Shihab, and Robert Higgins. Additional members are Pat McDonough and Chris McLaughlin. Dr. James Wynn, incoming MPSC chair, has been asked to participate. This committee will meet by conference call in January to further discuss its charge and path forward.

The OPO Performance Metrics Work Group was been formed with members from the MPSC and the OPO Committee, both of which have been tasked with addressing the goal of developing performance metrics to maximize utilization of organs. This work group will include the following MPSC members: Tim Brown, Lynn Driver, Dr. Chris Freise, and Rich Luskin. A Work Group call will be scheduled for January 2008.

23. UNOS Actions: During the November meeting, the Committee members agreed that actions regarding Bylaws, Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions.

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

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

**Attendance at the Membership and Professional Standards Committee Meeting  
November 13-14, 2007**

<b>NAME</b>	<b>POSITION</b>	<b>ATTENDED Aug 1-2, 2007</b>	<b>ATTENDED Nov 13-14, 2007</b>
Robert S Higgins MD,MSHA	Chair	X	X
Carl Berg MD	Vice Chair	X	X
Paul Morrissey MD	Regional Rep.	X	X
Lynt Johnson MD	Regional Rep.	X	X
George Loss Jr, MD,PhD	Regional Rep.	X	X
John Goss MD	Regional Rep.		
Chris Freise MD	Regional Rep.	X	X
Jorge Reyes MD	Regional Rep.	X	
Yolanda Becker MD, FACS	Regional Rep.	X	X
Michael Voigt MD	Regional Rep.	X	X
Patricia Sheiner MD	Regional Rep.	X	
Lynn Driver CPTC	Regional Rep.	X	X
Tim Brown	At Large	X	X
Jonathan Chen MD	At Large		X
Niloo Edwards MD	At Large	X	X
James Gleason	At Large	X	X
Julie Heimbach MD	At Large	X	X
John Herre MD	At Large	X	X
Donald Hricik MD	At Large	X	X
John Lake MD	At Large	X	X
Geoffrey Land PhD	At Large	X	X
Richard Luskin MPA	At Large	X	X
Jill Maxfield RN, CPTC	At Large	X	
Patricia McDonough RN, CPTC, CCTC	At Large	X	X
Brendan McGuire MD	At Large	X	X
Jennie Perryman RN, PhD	At Large	X	X
Fuad Shihab MD	At Large		X
Randall Starling MD, MPH	At Large	X	X
Randolph Steadman M.D.	At Large	X	X
David Weill MD	At Large		X
James Burdick MD	Ex Officio		
Christopher McLaughlin	Ex Officio	X	X
Charlotte Arrington MPH	SRTR Liaison	X	X
Jack Kalbfleisch	SRTR Liaison		X
Robert Wolfe Ph.D.	SRTR Liaison	X	X
Sally Harris Aungier	Committee Liaison	X	X

<b>NAME</b>	<b>POSITION</b>	<b>ATTENDED Aug 1-2, 2007</b>	<b>ATTENDED Nov 13-14, 2007</b>
David Kappus MAS	Committee Liaison	X	X
Doug Heiney	Support Staff	X	
Terri Bessom	Support Staff		X
Heather Bowman	Support Staff		X
Elizabeth Coleburn	Support Staff	X	X
Jerry DeSanto	Support Staff	X	X
Rosey Edmunds	Support Staff	X	
Leah Edwards, Ph.D.	Support Staff	X	
Mary D. Ellison, Ph.D.	Support Staff	X	X
Alex Garza	Support Staff	X	X
Suzanne Gellner JD, CHC	Support Staff	X	X
Walter K. Graham	Support Staff	X	
Karl McCleary Ph.D., M.P.H.	Support Staff	X	X
Joel Newman	Support Staff	X	
Jacqueline O'Keefe MBA	Support Staff	X	X
Anne Paschke	Support Staff		X
John Persons, Esq.	Support Staff	X	
John Rosendale	Support Staff		X
Leah Slife	Support Staff	X	X
Donna Whelan	Support Staff		X

**EXHIBIT M-1**  
**OPTN/UNOS Membership and Professional Standards Committee (MPSC)**  
**Summary**

**CHARGE**

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

To accomplish this, the MPSC:

- Develops and recommends membership criteria for each class of membership to the Board of Directors.
- Recommends additions and revisions to membership criteria as needed.
- Reviews each membership application for Institutional Membership and adopts recommendations for Board action.
- Monitors member compliance with OPTN requirements.
- Reviews transplant program performance including outcomes and activity levels.
- Reviews reported policy violations and makes recommendations to the Board.

**OPTN MANDATE**

OPTN policies and bylaws were developed after circulation and discussion among organ transplant professionals and patient representatives. OPTN Bylaws and Policies have been adopted by the OPTN/UNOS Board of Directors as specified in the OPTN contract with the Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services (HHS). *UNOS is responsible under this federal contract for keeping these Bylaws and Policies up to date and for monitoring compliance by OPTN members. These Bylaws and Policies can be accessed at [www.optn.org](http://www.optn.org) and at [www.unos.org](http://www.unos.org).*

**OPTN USES CONFIDENTIAL MEDICAL PEER REVIEW PROCESS**

MPSC Committee work is conducted using the **medical peer review process**. This process assures quality patient care by *developing consensus recommendations and feedback from peers to achieve collective compliance* with applicable standards or policies. This peer review process is fundamental to OPTN/UNOS system for evaluating membership applications and monitoring and enforcing member compliance and performance. The Committee focuses on working with members to achieve voluntary compliance. The sanctions described in the Bylaws may be utilized to achieve compliance with policies when voluntary actions are unsuccessful. Confidentiality of medical peer review is assured to the extent permitted in the Bylaws, while also assuring the Secretary's access to information when and in the format the Secretary of the Department of Health and Human Services (DHHS) requests.

**MPSC COMPOSITION**

32 Members

12	Surgeons	10	Physicians
4	OPO Staff	1	Transplant Administrator
1	Lab Director	1	Transplant Coordinator
2	Transplant Recipients	2	DoT Representatives

(some individuals may fit multiple categories)

**STANDING SUBCOMMITTEES.** All Committee members are appointed to one of the following standing subcommittees: **Data Subcommittee (DSC) and Policy Compliance Subcommittee (PCSC).**

**Data Subcommittee (DSC)**

- Charged with monitoring transplant program performance. This is accomplished by using clinical outcome and volume triggers for inquiry relating to one-year post-transplant patient and graft survival rates and periods of inactivity.
  - *Survival Rates:* The DSC monitors all kidney, liver, heart, and lung transplant programs for outcomes. Using a statistically driven method, the Scientific Registry of Transplant Recipients (SRTR) uses blinded data derived from UNet<sup>sm</sup> to identify programs in which actual one-year patient and/or graft survival falls below the expected rates given individual center donor and recipient characteristics. The SRTR provides the Data Subcommittee with a report detailing program expected survival rates, observed survival rates, the ratio of observed to expected events (graft failure and/or death), and a p-value\* (see attachment A). Programs identified as having lower than expected outcomes are sent an inquiry regarding the transplant program operations. Data Subcommittee members review program responses, and request details regarding quality improvement efforts. A peer visit, which involves a team of transplant professionals (surgeon, physician, administrator), may be recommended to encourage performance improvement. The team prepares a report for the Data Subcommittee and the MPSC. The MPSC in turn issues the report to the Member Center detailing the findings from the peer visit.
    - In the circumstances when a program performs too few transplants to be analyzed by the above referenced statistical model, the Data Subcommittee is provided blinded center statistics, generated by the UNet<sup>sm</sup> system for review. The SRTR uses this data to identify programs in which nine (9) or fewer transplants were performed during a consecutive two and a half year interval (cohort) that resulted in at least one death and/or graft failure. In those instances in which nine or fewer transplants are performed by a program in a consecutive two and a half year period and there has been at least one death or graft failure, an inquiry will be conducted.
  - *Inactivity:* OPTN/UNOS Bylaws and Policies require, as a condition of membership, that all institutional members (including transplant hospitals) be active in the field of transplantation. An OPTN Member Transplant Hospital and UNOS designated transplant center that fails to remain functionally active with respect to any designated transplant program may voluntarily inactivate that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. A program is considered to be functionally inactive if a transplant has not been performed during a designated time period. The period of review for kidney, liver, and heart transplant programs is three months; pancreas and lung programs is six months; and stand alone pediatric hospitals is 12 months. The Data Subcommittee considers changes in key personnel when reviewing program activity levels and routinely requests that programs provide a plan for future program performance.

#### **Policy Compliance Subcommittee (PCSC)**

- Charged with ensuring that Members comply with OPTN Policies and reviewing OPTN/UNOS policy violations. PCSC may recommend action against Members in violation of policies. Each potential violation of organ allocation policy is evaluated to determine its severity and whether it is an indication of continued noncompliance. This is accomplished through a confidential peer review of routine surveys conducted by UNOS staff, allocation analyses, metrics, Regional Review Board issues referred from the Liver and Intestinal Organ Transplantation Committee, the Thoracic Organ Transplantation Committee, and Member and patient complaints. Compliance activities include:
  - Site Surveys of all heart, lung, and liver transplant programs, as well as all OPOs, on a three year cycle.
  - Allocation Analyses: UNOS staff reviews 100% of Organ Allocations, and any containing potential policy violations are investigated.

- Compliance metric analyses are statistical and numerical indicators reviewed by UNOS on a daily and monthly basis to proactively monitor the transplant system, identify system anomalies and take corrective actions. .
- Data Submission and Quality Review: UNOS conducts quarterly reviews of all OPTN Members for compliance with data submission policies, and the PCSC reviews any noncompliant Members.
- Review Boards: Regional Heart and Liver Review Board members and National Lung Review Board members are asked to approve requests to change a candidate's score or status. Cases in which the center disagrees with the Review Board's decision may be referred to the appropriate organ specific Committee. If that Committee judges the cases to be a potential policy violation, it is referred to the PCSC.
- Member and Patient Complaints: UNOS staff investigates all complaints from Members regarding conduct or potential policy violations of other Members, as well as any patient complaints with policy implications that come to UNOS via the patient hotline.

### References

OPTN Website [www.optn.org](http://www.optn.org)

<http://www.optn.org/policiesAndBylaws/> Links can be found to the Charter, Bylaws, Policies, Evaluation Plan, and the Final Rule.

<http://www.optn.org/members/committees.asp> Links to Committee Reports to the Board and Rosters.

UNOS Website [www.unos.org](http://www.unos.org)

<http://www.unos.org/resources/> Links can be found to the Articles of Incorporation, Bylaws, and Policies.

<http://www.ustransplant.org/> Links to US Transplant -- Scientific Registry of Transplant Recipients.

<http://www.hrsa.gov/> Link to Health Resources and Services Administration.

Additional Information about the Committee can be obtained by contacting the staff liaisons:

Sally Aungier, Administrator, Membership Services (804) 782-4812 or [aungiesh@unos.org](mailto:aungiesh@unos.org) or

David Kappus, Assistant Director, Membership (804) 782-4763 or [kappusdm@unos.org](mailto:kappusdm@unos.org).

### **Attachment A:**

If a program's observed minus expected events is greater than three (i.e. the program experienced an excess of three deaths/ failures over the expected events); the observed divided by expected events is greater than 1.5 (i.e. the program experienced 50% more deaths/failures than was expected); and the p-value is less than 0.05, the program will be identified for further MPSC review. The analytical model is described in more detail on the SRTR website, [www.ustransplant.org](http://www.ustransplant.org).

## EXHIBIT M-2

### Briefing Paper

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**Proposed Modification to the OPTN Bylaws, Appendix B, *Transplant Hospitals*; Section B. *Survival Rates*; and Section C *Inactive Membership Status*"; and Attachment I, Section II, *Inactive Program Status*"; and to the UNOS Bylaws, Attachment I, Section II *Inactive Program Status*" and Attachment II, Section XIII, C, (10) *Survival Rates.*" (Membership and Professional Standards Committee)**

#### Summary/Performance Objective – Aim

This proposed change to the Bylaws documents the Membership and Professional Standards Committee's (MPSC) current practice of holding informal discussions with Members during its review of survival rates and activity at transplant programs.

#### Background and Significance

These proposed modifications were considered by the MPSC during its August 1-2, 2007, meeting. The purpose of the proposal is to delineate when "informal discussions" may be held with an Institutional Member.

The Bylaws establish that a Member is entitled to an interview as part of its due process rights when the MPSC is considering taking specified actions against the members. However, the Committee found that it is useful to engage in discussions with the Member in other circumstances and it has been conducting informal discussions with members for several years; however, the process itself has not been codified in the Bylaws. This modification will document that the Committee can require the member to participate in a discussion when it is conducting performance reviews, including review of survival rates and activity, in a transplant program. The informal discussion can be conducted by the MPSC, or a subcommittee or work group, as the MPSC may direct. The purpose of the discussion is for the Committee to continue fact-finding, and at the same time encourage an open dialogue between the MPSC and the Member about its program. These discussions are conducted by conference call and are arranged in advance by UNOS staff.

The informal discussion established by the proposal is not an element of due process, nor is it a right of the Member.

#### Policy Proposal

The Committee approved the following resolution:

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

The Committee voted 25 For, 0 Against, 0 Abstentions.

### OPTN Bylaws, Appendix B

**B.** **Survival Rates.** In the distribution of survival rates of all OPTN Members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee ("MPSC") to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality. The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC's quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the OPTN Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to a summary of the discussion.

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is  $>3$  and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of  $<0.05$ .

Observed events represent deaths or graft losses as reported in UNOS database. Expected events represent deaths or graft losses as calculated utilizing organ specific transplant models. ~~Incomplete follow up data will be treated as a graft loss or patient deaths in the context of this analysis.~~

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality improvement. The Member's failure to do so shall constitute a violation of UNOS requirements.

**C.** **Inactive Membership Status.** An OPTN Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program (as defined below) may voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC's quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the OPTN Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to a summary of the discussion.

For purposes of these Bylaws, "functionally inactive" is defined as:

- (1) The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or
- (2) No transplant performed for a period of time defined as:
  - (iv) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,
  - (v) No transplant performed in six months in the case of pancreas and lung programs, and
  - (vi) No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals,

with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.

If the Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors notify the Secretary of HHS of the situation in the case of transplant programs approved by the Secretary of HHS for reimbursement under Medicare or transplant programs in Federal hospitals, or take appropriate action in accordance with Appendix A of these Bylaws in all other cases, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients (with a copy to the entity that operates the OPTN under contract with HHS (OPTN Contractor)) of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the patient to the list of another OPTN Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for OPTN membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.

To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.

It is expected that all Transplant Hospitals will duly inform their patients on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify the OPTN Contractor and their patients as described above.

## **UNOS Bylaws, Appendix B “Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership”**

### **II. Transplant Hospitals.**

A. No changes

**B. Survival Rates.** In the distribution of survival rates of all UNOS members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee (“MPSC”) to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality improvement. The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC’s quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion

is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to a summary of the discussion.

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is  $>3$  and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of  $<0.05$ .

Observed events represent deaths or graft losses as reported in UNOS database. Expected events represent deaths or graft losses as calculated utilizing organ specific transplant models. ~~Incomplete follow up data will be treated as a graft loss or patient deaths in the context of this analysis.~~

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality improvement. The Member's failure to do so shall constitute a violation of UNOS requirements.

**C. Inactive Membership Status.** A Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program (as defined below) may voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC's quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to a summary of the discussion.

For purposes of these Bylaws, "functionally inactive" is defined as:

- (1) The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or
- (2) No transplant performed for a period of time defined as:
  - (iv) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,
  - (v) No transplant performed in six months in the case of pancreas and lung programs, and
  - (vi) No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals,

with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.

If the Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws in all other cases, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the patient to the list of another Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Member be designated as an active member.

To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.

It is expected that all Transplant Hospitals will duly inform their patients on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify UNOS and their patients as described above.

## **ATTACHMENT I TO APPENDIX B OF UNOS BYLAWS**

### **Designated Transplant Program Criteria**

#### **II. Facilities and Resources. No changes**

**II. Inactive Program Status.** Designated transplant programs qualified in accordance with these Attachment I criteria that fail to remain functionally active shall voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC's quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to a summary of the discussion.

For purposes of these Bylaws, "functionally inactive" is defined as:

- (2) The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or
- (2) No transplant performed for a period of time defined as:
  - (vii) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,
  - (viii) No transplant performed in six months in the case of pancreas and lung programs, and
  - (ix) No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals, with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.

If the program fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients (with a of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the patient to the list of another Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors take appropriate action.

To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.

It is expected that all designated transplant programs will duly inform their patients on the waiting list if there will be an extended period of time when the program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify UNOS and their patients as described above.

### **XIII. Transplant Programs.**

**A. No changes**

**B. No changes**

C. Sections (1) – (9) No changes

- (10) **Survival Rates.** In the distribution of survival rates of all UNOS members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee (“MPSC”) to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality improvement. The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC’s quality improvement effort. The

discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to a summary of the discussion.

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is  $>3$  and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of  $<0.05$ .

Observed events represent deaths or graft losses as reported in UNOS database. Expected events represent deaths or graft losses as calculated utilizing organ specific transplant models. ~~Incomplete follow up data will be treated as a graft loss or patient deaths in the context of this analysis.~~

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality improvement. The Member's failure to do so shall constitute a violation of UNOS requirements.

## SUMMARY OF PUBLIC COMMENTS

### 1. INDIVIDUAL COMMENTS:

As of 12/21/2007, 30 responses have been submitted to UNOS regarding this policy proposal. Of these, 27 (90.00%) supported the proposal, 1 (3.33%) opposed the proposal, and 2 (6.67%) had no opinion. Of the 28 who responded with an opinion, 27 (96.43%) supported the proposal and 1 (3.57%) opposed the proposal. Comments on the proposal received to date are as follows:

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#### Comment 1:

*vote: Support*

*Date Posted: 10/02/2007*

Fact finding and an open dialog is an important part of the function of the committee. Bylaw changes to facilitate and improve this function as well as to formalize the approach can only help to improve the effectivity of the committee and in the end benefit the quality of patient care.

**Committee Response:**

No response required.

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#### Comment 2:

*vote: Support*

*Date Posted: 10/01/2007*

I congratulate you on making your informal process a part of your Bylaws. I agree with the modification. I received my liver transplant from Barnes-Jewish Hospital (St. Louis) in October 2004. It has been a new lease on life. To date, Barnes-Jewish has provided excellent care.

**Committee Response:**

No response required.

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#### Comment 3:

*vote: Support*

*Date Posted: 09/28/2007*

I support these efforts to discuss issues with performance/outcomes not only address concerns but work with members toward resolutions (if possible.)

**Committee Response:**

No response required.

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#### Comment 4:

*vote: Support*

*Date Posted: 10/03/2007*

I support this change with reservations. I think the rationale behind the change is unexceptionable: The utility of informally conversing with members of a program under review in the course of conducting a fact-finding activity is clear. But, if the MPSC has the discretion to make such conversations mandatory, it is not sufficient to simply assert that such conversations are not entangled with due process. After all, if actionable information or evidence is gleaned from one of these informal conversations, it thereby becomes very much a part of due process. I do wonder if requiring such conversations would have the unintended consequence of making such conversations more difficult in practice. It would be reasonable for the Member institution under investigation to view these mandatory informal conversations as contiguous with due process, MPSC's assertions to the contrary notwithstanding.

The key question (best answered by the MPSC, and not me) is whether there is a genuine need for this proposed policy because of an absence of or reluctance to engage in informal discussion, or whether this codifies in

policy what happens already in practice. Why not, instead, have a policy which encourages such conversations without making them mandatory?

If the Member institution declines to participate, that may trigger a more formal approach, clearly delineated as a component of due process. The message would be: Decline informal discussions if you will, but understand that the fact-finding mission will take place regardless. Or, if these informal conversations take place already and without difficulty, perhaps this policy making such conversations mandatory is not really necessary.

**Committee Response:**

*Response:* The bylaw language establishing the opportunity for the MPSC to engage in an informal discussion with a Member under MPSC review is codifying an existing practice. The informal discussion is part of the normal review process utilized by the MPSC. Should an adverse recommendation result from information gleaned during an informal discussion, the Member is still afforded all rights to due process, as described in Appendix A to the Bylaws. The informal discussion does not take away the option for due process. The informal discussion is a benefit to the Member at the discretion of the MPSC; it is not a Member right. Should a Member decline to participate in an informal discussion with the MPSC, the Committee may make an adverse recommendation as described in Appendix A of the Bylaws.

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**Comment 5:**

*vote: Support*

*Date Posted: 10/04/2007*

I think the period for a lull in lung transplant activity should be shortened to 3 months. An active transplant program doesn't have 6 months between transplants imo

**Committee Response:**

This comment does not relate to the informal discussion bylaw.

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**Comment 6:**

*vote: Support*

*Date Posted: 09/28/2007*

Open and fair dialog is important, and I endorse the current discussion practices and feel they should be part of policy.

**Committee Response:**

No response required.

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**Comment 7:**

*vote: Support*

*Date Posted: 09/28/2007*

This is simply codifying the existing MPSC practice. It is always appropriate to encourage discussion between the committee and/or it's designates and members in question regarding performance issues so that the facts are complete and clear to allow for the best action plans to be generated.

**Committee Response:**

No response required.

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**Comment 8:**

*vote: Support*

*Date Posted: 10/15/2007*

Why can't a spouse or immediate member of a living kidney donor have priority for receiving a kidney. I donated in 1979 to save a life and now my wife is on Dialysis for over three years and I can't help her People see the problem I have and they don't want to get themselves in the same situation by being a live donor and later someone in their family has kidney failure and receives no priority.

**Committee Response:**

The above comment does not appear to be in reference to the proposal under review.

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**Comment 9:**

*vote: Support*

*Date Posted: 10/09/2007*

Wouldn't it be appropriate, and in the spirit of the proposed modification to the Bylaws described, that a Member initiate informal discussion as outlined?

**Committee Response:**

*Response:* In an effort to review transplant program performance, the MPSC utilizes routine reports for Member reporting. An informal discussion is typically offered to a Member by the MPSC to gain additional insight into program operations that cannot be easily conveyed in written form. The Member can request an informal discussion with the MPSC, however the MPSC is not required to convene the informal discussion.

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**Comment 10:**

*vote: No Opinion*

*Date Posted: 10/02/2007*

Re: 5th Paragraph of Section B: "Incomplete follow-up data will be treated as a graft loss or patient deaths in the context of this analysis." Does this proposal mean that any follow up data not reported within 30 days of the patient's transplant anniversary (which is when the follow up forms are currently due) will be considered a graft loss or death when calculating outcomes?

If this is the case our concern relates to the fact that over many years and hundreds of patients followed, not all patients are on a yearly follow-up appointment schedule that coincides with their original transplant date. Therefore, there will be a large number of patients regularly followed by our center, with functioning grafts who would be considered graft failures or deaths just because their follow up appointments don't coincide with their anniversary date. This means patient and graft survival rates calculated by SRTR will be inaccurately lower than actual outcomes. Hopefully I am mis-interpreting the statement in this policy!

I would very much like to discuss this with someone at UNOS. Thank you. Margaret Davidson Transplant Compliance Manager Ochsner Multi-Organ Transplant Center New Orleans, LA 504-842-3945

**Committee Response:**

*Response:* The Bylaw language regarding incomplete follow up is inconsistent. Incomplete follow up data is not treated as a graft loss or patient death in the context of the analysis. The SRTR website, [www.ustransplant.org](http://www.ustransplant.org), includes all data analysis methodologies and convections should you desire further clarification. The Bylaw language will be corrected.

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## 2. REGIONAL COMMENT SUMMARY

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Did Not Consider
1	10/1/07	15 yes, 1 no, 0 abstentions		
2	11/9/07	22 yes, 0 no, 0 abstentions		
3	11/8/07	16 yes, 0 no, 0 abstentions		
4	11/9/07	15 yes, 0 no, 0 abstentions		
5	12/14/07	25 yes, 0 no, 1 abstention		
6	11/30/07		48 yes, 0 no, 0 abstentions	
7	11/9/07	16 yes, 0 no, 0 abstentions		
8	11/16/07	22 yes, 0 no, 0 abstentions		
9	10/24/07	14 yes, 0 no, 0 abstentions		
10	12/7/07	25 yes, 0 no, 0 abstentions		
11	11/9/07	18 yes, 0 no, 0 abstentions		

**Region 1:** The region supports the proposal but raised the following concerns:

- The MPSC should provide an agenda for the informal discussion so the member can be prepared and know what documentation they need, etc. Perhaps the MPSC could establish guidelines for informal discussions.
- Are the minutes from the informal discussions discoverable?

*Response:* The Member is provided with information regarding the informal discussion, including the focus of the discussion and additional documentation the Committee may request. The minutes from the informal discussion are protected by Medical Peer Review laws.

**Region 6:** The region supported the proposal with an amendment that the Committee add language to the bylaw stating that the Member can initiate the discussion with the MPSC regarding their performance review.

*Response:* In an effort to review transplant program performance, the MPSC utilizes routine reports for Member reporting. An informal discussion is typically offered to a Member by the MPSC to gain additional insight into program operations that cannot be easily conveyed in written form. The Member can request an informal discussion with the MPSC, however the MPSC is not required to convene the informal discussion.

## 3. COMMENTS FROM OTHER COMMITTEES

### Ad Hoc International Relations Committee

During its teleconference meeting on October 11, 2007, the Ad Hoc International Relations Committee discussed this proposal, and sought assurance that the medical peer review laws protected these informal discussions, including related summaries and conclusions. The Committee subsequently voted electronically to support the proposal (3-Supported the Proposal, 0-Opposed the Proposal, and 1-Abstained from voting).

### Executive Committee

No comments submitted.

### Finance Committee

No comments submitted.

**Histocompatibility Committee**

No comments submitted.

**Kidney Transplantation Committee**

The Kidney Transplantation Committee voted to approve this proposal without modification:  
18 in favor, 0 opposed, 0 abstentions.

**Liver and Intestinal Organ Transplantation Committee**

Unanimously supported the proposal (18 in favor, 0 opposed, 0 abstentions)

**Living Donor Committee**

No comments submitted.

**Minority Affairs Committee**

No comments submitted.

**Operations Committee**

The Operations Committee had no comment on this proposal.

**OPO Committee**

No comments submitted.

**Organ Availability Committee**

No comments submitted.

**Pancreas Transplantation Committee**

The Pancreas Committee discussed the proposed bylaw modifications on December 7, 2007. The Committee agreed that the practice of holding informal discussions with members is a good practice. The Committee voted to support the proposed changes (7- Support, 0- Oppose, 0- Abstain.)

**Patient Affairs Committee**

With a vote of 11:0:1, the Patient Affairs Committee supported the proposed Bylaws modification in assisting the MPSC in the performance review process and clarifying requirements of Members. No concerns were expressed.

**Pediatric Transplantation Committee**

The Pediatric Transplantation Committee reviewed the proposal during its November 29, 2007. Though this issue is not specifically pediatric in nature, the Committee agreed that an informal interview is beneficial to discuss cases where pediatric issues may not fall neatly into current Bylaws. After discussion, the Committee voted unanimously to support this proposal (18 yes, 0 no, 0 abstentions).

**Policy Oversight Committee**

No comments submitted.

**Thoracic Organ Transplantation Committee**

The Thoracic Committee reviewed the proposal at its meeting on October 2, 2007. The Committee voted to support this proposal (15-Yes, 0-No, 1-Abstention), but would like to know which state statute has jurisdiction over the "summary" referenced in the following sentence of the proposed language: "A Member who participates in a discussion with the MPSC is entitled to a summary of the discussion."

The Committee would also like to know who reviews the document.

Response: An informal discussion is a benefit to the Member and is offered to a Member at the discretion of the MPSC; it is not a Member right. The MPSC utilizes informal discussions to gain better insight into transplant program operations, as the Committee determines necessary. A Member may request an informal discussion with the MPSC, but the MPSC does not have to grant such request.

#### **Transplant Administrators Committee**

No Comment.

#### **Transplant Coordinators Committee**

The TCC supported this proposal with a vote of 8 in favor, 3 opposed, and no abstentions.

Concerns included:

What is the time frame between the program being notified of an issue and the interview?

Will the program have an opportunity to provide updated data?

Response: An informal discussion may be offered to a program at any point during the MPSC review process. The program should receive written documentation offering the informal discussion at least 30 days prior to the proposed informal discussion. All programs are afforded the opportunity to submit additional information including updated data at any point during the MPSC review process and certainly may do so before or during the informal discussion.

### **FINAL PROPOSALS**

These proposals were issued to a mailing list of approximately 13,100 individuals and organizations for a comment period of 85 days beginning on September 28, 2007 and ending December 21, 2007. Notifications of all policy and bylaw proposals issued for public comment are either mailed to the distribution list in hard copy form, or via electronic mail with website link by request.

The MPSC met on November 13-14, 2007, and considered the input received to date from individuals, the Regions, associations, and other OPTN/UNOS Committees. The public comment period would not end until December 21; therefore the Committee was unable to make final recommendations on the proposals, but they reviewed the response that had been received to date. The Committee agreed to review the remaining comments electronically after the end of the public comment period.

The Committee agreed to forward this amended proposal to the Board for their consideration.

**\*\* RESOLVED, that the following modifications to Appendix B, Section II, Paragraphs B and C, having been distributed for public comment and subsequent reconsideration by the Committee, are approved effective February 21, 2008.**

The vote was unanimous.

#### **Summary of Comments**

One of the questions that was raised during the public comment period related to the general nature of peer review. In the event the informal discussion is convened using a Subcommittee, prior to the full MPSC meeting, the conference call is subject to Virginia Peer Review statutes. The documentation prepared after the informal discussion, including the summary, is subject to Illinois Peer Review statutes. Should the Informal Discussion be convened during an MPSC meeting, the discussion and corresponding documentation is subject to Illinois Peer Review statutes.

One of the comments received pointed out an error in the Survival Rates section of the Bylaws and the Committee agreed that it should be fixed. The Bylaw presently states that "incomplete follow-up data will be treated as a graft loss or patient deaths in the context of this analysis." Incomplete follow up data is not treated as a graft loss or patient deaths so this language is shown as removed in the final proposal.

Another comment asked about the guidelines for the process. The template for the informal discussion includes a list of personnel present, both Committee members and Member representatives; a summary of the Member presentation; and, a summary of the question and answer session.

## Final Language

### Proposed Modifications to Appendix B, Section II, Paragraphs B and C in the UNOS and OPTN Bylaws

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

#### OPTN Bylaws, Appendix B

**B. Survival Rates.** In the distribution of survival rates of all OPTN Members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee (“MPSC”) to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality. The MPSC may also require, at its discretion, that the Member participate in a discussion regarding a performance review in the MPSC’s quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the OPTN Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is  $>3$  and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of  $<0.05$ .

Observed events represent deaths or graft losses as reported in UNOS database. Expected events represent deaths or graft losses as calculated utilizing organ specific transplant models. ~~Incomplete follow up data will be treated as a graft loss or patient deaths in the context of this analysis.~~

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality improvement. The Member’s failure to do so shall constitute a violation of UNOS requirements.

**C. Inactive Membership Status.** An OPTN Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program (as defined below) may voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC’s satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting

transplantation. The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC's quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the OPTN Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

For purposes of these Bylaws, "functionally inactive" is defined as:

- (1) The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or
- (2) No transplant performed for a period of time defined as:
  - (x) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,
  - (xi) No transplant performed in six months in the case of pancreas and lung programs, and
  - (xii) No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals,

with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.

If the Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors notify the Secretary of HHS of the situation in the case of transplant programs approved by the Secretary of HHS for reimbursement under Medicare or transplant programs in Federal hospitals, or take appropriate action in accordance with Appendix A of these Bylaws in all other cases, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients (with a copy to the entity that operates the OPTN under contract with HHS (OPTN Contractor)) of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the patient to the list of another OPTN Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for OPTN membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.

To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.

It is expected that all Transplant Hospitals will duly inform their patients on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify the OPTN Contractor and their patients as described above.

## UNOS Bylaws, Appendix B “Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership”

### II. Transplant Hospitals.

A. No changes

**B.** **Survival Rates.** In the distribution of survival rates of all UNOS members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee (“MPSC”) to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality improvement. The MPSC may also require, at its discretion, that the Member participate in a discussion regarding a performance review in the MPSC’s quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is  $>3$  and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of  $<0.05$ .

Observed events represent deaths or graft losses as reported in UNOS database. Expected events represent deaths or graft losses as calculated utilizing organ specific transplant models. ~~Incomplete follow up data will be treated as a graft loss or patient deaths in the context of this analysis.~~

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality improvement. The Member’s failure to do so shall constitute a violation of UNOS requirements.

**C.** **Inactive Membership Status.** A Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program (as defined below) may voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC’s satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC’s quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

For purposes of these Bylaws, “functionally inactive” is defined as:

- (1) The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or
- (2) No transplant performed for a period of time defined as:
  - (vii) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,
  - (viii) No transplant performed in six months in the case of pancreas and lung programs, and
  - (ix) No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals,

with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.

If the Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws in all other cases, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients of the need to inactivate, removal of these patients from the program’s waiting list, or - if the patient desires - transfer of the patient to the list of another Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Member be designated as an active member.

To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.

It is expected that all Transplant Hospitals will duly inform their patients on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify UNOS and their patients as described above.

**ATTACHMENT I  
TO APPENDIX B OF UNOS BYLAWS**

**Designated Transplant Program Criteria**

**III. Facilities and Resources. No changes**

**II. Inactive Program Status.** Designated transplant programs qualified in accordance with these Attachment I criteria that fail to remain functionally active shall voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. The MPSC may also require, at its discretion, that the Member participate in a discussion regarding a performance review in the MPSC's quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

For purposes of these Bylaws, "functionally inactive" is defined as:

- (3) The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or
- (2) No transplant performed for a period of time defined as:
  - (i) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,
  - (ii) No transplant performed in six months in the case of pancreas and lung programs, and
  - (iii) No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals, with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.

If the program fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients (with a of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the patient to the list of another Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors take appropriate action.

To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the

waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.

It is expected that all designated transplant programs will duly inform their patients on the waiting list if there will be an extended period of time when the program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify UNOS and their patients as described above.

### **XIII. Transplant Programs.**

**A. No changes**

**B. No changes**

C. Sections (1) – (9)      No changes

**(10) Survival Rates.** In the distribution of survival rates of all UNOS members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee (“MPSC”) to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality improvement. The MPSC may also require, at its discretion, that the Member participate in a discussion regarding a performance review in the MPSC’s quality improvement effort. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is  $>3$  and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of  $<0.05$ .

Observed events represent deaths or graft losses as reported in UNOS database. Expected events represent deaths or graft losses as calculated utilizing organ specific transplant models. ~~Incomplete follow up data will be treated as a graft loss or patient deaths in the context of this analysis.~~

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality improvement. The Member's failure to do so shall constitute a violation of UNOS requirements.

Implementation Package

# Proposed Modifications to the Bylaws, Appendix B, Section II, Paragraphs B and C

## Proposal Summary

This proposed change to the Bylaws documents the Membership and Professional Standards Committee's (MPSC) current practice of holding informal discussions with Members during its review of survival rates and activity at transplant programs.

For review by the BOD

Sponsoring Committee: OPTN/UNOS Membership and Professional Standards Committee

Author(s) - *Sally Aungier & Jacqui O'Keefe*

Date: January 21, 2008



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## Summary/Background

Proposal Summary	
Subject	Description
Brief summary of proposed Policy	This proposed change to the Bylaws documents the Membership and Professional Standards Committee's (MPSC) current practice of holding informal discussions with Members during its review of survival rates and activity at transplant programs.
Primary goal(s) of Policy as set forth by sponsoring Committee	To delineate when "informal discussions" may be held with an Institutional Member
Primary metric(s) identified to assess policy	Not applicable

## Article I. 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

### Section 1.01 Additional supporting data/analyses

Not applicable

## Article II. Program Goals, Strategic Plan and Relationship to OPTN Final Rule

<b>Goals</b>	
<b>Program Goal</b>	<b>Impact</b>
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
<b>Strategic Plan</b>	<b>Impact</b>
Increase donors and transplants in support of HHS Program Goals	Not applicable
Refine allocation policies, incorporating concepts of: <ul style="list-style-type: none"> <li>• donor risk</li> <li>• recipient benefit, and</li> <li>• net benefit</li> </ul>	Not applicable
Reduce variation of death on the waiting list across the country	Not applicable
Optimize a safe environment for living donor transplantation	This bylaw will codify existing practices in monitoring transplant program performance to ensure patient safety and improving quality.
Improve compliance with policies to protect patient safety and preserve public trust	This bylaw will codify existing practices in monitoring transplant program performance to ensure patient safety and improving quality.
Improve the OPTN data system	Not applicable

<b>Comportment with the Final Rule</b>	
Section §121.10 Reviews, evaluation, and enforcement, including but not limited to subsection (b) Review and Evaluation by the OPTN which allows for the OPTN to conduct ongoing and periodic reviews	

and evaluations of each member OPO and transplant hospital for compliance with the Final Rule and OPTN Policies..

### Article III. New/Modified Data Collection Requirements

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

## Article IV. Public Comment Summary

### Section 4.01 Public Comment Distribution

Has the proposal been distributed for public comment? YES

Date of distribution: 09/28/2007

Public comment end date: 12/21/2007

Public Comment Response Tally				
Type	Response Total	In Favor	Opposed	No Comment
Individual Comments	30	27/90 %	1 /3.3 %	2/6.67 %
Regional Comments * note - 48 votes to approve with amendment	236	188	1	1

### Section 4.02 Primary Public Comment Concerns/Questions

One of the questions raised during the public comment period related to the general nature of peer review. In the event the informal discussion is convened using a Subcommittee, prior to the full MPSC meeting, the conference call is subject to Virginia Peer Review statutes. The documentation prepared after the informal discussion, including the summary, is subject to Illinois Peer Review statutes. Should the Informal Discussion be convened during an MPSC meeting, the discussion and corresponding documentation is subject to Illinois Peer Review statutes.

## Article V. Estimated UNOS Resource Utilization

UNOS Resource Estimates for Implementation	
Area	Impact
Resource Impact	
Estimated FTEs	

## Article VI. Implementation Strategy

Implementation Plan Status		
Documentation/Plan	Complete?	Status Comments
Functional and Technical Specification Documents	N/A	No programming required.
Resource Analysis Assessment	N/A	No additional resources anticipated. This is an existing process.
Communications and Education Plan		This change to the bylaws codifies an existing process. Communication regarding the change will be in the standard post Board meeting policy notice.

Monitoring Plan	NA	NA
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## Article VII. Board of Directors Review

Date(s) proposal submitted to Board of Directors: February 20-21, 2008

## Article VIII. Appendix A: Resource Analysis Plan

UNOS Staff Resources: Policy Development and Implementation			
Department	Brief Detail	Annual Staff Hour Percentage	Cost Estimate
Communications		0	
Corporate Counsel		0	
Evaluation and Quality		0	
Information Technology		0	
Membership /Regional Administration	Informal discussions are already happening under the current process. Approximately, 8-10 are expected to occur each year.	20	
Policy		0	
Professional Services		0	
Research		0	
<b>Total</b>		<b>20</b>	

Community and Membership Impact	
Community/Member/Organization	Impact Description
Transplant Center/Program	The purpose of the discussion is for the Committee to continue fact-finding, and at the same time encourage an open dialogue between the MPSC and the Member about its program.

Article IX. Appendix B: Communication and Education Plan

Communication Responsibilities and Outcomes			
Type of Communication	Audience(s)	Delivery Method(s)	Timeframe
Policy Notice	Transplant Program Directors, Transplant administrators	Policy Notice	Within 30 days following the Board meeting

Education / Training Responsibilities and Outcomes			
Education / Training Description	Audience(s)	Delivery Method(s)	Timeframe
<i>Article/notice</i>	Transplant Program Directors, Transplant administrators	<i>UNOS Update</i>	Issue following Board meeting.

Article X. Appendix C: Monitoring Plan

Member Expectations	
Member Description/Group	Action
This section not applicable	

Monitoring Effort Summary		
#	Monitoring Action Planned	Plan Detail
1	This section not applicable	
2		