

OPTN/UNOS Membership and Professional Standards Committee (MPSC)
Meeting Minutes
October 18-19, 2017
Chicago, Illinois

Jeffrey Orlowski, MS, CPTC, Chair
John Friedewald, M.D., Vice Chair

Introduction

The Membership and Professional Standards Committee met in Chicago, Illinois, on October 18-19, 2017, to discuss the following agenda items:

1. Overview of Committee Projects with MPSC Representation
2. Modifications to OPTN Bylaws Regarding the Approval of Transplant Fellowship Programs
3. Modifications to OPTN Bylaws, Appendix L
4. Member Related Actions
5. Living Donor Adverse Events
6. Living Donor Follow-up Reporting
7. OPO Performance Metrics
8. Due Process Proceedings
9. Member Education Opportunities Identified

The following is a summary of the Committee's discussions.

1. Overview of Committee Projects with MPSC Representation

MPSC members are serving on two separate work groups to support OPTN projects sponsored by other OPTN/UNOS Committees. MPSC members are actively involved with a work group that is supporting a Pancreas Transplantation Committee-sponsored project focused on reviewing pancreas functional inactivity Bylaws requirements. Separately, MPSC members are also actively involved with a work group that is supporting an Organ Procurement Organization Committee-sponsored project to establish a formal system for expedited organ placement.

During its October 2017 meeting, UNOS staff provided a brief update on the progress of both of these efforts, and directed MPSC members to the meeting materials where greater detail could be found. Staff informed the Committee that both of these groups had met twice since the Committee's last update in July, and that the focus of these calls for both groups was primarily data requests and data reviews to help inform and develop solutions to these matters. The Committee will continue to receive updates on these groups, and it will be asked to comment on the solutions as they are being finalized in preparation for public comment consideration.

2. Modifications to OPTN Bylaws Regarding the Approval of Transplant Fellowship Programs

During the public comment period that ran from July 31 – October 2, 2017, the Committee sponsored a proposal entitled, "Addressing Approved Transplant Fellowship Training Programs Bylaws." This proposal recommends deleting Bylaws that establish ongoing review and approval of transplant fellowship training programs by the MPSC. The proposal recommends deleting the MPSC's ongoing review and approval of transplant fellowship training programs because it is not a process that the MPSC undertakes, nor has it historically done so.

During its October 2017 meeting, the Committee reviewed the public comment feedback provided in response to this proposal. Public comment feedback included 15 comments including:

- All 11 regions voted in support (proposal included on the “Non-discussion Agenda” for each regional meeting)
- The American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), and NATCO expressed their support for the proposed changes.
- One individual commenter suggested that language requiring the transplant fellowship training program be completed at an institution that has Accreditation Council for Graduate Medical Education (ACGME) approval was duplicative and unnecessary if the transplant fellowship training program is approved by ASTS, AST, or the Royal College of Physicians and Surgeons of Canada (RCPSC).

After reviewing this feedback, the Committee expressed its appreciation for those who reviewed and supported its proposal. Regarding the individual comment about ACGME approval, the MPSC responded that it is important to note that the requirement that a fellowship training program be at an institution that has ACGME approval in general surgery or nephrology specifically applies to those fellowship programs that *are not* approved by ASTS, AST Adult Transplant Nephrology Fellowship Training Program, or RCPSC. Because the OPTN is prohibited from endorsing specific entities or businesses, these additional fellowship training program requirements are necessary so that a transplant program key personnel applicant has the option of qualifying through one of the fellowship pathways in the Bylaws without necessarily having completed their training at a program approved by ASTS, AST Adult Transplant Nephrology Fellowship Training Program, or RCPSC. Key personnel applicants applying through one of the Bylaws’ fellowship training pathways who did not perform their fellowship training at an ASTS, AST Adult Transplant Nephrology Fellowship Training Program, or RCPSC approved fellowship program must have obtained their fellowship training at an institution with ACGME approval, in addition to the other requirements specified in the proposed Bylaws.

Following its review of the public comment feedback provided, the MPSC voted in support (34 Yes, 0 No, 0 Abstentions) of a motion to send the Bylaws language changes proposed during public comment for the OPTN/UNOS Board of Directors’ final consideration at its December 2017 meeting.

3. Modifications to OPTN Bylaws, Appendix L

UNOS staff updated the Committee on progress made to revise OPTN Bylaws Appendix L. This project is slated to be distributed for public comment in January 2018, and staff informed the MPSC members of the timeline, and their roles within that timeline, so that this goal will be realized.

Staff proceeded to review updated project goals. Originally, the project aimed to specify each step of the review pathways for the MPSC’s review of potential noncompliance with OPTN Obligations, and the details for when and how to change pathways during a review. Increased flexibility was also a goal, to avoid undertaking steps in the review process (i.e., interviews and hearings) at times when they may not add value. Working through this project, it became apparent that specifying exact review paths while also increasing flexibility is somewhat in conflict as every possible scenario cannot be anticipated. Trying to do so will result in extremely complex Bylaws language that would likely be confusing, and not a helpful resource. In light of this, it is recommended that this project continue to pursue increased flexibility, but in a framework that is adaptable to future, unexpected situations. To achieve this framework, the proposed Bylaws will specify minimum requirements and expectations for MPSC reviews of potential noncompliance. Critical to this approach is allowing the MPSC and its Chair flexibility

to conduct these reviews at a pace that is appropriate relative to the matter being reviewed (urgent matters will be reviewed as fast as allowed by the Bylaws minimal requirements, and more time may be given to review less urgent matters). Flexibility also would apply to the steps of the review in that the Committee could offer the member multiple informal discussions or interviews to work with the member and evaluate their progress. Only if progress is not being made would a matter advance to the possibility of an adverse action recommendation, in which case the member would be offered a hearing before the MPSC made such a recommendation to the Board of Directors.

The MPSC expressed its support for moving in this direction. Staff then reviewed aspects of an informal discussion, interview, hearing, and appearance before the Board of Directors that described the differences between these steps in the review process, and the minimum requirements that would be included in the proposed Bylaws.

Following this presentation, the Committee divided into five smaller work groups to review and discuss the proposed changes to Appendix L. Each group individually reviewed a section of the proposed Bylaws, and then every group reported out to all meeting attendees the feedback and recommended changes for the section just reviewed.

This exercise produced a vast amount of feedback for staff and the Appendix L work group to consider as they continue to refine the Bylaws modifications that will be proposed. To summarize some of the major themes that resulted from the work groups discussions:

- The Bylaws should include informal discussions and interviews- Work groups had some discussion about the differences between an informal discussion and an interview, and whether the Bylaws needed to include the possibility of an informal discussion. Ultimately, the Committee believed that the informal, back-and-forth nature of informal discussions is valuable and appreciated by members. Because of this, the MPSC felt it was important to include informal discussions and interviews as possibilities to interact with members.
- The Bylaws should not include the possibility of public notice prior to the conclusion of due process- Previously, the MPSC had considered whether the Executive Committee should be allowed to distribute public notice prior to the conclusion of due process in cases where there is a urgent threat to patient health and public safety, and the member fails to mitigate the threat. This option would only be pursued in the direst circumstances to expedite public awareness about the potential threat. Ultimately, the Committee was uncomfortable with a public announcement before the member had been afforded all of its due process rights.
- The MPSC may make recommendations to the Board of Directors regarding public notice when it makes a recommendation for Probation- MPSC discussion acknowledged that the current public notification requirements after the Board of Directors takes an adverse action may not be relevant to the noncompliance that prompted the adverse action. To allow some flexibility in these types of situations, the MPSC recommends including a provision in the Bylaws allowing it to make recommendations, for the Board of Directors' to make the final determination, to deviate from Bylaws' member notification requirements when a member is placed on Probation. The Committee's recommendation could be to eliminate or add specific notification requirements for the particular member it is recommending to be placed on Probation.
- The Bylaws should retain the option to downgrade Member Not in Good Standing to Probation- The Committee suggested that members should still be able to request a Member Not in Good Standing designation to be downgraded to Probation. Although these situations are thought to be rare, the Committee agreed this option could be helpful for

members in certain circumstances, and it didn't recognize any potential negative consequences of retaining this possibility.

4. Member Related Actions

During the meeting, the Committee considered the following member specific issues.

Membership Application Actions- Consent Agenda

The Committee is charged with determining whether member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants. The Committee reviewed the applications and status changes listed below and will recommend that the Board of Directors take the following actions when it meets in December:

New Members

- Fully approve 1 new transplant hospital
- Fully approve 2 public organizations for a two year term
- Fully approve 3 medical/scientific organizations for a two year term
- Fully approve 1 individual member for a two year term

Existing Members

- Fully approve 2 new transplant programs and 1 new living donor component
- Fully approve reactivation of 2 programs and 1 living donor component
- Fully approve 1 program change from full to conditional status
- Fully approve 1 program requesting an extension of voluntary inactivation

The Committee also reviewed and approved the following actions:

- 57 Changes in transplant program and living donor component personnel
- 3 Changes in histocompatibility lab personnel

The Committee also received notice of the following membership changes:

- 1 Transplant program inactivated
- 1 Histocompatibility lab withdrew
- 2 Changes in OPO personnel

UNOS staff also updated the Committee on implementation plans for the Intestine Transplant Program membership requirements, the Histocompatibility Laboratory General Supervisor key personnel requirements, the VCA Transplant Program membership requirements, the transplant hospital definition bylaw and the Pediatric component membership requirements.

5. Living Donor Adverse Events

The Committee reviewed five items that were placed on the consent agenda, which included three aborted procedures, one death of a living donor due to drug overdose, all of which were closed with no action. Additionally, the Committee continued its review of one aborted procedure and voted for the member to be released from monitoring. The Committee approved the consent agenda by a vote of 27 Yes, 0 No, 0 Abstentions.

The Committee also reviewed two items on discussion and issued one Notice of Uncontested Violation and closed the other with no action.

6. Living Donor Follow-up Reporting

An overview of the Living Donor Follow-up policy requirements was shared with the Committee along with the Committee's approved operational rules for monitoring Policy 18.5.A. Following the July meeting, four of the eight members identified as potentially requiring further review received a request for updates and additional information. The Committee reviewed the four programs that submitted additional information.

The Committee requested additional monitoring for each of the members, including an informal discussion with two members and a Notice of Uncontested Violation for one member. Additionally, the Committee approved the consent agenda by a vote of 30 Yes, 1 No, 0 Abstentions.

7. OPO Performance Metrics

Consent Agenda: The Committee approved the release of two OPOs that had been under review for lower than expected organ yield by a vote of 33 Yes, 0 No, 0 Abstentions.

8. Due Process Proceedings

During the meeting, the Committee conducted one interview with an OPO.

9. Member Education Opportunities Identified

MPSC members discussed educational opportunities and topics that should be addressed in the transplant community. One suggestion was to provide a program on kidney laterality, which continues to be an issue for the OPO's because of a lack of standardization in the process.

Members shared that serving on the Committee gave them a better understanding of how the OPTN/UNOS works. They also agreed that we need to continue to share the message that the Committee is trying to help members improve and is not just a punitive body. To achieve that goal they suggested the following:

- Improve awareness of the broad range of topics typically addressed on the MPSC meeting agenda
- Share issues frequently reviewed by the MPSC, such as the top 5 policy violations (tailored to the audience).
- Share the graphical representation of reviews by type or subcommittee with clear delineation of the small percentage that actually end up receiving a formal (public) action. This may help allay the some of the negative perceptions.
- Share information about the roles of the PAIS and PCSC
- Provide education regarding the roles of MQ staff/processes and the relationship to the MPSC (e.g. site survey).
- Streamline the resources that are provided to members to make it easier to find information related to performance improvement and educational opportunities (e.g. UNOS Connect, UNOS Tech News, System Notices, and TransplantPro).

Upcoming Meetings

- November 21, 2017, 3:00 - 5:00pm Conference Call
- December 11, 2017, 12:00 - 2:00pm Conference Call
- February 27 - March 1, 2018, Chicago
- July 17-19, 2018, Chicago
- October 16-18, 2018, Chicago