

## **OPTN Membership and Professional Standards Committee**

### **Meeting Summary**

**March 29, 2024**

**Conference Call**

**Zoe Stewart Lewis, M.D., Chair**

**Scott Lindberg, M.D., Vice Chair**

### **Introduction**

The Membership and Professional Standards Committee (MPSC) met via Webex in both open and closed session on March 29, 2024, to discuss the following agenda items:

1. Membership Requirements Revisions
2. Compliance Issues
3. Membership Issues
4. Investigative Activities

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

#### **1. Membership Requirements Revisions**

The Committee continued its review of the components of the Membership Requirements Revision Proposal for *Appendix A: Membership and Designated Transplant Program Application and Review*, *Appendix B: Organ Procurement Organization (OPO) Members* and *Appendix D: Transplant Hospital Members and Designated Transplant Programs*. This work began at the in-person Committee meeting held on March 5-7, 2024, and focused on familiarizing the Committee with the content and addressing issues that may result in updates to the proposal, and to facilitating discussion of the changes and key issues.

Staff provided an overview of the phased approach to the project, reminding the Committee that the project is split into three phases, with Phase 1.A focusing on the current proposal and developing a framework for key personnel training and experience requirements. In addition, a separate proposal drafted in 2020 for revisions to *Appendix C: Membership Requirements for Histocompatibility Laboratories* is under review and will be included in a proposal by the Histocompatibility Committee for summer 2024 public comment. The MPSC previously reviewed the draft Appendix C proposal, and the Committee will have the opportunity to review the proposal and any changes made at the May 21, 2024, meeting.

In future phases of the project, the Committee will review and propose revisions to *Appendix K: Inactive Waiting List, Program Inactivation, Withdrawal and Termination* and will consider revisions to the previously proposed framework for key personnel training and experience requirements and apply that framework to the organ specific Appendices in collaboration with organ specific OPTN committees. The Committee will also consider the development of requirements for third party membership.

Staff provided an overview of the considerations for revisions developed by the MPSC, including compliance with the Final Rule, support for periodic reassessment of membership status, consistency

with current practice and qualifications, reduced complexity to simplify the application process and review, and ways to stratify requirements based on the type of application.

An overview of changes to Appendix D in the proposal included:

- General revisions:
  - Addressing areas where “should” vs “must” language was used
  - Removal of repetitive or outdated language
  - Removal of provisions preventing the implementation of periodic assessment of membership status
  - Use of current bylaws as base for proposal rather than “approved not yet implemented” version since do not expect the Islet program requirements to be implemented before implementation of this proposal
  - Update of section title language and other language for consistency between Appendices
  - Evaluation of use of language that states that certain documentation must be “available upon request” for consistency in use in all Appendices
- Appendix D.2.B. Transplant Program Key Personnel & C. Surgeon and Physician Coverage (Program Coverage Plan)
  - Removal of requirement for designation of a transplant program director
  - Consolidation of provisions related to changes in key personnel
  - Removal of the requirement for new primary surgeons and physicians to submit an assessment of all physicians and surgeons
  - Removal of section limiting evaluation of primary surgeon and physician qualifications to when there is a change in primary surgeon or primary physician
  - Addition of language clarifying program responsibilities if they do not have all required key personnel
  - Reorganization of Program Coverage Plan requirements for clarity
  - Request for feedback on program coverage plan requirement that a surgeon or physician may not be on call simultaneously for two programs more than 30 miles apart
- D.2.D. Other Transplant Program Personnel
  - Addition of primary program administrator and primary data coordinator as required personnel
  - Revision to transplant pharmacist subsection
  - Removal of lists of potential responsibilities from all subsections since these are not requirements. Includes a plan to provide this information in a resource made available on OPTN website
- Other Transplant Program Requirement Revisions
  - D.2.E Vascularized Organ Transplants Not Covered by OPTN Requirements revision for clarity and to update language around multi-visceral transplants
  - Removal of relocation or transfer of a designated transplant program
  - Clarification in D.3 Requirements for Transplant Hospital Members that OPTN requirements are not required to be approved as a member or designated transplant program, but that failure to comply could result in action by the MPSC

Summary of Discussion:

**Decision #1:** The Committee supported additional consideration by the Membership Requirements Revisions Subcommittee of alternative language to “substantial changes” in the program coverage plan for purposes of patient and OPTN notification.

**Decision #2:** The Committee supported requesting feedback from the Transplant Administrators Committee on an appropriate definition for the role of the Primary Program Administrator.

**Decision #1:** The Committee supported additional consideration by the Membership Requirements Revisions Subcommittee of alternative language to “substantial changes” in the program coverage plan for purposes of patient and OPTN notification.

Staff requested feedback from the Committee on the provision within Appendix D.2.C requiring transplant programs to notify patients when there are “substantial changes” in program coverage, as well as the lack of a requirement for OPTN notification of “substantial” program coverage plan changes. Considerations for discussion included thinking of how substantial changes could be defined, when notification to patients and/or the OPTN should be required, common questions around the current requirement for patient notification of “substantial changes” received from transplant hospital members, and whether more specific language could result in unintentional exclusion of scenarios where notification should be required.

The Committee concurred that the existing “substantial changes” verbiage does not make it clear when patients must be notified, and that scenarios requiring patient notification should also require OPTN notification. The discussion of scenarios requiring notification focused on increases versus decreases in surgeon and/or physician capacity, especially decreases to single surgeon or physician; defining single surgeon and physician programs; and requirements for surgeons and physicians designated as additional transplant surgeons or physicians.

The Committee decided to have the Membership Requirements Revision Subcommittee continue discussion of defining substantial changes and develop specific language for inclusion in the proposal for notification to the OPTN as well as patients.

**Decision #2:** The Committee supported requesting feedback from the Transplant Administrators Committee on an appropriate definition for the role of the primary program administrator.

Staff requested the Committee’s feedback on defining the primary program administrator role that has been added as required Other Transplant Program Personnel for transplant programs. Staff explained that this bylaw addition would align the bylaws with the long standing OPTN practice of requiring transplant programs to provide a name for the primary program administrator as a contact. Previous Committee discussion did not lead to a satisfactory definition due to lack of consensus, in part due to the variability in responsibilities of primary program administrators from program to program. Future considerations for discussion included ensuring the primary program administrator definition does not conflict with the defined role of the OPTN representative to act for the member on all OPTN business and defining the role in terms of the OPTN rather than hospital job descriptions.

The Committee requested that feedback be solicited from the Transplant Administrators Committee to help define the role. Staff will do so and present feedback at a future meeting.

## Next Steps

Staff outlined the next steps for the project, which include subcommittee discussion of:

- Key personnel change sections of Appendix D
- Defining “substantial changes” to program coverage
- Gathering feedback from the Transplant Administrators Committee on an appropriate definition of primary program administrator in the context of the OPTN
- Development of recommendations on how to address transplant professional misconduct in bylaws or policy

The proposal is targeted for a full Committee vote on release of the proposal for Summer 2024 public comment at the May 21, 2024, MPSC meeting. A representative of the Histocompatibility Committee will also present on the draft proposal for revisions to *Appendix C: Membership Requirements for Histocompatibility* at the May 21, 2024, meeting.

## **2. Compliance Issues**

The Committee continued its review and monitoring for appropriate implementation of OPTN Policy 3.7.D (*Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations*). As of January 4, 2024, all kidney programs have submitted an attestation that the policy requirements were met. HRSA raised concerns and requested that the Executive Committee discuss potential further action for members who submitted an attestation but did not submit (or submitted few) modifications while having Black/African American candidates on their lists.

The MPSC discussed how to address members who submitted attestations but had few modifications and decided to send an inquiry to programs in the lower 25th percentile, who submitted modifications for fewer than 20% of their patients listed as Black/African American. Programs identified by this data review were asked to provide a template of notifications with dates, the process for evaluating eligible patients, the time and effort required for the policy implementation, the evaluation process for dialysis patients, and an explanation for the low number of modifications.

After the 30-day deadline, 56 members received inquiries, 48 responses were received on time, and 8 were late. The last 3 late responses were received before the MPSC meeting but were not able to be posted so they were included on the discussion agenda. The OPTN contractor staff reviewed the outcomes from subcommittee reviews and determined that 41 programs could be closed with no action on a consent agenda and that 15 programs needed further discussion. The consent agenda was approved by a vote of 25 Yes, 0 No, 0 Abstentions. The staff presented 15 cases to the committee for discussion and it agreed to close 4 with no action and to request additional information from 11.

The Committee also reviewed a transplant hospital peer visit report including the original case details, documentation submissions, and subcommittee recommendations. The Committee plans to continue to monitor it based on recommendations in the Peer Visit report. The MPSC asked the hospital to submit their Plan for Quality Improvement (PQI) in response to the Peer Visit report and approved the peer report, including the peer visit team’s findings and recommendations;

### **3. Report of Investigative Activities**

OPTN Contractor staff supplied a summary of investigative activity from February 2024. The report included the number of reports staff received, modes of receipt, reporting and subject, member type, general classification of the issue, and how many cases staff referred to the MPSC, closed without sending to the MPSC, or are still actively investigating. Most of the report focused on reports that staff did not refer to the full MPSC for review, and the reasons why. Reasons for non-referral included an inability to substantiate the claim, lack of patient safety issue or policy noncompliance.

### **4. Membership Issues**

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 and applications are presented to the MPSC members on either a consent or discussion agenda. The Committee reviewed and approved the consent agenda by a vote of 23 For, 0 Against, and 1 Abstentions.

The Committee considered the applications and other actions listed below and will ask the Board of Directors to approve the following recommendations during the June 2024 meeting as listed below and in Exhibit A, hereto entitled "Members, Programs, and Components - Recommended for Action by the Board of Directors."

- Approve 1 Program Reactivation
- Approve 1 Component Reactivation
- Approve 1 New Laboratory
- Approve 4 Non-institutional membership renewals

The Committee also reviewed and approved the following program related actions and personnel changes.

- 12 applications for changes in key personnel in Transplant Programs or Components
- 4 applications for new key personnel in Histocompatibility Laboratories

The Committee received notice of member and program withdrawals OPO key.

The Committee also received a summary of an earlier informal discussion regarding a lung transplant program pediatric component using the Alternative Pathway for predominantly pediatric programs.

### **Upcoming Meetings**

- Apr 23, 2024, 3-6pm, ET, Conference Call
- May 21, 2024, 2-5pm, ET, Conference Call
- June 28, 2024, 2-5pm, ET, Conference Call
- July 23-25, 2024, Detroit

## Attendance

- **Committee Members**
  - Alan Betensley
  - Kristine Browning
  - Anil Chandraker
  - Chad Ezzell
  - Robert Fontana
  - Roshan George
  - Darla Granger
  - Lafaine Grant
  - Shelley Hall
  - Robert Harland
  - Rich Hasz
  - Kyle Herber
  - Victoria Hunter
  - Michelle James
  - Catherine Kling
  - Peter Lalli
  - Scott Lindberg
  - Melinda Locklear
  - Maricar Malinis
  - Amit Mathur
  - Deborah McRann
  - Nancy Metzler
  - Cliff Miles
  - Saeed Mohammad
  - Regina Palke
  - Martha Pavlakis
  - Deidre Sawinski
  - Malay Shah
  - J. David Vega
  - Mark Wakefield
- **HRSA Representatives**
  - Marilyn Levi
  - Arjun Naik
  - Kala Rochelle
- **SRTR Staff**
  - Jonathan Miller
  - Jon Snyder
  - Bryn Thompson
- **UNOS Staff**
  - Robert Albertson
  - Anne Ailor
  - Stephanie Anderson
  - Sally Aungier
  - Matt Belton
  - Nadine Cahalan

- Elinor Carmona
  - Katie Favaro
  - Liz Friddell
  - Jasmine Gaines
  - Caroline Hales
  - Asia Harden
  - Houlder Hudgins
  - Elias Khalil
  - Lee Ann Kontos
  - Krissy Laurie
  - Jon McCue
  - Amy Minkler
  - Rebecca Murdock
  - Heather Neil
  - Delaney Nilles
  - Julie Nolan
  - Jacqui O'Keefe
  - Laura Schmitt
  - Sharon Shepherd
  - Chris Stadolnik
  - Sarah Stevenson
  - Stephon Thelwell
  - Marta Waris
  - Betsy Warnick
  - Trevi Wilson
  - Claudia Woisard
  - Emily Womble
  - Amanda Young
- **Other Attendees**
    - None