

**OPTN Membership and Professional Standards Committee
Membership Requirements Revision Subcommittee
Meeting Summary
October 2, 2020
Conference Call**

Clifford Miles, MD, Chair

Introduction

The Membership Requirements Revision Subcommittee of the Membership and Professional Standards Committee met by conference call and GoToTraining on October 2, 2020, to discuss the following agenda items:

1. Overview of Project Progress
2. Appendix D Topics Review
3. Transplant Program Key Personnel Format
4. Next Steps
5. The following is a summary of the Subcommittee's discussions.

1. Overview of Project Progress

Staff reviewed the agenda for the meeting and provided an overview of feedback from the regional meetings. During each of those meetings, the regional representative presented the MPSC's two projects and requested feedback from the attendees. There was a lot of expression of support for the goals of the project. Additionally, there were comments about the difficulty of obtaining recommendation letters and locating fellowship logs. The subcommittee aims to look at more current training and experience to address those challenges expressed at the regional meetings.

2. Appendix D Topics Review

- Relocation of Transplant Programs – The Subcommittee reviewed background information on the provision for relocation or transfer of a designated transplant program. The provision was added to the bylaws in 1989 in response to a specific situation where a transplant program wanted to move from one-member hospital to another member hospital in the same metropolitan area. In November 2019, the MPSC reviewed the topic, but did not come to a consensus. Several issues have been identified with this provision including regulatory issues of transferring patient data. The subcommittee discussed if this revision should be removed or retained in the bylaws. The Subcommittee reviewed information, provided feedback, and made recommendations.

Subcommittee Discussion:

Subcommittee members supported removal of this section noting that the OPTN is moving towards a more streamlined membership application and requests under this provision are rare, occurring only 2-3 times since 1989. Concerns were also noted that the privacy and Health Insurance Portability and Accountability Act (HIPPA) rules would make a wholesale relocation of a program difficult. Subcommittee members supported requiring the submission of a full transplant program application in these situations.

Decision: The Subcommittee recommended that the provision should be removed.

- Inactivation, Withdrawal, and Termination of Transplant Programs – The Subcommittee received an overview of the provisions in Appendix K regarding inactivation, withdrawal, and termination of transplant programs. The content of Appendix K will be moved to Appendix D since Appendix K currently addresses only the inactivation, withdrawal and termination of transplant programs. Moving these topics into Appendix D will consolidate all of the general bylaw sections that affect transplant hospitals and transplant programs into one Appendix. A number of inconsistencies between the provisions on program inactivation have been identified. The Subcommittee discussed whether the current structure of Appendix K should be maintained or if a new structure should be developed.

Subcommittee Discussion:

In response to questions about the difference between waiting list and program inactivation, staff noted that waiting list inactivation allows programs to turn off their waiting list through UNetsm, whereas for program inactivation, the program notifies the OPTN, and the program status is made inactive and the waiting list is turned off from the OPTN side. When a program inactivates, it must request MPSC approval to reactivate while for a waiting list inactivation, the program can turn their waiting list back on without notification to or intervention by the MPSC.

In response to Subcommittee members' questions regarding the responsibility of programs with a single surgeon or single physician to notify patients of waiting list inactivity, staff noted that the current bylaws require that a program advise its patients during the evaluation process that the program is a single surgeon/physician program or at any time that a program becomes a single surgeon/physician program. For monitoring purposes, an inquiry is sent to programs who have met the thresholds over the last calendar year to request documentation that patient notification occurred.

Several subcommittee members supported a requirement for notification of the OPTN anytime there would be a requirement to notify patients rather than doing a retrospective review to determine if patients were notified, particularly if the waiting list is turned off for more than 28 days during a calendar year. That would mean that for the patients on the waiting list did not have an opportunity to get an offer for approximately 1/12 of the year patients did not. On the other hand, if we make it too burdensome, programs will either code patients to status 7 (inactive) or not turn off the waiting list.

Subcommittee members also noted that functional inactivity requirements should be considered during the discussion of inactivation as well since it evaluates patient access to transplant. Functional inactivity thresholds are lenient requiring only one transplant every three months for kidney programs, for example.

The subcommittee was more concerned about the interplay between short-term/waiting list inactivation, long-term/program inactivation and functional inactivity than with the provisions around withdrawal or termination. The Committee should focus on these areas. One subcommittee member noted that he appreciates the inclusion of clear, transparent thresholds in the bylaws but recognizes it is a challenge to monitor.

A subcommittee member requested data on programs that may be changing 100% of their patients to status 7 rather than turning off their waiting list. Also, are there programs that refusing all organs for a particular period of time or using refusal code for "surgeon not available" for significant amount of time like a week or two weeks? Many programs do not use that code. Staff responded that we could look into getting data for the committee to review. Another subcommittee member responded that there is a difference between looking at inactivity and trying to drill down into

refusal codes. There are differences in how aggressive programs are so seems like it would chasing down a rabbit hole to look at refusal codes when there are going to be natural variations in practice patterns. Programs that are approved to do a certain type of organ transplant but are not performing those transplants looking at not only overall functional inactivity but also living donor transplants.

The subcommittee chair stated that based on the comments by the subcommittee, we need to retain oversight of inactivity beyond the scope of functional inactivity. How we phrase and oversee compliance needs more thought.

Additional discussion of this topic is planned for the MPSC meeting in October.

3. Transplant Program Key Personnel Format

The Subcommittee reviewed key personnel topics discussed during the July and August MPSC meetings. The subcommittee will initially address topics that did not get a consensus from the MPSC to include: board certification, fellowship and pathways, one person serving the role of surgeon and physician at two different hospitals, letters of reference and recommendations, and physician observations of procurements and transplants.

- Board Certification, Fellowship & Pathways: According to a poll conducted of the MPSC members, there was disagreement as to whether board certification should be required for primary surgeons and physicians. During the MPSC discussion, there was mention of fellowship training serving as a possible alternative to board certification. Based on the discussion at the MPSC meeting in July and August, the evaluation of board certification requirements, fellowships and the consolidation of the pathways for surgeons and physicians will be discussed together. The subcommittee reviewed the current pathways for approval of primary physician and surgeon.

Subcommittee Discussion:

Several Subcommittee members noted that the OPTN has a responsibility to patients to ensure that surgeons and physicians are qualified. Board certification for individuals trained in the United States and Canada is a minimum requirement for qualification that serves as a base threshold for competence. Some members felt that most board certification was unrelated to transplant and should rely on transplant fellowships and experience, although a Subcommittee member noted that fellowships are not mandatory. Subcommittee members clearly supported the inclusion of an alternative for individuals who are unable to gain board certification based on training outside of the United States and Canada. The next step is for the subcommittee to be thinking about the development of this pathway.

The Subcommittee expressed support for the inclusion of an OPTN orientation curriculum requirement that would provide knowledge regarding the United States transplant system and the role and responsibilities of the key personnel to both those individuals who have trained or gained experience outside the United States and those who are being proposed as a primary for the first time. Staff responded that a majority (94%) of the MPSC supported the development and requirement of an OPTN orientation and curriculum at the July meeting.

The subcommittee responded to polls regarding the retention of board certification as a requirement for transplant program key personnel.

Table 1: Results of poll on whether to retain requirements for board certification and focus on an alternative pathway for foreign-trained individuals.

Board Certification should be retained in requirements and focus on pathway for foreign trained.	
Strongly Agree	36%
Agree	36%
Neutral	14%
Disagree	14%
Strongly Disagree	0%

Table 2: Results of poll on whether to require maintenance of board certification when move to new program or for periodic reassessment of compliance with membership requirements.

Require maintenance of current board certification when move to new program or for reassessment.	
Strongly Agree	21%
Agree	43%
Neutral	21%
Disagree	14%
Strongly Disagree	0%

- **Consolidation of Pathways:** The Subcommittee reviewed the current pathways for physicians and surgeons to become primaries. Staff provided an example of a single pathway using the current intestine transplant program key personnel requirements. The Subcommittee provided feedback on whether they think it is important to consolidate pathways to include a combination of fellowship and post-fellowship experience requirements.

Subcommittee Discussion:

Subcommittee members supported consolidation. One Subcommittee member expressed concern about a requirement for currency for procurements. Many of the older surgeons will have procurements from years ago and may not have procurements that are more recent. The subcommittee member suggested requiring procurement experience only for applicants who have not previously served as primary surgeons.

The subcommittee responded to polls regarding consolidation of the multiple pathways for key personnel and the transplant surgeon requirement for procurements.

Table 3: Results of poll on whether to consolidate multiple pathways to qualify and accept fellowship, clinical or combined fellowship and clinical experience.

Consolidate pathways to accept fellowship or clinical or combined fellowship/clinical experience.	
Strongly Agree	38%
Agree	62%
Neutral	0%
Disagree	0%
Strongly Disagree	0%

Table 4: Results of poll on whether procurements should only be required for proposed primary surgeons that had not previously served as a primary.

Procurements only required for proposed primaries that have not previously served as primary.	
Strongly Agree	36%
Agree	50%
Neutral	7%
Disagree	7%
Strongly Disagree	0%

4. Next Steps

The Subcommittee will discuss the topic of recommendation letters at the next subcommittee meeting scheduled for October 20, 2020.

Upcoming Meetings

- Membership Requirements Revision Subcommittee Call - October 20, 2020, 3 - 5 pm EST
- MPSC Meeting – October 27 – 29, 2020 EST
- Membership Requirements Revision Subcommittee Call – November 6, 2020, 2 – 4 pm EST
- MPSC Conference Call – November 9, 2020, 2- 4 pm EST
- Membership Requirements Revision Subcommittee Call – November 20, 2020, 11:00 am - 1:00 pm EST
- Membership Requirements Revision Subcommittee Call – December 2, 2020, 1 - 3 pm EST
- MPSC Conference Call – December 15, 2020, 1 – 3 pm EST – Final Approval of public comment proposal

Attendance

- **Subcommittee Members**
 - Clifford D. Miles (Subcommittee Chair)
 - Christina D. Bishop
 - Theresa M. Daly
 - Maryjane A. Farr
 - PJ Geraghty
 - Edward F. Hollinger
 - Ian R. Jamieson
 - Heung Bae Kim
 - Jon A. Kobashigawa
 - Anne M. Krueger
 - Saeed Mohammad
 - Nicole A. Pilch
 - Scott C. Silvestry
 - Lisa M. Stocks
 - Parsia A. Vagefi
 - Gebhard Wagener
 - Rajat Walia
- **HRSA Representatives**
 - Marilyn E. Levi
 - Arjun U. Naik
 - Raelene Skerda
- **UNOS Staff**
 - Sally Aungier
 - Matt Belton
 - Nicole Benjamin
 - Tameka Bland
 - Demi Emmanouil
 - Katie Favaro
 - Michelle Furjes
 - Amanda Gurin
 - Asia Harris
 - Krissy Laurie
 - Sandy Miller
 - Liz Robbins Callahan
 - Sharon Shepherd
 - Leah Slife
 - Olivia Taylor
 - Roger Vacovsky
- **Other Attendees**
 - None