

**OPTN Membership & Professional Standards Committee
Membership Requirements Revision Subcommittee
Meeting Summary
August 31, 2020
Conference Call**

Clifford Miles, M.D., Subcommittee Chair

Introduction

The Membership Requirements Revision Subcommittee (the Subcommittee) of the Membership and Professional Standards Committee met by conference call and GoToTraining on August 31, 2020, to discuss the following agenda items:

1. Overview of Project Progress
2. Continuation of Appendix D Review
3. Transplant Program Key Personnel Format
4. Next Steps

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

1. Overview of Project Progress

Staff gave an overview of the Membership Requirements Revision Project and provided an expected timeline of project goals. The project is expected to be completed in two phases. Phase 1 includes the review and revision of the first four Appendices (Appendix A – D) in the bylaws, and development of a concept paper of proposed new format for transplant program key personnel. The MPSC plans to request public comment on the proposal for revisions to the first four appendices and the concept paper during the winter public comment cycle that starts in late January 2021. The goal of Phase 2 is to apply the new format for transplant program key personnel to the organ specific bylaw appendices.

2. Continuation of Appendix D Review

The Subcommittee reviewed possible revisions to sections of Appendix D.

- **Appendix D.3 Designated Transplant Program Requirement including multi -visceral transplant language:** The Subcommittee discussed the addition of language in Appendix D.3 to clearly state that a transplant program must receive program approval for specific organ types in order to list candidates and receive offers for that organ type. This language tracks the Final Rule § 121.9 that states that a transplant program meet OPTN membership requirements “to receive organs for transplantation.”

Decision: the Subcommittee recommended adding this language.

The Subcommittee also discussed revising the multi-visceral language contained in Appendix D.3. Staff provided the history of the provision. The multi-visceral language was originally inserted into the bylaws in 2005 and the stated purpose was to allow for inclusion of a pancreas in a multi-visceral transplant for technical reasons without gaining approval for pancreas designated transplant program. “Kidney” was added to the definition of multi-visceral in

Appendix M: Definitions, which was not intended in the original proposal in 2005. Finally, at the time of the insertion of this language, the bylaws did not contain specific requirements for intestine transplant programs.

Recommendation: Following discussion, the Subcommittee recommended retaining language regarding multi-visceral transplants in the bylaws but revising it to require designated intestine and liver transplant programs and clearly noting the ability to include a pancreas for technical reasons only without an approved designated pancreas transplant program. The Subcommittee also supported revising the definition of “multi-visceral” in Appendix M to remove “kidney.”

- **D.8 Assessment of Physicians and Surgeons & D.11 Investigation of Transplant Personnel:** Section D.8 *Primary Transplant Surgeon and Physician* includes a paragraph that requires each primary surgeon and primary physician to submit an assessment of physicians and surgeons in the program. In addition, section D.11 *Investigation of Transplant Personnel* provides the MPSC an option to request that a transplant hospital member investigate an individual’s role in a matter reviewed or currently under review by the MPSC. These requirements, as well as the requirement for letters of recommendation for primary surgeons and physicians, were added to the bylaws in 2007 and, based on the briefing paper, were an effort to “address misconduct for which an individual physician or surgeon was uniquely responsible.” The stated purpose in the briefing paper was to “prevent an individual physician or surgeon who has been involved in non-compliant activity at one institution from continuing that or similar activity at the same or another institution.” Currently, under the assessment provision in D.8, new primary surgeons or primary physicians are required to sign a certification that they have performed an assessment of each surgeon and physician.

Decision: The Subcommittee found that the information required to do the assessment is rarely available to the new primary and the Subcommittee found that the provision does not serve its intended purpose. Therefore, the Subcommittee recommended that the assessment paragraph be removed from the bylaws. The Subcommittee supported retaining the provision in D.11 for investigation of transplant personnel finding that there may be instances where it is appropriate and necessary to request that a hospital investigate the actions of an individual in connection with a matter under review by the MPSC, particularly where patient safety is involved. The Subcommittee requested that the language be simplified and a reference to an MPSC defined timeline be added. The Subcommittee also considered a suggestion for a requirement to notify the OPTN of any state or federal license actions related to program personnel. The Subcommittee rejected this suggestion, noting that it would be difficult to monitor without specific language as to what should be reported and that these matters are best left to the program or hospital.

- **D.9 Changes in Key Transplant Program Personnel:** The Subcommittee reviewed a reorganization of this section to consolidate multiple subsections, including a question as to whether or not to retain the reinstatement provision that allowed an individual who had been a primary at the program to return within one year without submitting a full application. The reinstatement provision is used most often in cases of temporary medical or maternity/paternity leave, deployment and sabbaticals.

Decision: The Subcommittee supported the reorganization and retaining the reinstatement provision. They requested that use of “departure” in the reinstatement provision be revised to encompass all situations where an individual might be proposed as the primary within one year of moving out of the position.

- **D.10 Other Transplant Program Personnel:** The Subcommittee reviewed a revised Other Transplant Program Personnel section that incorporated a number of recommendations from the MPSC and the Subcommittee, including.
 - Primary program administrator and data coordinator were added to the section with no specific qualifications since individuals move into these positions with varying backgrounds.
 - “Should” was replaced with “must” where applicable in the section.
 - Clinical Pharmacist was changed to a required position.
 - In addition, the sections that note who each role will work with as part of the team and the responsibilities of each of the roles were removed and will be included in a resource document available on the compliance page of the OPTN website.

Decision: The Subcommittee supported these revisions.

The Subcommittee also reviewed the section that lists required medical expert support. The current provision includes only the medical expert support contained in the Final Rule. A number of suggestions were made to add other expertise. As the Subcommittee was considering additions, concern was raised that it would not be possible to create an exhaustive list of all expertise that may be required.

Decision: The Subcommittee concluded that it might be best to default to the list contained in the Final Rule rather than creating an exhaustive list and requested that the issue be brought to the full MPSC for review and decision.

- **Addition of on-site definition to Appendix M:** The Subcommittee discussed the use of the term “on-site” in the bylaws as it relates to transplant program key personnel. The MPSC has had difficulty coming up with an alternative for that term. The MPSC Subcommittee discussed the possibility of inserting a definition of “on-site” into Appendix M. A Subcommittee member noted that it is a good idea to add a definition, but the definition must align with the Final Rule. Another Subcommittee member suggested using the language that CMS uses, which articulates living within a certain radius of the transplant hospital. Another Subcommittee member did not agree and suggested that “on-site” means that “the individual is physically capable of performing transplant related activities at the center.” A Subcommittee member stated that the intent of this bylaw is to have primaries available to help when there is a problem while another Subcommittee member noted that he believes it may be easier to describe “on-site” as the program having a coverage schedule. The current use of “on-site” in the bylaws means that they are spending the majority of their time at that hospital and does not address the use of additional surgeons or physicians. Staff noted that the bylaws include a separate provision that requires a coverage plan that includes the use of additional surgeons and physicians to provide 24/7 coverage to the program. A definition of “on-site” would need to address the expectation for the primary surgeon and primary physician. The Subcommittee requested that the topic be brought back to the full MPSC and that the staff summary include information on all uses of “on-site” and the program coverage plan. The staff summary will also include examples of situations that the MPSC has suggested would not be compliant with the term “on-site.”

3. Transplant Program Key Personnel Format

The Subcommittee did not have time for this discussion.

Upcoming Meetings

- September 29, 2020: MPSC Meeting
- October 2, 2020: Membership Requirements Revision Subcommittee
- October 27-29, 2020: MPSC Meeting
- November 6, 2020: Membership Requirements Revision Subcommittee
- November 9, 2020: MPSC Meeting
- December 2, 2020: Membership Requirements Revision Subcommittee
- December 15, 2020: MPSC Meeting

Attendance

- **Subcommittee Members**
 - Clifford Miles
 - Ian Jamieson
 - Christina Bishop
 - Theresa Daly
 - Maryjane Farr
 - Jonathan Fridell
 - PJ Geraghty
 - Edward Hollinger
 - Jon Kobashigawa
 - Anne Krueger
 - Saeed Mohammad
 - Nicole Pilch
 - Lisa Stocks
 - Parsia Vagefi
 - Gebhard Wagener
 - Rajat Walia
- **HRSA Representatives**
 - Marilyn Levi
 - Arjun Naik
 - Raelene Skerda
- **SRTR Staff**
 - None
- **UNOS Staff**
 - Sharon Shepherd
 - Sally Aungier
 - Matt Belton
 - Demi Emmanouil
 - Katie Favaro
 - Amanda Gurin
 - Asia Harris
 - Krissy Laurie
 - Sandy Miller
 - Jacqueline O'Keefe
 - Liz Robbins Callahan
 - Leah Slife
 - Olivia Taylor
 - Roger Vacovsky
 - Gabe Vece
 - Marta Waris
- **Other Attendees**
 - None