OPTN Membership and Professional Standards Committee
Membership Requirements Revision Subcommittee
Meeting Summary
April 5, 2024
Conference Call

Nancy Metzler, Chair

Introduction

The MPSC Membership Requirements Revision Subcommittee met in open session virtually via Webex on April 5, 2024, to discuss the following agenda items:

1. Potential changes to Membership Requirements Revision Proposal
    a. Key personnel reinstatement
    b. Substantial changes to program coverage plan
    c. Primary Data Coordinator requirement – consistency between OPO and transplant program requirements
2. Next Steps

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

1. Potential Changes to Membership Requirements Revision Proposal

a. Key personnel reinstatement

OPTN staff outlined Appendix D.2.B.1. *Changes in Transplant Program Key Personnel* definitions of change in key personnel, which includes departure of the primary surgeon or primary physician, change in position from primary surgeon or primary physician to an additional surgeon or physician, temporary leave for greater than 30 days, or reinstatement of the previously designated primary surgeon or primary physician.

At the March 5-7, MPSC meeting, some members raised concerns regarding the burden placed on transplant programs by the OPTN consideration of key personnel temporary leave for more than 30 days as a triggering event for a key personnel change, particularly in the context of maternity and medical leave. The MPSC discussion included a suggestion of a preemptive approval process for backup individuals who would potentially serve in a key personnel role in an interim capacity while the individual designated in that key personnel role took temporary leave.

Staff provided the Subcommittee with the context for the 30-day timeframe, noting that it is the time period identified by the Committee as the longest a program could safely function without a primary. Use of the 30-day timeframe is consistent with both key personnel change application submission timeline requirements and maximum time a program can remain active without a complete key personnel change application or a Committee approved extension. The Committee previously discussed the potential of a preemptive approval of backup individuals during initial development of the proposal and determined that it was not feasible, as the qualifications for the primary should be determined at the time that they are proposed as a primary, particularly noting the importance of currency.

Staff gave an overview of the process for reinstatement of key personnel, which allows key personnel who return to the same position at the same program within 1 year to apply for approval with limited

documentation rather than a full key personnel change application. The overview included proposed changes that reorganize the language outlining the written documentation requirements for clarity and consistency. Staff requested feedback on whether the improvements to the reinstatement process could reduce the administrative burden when key personnel take temporary leave. The Subcommittee did not have any recommendations for further changes to reinstatement requirements.

Summary of Discussion:

Decision #1: The Subcommittee supports retaining a consistent 30-day limit for a program to be without key personnel.

Decision #2: The Subcommittee supports the consideration of limited requirements for short term interim service in key personnel positions when a designated primary takes temporary leave as part of the future revisions to key personnel training and experience requirements.

Decision #1: The Subcommittee supports retaining a consistent 30-day limit for a program to be without key personnel.

The Subcommittee discussed potentially raising the 30-day threshold for temporary leave to a longer time period such as 90 days, considering that it is common for many types of temporary leave to have a duration of longer than 30 days, including maternity and other types of medical leave.

Staff noted the importance of consistency in maximum allowable timeframes for a program to be without an approved primary on-site, no matter the situation that leads to the lack of primary, and that changing the timeframe from 30 days to 90 days for temporary leave would require changing the timeframe across the board for all situations.

The Subcommittee agreed to retain the 30-day timeframe as currently written.

Decision #2: The Subcommittee supports the consideration of limited requirements for short term interim service in key personnel positions when a designated primary takes temporary leave as part of the future revisions to key personnel training and experience requirements.

The Subcommittee discussed the need for a balance between ensuring patient safety through requirements for on-site, qualified personnel and reasonableness of the administrative process in the case of the key personnel temporary leave. The Subcommittee noted the material difference between the departure of key personnel and temporary leave of key personnel, including the way transplant hospital processes differ when it comes to putting new transplant program leadership in place versus handling temporary leave.

Members expressed support for further discussion of the possibility of a bylaw provision allowing for an individual to gain approval for short term, interim service in a key personnel position based on limited requirements in cases when a fully approved primary takes temporary leave.

b. Substantial changes to program coverage plan

OPTN staff reviewed the language in Appendix D.2.C. *Surgeon and Physician Coverage (Program Coverage Plan)* requiring that transplant programs "provide patients a written summary of the program coverage plan . . . when there are any substantial changes in the program or its personnel." The bylaw further requires that "[a] transplant program must inform its patients if it is staffed by a single surgeon or physician and acknowledge the potential unavailability of these individuals, which could affect patient care and the ability to accept organ offers, procurement, and transplantation." Requirements state that the primary surgeon and primary physician must submit a detailed Program Coverage Plan to the OPTN

at time of application to become a program and if there is a key personnel change application but does not require notification to the OPTN when there are substantial changes to the Program Coverage Plan or if the program becomes a single surgeon or single physician program.

At the March 29 MPSC meeting, the Committee discussed frequent OPTN member confusion about the definition of "substantial changes" to the program coverage plan and the lack of a requirement of notification to the OPTN. The Committee supported the inclusion of a requirement that the transplant programs notify the OPTN whenever patients would need to be notified and supported clarification of what changes to the Program Coverage Plan would require notification to patients and the OPTN, referring the issue to the Subcommittee for discussion.

OPTN staff presented a list of frequent member questions surrounding the definition of "substantial changes" to the Subcommittee. The Subcommittee considered the scenario presented in each question and discussed how to define "substantial changes" that would require programs to notify patients and the OPTN of changes in the Program Coverage Plan.

Summary of Discussion:

Decision #3: The Subcommittee confirmed support for notification to the OPTN whenever a transplant program is required to notify patients.

Decision #4: The Subcommittee decided to provide two options for replacement language for "substantial changes" to the MPSC for decision.

Decision #5: The Subcommittee did not reach a consensus on whether to pursue development of expanded, organ-specific requirements for additional surgeon and physician designation as part of future revisions to key personnel training and experience requirements so this issue will be revisited in phase 2 of the project.

Decision #3: The Subcommittee confirmed support for notification to the OPTN whenever a transplant program is required to notify patients.

The Subcommittee chair commented that it is important that the OPTN be notified when patients are notified to allow for monitoring of transplant program compliance with notification requirements, and for information about substantial changes in coverage to inform case reviews. The other members of the Subcommittee agreed.

Decision #4: The Subcommittee decided to provide two options for replacement language for "substantial changes" to the MPSC for to consider.

The scenarios discussed by the Subcommittee included personnel changes that result in: a program moving to or from a single surgeon or single physician program, a material change in the program's ability to transplant or provide care, the inability of the program to accept organ offers 24/7/365, or a substantially decreased ability of the program to accept the same number of offers or perform the same volume of transplants.

Themes of the discussion included the distinction between when notification should be required versus when it would be recommended as a beneficial practice, the risk of causing confusion for patients by requiring notification of changes in key personnel that have no impact to patient care or experience, what program coverage changes are relevant to patient decisions on where they are listed, and how to clarify notification requirements in a way that enables monitoring of compliance with requirements.

The Subcommittee did not reach a consensus on clarifying language to supplement or replace "substantial changes," and requested that staff bring options to the April 17 Subcommittee conference call.

Decision #5: The Subcommittee did not reach a consensus on whether to pursue development of expanded, organ-specific requirements for additional surgeon and physician designation as part of the future revisions to key personnel training and experience requirements so this issue will be revisited in phase 2 of the project.

The Subcommittee discussed the concerns raised at the March 29 MPSC meeting over criteria that must be met to designate "additional" surgeons and physicians, specifically that current requirements do not provide enough information to ascertain whether these individuals are meaningfully contributing to transplant program coverage, and how that relates to assessing whether a program is a single surgeon or single physician program. The Subcommittee did not reach a consensus on whether to pursue development of expanded, organ-specific requirements for additional surgeon and physician designation as part of the next phase revisions to key personnel training and experience requirements. Staff informed the Subcommittee of past discussion of an OPTN system enhancement that would allow for better tracking of all surgeons that performed a particular transplant, which could potentially support verification of whether individuals listed as additional surgeons are actively performing transplants, for which the Subcommittee expressed support. Members noted that this enhancement could have many uses, including verification of surgeon logs.

c. Primary Data Coordinator Requirement

OPTN staff gave an overview of the proposal's addition of language requiring that a Primary Data Coordinator be named for transplant programs. The position was added to align bylaws with existing OPTN practice to require transplant programs, OPOs, and histocompatibility lab members to provide the name of a primary data coordinator. The original proposal did not include the addition of Primary Data Coordinator in Appendix B for OPOs or Appendix C for histocompatibility labs.

At the March 5–7 MPSC meeting, when the Committee was asked if a requirement for a Primary Data Coordinator for OPOs should be added to Appendix B, the Committee did not support the addition, citing the ability of the OPTN to require this without a corresponding bylaw requirement and the potential burden of a more complicated OPTN staff change process that would be created by adding it to the bylaws.

OPTN staff brought the issue to the Subcommittee for further consideration in light of concerns not previously raised with the MPSC about inconsistency in the bylaw requirements for different members, recommending that since transplant programs, OPOs, and histocompatibility labs are all currently required to designate a Primary Data Coordinator, the bylaw requirements should be consistent for all three member types. Staff clarified that inclusion of the requirement in the bylaws would not change the already existing practice that all three member types to complete a form to designate and make changes to the individual in this role.

Summary of Discussion:

Decision #6: The Subcommittee supports inclusion of the Primary Data Coordinator requirement for transplant hospital, OPO, and histocompatibility laboratory members and recommended inclusion of language requiring notification to the OPTN when the designated individual changes.

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The Subcommittee considered two options, to either include the requirement for Primary Data Coordinator in the bylaws for transplant programs, OPOs, and histocompatibility labs, or not including it for any of the three member types and maintaining the status quo. Members supported including the requirement for all three member types, noting the importance of members providing a point of contact to prevent delays in communication with the OPTN and the project goal of aligning bylaws with practice. Members commented on the need to add a requirement for notification of a change in the designated Primary Data Coordinator, citing concerns over communication difficulties stemming from lack of a designated contact potentially compounding patient safety issues.

1. Next Steps

OPTN staff will bring options for language to supplement or replace "substantial changes" in Appendix D.2.C. *Surgeon and Physician Coverage (Program Coverage Plan)* to the April 17 Subcommittee conference call, during which the Subcommittee will also discuss transplant professional misconduct. The Subcommittee's recommendations will be presented to the full Committee at the April 23 full committee meeting.

Upcoming Meetings

Subcommittee Conference Call, April 17, 2024, 1:00 – 3:00 pm ET

MPSC Meeting, April 23, 2024, 3:00 – 5:30 pm ET

Attendance

- **Subcommittee Members**
  - Nancy Metzler, Subcommittee Chair
  - Clifford Miles, Incoming Committee Chair
  - Chad Ezzell
  - Maricar Malinis
  - Mark Wakefield
- **HRSA Representatives**
  - Arjun Naik
  - James Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Jonathan Miller
  - Bryn Thompson
- **UNOS Staff**
  - Sharon Shepherd
  - Marta Waris
  - Sally Aungier
  - Matt Belton
  - Nadine Cahalan
  - Amanda Gurin
  - Houlder Hudgins
  - Krissy Laurie
  - Jasmine Gaines
- **Other Attendees**
  - None