

## **OPTN Membership and Professional Standards Committee (MPSC)**

### **Meeting Summary**

**November 9, 2020**

### **Conference Call with GoToTraining**

**Ian Jamieson, Chair**

**Heung Bae Kim, M.D., Vice Chair**

#### **Introduction**

The Membership and Professional Standards Committee (MPSC) met by conference call in open via Citrix GoToTraining on November 9, 2020, to discuss the following agenda items:

1. Membership Requirements Revision Project

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

#### **1. Membership Requirements Revision Project**

Staff provided an update on the Membership Requirements Revision Project progress since the committee last met. The bylaw proposal going out for public comment in January 2021 will include revisions to the following Appendices:

- Appendix A: Membership and Designated Transplant Program Application and Review
- Appendix B: Organ Procurement Organization (OPOs) Members
- Appendix D: Transplant Hospital Members and Designated Transplant Programs

In addition, a Request for Feedback will be distributed to gather input on the format of the transplant program key personal sections of the bylaws. The subcommittee discussed this part of the project during its meeting on November 6, and it plans to continue working on it during its next call on November 24. The goal is to have a draft paper for the subcommittee to review during its next subcommittee meeting. Additionally, the plan is to have the following sections ready for public comment for the Summer 2021 cycle.

- Appendix C: Histocompatibility Laboratory Members
- Transplant program inactivation, reactivation, and withdrawal/termination

The Committee discussed the following topics:

#### Appendix A – Application Review Process

Concern was raised previously about the current process for application review not meeting the Final Rule requirement for approval or rejection of an application within 90 days. Staff is drafting language that will describe a new process for the OPTN Board of Directors to delegate authority to approve applications to the OPTN MPSC. This change would allow the MPSC to take a final rather than an interim action that later had to be affirmed by the Board.

#### Definition of On-site and Program Coverage Plan:

The Committee discussed the current bylaws language that is based on the OPTN Final Rule §121.9 requirement that transplant surgeons and physicians be "on site." As drafted, the proposal would retain

bylaw language referencing “on site” within the program coverage plan. This language allows primary surgeons and physicians, along with additional surgeons and physicians (as defined in the bylaws) to provide on-site coverage. A suggestion had been made to remove the term “on site” from requirements for primary surgeons and physicians. However, the MPSC would need to determine language to describe the commitment expected for primary surgeons and physicians.

The MPSC provided the following feedback:

- The wording implies that the hospitals are responsible for credentialing the secondary surgeon and physician (i.e. additional). An MPSC member suggested that there are programs that do not have secondary personnel who could meet all of the primary requirements. Staff clarified that the additional surgeons and additional physicians do not need to meet the primary requirements. The bylaws require that the hospital credentialing committee need only certify that the additional surgeons and physicians have been accepted onto the hospitals staff to provide transplant services and that they can independently provide care for transplant patients.
- What sort of document do we ask programs to provide to patients if they have provided the MPSC with an explanation about their gaps in coverage? Another MPSC member noted that with the use of secondary coverage personnel, it is important to ensure that proper documentation and communication with patients is intact at all time. Staff responded that documentation is a part of the program’s coverage plan and that the bylaws require that transplant programs provide patients with a written summary of the Program Coverage Plan when they are placed on the waiting list and when there are any substantial changes in the program or its personnel. Staff does not perform any follow-up, such as a review of documentation during site surveys. This is something that could be added as an item to be verified during ongoing reviews.
- The MPSC should be careful about creating something that becomes a platform for additional regulation in other areas.

Staff asked the committee to address how we should deal with the use of “on site” in the sections for primary surgeon and primary physician in the bylaws. The Committee was presented with these three options for discussion:

- Option 1: Strike “and be on site at this hospital.” The MPSC would not be able to consider the person’s geographic location.
- Option 2: Leave as is and don’t define “on site”, which gives the MPSC some discretion
- Option 3: Replace “and be on site at this hospital” with “and the applicant’s residence is within X miles”

The Committee raised the following concerns:

- One MPSC member noted that he supports Option 3 and the surgeon/physician should be within 60 or 90 minutes. The focus should be on patient access to transplant.
- Another MPSC member remarked that he does not know what the term “on site” would be used for because the primary can handle most responsibilities without having to be on site.
- Another MPSC member is in support but wants the criteria to be easily definable (time versus miles) and applicable to all programs. Travel time/miles in a large metropolitan area may be very different when compared to more urban area.

Staff provided an example of how the term “on site” has been used in the past by the MPSC and requested feedback about what the location requirements should be for the primary. Staff shared a recent example of the rejection of an application for a primary surgeon who would be splitting time between two hospitals in non-contiguous states. The MPSC provided additional feedback and asked if it is acceptable for a primary to divide their time in this way?

An MPSC member agreed that the language currently in the bylaws has been helpful and has given the committee the latitude to make judgements based on the individual cases. He is opposed to adding a specific distance or travel time for the primaries and feels like it is already accounted for in the coverage plan. He does think that one of the surgeons needs to be in close proximity to the hospital, but it does not need to be the primary. He asked if there were cases where the current bylaws did not work.

Staff responded that there were no major problems with the committee applying the current bylaws but that staff receives questions about what “on site” means, which raises questions about whether or not it is sufficiently transparent. As currently worded, the MPSC has had the ability to apply the bylaw to a variety of situations. Committee members also had the following questions and comments:

- Is there an option to use language from the American College of Surgeons? Staff responded that if the MPSC is comfortable with staff locating other similar language, and with the subcommittee making the final decision, that we can consider this option. The MPSC will not have another opportunity to weigh in on this language until it conducts the final pre-public comment review of this proposal on December 15.
- A committee member sought affirmation that language from other source documents would not be incorporated into the proposal without being reviewed at a committee meeting. Staff responded the proposal will be reviewed by the MPSC at its December conference call and may be revised later in response to public comments. The chair affirmed that the final post public comment language would not go to the Board without being reviewed and endorsed by the MPSC first.
- Is there a way to ensure the primary and their proxy can be included in the language?
- The primary also has an administrative responsibility to ensure things are going correctly in the program. An MPSC member suggested including language that incorporates a percentage of time that the primary must spend at a hospital where they are the designated primary. Staff reminded members that a person could be the primary at more than one hospital.

The chair asked the committee if it is comfortable with the subcommittee and staff making additional changes in response to this discussion. The changes would be sent out in the proposal package in advance of the full MPSC meeting on December 15. That meeting will be the last opportunity for the MPSC to review and approve the proposed modifications before they go out for public comment

Staff will continue to work on language that incorporates the MPSC’s recommendations.

#### Transplant Program Key Personnel Format

Staff presented additional program key personnel format topics considered during the last subcommittee meeting. The subcommittee recommended including a requirement that previous service as a primary be within the last 10 years, and include a question in the Request for Feedback paper about the timeframe. The subcommittee also discussed the evaluation requirement for a primary physician. The Committee was asked to weigh in on the conditional pathways in the bylaws during this meeting.

#### Conditional Pathways

The MPSC reviewed the current conditional pathways in the bylaws, discussed whether they should be maintained, and if so should there be conditional options for both primary surgeons and physicians. Additionally, the Committee provided feedback on which elements in the conditional pathways should be standard across all organs.

The Committee had the following questions and feedback:

- Has a conditional pathway ever been misused in any situation? The MPSC member also noted that conditional pathway is hard to define in a bylaw. Could there be an option for a member to bring a proposal to the MPSC for review prior to submitting an application?
- The conditional pathway can be used for sudden departures or death of staff.
- How do you decide where to draw the line when determining minimum thresholds for cases?
- Could a mentor step in as the primary until the applicant reaches their required number of patients? Staff advised that a mentor is usually located at another transplant hospital and may not be in the same geographic area.
- Support members so that they can be successful but need to be careful of how much we ask of a mentor due to legal/risk management concerns.
- Staff pointed out that terminology is important when referencing consulting vs. mentorship. Based on recent inquiries consulting relationships may involve drawing up a formal contract between the facilities, whereas, mentorship seems less formal.

The Committee was polled to see if they supported maintaining the conditional pathways in the bylaws. The Committee voted in favor of maintaining the pathways by a vote of 26 For, 5 Against, 0 Abstentions. The comments from the Committee will be used when developing the Request for Feedback regarding conditional approval pathways.

#### Pediatric Physician Pathways for Kidney and Liver Transplant Programs

The MPSC reviewed the current bylaws for approval of pediatric physicians as primary physicians for kidney and liver programs, which include three pathways for individuals with pediatric training or clinical experience. Staff suggested consolidating the three pathways into one pediatric pathway that supports a combination of fellowship training and clinical experience. Using this approach, a pathway for pediatricians to serve as primary physicians at predominately pediatric kidney and liver programs is maintained, and the newly implemented pediatric component requirements, which reference these pediatric pathways, would not need any significant revisions. Staff requested feedback from the MPSC regarding consolidation of the pediatric primary physician pathways. A comment in support of this approach was made by the vice chair, who was involved in the development of the pediatric bylaws.

The intent to consolidate the pediatric pathways will be included in the Request for Feedback.

#### **Upcoming Meetings**

- December 15, 2020, 1-3:00pm ET, Conference Call
- January 19, 2021, 2-4:00 pm, ET, Conference Call
- February 23-25, 2021, Virtual, Conference Call
- March 25, 2021, 1-3:00 pm, ET, Conference Call
- April 22, 2021, 1-3:00 pm, ET, Conference Call
- May 25, 2021, 2-4:00 pm, ET, Conference Call
- June 24, 2021, 1-3:00 pm, ET, Conference Call

- July 20-22, 2021, Chicago

## Attendance

- **Committee Members**
  - Sanjeev K. Akkina
  - Nicole Berry
  - Christina D. Bishop
  - Errol Bush
  - Matthew Cooper
  - Theresa M. Daly
  - Maryjane A. Farr
  - Richard N. Formica Jr
  - Adam M. Frank
  - Catherine Frenette
  - Jonathan A. Fridell
  - Michael D. Gautreaux
  - PJ Geraghty
  - David A. Gerber
  - Alice L. Gray
  - John R. Gutowski
  - Edward F. Hollinger
  - Ian R. Jamieson
  - Christy M. Keahey
  - Mary T. Killackey
  - Heung Bae Kim
  - Jon A. Kobashigawa
  - Anne M. Krueger
  - Didier A. Mandelbrot
  - Virginia(Ginny) T. McBride
  - Clifford D. Miles
  - Saeed Mohammad
  - Willscott E. Naugler
  - Matthew J. O'Connor
  - Nicole A. Pilch
  - Steven Potter
  - Jennifer K. Prinz
  - Scott C. Silvestry
  - Lisa M. Stocks
  - Parsia A. Vagefi
  - Gebhard Wagener
- **HRSA Representatives**
  - Marilyn Levi
  - Arjun U. Naik
  - Raelene Skerda
- **SRTR Staff**
  - Nicholas Salkowski
  - Bryn Thompson

- **UNOS Staff**
  - Sally Aungier
  - Matt Belton
  - Nicole Benjamin
  - Tameka Bland
  - Tory Boffo
  - Jadia Bruckner
  - Robyn DiSalvo
  - Nadine Drumn
  - Demi Emmanouil
  - Katie Favaro
  - Amanda Gurin
  - Asia Harris
  - Danielle Hawkins
  - David Klassen
  - Kay Lagana
  - Krissy Laurie
  - Marc Leslie
  - Ellen Litkenhaus
  - Jason Livingston
  - Anne McPherson
  - Sandy Miller
  - Amy Minkler
  - Steven Moore
  - Sara Moriarty
  - Alan Nicholas
  - Jacqui O'Keefe
  - Rob Patterson
  - Michelle Rabold
  - Liz Robbins
  - Sharon Shepherd
  - Leah Slife
  - Tynisha Smith
  - Olivia Taylor
  - Stephon Thelwell
  - Roger Vacovsky
  - Gabe Vece
  - Marta Waris
  - Betsy Warnick
  - Trevi Wilson
  - Emily Womble
  - Karen Wooten
- **Other Attendees**
  - None