

**OPTN Membership and Professional Standards Committee
Membership Requirements Revision Subcommittee
Meeting Summary
April 17, 2024
Conference Call**

Nancy Metzler, Chair

Introduction

The MPSC Membership Requirements Revision Subcommittee met in open session virtually via Webex on April 17, 2024, to discuss the following agenda items:

1. Potential changes to Membership Requirements Revision Proposal
 - a. Options to replace “substantial changes” language in program coverage plan
 - b. Transplant Professional Misconduct
2. Next Steps

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

OPTN Staff reviewed the recommendations made by the Subcommittee at its April 5 conference call for the benefit of Subcommittee members not in attendance at the call.

1. Potential changes to Membership Requirements Revision Proposal

a. Options to replace “substantial” changes language in program coverage plan

The Subcommittee, at its April 5 meeting, supported replacing the language that requires transplant programs to notify patients when there are “substantial changes” to the program coverage plan with more specific descriptive language and asked staff to bring options for the Subcommittee to consider to its next meeting. The majority of Subcommittee members on the call supported notification being submitted to the OPTN when a program was moving to or from a single surgeon or single physician program.

OPTN staff presented the three options below to the Subcommittee. All three options included language requiring notification to the OPTN when patients are notified, a requirement for notification when changing to or from single surgeon or physician status and clarifying that a single surgeon and/or physician program has only one surgeon and/or physician who meets “additional” criteria. Relevant CMS requirements were provided to the Subcommittee to support decision-making.

Summary of Discussion:

Decision #1: The Subcommittee recommends the full Committee choose between two options to replace “substantial changes” as a trigger for patient and OPTN notification of changes to the program coverage plan.

Decision #1: The Subcommittee recommends the full Committee choose between **two options** to replace “substantial changes” as a trigger for patient and OPTN notification of changes to the program coverage plan.

The Subcommittee considered three options:

- Option 1: Inform of change to or from single transplant surgeon or single transplant physician only
- Option 2: Inform of change to or from single transplant surgeon or single transplant physician and change that results in inability to provide 24/7/365 coverage
- Option 3: Inform of change to or from single transplant surgeon or single transplant physician and a long-term change in the level of staffing that results in a material decrease in the ability to accept the same volume of organ offers and perform the same volume of transplants

The Subcommittee provided feedback on some of the language included in all three options, including the language clarifying the definition of single surgeon and physician programs and the added language for the requirement of notification to the OPTN.

Members ruled out Option 3 due to its wide scope and open-ended nature. Support was split between Option 1 and Option 2, so the full Committee will be asked to determine which one of the two should be included in the proposal.

b. Transplant Professional Misconduct

OPTN staff provided background on the issue. The MPSC's Required Reporting of Patient Safety Events public comment proposal included a requirement for members to report sanctions taken against transplant professionals. The HRSA criteria contained in the OPTN contract requires that the OPTN notify HRSA of "any sanction taken by a state medical board or other professional body against a transplant professional working for an OPTN member" within one business day of becoming aware. The Committee removed this requirement from the final proposal because it needed additional consideration of the appropriate language. Public comment feedback noted that the language was vague and not specific enough for members to know what to report. The Board of Directors, at its December 2023 meeting, identified the need for the MPSC to develop an appropriate mechanism to identify individual misconduct and requested that the MPSC continue consideration of the reporting requirement.

OPTN staff reviewed considerations that were discussed by the Board of Directors. Members of the Board of Directors expressed concern over individual misconduct but had questions about the OPTN's ability to take action or consider individual misconduct. Questions were raised about the extent to which the MPSC should be aware of individual misconduct and how that past misconduct could factor into an individual's ability to gain approval for program key personnel roles. There was also mention of the use of the National Practitioner Data Bank (NPDB), an HRSA operated system for reporting misconduct of providers. With regard to consideration of past individual misconduct in decisions about approval for new key personnel roles, the Board of Director members noted there were implications for compliance with MPSC's confidential medical peer review process and for potential risk for liability under employment law, such as employment interference.

Historically, in 2007, the OPTN Board of Directors approved revisions to the OPTN Bylaws to "enhance oversight of individual physicians and surgeons." In addition to the requirement for letters of recommendation for proposed primary surgeons and physicians that address the overall qualifications and the individual's personal integrity, honesty, and familiarity with and experience in adhering to OPTN

requirements and compliance protocols, the 2007 proposal added the following provisions to the OPTN Bylaws:

- Transplant hospitals to conduct investigations, upon request, according to their peer review protocols and report to the OPTN. This provision is retained in the current proposal with some changes which provide the MPSC the ability to require that a transplant hospital investigate the role of any personnel on staff at a designated transplant program in a matter reviewed or currently under review by the MPSC.
- Applicants for primary physician or surgeon to submit assessments of prior non-compliant behavior with which they or other individuals proposed as part of the transplant team have been involved, as well as plans to ensure that the improper conduct is not continued. In its review in 2020, the Committee proposed removing the requirement for “each primary surgeon or primary physician to submit an assessment of all physicians and surgeons in the program” that includes “any involvement in prior transgressions of OPTN obligations and plans to ensure compliance.” The Committee found that the information required to do the assessment is rarely available to a new primary and that the provision had not served its intended purpose.

Finally, staff noted that the OPTN has authority over members and is not a credentialing body for individuals, and as such, has historically placed the responsibility of evaluation of transplant program staff members’ suitability for employment on the transplant hospital member. This is evidenced by the requirements for hospital credentialing letters for primaries that certify that the hospital credentialing body has verified certain qualifications.

Summary of Discussion:

Decision #2: The Subcommittee recommends retaining the proposed changes to bylaws in the proposal and no new policy requirement.

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The Subcommittee considered a number of options including:

1. Retain the proposed changes to bylaws in the proposal and no new policy requirements.
2. Reinsert a requirement for an assessment of all transplant surgeons and physicians or all program personnel for OPTN transgressions and/or sanctions by specific types of entities on a periodic basis rather than just on new program or key personnel applications.
3. Add a requirement to Policy 18 to require members to report sanctions by specific types of entities to replace the vague language from the MPSC’s Require Reporting of Patient Safety Events proposal.
4. Add a requirement in bylaws that members review the NPDB or other body that regulates practitioner licensing and/or certification and certify that review of the database has been completed on key personnel applications and during reassessments of membership status.
5. Add OPTN tracking of identified individual misconduct and/or review of NPDB for use in evaluation of primaries but raises employment law risk concerns for OPTN.

The Subcommittee evaluated the five options and ultimately recommended that the MPSC not make any changes to the bylaws as reflected in the proposal or add a reporting requirement to policy.

The Subcommittee rejected option 2 based on the Committee's previous conclusions that the certificate of assessment did not add value or serve its intended purpose.

In the discussion of option 3, the Subcommittee noted that a policy requirement could be limited to sanctions against a professional's license to eliminate the vagueness but questioned the purpose for collecting this information and what actions would or could the MPSC take based on this information since the OPTN has authority to monitor member institutions, not individuals. The Subcommittee discussed the fact that there are many other entities, such as hospital credentialing committees, state licensing boards, courts in the case of medical malpractice, certification boards, and local medical societies and professional associations that address medical professional, including transplant professional, misconduct. The OPTN should rely on those entities to address individual misconduct.

The Subcommittee did not believe it was in the OPTN's purview or was necessary to require that hospital credentialing committees consult the National Practitioner Data Bank (NPDB) and noted that individual misconduct related to OPTN transgressions are not reportable to the NPDB and should not be made reportable based on the OPTN's use of confidential medical peer review. Therefore, the Subcommittee rejected option 4.

The Subcommittee rejected option 5 based on concerns about maintaining confidential medical peer review and risk of OPTN liability such practices could pose under employment law. Subcommittee members noted that we do not want to undermine the culture of self-disclosure that is inherent in confidential medical peer review by using information gathered on individuals in the context of patient safety related cases in the evaluation of key personnel approval decisions at another member. Additionally, the Subcommittee believed this would be outside the OPTN purview over members and noted that most, if not all, of the concerning patient safety related cases are complex, often involving transplant program culture and professionalism and not clear, concrete individual misconduct.

Next Steps

OPTN staff will present the Subcommittee's recommendations to the full Committee at the April 23, 2024, MPSC meeting.

Upcoming Meetings

MPSC Meeting, April 23, 2024, 3:00 – 6:00 pm ET

Subcommittee Conference Call, May 2024, TBD

MPSC Meeting, May 21, 2024, 2:00 – 5:00 pm ET

Attendance

- **Subcommittee Members**
 - Nancy Metzler, Subcommittee Chair
 - Zoe Stewart Lewis, Committee Chair
 - Clifford Miles, Incoming Committee Chair
 - Scott Lindberg, Committee Vice-Chair
 - Chad Ezzell
 - Mark Wakefield
 - Catherine Kling
 - Roshan George
- **HRSA Representatives**
 - Arjun Naik
 - James Bowman
 - Marilyn Levi
 - Kala Rochelle
- **SRTR Staff**
 - Jon Snyder
 - Jon Miller
- **UNOS Staff**
 - Sharon Shepherd
 - Marta Waris
 - Sally Aungier
 - Amanda Young
 - Elias Khalil
 - Heather Neil
 - Houlder Hudgins
- **Other Attendees**
 - None