OPTN Patient Affairs Committee
Meeting Summary
June 17, 2025
Conference Call

Molly McCarthy, Chair
Lorrinda Gray Davis, Vice Chair

Introduction

The OPTN Patient Affairs Committee (PAC) met via WebEx teleconference on 06/17/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. MPSC Compliance Monitoring and Oversight
3. Open Forum

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

1. Welcome and Announcements

The Chair welcomed the committee members. The Committee recognized and congratulated PAC members who were elected to the OPTN Board of Directors. The Committee also recognized and thanked PAC Members concluding their terms this month. The Chair and Vice Chair encouraged members to share the OPTN volunteer interest form with individuals who may be interested in serving on the PAC.[1]

2. MPSC Compliance Monitoring and Oversight

Members of the OPTN Membership and Professional Standards Committee (MPSC) delivered a presentation outlining the committee's compliance monitoring and oversight activities.

Summary of presentation:

The MPSC monitors compliance through several different modalities.

- Allocations reviews: The OPTN retrospectively reviews each deceased donor match run that results in a transplant. OPTN contractor staff send inquiries to Organ Procurement Organizations (OPO) and transplant hospitals regarding any potential policy violations, and inquiries are reviewed by the MPSC.
- Compliance and Patient Safety: OPTN members and non-members are encouraged to report any potential noncompliance with OPTN obligations or a potential threat to patient safety, public health, or the integrity of the OPTN. Reports can be made through the Patient Safety Portal, or via email, phone, or media. OPTN policy requires certain patient safety events to be reported within 72 hours, and other events must be reported to HRSA within 24 hours. Each report is investigated and HRSA is involved in all MPSC activities.
- Continuous Monitoring: This term refers to automatic system reports generated based on information entered into the OPTN computer system. An example of information that would

---

[1] https://optn.transplant.hrsa.gov/about/how-to-get-involved/how-to-volunteer-apply/

generate an automatic report is a patient listed at multiple transplant programs with different blood types. Reports generate an internal review or inquiry with the program.

- Disease Transmission Monitoring: OPTN policy requires OPOs and transplant hospitals to communicate various test results and potential disease transmission events for all donors and recipients. monitoring for potential disease transmission. Most cases are reviewed by the OPTN Disease Transmission Advisory Committee (DTAC), but the MPSC may also review cases depending on their scope and impact.
- Performance Reviews: The MPSC conducts performance reviews of OPO and transplant programs. OPOs are evaluated based on organ yield and transplant programs are assessed using several pre- and post-transplant outcome measures. The SRTR supports the development of thresholds for each metric and generates program-specific reports to flag programs that do not meet expected thresholds.
- Site surveys: Site surveys are conducted on a rolling 3-year basis, with one third of transplant hospitals and OPOs being surveyed each year. Surveys include data validation, medical record and policy reviews, staff interviews, and educational demonstrations. Follow-up desk reviews occur when instances of noncompliance are found.
- Membership reviews: OPTN Membership is a requirement for transplant hospitals, OPOs, and histocompatibility labs. The MPSC reviews membership policies and requirements for new and existing entities to ensure they meet OPTN requirements.

The MPSC has different interventions available to it when potential policy violations or safety issues are identified. The MPSC considers a range of actions based on the nature and severity of the issue. It may weigh first-time noncompliance differently from ongoing or systemic concerns within a program or member organization.

- Informal Discussions: Virtual discussion between a group of MPSC reps and the Member under review. The member responds to a list of questions and concerns and participates in a question-and-answer session with the MPSC.
- Peer Visits: On site review of a Member by a group of subject matter experts, including MPSC and non-MPSC members. These visits typically last two days and may be announced or unannounced.
- Interviews: Members deliver a formal presentation and participate in a Q&A session with the MPSC. Interviews are typically offered before the MPSC considers further action, such as a hearing.
- Hearings: In person presentation where the Member and MPSC present information and engage in Q&A. This is the final step before the MPSC may recommend probation or a designation of "member not in good standing." Members present their case in person. Interviews and hearings are required to recommend probation, a member not in good standing, or referral to the Secretary.

The MPSC may take a range of actions to take towards a Member after conclusion of the above interventions. Actions include: Close with No Action, Notice of Non-Compliance, Letter of Warning, Probation, Member not in Good Standing, and Referral to the Secretary.

Summary of discussion:

Decision #1: No decisions were made

The Chair requested additional context on patient safety events which require direct reporting to HRSA. OPTN contractor staff elaborated that these events include failures in a program's internal safety checks that could result in adverse patient outcomes. A full list of required HRSA reporting events is available on the OPTN website.[2] Members asked questions around the time frame for resolving complaints, and HRSA staff provided information on average resolution times. A Member asked if an event like an adverse pediatric patient outcome could result in a program being flagged for review. MPSC members noted that individual patient outcomes are typically not flagged under the current monitoring framework unless they represent a pattern that exceeds community norms.

The Chair inquired about the logistics of site surveys. MPSC presenters explained that members are asked to submit documentation, and the process typically takes about three months. Site surveys have transitioned to a virtual format and include two days of staff interviews and case reviews. Members receive a follow-up report outlining any compliance issues and required follow-up actions.

A Member noted kidney post-graft survival metrics, which are part of the performance metrics, could be better optimized to reflect kidney function rather than patient or graft survival. The member noted the metric may not capture cases where a patient is relisted for transplant but not yet on dialysis.

The Chair questioned whether MPSC hearings are public and how patients learn of program findings. MPSC members explained that hearings are confidential and conducted under medical peer review. If the MPSC recommends probation or designates a member as not in good standing, that information becomes public and the program must notify its waitlist. However, programs on probation may continue performing transplants. If a program discontinues a transplant service, the OPTN is responsible for transferring patients to another program. HRSA staff noted that facility-level quality metrics are available through Medicare's Care Compare website and a similar tool may be useful for OPTN programs.

Members discussed the broad scope of MPSC's responsibilities and reviewed information from the 2024 Board Report quantifying the number of compliance actions.[3] HRSA staff noted they are concluding a discovery process to explore improvements to the oversight and compliance process and expressed interest in sharing findings with the PAC in the future.

The Vice Chair raised concerns about insurance limitations in cases where patients either need or want to transfer programs because their original program is inactivated or placed on probation for noncompliance. MPSC members agreed this is a critical issue and emphasized the importance of early communication between transplant centers and insurers. They noted that insurance companies typically assign case managers to assist patients and that MPSC considers patient impact when evaluating program status.

Another member asked how new transplant programs without historical experience or data can be supported and learn from some of the compliance issues that other programs have had. MPSC members responded that new centers undergo MPSC review before approval and agreed that sharing best practices and lessons learned across programs is an important goal and opportunity for the Committee.

At the conclusion of the meeting, Committee members were informed of a volunteer opportunity to participate in the OPTN response to a recent HRSA directive involving the development of family information requirements for donation after circulatory death (DCD) organ procurement.

---

[2] https://optn.transplant.hrsa.gov/media/gqrbxjba/monitoring_processes_20250313.pdf
[3]https://optn.transplant.hrsa.gov/media/2qshp3rk/20241202_mpsc_report-to-the-board-final.pdf

Next steps:

OPTN Contractor staff will provide more information via email to PAC members about the volunteer opportunity to take part in the HRSA directive response.

3. **Open Forum**

There were no comments or speakers for public forum.

Upcoming Meeting

- July 15, 2025

Attendance

- **Committee Members**
  - Molly McCarthy, Chair
  - Lorrinda Gray Davis, Vice Chair
  - Patrice Ball
  - Michael Brown
  - Tonya Gomez
  - Calvin Henry
  - Karlett Parra
  - Andreas Price
  - Cody Reynolds
  - Michael Slipowitz
  - Steve Weitzen
  - Justin Wilkerson
  - Jenny Templeton
- **HRSA/Federal Government Staff**
  - Brianna Doby
  - Tom Duvall
  - Annie Tor
  - Christina McCormick
- **SRTR Staff**
  - Avery Cook
  - Earnest Davis
- **UNOS Staff**
  - Cole Fox
  - Betsy Gans
  - Houlder Hudgins
  - Lindsay Larkin
  - Carly Rhyne
  - Kaitlin Swanner
  - Laura Schmitt
- **Other Attendees**
  - Deb Maurer (MPSC)
  - Kyle Herber (MPSC)