

Meeting Summary

OPTN Ad Hoc Multi-Organ Transplantation Committee Meeting Summary June 25, 2025 Conference Call

Lisa Stocks, RN, MSN, FNP, Chair Zoe Stewart Lewis, MD, PhD, MPH, FACS, Chair

Introduction

The OPTN Ad Hoc Multi-Organ Transplantation Committee (the Committee) met via WebEx teleconference on 06/25/2025 to discuss the following agenda items:

- 1. Welcome and updates
- 2. Committee roster updates
- 3. Modify Effect of Acceptance: 6-month monitoring report
- 4. Implementation updates and considerations

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

1. Welcome and updates

The OPTN Contractor Staff (staff) shared the timeline for finalizing the policy proposal. Staff thanked the Committee members for providing feedback and noted that the draft is undergoing additional review by the OPTN Contractor and Health Research and Services Administration (HRSA).

Summary of discussion:

No discussion.

2. Committee roster updates

The Committee thanked several members who are rolling off at the end of the 2024-2025 term. Staff is working with leadership to fill the open positions. The current Vice Chair is rolling off, and the OPTN Board of Directors appointed Christopher Sonnenday as Vice Chair for 2025-2026.

Going forward, the Committee will meet once a month. Staff share a poll to determine a new meeting time.

Summary of discussion:

No discussion.

3. Modify Effect of Acceptance: 6-month monitoring report

Staff presented the 6-month monitoring report on the changes to *OPTN Policy 5.6.D: Modify Effect of Acceptance. Policy 5.6.D* states that when a transplant hospital accepts an organ offer without conditions, the acceptance is binding and the organ is not required to be offered to multi-organ candidates.

Summary of presentation:

The report analyzes several metrics in the pre-policy (July 25, 2023-January 24, 2024) and post-policy (July 25, 2024-January 24, 2025) eras.

Transplant volumes for single-organs increased from 18,001 to 18,457, with increases in liver-, heart-, and lung-alone transplants. Multi-organ transplants decreased from 1,140 to 1,118. Heart-lung, lung-liver, and multivisceral transplants increased. Liver-kidney, heart-kidney, and lung-kidney transplants decreased, which was likely due to the impacts of policy establishing eligibility criteria and safety net policies, which took effect in September 2023.

There were no statistically significant differences in the probability of waitlist removal for death or too sick within 90 days of listing. There were no notable differences in median sequence number at acceptance. Kidney and heart non-use rates remained similar; liver and lung non-use rates increased.

Summary of discussion:

A Co-Chair noted that the lack of major impacts may be reassuring in this instance, as it highlights there are no unintended consequences for candidates. They agreed that the decrease in kidney multi-organ transplants likely results from the safety net and eligibility criteria that went into effect in 2023. A representative from the OPTN Heart Committee noted that they have not heard concerns from the heart community regarding the changes and agreed that the medical eligibility and safety net criteria probably influenced heart transplant numbers.

A Co-Chair noted that the upcoming policy proposal will require that organ offers are made sequentially, rather than simultaneously for covered donors and candidates, which could reduce the need for *Policy 5.6.D*.

Next steps:

The next monitoring report will be provided approximately 1 year post-implementation.

4. Implementation updates and considerations

The Committee considered several implementation considerations: transition procedures, timeline, and resources.

Summary of presentation:

The Final Rule requires the OPTN to consider whether to adopt transition procedures, including when populations may be treated "less favorably than they would have been treated under the previous policies." The proposed policy would remove priority for certain multi-organ candidates above single organ candidates, so the Committee considered whether transition procedures would be needed to support implementation.

Staff provided an update on the timeline and cost projections for the proposed policy changes. Because the changes would require significant updates to the OPTN Computer System, the implementation timeline will be finalized upon OPTN Board approval. Given the complexation of the project, it is likely to be a multi-year implementation timeframe, though timing will depend on OPTN prioritization and resourcing decisions. Estimated implementation costs are approximately \$2.8 million, including system development, coding, and testing as well as upgrades to the organ matching systems and the development and implementation of communications, trainings, and outreach materials. Estimated post-implementation costs are approximately \$400,000 for ongoing support, compliance monitoring, and post-implementation monitoring.

Summary of discussion:

Decisions:

The Committee agreed that transition procedures are not needed

 The Committee emphasized the need for strong communications, outreach, and preimplementation training to facilitate smooth implementation, especially for OPO users and for patients

A Co-Chair asked for examples of possible transition procedures, referencing phased implementation as one potential approach. Staff confirmed that a phased rollout is one option. Other examples include "grandfathering" certain candidates who previously had access or priority and using sunset clauses to phase out specific policy requirements over time. Staff noted, however, that some of these transition options could add additional complexity, as it would involve applying different versions of the policy to the same patient population. The Co-Chair and other members agreed and wished to avoid adding additional layers of complexity. Ultimately, the Committee agreed that transition procedures are not needed, however the Committee emphasized the need for strong communications, outreach, and pre-implementation training to facilitate smooth implementation, especially for OPO users and for patients.

A Co-Chair emphasized that effective communication with the OPO community will be essential, as OPOs will be responsible for handling inquiries from transplant centers and managing match runs. Staff noted options like simulation-based or practical training, which would help OPO staff become familiar with the new policy and related system changes. A Co-Chair supported this recommendation and added that the proposed policy had already been discussed at the recent Association of Organ Procurement Organizations (AOPO) national meeting. They expressed strong support for using multiple communication channels to ensure the OPO community is well-informed and prepared.

Several members expressed support for the proposed approach. A patient representative suggested that care teams should be encouraged to explain the policy to patients who may be affected, emphasizing that the policy is complex and may raise questions or concerns. Other members agreed, and a Co-Chair recommended the development of patient-facing educational materials.

A member noted implications for kidney-pancreas candidates and asked whether the Committee should re-engage the pancreas transplant community for additional input. A representative from the OPTN Pancreas Committee noted previous engagement and feedback to the Request for Feedback. They noted that the Pancreas Committee, and the community more broadly, appear aligned and supportive of the changes.

One member raised a concern about a small group of heart-liver and lung-liver candidates, particularly those with lower medical urgency, who could be disadvantaged under the proposed policy. While this group is very limited in size, the member noted that the issue may surface during the public comment period. The pediatric representative added that, although there are no major concerns from the broader pediatric community, some pediatric liver-kidney stakeholders may question the prioritization of kidney-alone candidates.

A Co-Chair asked whether HRSA had reviewed and provided input on the policy proposal, noting that in the past, proposals have been withdrawn from public comment following HRSA review. Staff responded that HRSA has not yet reviewed the proposed policy language, but feedback is expected soon.

A Co-Chair remarked that the estimated costs for the project were lower than anticipated. Another member pointed out that the figures presented reflect only OPTN-level expenses, and do not account for potential costs to OPOs or transplant centers. Staff confirmed this, noting that the estimate does not include additional financial impacts on members, though the level of impacts are estimated in the proposal.

Next steps:

- The Committee awaits HRSA feedback on the public comment proposal
- Staff will develop slides for public comment and regional meetings and present them at a future meeting for the Committee's input

Upcoming Meetings

• July 9, 2025

Attendance

• Committee Members

- o Rocky Daly
- o Rachel Engen
- o Precious McCowan
- o Oyedolamu Olaitan
- o Chris Sonnenday
- o Zoe Stewart Lewis

• SRTR Staff

- o Avery Cook
- o Jon Miller

UNOS Staff

- o Sarah Booker
- Houlder Hudgins
- o Sarah Roache
- o Laura Schmitt
- o Erin Schnellinger
- o Kaitlin Swanner
- Susan Tlusty
- o Stryker-Ann Vosteen
- o Ross Walton