

**OPTN Patient Affairs Committee
Meeting Summary
July 15, 2025
Conference Call**

**Molly McCarthy, Chair
Lorrinda Gray Davis, Vice Chair**

Introduction

The OPTN Patient Affairs Committee (PAC) met via WebEx teleconference on 07/15/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. Summer 2025 Public Comment Preview
3. Regional Meeting Preparation
4. Public Forum

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

1. Welcome and Announcements

The Chair welcomed the committee members. The Committee reviewed announcements and recent updates from the OPTN and the Board of Directors.

Summary of presentation:

- The next OPTN Board Meeting will be held Thursday, July 17th 1:45-3:00pm ET. Livestream and agenda information will be posted on the OPTN Calendar of Events webpage when available.
- Calls for nominations for open committee spots will be released as soon as they are approved. PAC will have openings for representatives from Region 1, Region 4, Region 5, and Region 7. Volunteer interest forms will be open for one month and then provided to the Regional Nominating Committees.
- There are four ongoing HRSA Directives to the OPTN.
 - Normothermic Regional Perfusion (NRP):
 - HRSA directed the OPTN to develop a plan to propose policies, policy definitions, data collection, technical and quality standards, and standard practices that address patient safety for organ procurement organizations using NRP in patients from whom organs may be procured, and OPTN data collection regarding the attempted and/or successful use of NRP in patients from whom organs may be procured.
 - Donation after Circulatory Death (DCD) Policy:
 - HRSA directed the OPTN to develop policies to improve safeguards for potential DCD patients and increase information shared with patient families regarding DCD organ procurement.
 - Rabies Transmission:
 - HRSA directed the OPTN to propose improvements to policy to reduce the risk of donor-derived rabies.
 - Allocation Out of Sequence (AOOS):

- HRSA directed the OPTN to develop a plan to:
 - Improve OPTN allocation policy requirements and policy definitions.
 - Create a detailed, prospective OPTN compliance plan to ensure OPTN members come into compliance with the regulatory wastage provision and otherwise comply with statutory and regulatory requirements for the allocation of organs.
 - Create transparency into the submission, approval, and performance of protocols under the OPTN expedited placement variance to ensure government oversight, increase patient awareness and public transparency of variances, and increase patient access to transplants.
 - Propose a tool to provide public transparency into how frequently patients are excluded from access to organs for which they have been matched as a consequence of AOOS.
- OPTN Updates: Board of Directors
 - During their meeting on June 9-10, the OPTN Board approved a resolution to discontinue non-critical meeting support for committees without active projects, exempting the Patient Affairs Committee (PAC), for the fourth quarter of fiscal year 2025 (July, August, September).
- HRSA issued the following directive (effective July 1) regarding policy work related to CD:
 - *“As the OPTN undertakes actions to comply with HRSA’s directive on allocation out of sequence (AOOS) remediation, HRSA has determined it is both prudent and responsible to pause new policy work related to CD to ensure that new AOOS policies are effective and evidence-based and ensure fairness in the OPTN allocation system. Pausing all new work related to CD until the OPTN has addressed AOOS is a HRSA decision to ensure that when the OPTN makes a new allocation policy, it does so with transparency, robust, reliable data, and accountability to all patients the system is designed to serve.”*
 - Based on this directive, all CD-related projects will be paused until further notice.

Summary of discussion:

<p>No decisions were made</p>

The Chair asked why new Committee appointments would be for four-year terms instead of three, expressing concern about the longer duration. Contractor staff explained that four-year terms are needed to maintain staggered membership, ensuring that one-third of the Committee rotates off each year. In the interim, former PAC members may be asked to temporarily fill regional vacancies and serve on the Regional Nominating Committee.

Members discussed the ongoing HRSA directives.

- The Vice Chair asked whether there have been any requests for PAC members to participate in the NRP directive. A HRSA representative responded that more information is forthcoming and that HRSA is recommending that PAC play a central role in the directive.
- The Chair asked about the frequency of rabies transmission through organ transplantation. A HRSA representative noted that a donor-derived case was reported late last year. Although rare, such cases have significant impact and require screening and post-exposure prophylaxis for potentially hundreds of individuals. HRSA has asked DTAC to develop a policy proposal for public comment later this year.

- Members discussed the AOOS directive. The Vice Chair noted the new Allocation Out of Sequence page is posted on the OPTN website¹ and an OPTN Board Member noted a workgroup is being formed.
 - A Member asked whether the workgroup would focus on specific organs. A HRSA representative responded that although AOOS is most common in kidneys, it occurs across all organs. The Chair asked whether technology investments are contributing to the response. A HRSA representative noted that improved communication among OPOs, transplant programs, and third-party partners will play a key role.
 - A Member suggested that friction could be reduced if patients had more input early in the process about which organs they are willing to accept and were educated on those choices. They described the current system as a “push model” and proposed shifting to a “pull model” to better match organs with recipients and reduce tension between OPOs and transplant programs.
 - Another Member emphasized the importance of involving caregiver support networks in these discussions, in addition to patients, and mentioned prior conversations with the data analytics team. A HRSA representative agreed, noting that placing patients at the center of the response is a priority. HRSA’s goals are to empower patients with the following information so that they may review and discuss expectations with their transplant program:
 - their status on the waitlist
 - the percentage of offers for which they were a suitable candidate, and
 - how often they missed offers due to AOOS
- Members discussed the recent OPTN board updates:
 - A member asked for clarification on the pause in non-critical meeting support, and it was clarified that staff support will be withdrawn and affected committees will not meet during the fourth quarter of 2025. A former Board Member noted the pause is necessary due to constraints in the OPTN operating budget. An OPTN Board Member added that there is ongoing discussion regarding meeting support for Committees without active projects. Members discussed whether this change could limit the introduction of new ideas or if ad-hoc meetings and workgroups could be sufficient substitutes.
 - An OPTN Board Member relayed concern about the pause in the Continuous Distribution (CD) initiative, noting the significant effort invested and its potential benefits. The Chair and other Members acknowledged community concerns and discussed the merits of the pause. The Chair suggested that pausing may be appropriate while more urgent systemic issues are addressed. Other Members noted that CD has required substantial resources while foundational issues like AOOS remain unresolved. Another member noted opposition to the pause within the community, and concern that the pause appears indefinite, with no clear timeline for resuming work.

2. Public Comment Preview

Committee members reviewed PAC’s historical approach to public comment proposals, which involves selecting a subset of proposals, dividing into teams, and finalizing Committee feedback.

PAC members also reviewed the results of a Committee poll assessing interest in potential Summer 2025 public comment items. The proposals receiving the most interest were:

¹ <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/allocation-out-of-sequence-aos/>

- Require Patient Notification for Waitlist Status Changes
- Update and Improve Efficiency in Living Donor Data Collection
- Establish National Kidney Expedited Placement Policy
- Data Collection on Normothermic Regional Perfusion (NRP) and Machine Perfusion

3. Regional Meeting Preview

Committee members reviewed the schedule for upcoming regional meetings and noted that regional representatives will be asked to confirm their availability to present. Speaker preparation sessions will also be scheduled.

The Committee discussed content for the PAC presentation. The Vice Chair encouraged members to share their personal stories, highlighting what serving on the PAC has meant to them and the value of being actively involved in projects. The Chair added they are reviewing PAC's contributions and will provide members with key messages on where the Committee has focused its efforts.

4. Open Forum

There were no comments or speakers for public forum.

Upcoming Meeting

- August 19, 2025

Attendance

- **Committee Members**
 - Molly McCarthy, Chair
 - Lorrinda Gray Davis, Vice Chair
 - Andreas Price
 - Cathy Ramage
 - Calvin Henry
 - Garrett Erdle
 - Jenny Templeton
 - Justin Wilkerson
 - Karlett Parra
 - Elizabeth DeVivo
 - Michael Brown
 - Michael Slipowitz
 - Robert Johnson
 - Steve Weitzen
- **HRSA/Federal Government Staff**
 - Ray Lynch
 - Heather Myers
- **SRTR Staff**
 - Avery Cook
 - Earnest Davis
- **UNOS Staff**
 - Cole Fox
 - Betsy Gans
 - Lindsay Larkin
 - Carly Rhyne
 - Kaitlin Swanner
 - Laura Schmitt