

**OPTN Patient Affairs Committee
Meeting Summary
August 19, 2025
Conference Call**

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

Introduction

The OPTN Patient Affairs Committee (PAC) met via Microsoft Teams on 08/19/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. Continuous Distribution Discussion - HRSA
3. Committee Updates
4. Public Forum

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

1. Welcome and Announcements

The Chair welcomed the committee members and provided opening announcements.

- PAC will hold an extended virtual meeting in September. Members should respond to the scheduling poll to indicate their availability.
- The next OPTN Board Meeting will be held on August 21st. Livestream and agenda information will be posted on the OPTN Calendar of Events webpage when available.
- The OPTN public comment period will be open from August 27 – October 1, 2025, and Regional Meeting dates have been finalized.

Summary of discussion:

No decisions were made

There were no comments or discussion.

2. Continuous Distribution Discussion - HRSA

HRSA representatives facilitated a discussion on allocation policy and Continuous Distribution (CD).

Overview of Presentation:

HRSA representatives displayed a presentation titled, "Organ Allocation Policy Changes, Compliance, and Outcomes" which included the following information:

- Continuous Distribution is an approach to organ allocation that considers all candidate attributes (distance, urgency, etc.) at once. A goal is to increase opportunities for individuals who are medically harder to match.
- CD for lung was rolled out in March 2023, and work on other organs has proceeded since then.
- In July 2025, HRSA directed the OPTN to pause new policy work related to CD.

- Pausing CD work does not mean CD will never be deployed. However:
 - Known and emerging challenges must be resolved, and
 - Resources must be available and budget constraints must be considered.

A visual was displayed showing rates of allocation policy compliance and rates of non-use.

- Allocation out of sequence (AOOS) rates have increased since 2019-2020.
- Over the same period, organ non-use (defined as organs procured but not transplanted) has been rising steadily. The data do not support the hypothesis that AOOS is necessary to avoid organ non-use.

A visual was displayed showing rates of allocation compliance by organ, with the dates of major allocation policy changes notated.

- While not definitively causal, the data suggest that policy compliance rates decrease after new allocation policies are implemented.
- HRSA supports a pause in CD until questions around policy compliance are addressed.
- Evidence has not been presented to HRSA that CD will address issues of policy non-compliance. Rather the data suggest that compliance rates have dropped (and AOOS has increased) since CD was introduced for lung.

Summary of discussion:

No decisions were made

- The Chair asked which committee originally developed the Continuous Distribution (CD) framework.
 - A representative from HRSA responded that CD was initiated by the Ad Hoc Geography Committee in the summer of 2018. Lung was selected to adopt CD first because it was the earliest organ to transition away from Donation Service Area (DSA) regions and involved a relatively low volume of transplants.
- A Member inquired about policy compliance rates prior to the implementation of CD.
 - A HRSA representative explained that policy compliance was between 95% and 100% in 2016, and lower compliance rates were observed after the introduction of new allocation policies such as Kidney Allocation System (KAS) 250 and CD.^{1,2} In kidney allocation specifically, compliance dropped from 95% to approximately 75–80% following the implementation of KAS 250.
- A Member asked for clarification on when and under what conditions CD implementation would resume, adding that many stakeholders are seeking clarity on the duration of the pause and the financial barriers to implementing CD. The Member relayed concerns from community members that the pause in CD will result in them not matching for an organ.
 - A HRSA representative responded that a clear date for CD implementation is not possible, but that they are encouraged by the work the OPTN has begun to address AOOS. Data suggests that organ use may increase when AOOS is reduced, resulting in more match opportunities for the community. They further noted that the OPTN has

¹ <https://optn.transplant.hrsa.gov/professionals/by-organ/kidney-pancreas/kidney-allocation-system/>

² <https://optn.transplant.hrsa.gov/professionals/by-organ/kidney-pancreas/kidney-allocation-system/removal-of-dsa-and-region-from-kidney-allocation-policy/>

eroded its operational reserve in recent years and that future work must be fiscally sound. While the OPTN has invested heavily in CD, it has not yet incorporated policy compliance into its development and evaluation plan. The HRSA representative stated deliberations on previous OPTN policy changes did not include policy compliance, and there is evidence from Lung CD that allocation policy is disregarded when the model does not appear to work appropriately.

- A Board Member added that the OPTN Board is leading a workgroup on AOOS that will result in improvements to the system, including better education and training for OPOs. The Board Member expressed optimism that the work to address AOOS will allow work on CD to resume.
- A Board Member asked if the OPTN had performed modeling after implementation of KAS 250 that would have helped predict rates of policy non-compliance?
 - A HRSA representative responded they were not aware of such modeling, and that the OPTN's CD monitoring reports do not evaluate policy non-compliance. They added that organ non-use and AOOS should be equally perceived as detrimental outcomes, and that some OPOs have reported decreasing rates of non-use in tandem with decreasing rates of AOOS.
- A Member asked if CD policy was designed to be modified over time.
 - A HRSA representative responded that policy should adapt to new information and the OPTN is empowered to optimize and adjust policies when new data is presented.
- The Chair and Committee Members discussed the impact of geography in AOOS and CD policy.
 - The Chair and a Member noted that CD was unpopular in their regions because of a perception that it would result in lower allocation rates in their location.
 - A HRSA representative noted that AOOS may be more prevalent in areas with lower availability of organs.
 - A Member voiced support for the prioritization of AOOS, noting that it may not be possible to assess the effectiveness of CD because overall policy compliance rates are so low.
- The Vice Chair expressed appreciation for the conversation and thanked HRSA for their participation and transparency.

Committee Members discussed the recent Congressional Hearing on ensuring patient safety.³ A Member inquired about reports of declines in donor registrations.

- A HRSA representative emphasized the importance of patient safety to the OPTN and HRSA, and the commitment HRSA has to this issue as a regulator. The public must trust that they will be treated the same way by the system regardless of their status as an organ donor.
- Members discussed how effective messaging could be provided to assure the public of the safety of the system and importance of organ donation. A Member questioned if this messaging should be coming from HRSA or the Federal Government. The Vice Chair and Chair encouraged PAC Members to lead the conversation as informed representatives of the OPTN in their communities. Other Members and HRSA agreed that transparency, good policy, and leadership are critical to restoring public trust.

³ <https://energycommerce.house.gov/posts/oversight-and-investigations-subcommittee-holds-hearing-on-ensuring-the-nation-s-organ-procurement-and-transplant-system-prioritizes-patient-safety>

3. Committee Updates

The Chair shared an update on their work on developing a Patient Bill of Rights with the Vice Chair. Input from Committee Members is welcome and this topic will be a focus of the PAC's upcoming extended virtual meeting.

The Ex Officio described a positive experience participating in an OPTN workgroup focusing on policies to safeguard Donation after Circulatory Death (DCD) patients, highlighting examples of workgroup members collaborating and sharing best practices.

4. Open Forum

A written comment to the Committee relating to Continuous Distribution was submitted as an Open Forum item. The comment was distributed to Committee members in advance of the meeting.

Upcoming Meetings

- September 25, 2025
- October 21, 2025

Attendance

- **Committee Members**
 - Molly McCarthy, Chair
 - Lorrinda Gray Davis, Vice Chair
 - Andreas Price
 - Cathy Ramage
 - Calvin Henry
 - Elizabeth DeVivo
 - Garrett Erdle
 - Karlett Parra
 - Elizabeth DeVivo
 - Michael Brown
 - Michael Slipowitz
 - Robert Johnson
 - Steve Weitzen
 - Tonya Gomez
- **OPTN Board of Directors**
 - Robert C. Reynolds
 - Justin Wilkerson
 - Shelley Hall
- **HRSA/Federal Government Staff**
 - Ray Lynch
 - Sarah Laskey
 - Annie Tor
 - Mesmin Germain
- **SRTR Staff**
 - Avery Cook
- **UNOS Staff**
 - Cole Fox
 - Betsy Gans
 - Lindsay Larkin
 - Carly Rhyne
 - Carlos Martinez
 - Houlder Hudgins