

**OPTN Operations and Safety Committee
Allocation Out of Sequence Workgroup
Meeting Summary
March 21, 2025
Conference Call**

**Kim Koontz, MPH, Chair
Steven Potter, MD, Vice Chair**

Introduction

The Operations and Safety Committee Allocation Out of Sequence Workgroup (the Workgroup) met via WebEx teleconference on 03/21/2025 to discuss the following agenda items:

1. Welcome
2. Review and Discussion: Allocation Out of Sequence Directive, Project Plan/Timeline

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

1. Welcome

The Chair welcomed the Workgroup members. The Workgroup reviewed a recap of the discussion from the previous meeting and an update following discussion with OPTN Board leadership.

Presentation summary:

The Chair shared that Board leadership said that the timeline for providing the project plan cannot be extended so the Workgroup will still need to outline a plan. The Workgroup could include a preamble that outlines the scope of the problem that highlights concerns.

Summary of discussion:

The Workgroup discussed that the plan is due to the Health Resources and Services Administration (HRSA) by March 31 as part of the broader response to the Allocation Out of Sequence (AOOS) directive from HRSA. The Workgroup is tasked with a subset of the items in the directive. A member noted that the timeline is short and suggested splitting up the work among Workgroup members. It was noted that expedited placement is important in thoracic organ placement due to the tighter time frame and the inability to place thoracic organs after procurement. The member reiterated that kidney should be treated separately from other organs and these discussions should include representatives from any expedited placement workgroups since expedited placement is in part intended to solve the same problem as reducing AOOS.

Contractor staff noted that the Kidney Committee is working on an expedited placement policy, and there is a separate section of the directive that speaks to the expedited placement variance. Additionally, once the Workgroup has an approved project plan, representatives from other groups can be pulled in as needed.

After the March 19th Workgroup meeting, the Operations and Safety Committee (the Committee) leadership debriefed with Board leadership to discuss the Workgroup's concerns and ask for guidance on addressing those concerns in their response to the directive. The Workgroup was advised that the deadline for a response could not be extended and that a plan would still need to be outlined. It was

suggested that a preamble be included in their response that would outline the scope of the problem and highlight the concerns voiced by the Workgroup. The Chair recommended that the Workgroup outline a phased approach for accomplishing the work, which could include the expedited placement work.

2. Review and Discussion: Allocation Out of Sequence Directive, Project Plan/Timeline

The Workgroup reviewed the proposed project plan in response to the Allocation Out of Sequence (AOOS) directive from HRSA.

Presentation summary:

Proposed project plan:

- Preamble:
 - Defining project scope: The current allocation system has competing factors that create barriers to the organ offer process (e.g. expansion of donation after circulatory death (DCD) donors, CMS regulations)
 - Consideration of reconvening other efforts
- A.3: Develop a proposed OPTN policy and associated definition to describe “batched organ offers”
 - Define/clarify terminology (“open offers” rather than “batched offers”)
 - Develop policy for when “open offers” should be made
 - Consider: “... organ offers must be made to individual transplant patients, and that organ offers cannot be made to transplant programs or transplant centers”
- A.4: Develop a proposed OPTN policy and associated definition for the “offer” of an organ by an OPO to a transplant center
 - Re-evaluation of OPTN policies related to organ offers
 - *1.2 Definitions*
 - *2.11 Required Deceased Donor Information* (already addressed in current committee project)
 - *5.4.B Order of Allocation*
 - *5.6 Receiving and Accepting Organ Offers*
 - Other considerations: OPTN Expeditious Task Force work
- A.5: Develop a proposed OPTN policy and associated definition to describe acceptable modalities and associated content of an organ offer made by an OPO to a transplant patient at a transplant center
 - Discuss and identify acceptable modalities/content of an organ offer to record all aspects of the offer process within the system
 - Develop list of system enhancements/processes that should be considered

Summary of discussion:

Decision #1: The project plan reviewed and discussed as well as the Workgroup’s feedback will be incorporated into the draft OPTN response for the AOOS directive.

Preamble

A member recommended proceeding with the “yes, and” approach described during the previous meeting. The member said that there should be some definite auditing guardrails in the bypass code out. There should be some development in addressing late reallocation.

Another member noted that different groups are working on parts of the response to the directive and said it feels disconnected since some of the items that would fall under the preamble may also fit under other aspects of the directive. The member asked how the final response will be codified. Contractor staff explained that staff will codify the responses from the different groups and send to OPTN leadership for review.

The Vice Chair said the Workgroup should consider the implications of any statements that are put forward in the response. A member said the response needs to clearly respond to the asks in the directive. The response will need to be deliberative, intentional, and thoughtful about downstream effects and how this response may be interpreted and executed.

Another member asked if the preamble will also cover why the OPTN is in this place which is not just due to policy or regulations but also because of operational factors, like a late decline of an organ offer in the operating room. The Chair affirmed this is the intent of the preamble. The system was not built to address the current needs. The preamble will also include the misalignment between the Centers for Medicare and Medicaid Services (CMS) regulations and the HRSA directive. A member agreed the preamble needs to include why AOOS is increasing but also why it is an effort to honor the best interests of the patient. Inefficiency increased with the implementation of the updated kidney allocation system (KAS) in 2021; members are trying to reduce organ non-use; and OPOs are procuring more medically complex donors. The member noted that the goal is to place those organs with candidates who would otherwise die on the waiting list, whereas candidates with high priority on the waiting list can afford to wait for a “safer” offer.

Another member recommended reiterating that these are system failures and not people failures. People are trying to respond to the system, so the goal should be more investment in addressing systemic challenges. A member reiterated the importance of explaining to the public that this is a necessary part of transplant to get the right organ to the right patient quickly. Another member mentioned that one of the two articles that recently came out in the American Journal of Transplantation (AJT), had graph representations that showed that the kidney donor risk index (KDRI) has increased over time. The article also showed some of the other donor characteristics that demonstrated how medically complicated the donor population is and some representation of the number of times the offer had been made before the offer was out of sequence. The member suggested calling out some of this data that shows some of the variables that are being introduced into the system (the complexity of the allocation model and donors) and how many times many of these organs have been turned down by the time there was an out of sequence allocation.

Another member said that continuous distribution could modify allocation to better match the right organ to the right person but it will take time so expedited placement is a band-aid solution until a more comprehensive solution can be put forward. The member noted that the details of a kidney continuous distribution proposal had largely been finalized when the Committee was asked to expand the scope of the work and consider further adjustments to the policy. A member said that the response may be more powerful if the patient voice is included since HRSA appears concerned that the community is not respecting the interests of the patients. Members agreed. A member suggested including a patient education component of this work as well to build trust in the process. A member noted there were six patient representatives on the Task Force that reviewed relevant data so they would be good resources.

A.3 Batched organ offers

A member noted the article cited in the directive as a footnote outlining what a batched offer could look like and described that as a practice that HRSA wants the OPTN to prohibit. Batch allocation is described

as offers simultaneously sent out to the next ten patients and whichever program responds first will be the offer. Knowing this context may be helpful in responding to this item.

Another member described some of the work to date developed for accelerated or expedited placement but noted that the practices are not aligned. The member recommended caution in terminology since this is the language that HRSA has chosen and the language that is out in the public. A member agreed with this and added that it is helpful to use language to describe what it is actually happening to make it easier for members of the public to understand.

A.4 Organ offer & A.5 offer modalities

A member commented that the letter itself is out of sequence and so the response should be reframed to address these pieces together. The Chair noted that the Committee previously shared potential changes to provisional yes for public comment feedback so the Workgroup could review that feedback as part of this work. The member agreed with this and noted that holding everyone accountable to existing policy is part of this process. Another member stated that the previous provisional yes work was intended to address mutual accountability and authenticity between transplant programs and OPOs in the organ offer process and it would be helpful to reconsider the previous work with that goal in mind.

A member asked if there is data available on AOOS and the quality of the kidneys. A Scientific Registry of Transplant Recipients (SRTR) representative confirmed there was data available. It can be challenging to assess the quality of a kidney that is offered out of sequence or why a kidney was allocated out of sequence but there is a lot of data that can provide a broad assessment about the usage of expedited placement and when AOOS is used.

Another member agreed with being data driven with some of the response. Additionally, the member stated that including the patient's voice in this would also make this response more powerful. Another member added that including a patient education piece to this project would be beneficial. A member commented that in addition to this, it should be considered how the programs are being educated on how to help manage/direct their patients. Another member agreed with this and suggested collaboration with the OPTN Patient Affairs Committee (PAC) as well as the OPTN Minority Affairs Committee (MAC) to help with the development of educational modules that be used a template for programs to use.

There were no additional comments or questions. The meeting was adjourned.

Next Steps:

- The Workgroup's feedback and project plan discussed will be incorporated and included in a formal response that will be submitted by March 31st.
- The Committee/Workgroup will await feedback/further direction before any work can begin.

Upcoming Meetings

- TBD

Attendance

- **Workgroup Members**
 - Kim Koontz, Chair
 - Steve Potter, Vice Chair
 - Jamie Bucio
 - Chris Curran
 - Meelie DebRoy
 - Anja DiCesaro
 - Kaitlyn Fitzgerald
 - Colleen Jay
 - Robert Johnson
 - Jim Kim
 - Sarah Koohmaraie
 - Anne Krueger
 - David Marshman
 - Karl Neumann
 - Jason Smith
 - Justin Wilkerson
- **SRTR Staff**
 - Nick Wood
- **UNOS Staff**
 - Lloyd Board
 - Matt Cafarella
 - Rebecca Fitz Marino
 - Betsy Gans
 - Chelsea Hawkins
 - Rebecca Murdock
 - Laura Schmitt
 - Kaitlin Swanner
 - Niyati Upadhyay
 - Joann White
 - Ben Wolford