

**OPTN Executive Committee
Meeting Summary
January 16, 2025
Webex**

Richard Formica, MD, Chair

Introduction

The OPTN Executive Committee met via Webex teleconference on 1/16/2025 to discuss the following agenda items:

1. Welcome & Announcements
2. Winter 2025 Public Comment*

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

1. Welcome & Announcements

Richard Formica, Chair of the Executive Committee, welcomed the Committee to the meeting and presented the agenda. Dr. Formica shared in November 2024, Health and Human Services (HHS) updated the HHS Final Rule to no longer require kidney, liver, or liver-kidney transplants to meet HOPE Act research criteria. He shared that the Board will consider policy changes on the topic to align with the Final Rule in the near future.

2. Winter 2025 Public Comment*

Jennifer Prinz, Chair of the Policy Oversight Committee (POC), presented the items proposed for Winter 2025 Public Comment. Ms. Prinz shared POC's review process and the questions considered in informing their recommendation for the Executive Committee to approve proposals for public comment.

Ms. Prinz shared that the POC reviewed each item and recommended the following to the Executive Committee for release for public comment:

- Continuous Distribution of Kidneys Update
- Continuous Distribution of Pancreata Update
- Monitor Ongoing eGFR Modification Policy Requirements
- Clarify Requirements for Reporting a Potential Unexpected Disease Transmission
- Establish Comprehensive Multi-Organ Allocation Policy RFF
- Updates to NLRB and Further Alignment with LI-RADS
- Modify Lung Donor Testing Data Collection
- Barriers to Evaluating International Living Donors
- Escalation of Status for Time on Left Ventricular Assist Device
- Ethical Analysis of Allocating Organs Out of Sequence
- Update Membership Requirements for OPOs, Transplant Hospitals, and Transplant Programs

The voting and approval of the slate for Winter 2025 Public Comment took place and all items were set to be released for public comment on January 21, 2025, aside from two: the white paper on *Ethical Analysis of Allocating Organs Out of Sequence* and the *Update Membership Requirements for OPOs, Transplant Hospitals, and Transplant Programs* proposal. These two items were considered separately due to feedback received from HRSA prior to the meeting. After discussion, the Committee voted to

delay the release of the MPSC public comment proposal and the Ethics white paper to a launch date of January 24, 2025, to allow for additional discussion with HRSA on their feedback.

Summary of Discussion:

Regarding the MPSC proposal, HRSA directed that the proposal was not to be released in this cycle due to concerns regarding the scope of the proposal exceeding the authority within the Final Rule. In addition, HRSA stated that ongoing modernization efforts may inform subsequent changes to membership requirements. Importantly, these proposals will be considered in modernization review efforts.

Regarding the Ethics white paper, *The Ethical Analysis of Allocating Organs Out of Sequence*, HRSA directed that the release of the white paper be postponed given the an open critical comment on allocation out of sequence. HRSA also provided feedback that determinations related to the critical comment may provide relevant considerations for the Ethics Committee to incorporate into the white paper.

Once the HRSA feedback was presented, the Committee discussed the authority of the OPTN and HRSA on the final decision to submit proposals for public comment. HRSA clarified that their process is that proposals are reviewed for accuracy as it pertains to the purview of NOTA and the Final Rule before being released into the public domain.

The Committee discussed benefit scores assigned to each project and discussed how these scores are determined by the POC. The Committee discussed some of the specific benefit scores given to the proposed public comment items. A Committee member asked that although the estimated cost associated with each project is shared, they asked that a total estimate be shared with the Committee for the public comment cycle as well.

The Committee discussed the proposal from the MPSC to *Update Membership Requirements for OPOs, Transplant Hospitals, and Transplant Programs*. The Committee continued to express concerns regarding the Final Rule and OPTN Modernization efforts not being in sync with one another. Dr. Formica asked for clarity on how the components of the proposal could be incorporated into the modernization efforts if the components were outside the scope of the OPTN. HRSA responded that the Final Rule could change, which would impact the scope of the OPTN. One member commented that a continuous push back on the proposal would affect membership requirements and the success of centers and that it was important that the proposal not be delayed any further. HRSA stated again that the question of the OPTN's authority was at issue. Dr. Formica made a motion to have the proposal be released for public comment on a delayed launch of January 24, 2025 to allow Board Leadership and HRSA to discuss the feedback further. The motion carried without opposition or abstention. Following the vote, a member stated that if any changes needed to be made then it should come back to the full Executive Committee for a second vote. Dr. Formica agreed that he would share any updates following the meeting and that if the proposal should not be released, an additional Executive Committee meeting would be called to order.

The Committee then discussed the proposed white paper from the Ethics Committee on the *Ethical Analysis of Allocating Organs Out of Sequence*. Dr. Formica shared that he did not agree with the feedback provided by HRSA on the proposed Ethics white paper. Committee members shared that they believed it was important for the proposal to go out for public comment and that it was important to

note that the proposal was a white paper and not a policy or guidance proposal. The Chair of the Ethics Committee shared the opinion of the Ethics Committee and helped answer questions.

Dr. Formica shared that the topic of allocations out of sequence is a timely topic in the world of transplant and that it is important for the OPTN to release content on the topic and that the community knows the topic is being discussed. A Committee member questioned the purview of HRSA to pull a proposal for public comment under the rationale HRSA provided. A Patient and Donor Family Representative shared that information on allocations out of sequence is important to share with the wider community so patients are well informed on the topic. A representative from HRSA reiterated that their direction was for a postponement until the critical comment issue had been resolved, and that it was not the intent that the paper would be pulled from going to public comment permanently. When asked by a committee member as to how long the postponement may be, HRSA responded that they were unsure. The Committee voted on sending the white paper out for public comment with the same delayed launch date as the MPSC proposal, to allow for additional discussion between Board leadership and HRSA.

Vote:

1. The Executive Committee unanimously approved the following items for Winter 2025 Public Comment:
 - Continuous Distribution of Kidneys Update
 - Continuous Distribution of Pancreata Update
 - Monitor Ongoing eGFR Modification Policy Requirements
 - Clarify Requirements for Reporting a Potential Unexpected Disease Transmission
 - Establish Comprehensive Multi-Organ Allocation Policy RFF
 - Updates to NLRB and Further Alignment with LI-RADS
 - Modify Lung Donor Testing Data Collection
 - Barriers to Evaluating International Living Donors
 - Escalation of Status for Time on Left Ventricular Assist Device
2. The Executive Committee unanimously approved the MPSC proposal to be released for public comment on a delayed date of January 24, 2025
3. The Executive Committee unanimously approved the Ethics white paper to be released for public comment on a delayed date of January 24, 2025.

Next Steps:

Winter 2025 Public Comment will run from January 21 until March 19. The public comment for the MPSC and Ethics projects will run beginning January 24, unless there is additional action taken by the Executive Committee prior to that date.

Attendance

- **Committee Members**
 - Andrea Tietjen
 - Dianne LaPointe Rudow
 - Emily Blumberg
 - Erika Demars
 - George Surratt
 - Jen Lau

- Jennifer Muriett
- Lloyd Ratner
- Macey Levan
- Richard Formica
- Silas Norman
- **HRSA Representatives**
 - Aite Aigbe
 - Christopher McLaughlin
 - Frank Holloman
 - Jayme Locke
 - Raymond Lunch
 - Stephanie Grosser
- **UNOS Staff**
 - Cole Fox
 - Emily Ward
 - Emy Trende
 - Jacqui O'Keefe
 - Kim Uccellini
 - Krissy Laurie
 - Lindsay Larkin
 - Morgan Jupe
 - Rebecca Murdock
 - Susan Tlusty
 - Taylor Michalski
- **Other Attendees**
 - Andrew Flescher
 - Anthony LaBarrie
 - Christina Sledge
 - Christine Jones
 - Clifford Miles
 - Jennifer Prinz
 - Karen Edwards
 - Mary Lavelle
 - Rachel Shapiro
 - Rexanah Wyse Morissette
 - Stephanie Grosser
 - Tennille Daniels