

**OPTN Policy Oversight Committee
Meeting Summary
January 15, 2025
Teleconference Call**

**Jennifer Prinz, BSN, MPH, Chair
Erika Lease, MD, Vice Chair**

Introduction

The OPTN Policy Oversight Committee (POC) met via teleconference on 01/15/2025 to discuss the following agenda items:

1. Public Comment Review & Recommendations to the Executive Committee

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The Committee reviewed the projects and proposals going out for Winter 2025 public comment.

Voting Results:

Continuous Distribution of Kidneys Update: 15 yes, 0 no, 0 abstain

Continuous Distribution of Pancreata Update: 15 yes, 0 no, 0 abstain

Monitor Ongoing eGFR Modification Policy Requirements: 15 yes, 0 no, 0 abstain

Clarify Requirements for Reporting a Potential Unexpected Disease Transmission: 15 yes, 0 no, 0 abstain

Establish Comprehensive Multi-Organ Allocation Policy RFF : 15 yes, 0 no, 0 abstain

Updates to NLRB and Further Alignment with LI-RADS : 15 yes, 0 no, 0 abstain

Modify Lung Donor Testing Data Collection: 15 yes, 0 no, 0 abstain

Barriers to Evaluating International Living Donors: 15 yes, 0 no, 0 abstain

Escalation of Status for Time on Left Ventricular Assist Device: 15 yes, 0 no, 0 abstain

Ethical Analysis of Allocating Organs Out of Sequence: 16 yes, 1 no, 0 abstain

Update Membership Requirements for OPOs, Transplant Hospitals, and Transplant Programs: 8 yes, 0 no, 1 abstain

Summary of discussion:

Clarify Requirements for Reporting a Potential Disease Transmission:

- Members supported the proposal's release for Public Comment based on review criteria. Members advised that the proposed policy is well-written, but there are ambiguities regarding malignancy development timelines and the handling of slow-growing organisms, such as micro bacteria and certain fungi. Members suggested there could be additional verbiage to more clearly define.

Escalation of Status for Time on Left Ventricular Assist Device:

- Members supported the proposal's release for Public Comment based on review criteria. There was a suggestion to ask the community if the Committee should wait until implementation of Heart Continuous Distribution to account for these patients.

Updates to National Liver Review Board Guidance (NLRB) and Further Alignment with Liver Imaging Reporting and Data System (LI-RADS):

- Members supported the proposal's release for Public Comment based on review criteria.

Monitor Ongoing eGFR Modification Policy Requirements:

- Members supported the proposals release for Public Comment based on review criteria. Members commented clarification is needed regarding the retrospective application of the January 2024 eligibility notification requirement.
- Members suggested additional community feedback is recommended on race identification processes, particularly if patients decline to self-identify, and the clarity of policy impact notifications.
- The POC acknowledged past challenges in ensuring programs understood and adhered to requirements but expressed confidence in this framework.

Modify Lung Donor Testing Data Collection:

- Members supported the proposals release for Public Comment based on review criteria.

Barriers to Evaluating International Living Donors:

- Members supported the proposals release for Public Comment based on review criteria.
- Members noted that responses may primarily represent program perspectives rather than donors, potentially narrowing the stakeholder scope. Members suggested that a public comment question be designed to ensure the living donor perspective is represented.

Establish Comprehensive Multi-Organ Allocation Policy:

- Members supported the proposals release for Public Comment based on review criteria and suggested to provide greater clarity on the status of pediatric priority and involve more pediatric patient families to ensure their perspectives are represented.
- Community feedback should specifically include input from the pediatric transplant community.
- HRSA also recommends a thorough review by the Ethics Committee during Public Comment.

Continuous Distribution of Kidneys Update, January 2025:

- Members supported the proposals release for Public Comment based on review criteria.

Continuous Distribution of Pancreata Update, January 2025:

- Members supported the proposals release for Public Comment based on review criteria.

Update Membership Requirements for OPOs, Transplant Hospitals and Transplant Programs:

- Members recommended this item for public comment release ahead of the call, prior to receiving HRSA direction that the proposal not be released for public comment due to concerns regarding scope exceeding authority of the Final Rule. Members requested clarity from HRSA on the time frame for when this work could continue and requested this work will be considered a key resource during modernization efforts.

- Members expressed concerns about not moving forward with important work that's already been done, for a time frame that was open-ended.
- MPSC Leadership commented they have been working on this project for a long time and believe it is important work to address substantial issues.
- The POC requested to hold a sentiment vote to move the proposal forward for the Executive Committee's consideration.

Ethical Analysis of Allocating Organs Out of Sequence:

- HRSA directed the release of this proposal be postponed. Members provided substantial feedback with suggestions for how to improve the proposal. A member supported the release of the paper for public comment, citing it as timely.
- One member recommended not releasing the proposal for public comment due to concerns with insufficient data, lack of patient representation in the proposal's development, clarity of implementation, and engagement mechanisms. The member also recommended more patient feedback and involvement.
- The Ethics Committee Chair emphasized that the proposed white paper is an ethical analysis, not policy. They also expressed concern for misrepresentation of the proposed white paper and how prescriptive the analysis is. Ethics Leadership stated the paper was developed at the request of the Executive Committee and under advisement of the POC and HRSA. Ethics Leadership noted the Committee has followed the policy development process fully and does not want to set a precedent for a committee pulling their own proposal when they've followed the process. The Ethics Committee Chair stated Public Comment is the appropriate venue to hear other feedback that may come out of the critical comment process; the Committee would have time to incorporate that feedback following public comment.
- The POC requested to hold a sentiment vote to move the proposal forward.

Next steps:

The Committee will send their recommendations to the Executive Committee for final approval.

Upcoming Meeting (s)

- February 13, 2025
- March 13, 2025

Attendance

- **Committee Members**
 - Jennifer Prinz
 - Erika Lease
 - Sanjay Kulkarni
 - Kelley Hitchman
 - Neha Bansal
 - Aneesha Shetty
 - Paige Porrett
 - Lorrinda Gray-Davis
 - Ty Dunn
 - Shimual Shah
 - Dennis Lye
 - Scott Lindberg
 - Lisa Stocks
 - Marilyn Levi
 - Cynthia Forland
 - Macey Levan
- **HRSA Representatives**
 - Steven Keenan
 - Amy Harbaugh
 - Frank Holloman
 - Stephanie Grosser
- **UNOS Staff**
 - Cole Fox
 - Emily Ward
 - Kaitlin Swanner
 - Kimberly Uccellini
 - Kelley Poff
 - Krissy Laurie
 - Laura Schmitt
 - Lindsay Larkin
 - Roger Brown
 - Rebecca Murdock
 - Rebecca Goff
 - Susan Tlusty
 - Sharon Shepherd
 - Viktoria Filatova
- **Guests**
 - Andy Flescher
 - Lara Danziger-Isakov