Thank you to everyone who attended the Region 2 Winter 2025 meeting. Your participation is critical to the OPTN policy development process.

Regional meeting presentations and materials

Public comment closes March 19th! Submit your comments

The sentiment and comments will be shared with the sponsoring committees and posted to the OPTN website.

Discussion Agenda

<u>Clarify Requirements for Reporting a Potential Disease Transmission</u> Ad Hoc Disease Transmission Advisory Committee

Sentiment: 8 strongly support, 7 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose

Comments: Members of the region are supportive of the proposal. There is support for clarifying the distinction between colonization and clinical infection, recognizing that this determination takes time and may not be clear within the first 24 hours. The impact of pathogens varies by organ type, with some being more concerning for certain recipients than others. There is agreement on the need for clearer guidelines on potential disease transmission and support for the recently refined Pathogen of Special Interest list. However, access to this list within OPTN policy should be improved, with clearer links to reporting requirements in Policy 15.4 to help meet the 24-hour reporting deadline. Additionally, there is a recommendation to adjust the reporting timeframe to account for business days, aligning better with transplant program workflows.

Escalation of Status for Time on Left Ventricular Assist Device

Heart Transplantation Committee

Sentiment: 6 strongly support, 5 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose

Comments: Overall, members of the region are supportive of the proposal. There was strong support for updating status criteria to allow LVAD patients to qualify for higher statuses. Some attendees believe the proposed policy does not go far enough to expedite transplants for these patients and suggest reducing the time requirements, proposing eligibility for Status 3 at three years and Status 2 at five years post-implantation. These changes could impact initial listing decisions, potentially leading to more LVAD implantations and fewer urgent cases requiring Impella or balloon pumps. Another attendee noted concerns about the length of time an LVAD remains implanted, as longer durations can lead to complications and make extraction more difficult. Clarifications were provided that time is counted from the primary device implantation, and receiving a secondary device does not reset the timeline. Patients must be healthy enough to remain on the transplant list, as determined by their transplant center. LVAD patients do not require hospitalization for status 2 or 3 and the 30-day VAD time for status 3 remains unchanged.

Modify Lung Donor Data Collection Lung Transplantation Committee

Sentiment: 4 strongly support, 7 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose

Comments: Members of the region are supportive of the proposal. There is support for modifying donor data collection to enhance the continuous distribution of lungs, improving efficiency, equity, and transparency. However, challenges exist in accurately obtaining a smoking history from donor family members, particularly regarding marijuana use. It is suggested that updates be made to the Uniform Donor Risk Assessment Interview (UDRAI) tool to ensure consistent data collection. While the proposed changes are supported, there is acknowledgment that they may add an operational burden to the OPO community, which must be balanced against the benefits of improved communication.

Establish Comprehensive Multi-Organ Allocation Policy

Ad Hoc Multi-Organ Transplantation Committee

Comments: There is strong support for improving multi-organ allocation policies to ensure fairness and clarity. Concerns were raised about the complexity of the proposal, particularly regarding how allocation staff will interpret and apply it, especially in urgent situations. There were calls for visual prompts or system guidance to aid decision-making. Attendees expressed concern that pediatric kidney-alone candidates may be disadvantaged compared to kidney-pancreas (KP) candidates. There is a need for safeguards to prevent pediatric patients, particularly those on dialysis or highly sensitized, from losing access to well-matched kidneys due to prioritization of multi-organ recipients. Suggestions included establishing criteria that allow pediatric candidates to be prioritized over adult KP recipients in certain cases. Several attendees emphasized the ethical concerns around how match runs are ordered and the importance of consistent oversight of OPO allocation practices to prevent unintended disadvantages for certain candidates. There was broad support for the Multi-Organ Transplantation Committee to ensure equitable allocation across organ groups and maintain ongoing updates to policy. The project was praised as a strong step forward in addressing a complex issue, with appreciation for the IT and policy efforts required. However, the committee was urged to develop a specific pathway for pediatric patients to ensure they are not disadvantaged under the new allocation framework.

Non-Discussion Agenda

Barriers Related to the Evaluation and Follow-Up of International Living Donors Ad Hoc International Relations Committee

Sentiment: 2 strongly support, 12 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. An attendee noted their support for the guidance document.

Monitor Ongoing eGFR Modification Policy Requirements Minority Affairs Committee

Sentiment: 2 strongly support, 13 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose

Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. One attendee noted that discussions with other pediatric programs revealed that only seven patients under 18 were affected by the policy, as race-based eGFR calculations are not standard practice in pediatrics. Given the minimal impact, transplant programs find the requirement burdensome and confusing for families. There is a call to find an alternative approach to meet the policy's intent without requiring all pediatric programs to comply with unnecessary notifications.

<u>Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS</u> Liver & Intestinal Organ Transplantation Committee

Sentiment: 2 strongly support, 11 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. One attendee noted their support for alignment with liver imaging reporting data systems.

Continuous Distribution of Kidneys, Winter 2025

Kidney Transplantation Committee

Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. There is support for the transition to continuous distribution of kidneys. However, clear rules must be established to define when a kidney is considered hard to place or at risk of being hard to place. Overall, moving to continuous distribution for kidneys is seen as an appropriate step.

Continuous Distribution of Pancreata, Winter 2025

Pancreas Transplantation Committee

Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. There is support for implementing continuous distribution of pancreata to better match donated organs with patients, improving efficiency, equity, and transparency. Overall, transitioning to this system is appropriate.

Updates

Councillor Update Comments: None

OPTN Patient Affairs Committee Update Comments: None

OPTN Update

Comments: The discussion covered program management contract assignments, updates on the HOPE Act, and the continuous distribution of lungs. As part of the OPTN Modernization, Summome Native Ventures is the contractor who has been assigned to oversee some of the program management aspects of the modernization. Regarding the HOPE Act, the initial goal was to integrate it directly into clinical processes so that every institution could participate. However, after further discussion, it was decided to adopt a traditional policy approach. This will involve seeking public comment, gathering community feedback, finalizing the proposal, and then transitioning it into clinical practice. The goal is to streamline policies for liver and kidney transplants, moving away from research-based protocols to more standardized clinical guidelines. Thoracic organs are not included in this effort. As for the continuous distribution of lungs, there is no definitive assessment yet on whether it has impacted OPO performance, but this is an area worth exploring. Data indicates that 30-90 day mortality rates remain unchanged, while lungs are now traveling slightly farther distances than before.

MPSC Update

Comments: None

Feedback Session on OPTN Modernization

Attendees provided feedback to HRSA's Division of Transplantation during this session.