

Thank you to everyone who attended the Region 10 Winter 2025 meeting. Your participation is critical to the OPTN policy development process.

Regional meeting <u>presentations and materials</u>

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

Clarify Requirements for Reporting a Potential Disease Transmission

Ad Hoc Disease Transmission Advisory Committee

Sentiment: 1 strongly support, 11 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose Comments: Overall, the region is supportive of the proposal, but several suggestions were offered. There were concerns raised about the definition of "sick" versus "unsick" in the proposal, particularly for lung transplant recipients who may develop complications post-transplant. It was suggested that a "sick" recipient should be defined as experiencing unexpected disease from the donor. It was noted that the definition is included in the proposal and is determined by the judgment of the managing team, with a guidance document in development to provide further clarity. Questions were also raised about reporting requirements for lung transplant recipients who initially do well but later develop pneumonia, as other pathologies aside from donor transmission could be responsible. It was suggested that the policy should incorporate a reasonable timeframe beyond which donor transmission is unlikely. There was additional concern that the current language could lead to mandatory reporting of all posttransplant infections in lung recipients, even if unrelated to donor transmission. Clarification was requested on the definition of "expected" infections. It was noted that the definition relates to the timing of donor cross-clamp—if an infection is identified before cross-clamp, the information is already shared and does not require reporting. However, infections identified after cross-clamp must be reported. Overall, the changes were seen as an improvement, though concerns about the implications for lung transplant recipients remain. A distributed FAQ was suggested to provide further clarification and would likely need adjustments over time.

Escalation of Status for Time on Left Ventricular Assist Device

Heart Transplantation Committee

Sentiment: 1 strongly support, 9 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose

Comments: The region is supportive of this proposal. An attendee noted that the proposal seems evidence-based and should improve access for LVAD patients. The impact on access to transplant for other Status 2 and 3 candidates should be monitored.



Modify Lung Donor Data Collection

Lung Transplantation Committee

Sentiment: 1 strongly support, 6 support, 3 neutral/abstain, 1 oppose, 1 strongly oppose **Comments:** Overall, the region is supportive of the proposal with some noted opposition. There was discussion about the overlap between the proposed data collection and the existing Donor Risk Assessment Interview (DRAI), which OPOs already dedicate significant effort to completing. A commenter questioned whether there could be a way to better capture this information to reduce redundancy. However, it was clarified that since the DRAI is separate from the OPTN Computer System, it is outside the scope of OPTN to modify directly. Suggestions were made to explore whether changes could be implemented in both OPTN and the DRAI simultaneously and whether the DRAI could be modified to integrate more seamlessly with the OPTN Computer System. Since the DRAI is managed by other organizations, a collaborative effort would be needed to coordinate updates, possibly revisiting and revalidating the DRAI. Another commenter pointed out that the DRAI does not always capture granular information, reinforcing the need for the Lung Committee's proposal while also agreeing that simultaneous updates to the OPTN Computer System and the DRAI would be beneficial. Clarification was requested regarding the type of smoking history currently transmitted in the OPTN Computer System whether it only included yes/no responses and pack years, and if vaping history was sometimes recorded but not standardized. Overall, the proposed changes were seen as an improvement, but further explanation and refinement are needed. There was also interest in seeing compliance data alongside PIP and a request for the OPTN Computer System to allow providers to customize their data display—such as selecting relevant information while collapsing unnecessary data. While there was support from a transplant program perspective, concerns from the OPO community about better integrating the DRAI and OPTN Computer System data were acknowledged.

Establish Comprehensive Multi-Organ Allocation Policy

Ad Hoc Multi-Organ Transplantation Committee

Comments: There was discussion about pediatric kidney candidates and whether they should be prioritized above multi-organ allocation tables. A suggestion was made to reserve one kidney from a donor for a multi-organ candidate while ensuring the other is allocated to a pediatric patient. However, it was noted that the committee avoided making changes to current allocation policies and did not address medical urgency within single-organ classifications when a candidate needs more than one organ. Alignment of pancreas and kidney allocation for 100% CPRA values was discussed, but since 100% CPRA is not currently a classification within pancreas allocation, it was not included in this request for feedback. There was also a recommendation to improve screening criteria for multi-organ placement to create a more dynamic system that accounts for real-time information. Overall, there was support for the committee's direction, with acknowledgment that continuous distribution (CD) for pancreas may address concerns for highly sensitized candidates. However, concerns remain that pediatric kidney candidates will continue to be underrepresented, and modifications to allocation policy should be considered. While there was strong support for prioritizing high CPRA candidates, concerns were raised about pediatric patients being bypassed for kidneys that instead go to multi-organ transplant recipients. This was seen as increasing risks for pediatric patients by prolonging wait times and delaying transplants. A suggestion was made to prioritize pediatric kidney candidates in specific cases by modifying allocation policies for donors aged 18-69 with KDPI 0-34%, moving kidney alone pediatric candidates above



kidney/pancreas candidates. A further category could be created for brain dead donors aged 18-69 with KDPI 0-19%, prioritizing pediatric kidney candidates in a similar manner. It was suggested that modeling be conducted to evaluate the potential impact of these options and that input from the Pediatric Committee be incorporated into future policy modifications.

Non-Discussion Agenda

<u>Barriers Related to the Evaluation and Follow-Up of International Living Donors</u> *Ad Hoc International Relations Committee*

Sentiment: 1 strongly support, 9 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. An attendee noted that the guidance document is well-constructed and could serve as a nice template for program policy development for these donor candidates.

Monitor Ongoing eGFR Modification Policy Requirements Minority Affairs Committee

Sentiment: 3 strongly support, 8 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. The proposed policy update is seen as a valuable step toward enhancing equity. However, concerns have been raised about the lack of discussion on the topic and the administrative burden it places on transplant centers. A broader review of the policy's impact on different groups and potential modifications should be considered. While the update appropriately refines previous policy language, it may increase the workload for centers responsible for notifying patients. The flexibility in notification methods is viewed as a positive aspect. Additionally, there is a need for stricter guidelines on acceptable practices for eGFR modifications to ensure consistency and prevent incorrect applications.

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

Sentiment: 0 strongly support, 9 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. An attendee highlighted that these changes represent an improvement and are supported as they align with current practices. Another attendee noted that the most significant aspect is the specific exception score recommendations for transplant oncology indications. While there is some inconsistency in the HEHE guidelines—particularly regarding limited extrahepatic disease not being a contraindication—it is understood that the final draft of the HEHE guidance may not have been included in this public comment item.

<u>Continuous Distribution of Kidneys, Winter 2025</u> *Kidney Transplantation Committee*

OPTN

Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. Attendees noted significant concerns regarding kidney distribution, particularly for higher KDPI kidneys. While the current allocation system works well for reasonable KDPI organs, an alternative allocation system may be more effective for kidneys with a KDPI above 60, prioritizing efficiency and speed over strict equity. There was strong support for a formal presentation on this topic to allow for discussion and clarification. The criteria for hard-to-place kidneys needs further refinement, as the current six-hour CIT threshold may be too short, and greater transparency is needed regarding how OPOs select transplant centers. While the overall concept is supported, concerns remain about increased logistical complexity, costs, and the potential for prioritizing sicker patients at the expense of more non-use. Additionally, the significance of small differences in composite allocation scores should be evaluated to determine if categorization is necessary. One attendee mentioned that this system closely resembles LYFT, an allocation model that was previously rejected by the community several years ago. Despite these concerns, continuous distribution of kidneys is seen as a promising and more equitable approach, and the proposed criteria for identifying hard-to-place kidneys appear reasonable. However, all transplant programs should have the opportunity to participate in expedited placement and define which candidates they would consider for these kidneys.

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. An attendee expressed strong support for a formal presentation on this topic to allow for discussion and clarification.

Updates

Councillor Update

• Comments: None

OPTN Patient Affairs Committee Update

• Comments: None

OPTN Update

• Comments: None

MPSC Update

• Comments: An attendee inquired about the committee's scope and its ability to scale to meet the demands of an increasingly complex system, particularly with OPTN modernization and focus on Allocation Out of Sequence (AOOS) and Continuous Distribution (CD). The presenter acknowledged the challenge, emphasizing that reviewing each AOOS case is a significant task. Instead, the committee focuses on identifying patterns and problematic trends. Ensuring appropriate oversight requires a large team to manage the workload effectively.

Feedback Session on OPTN Modernization

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