Thank you to everyone who attended the Region 7 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**

#### Clarify Requirements for Reporting a Potential Disease Transmission

#### Disease Transmission Advisory Committee

Sentiment: 2 strongly support, 7 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose Comments: The region is supportive of this proposal. Attendees noted that the changes would help improve OPO operations by reducing the number of unnecessary reports that OPOs are required to follow up on, though this benefit was not explicitly addressed in the policy proposal. Multiple attendees emphasized the importance of limiting required reporting to only unexpected disease transmissions that were not known prior to procurement. They explained that currently, many notifications are submitted for transmissions that were already known and expected, which clutters the system and places unnecessary strain on resources. One attendee suggested incorporating a way to date and timestamp result updates, such as when a culture that was initially reported as negative later turns positive. Another attendee noted that the proposal would provide greater clarity for transplant centers regarding when they should report a disease transmission as unexpected. Additional comments highlighted the need for clearer guidance or an endpoint to determine when an infection is less likely to be donorderived. One attendee recommended avoiding redefining the term "sick" for the purposes of this proposal and instead using alternative terminology. Another attendee stated that the addition of the word "unexpected" to the policy would be very helpful in distinguishing which cases should be reported. There was also discussion about incorporating a method to track serologies that were initially entered as negative or pending but later converted to positive in the OPTN computer system. Finally, attendees raised concerns about how to differentiate donor-acquired infections from those acquired posttransplant and recommended establishing a specific timeframe to determine when an infection should be considered donor-derived.

#### Escalation of Status for Time on Left Ventricular Assist Device

#### Heart Committee

Sentiment: 2 strongly support, 9 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose Comments: The region is supportive of this proposal. Discussion centered on the potential impact of the proposed changes, with particular concern regarding the timeframe for escalation. Several attendees felt that the proposed 5-7 year period was too long, emphasizing that post-LVAD mortality is around 50% after five years and that most patients develop complications qualifying them for Status 3 within that timeframe. Some suggested that the escalation should occur earlier to better serve patients who have been dependent on LVAD for extended periods. A patient representative stressed the importance

of early transplantation. The presenter acknowledged these concerns and committed to ongoing monitoring, with reports every six months to assess the impact and identify necessary adjustments. Attendees also asked about the statistical modeling used to predict the impact of the proposal, the implications for pediatric patients, and whether continuous distribution policies would eventually incorporate extra points for LVAD duration. The presenter reiterated the Heart Committee's intent to work closely with pediatric representatives and maintain an attribute in continuous distribution to reflect time on LVAD. Concerns about balancing LVAD patient needs with those of other transplant candidates were also noted, with some attendees advocating for shorter timeframes and further evaluation of clinical outcomes related to the proposed escalation periods.

#### Modify Lung Donor Data Collection

#### Lung Committee

Sentiment: 0 strongly support, 9 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose Comments: The region is generally supportive of this proposal. Some attendees expressed concern regarding documentation requirements. A key issue was the requirement for Peak Inspiratory Pressure (PIP) documentation, as many donor hospitals do not record PIP at the same time as Arterial Blood Gases (ABGs), especially before donor management begins. Concerns were raised about the difficulty for OPOs to consistently obtain and report this data, with a suggestion to make it optional to reduce documentation burden. Additionally, there was discussion on aligning data collection with the Donor Risk Assessment Interview (DRAI) to ensure consistency, particularly for information related to vaping, marijuana, and cigarette smoking. While there was agreement on the importance of collecting this information, ensuring updates to the DRAI before implementing these changes was seen as essential for standardization.

## Establish Comprehensive Multi-Organ Allocation Policy

#### Ad Hoc Multi-Organ Transplantation Committee

Comments: Attendees discussed the process by which the OPO would transition from completing the allocation plan to utilizing allocation tables ordered by descending medical urgency and then reverting to the current policy if necessary. They asked about several key operational issues, including how to account for donor family time constraints, manage scenarios when an organ's status changes unexpectedly (such as a non-eligible organ becoming eligible), and determine appropriate actions when an organ is declined at the cross-clamp stage. There was a strong emphasis on establishing a robust tracking mechanism to monitor OPO performance and donor management changes during the initial match run phase, even as data collection methods are still under discussion. Attendees also pointed out the importance of addressing the unique needs of pediatric candidates and achieving equity through standardization of the allocation process. Attendees also discussed the potential impact of multi-organ allocation on single-organ processes and noted the challenges of relying on current modeling and historical data to predict these effects.

## Non-Discussion Agenda

## Barriers Related to the Evaluation and Follow-Up of International Living Donors

#### Ad Hoc International Relations Committee

Sentiment: 0 strongly support, 5 support, 5 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 region was generally supportive of this guidance document. One attendee stating: "Strongly support the proposal to support international donation but to prevent exploitation."

#### Monitor Ongoing eGFR Modification Policy Requirements

#### Minority Affairs Committee

Sentiment: 2 strongly support, 4 support, 4 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 region was supportive of this proposal. One attendee commented: "This proposal should hopefully ensure that all candidates left who don't understand the modification are notified."

#### Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS

#### Liver & Intestinal Organ Transplantation Committee

Sentiment: 1 strongly support, 5 support, 5 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 region was generally supportive of this proposal. One attendee commented: "Outstanding work! The policy is catching up with disease realities. Obviously, the need for this update is that folks with these diseases do not deteriorate in line with other diseases. This proposal will ensure that patients with these diseases, some of which can cause sudden cancers and other issues, are hopefully able to reach transplant before it is too late."

## 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. Attendees expressed support for the definition change and on moving forward with continuous distribution.

## 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. Most attendees expressed support for moving forward with continuous distribution, and support for the new criterion for medical urgency. One attendee expressed concern that Kidney Allocation System (KAS) 250 may have resulted in fewer pancreas transplants; and with revisions to multi-organ transplant policy and continuous distribution they expressed concern that these policy changes could be detrimental to pancreas only candidates.

# Updates

## **Councillor Update**

• No comments.

## **OPTN Patient Affairs Committee Update**

• No comments.

#### **OPTN Update**

Comments: Attendees raised questions about the criteria for candidacy on the Transitional Nominating Committee, particularly regarding restrictions on prior service on the OPTN Board. There was also concern from the pancreas transplant community about the effectiveness of the KAS 250 system, with requests for data on its impact on transplant volume, waitlist times, and mortality rates. Additionally, questions were raised about the transparency of the Nominating Committee's criteria for the new Board, with calls for public review. Another key discussion point was the challenge of kidney allocation out of sequence and the broader issue of organ non-utilization. The presenter acknowledged these challenges, noting that stressors such as the new 250 nm allocation circle and OPO performance have contributed to the current situation. Plans for process improvement initiatives were put on hold due to critical feedback, but there remains a collective effort to improve organ utilization while acknowledging that a zero non-use rate is neither feasible nor desirable.

#### **MPSC Update**

Comments: One attendee asked for an approximate date for communication regarding the hazard ratio increase, the presenter responded that those communications will not go out until after the March meeting for MPSC.

#### Feedback Session on OPTN Modernization

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