

Thank you to everyone who attended the Region 11 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

Disease Transmission Advisory Committee

Sentiment: 5 strongly support, 15 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose Comments: Region 11 supports this proposal. An attendee voiced concern regarding insurance coverage, however the proposal does not address insurance coverage. Another attendee asked if disease transmissions that are known or expected need to be reported, this proposal only addresses unexpected disease transmissions.

Escalation of Status for Time on Left Ventricular Assist Device

Heart Committee

Sentiment: 4 strongly support, 11 support, 8 neutral/abstain, 1 oppose, 0 strongly oppose Comments: Region 11 supports this proposal. An attendee inquired about patients doing well on LVAD support, questioning if they would have the same status as status 2 or 3 patients with post-VAD complications, if modifiers would apply, and if status 3 patients could remain at home given long waiting times. Another attendee raised questions about patients never added to the waiting list, regional disparities in LVAD patient listings, potential regional imbalances, waiting times for hospitalized status 2 patients with devices, and policy granularity for patients with complications being downgraded after treatment. An attendee asked how blood type factors into LVAD status, with clarification that current escalation status is temporary until Continuous Distribution implementation, where blood type will become a composite score factor. Questions were raised by attendees about prioritizing time for multiple LVAD patients upgraded to status 2 from the same center, with confirmation that status and waitlist time are current determining factors. One attendee suggested running a model to estimate wait time changes across regions, while another sought clarification on whether waitlist time or implant time determines status upgrades. Attendees expressed support for the proposal as LVAD patients were severely impacted by previous allocation changes. An attendee requested the Committee provide more clarity in the proposal and another suggested shortening the timeframe to 3-4 years with less than 18 months for the next reduction.

Modify Lung Donor Data Collection

Lung Committee

Sentiment: 3 strongly support, 11 support, 9 neutral/abstain, 1 oppose, 0 strongly oppose



Comments: Region 11 supports this proposal. Members expressed concern that donor families are often unaware of the amount of tobacco and marijuana use of the donor was using. A representative from the Committee noted the committee's desire for a good faith effort to be made in obtaining this information while acknowledging it may not always be feasible.

Establish Comprehensive Multi-Organ Allocation Policy

Ad Hoc Multi-Organ Transplantation Committee

Comments: Several attendees commended the committee for addressing multi-organ transplantation while emphasizing the need to not lose sight of high CPRA patients who are difficult to match. Multiple attendees supported standardization of multi-organ transplantation, particularly to help prioritize pediatric transplants, while noting the need to incorporate these changes with the upcoming roll-out of CAS for liver, kidney, and heart. Several attendees strongly supported defined priorities for multi-organ grafts, and one suggested to place all recipients on a single allocation list in order to avoid unnecessary confusion. An attendee questioned where liver-intestine-pancreas patients would fall in the allocation sequence and suggested these combinations should be called out separately. Another attendee expressed concern that kidney-pancreas candidates with 100% CPRA are prioritized lower than kidneyalone candidates with 100% CPRA, noting that outcomes under the safety net have been favorable, and questioned whether access to lifesaving organs should drive priority differently. An attendee asked about the possibility of having all organs matched on a single list, calling it "the dream," while another raised concerns about finding appropriately sized organs for pediatric Status 1B patients. Concerns were raised about whether allocation tables could be automated in match runs, and if not, acknowledged the need for public distribution of the decision tree. One attendee expressed concern about failing to include Kidney Class 6 candidates with Classes 1-5, which could disadvantage vulnerable pediatric populations.

Non-Discussion Agenda

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

Ad Hoc International Relations Committee

Sentiment: 5 strongly support, 14 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose Comments: Region 11 supports this proposal. No comments were provided.

Monitor Ongoing eGFR Modification Policy Requirements

Minority Affairs Committee

Sentiment: 7 strongly support, 12 support, 2 neutral/abstain, 1 oppose, 1 strongly oppose Comments: Region 11 supports this proposal. One member inquired about methods to verify candidate race beyond self-reporting. Another member questioned whether pre-emptive status should be considered when qualifying eGFR is provided with referrals to transplant centers despite current eGFR being greater than 20. Multiple members commented that pediatric candidates should be excluded from this policy since pediatric eGFR calculations do not use race-based coefficients. Another member addressed the significant administrative burden placed on transplant programs, suggesting implementation should have coincided with the policy change, and noting that retrospective notification may cause confusion for recipients and their families.



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

Liver & Intestinal Organ Transplantation Committee

Sentiment: 5 strongly support, 12 support, 7 neutral/abstain, 0 oppose, 0 strongly oppose Comments: Region 11 supports this proposal. One member explained that contrast enhanced ultrasound is not performed nationally and radiologists differ on whether it provides enough granularity for diagnosis.

Continuous Distribution Updates

Continuous Distribution of Kidneys, Winter 2025

Kidney Transplantation Committee

Comments: A member expressed strong support for the proposal, noting it could positively impact kidney non-use issues. The member emphasized the need for specific definitions and allocation policies for hard to place kidneys as part of the continuous distribution policy. They stressed the importance of formalizing and protocolizing allocation practices for hard to place kidneys, especially given the dramatic rise in allocation out of sequence with KAS 250 and other changes. The member suggested that improving transparency around how transplant centers are identified for aggressive center lists would help maintain public trust. They noted that while current allocation policies and IT infrastructure may not improve immediately, making the process more procedural and consistent across OPOs and centers could reassure the public that out of sequence allocation is patient-focused and helps reduce organ waste. The member suggested the proposed change enhances flexibility and equity in kidney allocation, ensuring organs are distributed based on patient needs and medical urgency rather than rigid categories, ultimately improving transplant numbers.

Continuous Distribution of Pancreata, Winter 2025

Pancreas Transplantation Committee

Comments: Members expressed support for the ongoing effort to create continuous distribution of pancreata. One member expressed support noting they believed this will help reduce non-use of pancreata.

Updates

Councillor Update

Comments: No comments were provided.

OPTN Patient Affairs Committee Update

Comments: No comments were provided.

OPTN Update

• Comments: An attendee asked if the current plan to remove OPTN Board Members and hold a special election to replace them was consistent with NOTA and the final rule. A HRSA representative responded that the plan is consistent with NOTA and the final rule.



MPSC Update

Comments: An attendee asked about increasing the flagging threshold for hazard ratios to
above 2.25. Another attendee raised concerns about allocation out of sequence. Another
attendee questioned whether allocation out of sequence situations should be reported at all.
Multiple participants recommended establishing clearer guidelines and standardized practices
for high-risk kidneys and expedited allocation. Concerns were expressed by multiple attendees
about media reporting on allocation out of sequence without full context. Other attendees
expressed frustration of "provisional yes" responses. An attendee suggested implementing
standards for non-family restricted allocations regarding hours of allocation and/or sequence
numbers before approaching more aggressive centers.

Feedback Session on OPTN Modernization

• In lieu of a feedback session during the meeting, HRSA will follow up with meeting attendees with questions about the OPTN Modernization.