OPTN

Thank you to everyone who attended the Region 7 Summer 2025 meeting. Your participation is critical to the OPTN policy development process.

Regional meeting presentations and materials

Public comment closes October 1st! Submit your comments

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

Non-Discussion Agenda

Modify Guidance for Pediatric Heart Exception Requests to Address Temporary Mechanical Circulatory Support Equipment Shortage

Heart Transplantation Committee

Sentiment: 5 strongly support, 4 support, 8 neutral/abstain, 0 oppose, 0 strongly oppose

- Comments: None

2025 Histocompatibility HLA Table Update

Histocompatibility Committee

Sentiment: 4 strongly support, 9 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose

- Comments: None

Discussion Agenda

Require West Nile Virus Seasonal Testing for All Donors

Ad Hoc Disease Transmission Advisory Committee

Sentiment: 3 strongly support, 8 support, 4 neutral/abstain, 2 oppose, 0 strongly oppose

- Comments: Attendees raised concerns and differing views regarding West Nile Virus (WNV) NAT testing for donors. Some centers test seasonally and report very few positive cases, questioning the need for universal testing. Others perform year-round testing and support the proposal, citing safety and consistency benefits. Concerns were expressed about the feasibility of completing testing within a 7-day window for living donors, citing donor inconvenience, test availability, and turnaround times. Questions were raised about compliance if testing is only required seasonally, the potential for false positives leading to unnecessary organ discards, and the impact on allocation timelines. Attendees also highlighted that WNV primarily affects the central nervous system, raising questions about the clinical utility of blood-based NAT testing. The financial impact of implementing testing nationwide was noted, with cost estimates ranging from $2–3 million annually for OPOs and $700K–1.2M for living donor programs. Some requested more data on test performance, the number of confirmed transmissions, and whether previous positive donor cases had been detected through NAT.

Update and Improve Efficiency in Living Donor Data Collection

Living Donor Committee

Sentiment: 2 strongly support, 8 support, 5 neutral/abstain, 2 oppose, 0 strongly oppose

- Comments: Attendees discussed questions and concerns regarding living donor data collection and follow-up. Several asked for clarification on what constitutes the "first in-person visit," whether it begins with initial blood draws for ABO compatibility or after a donor is determined compatible and begins the formal evaluation process. Some supported standardization of follow-up and data collection but requested clarity on whether participation in the living donor collective would be mandatory, whether programs would have access to reports, and whether donors could opt out of future contact. Concerns were raised about the use of non-donor registration forms, noting that follow-up with individuals not approved as donors may not be well received. Attendees emphasized that in-person requirements should apply only after formal evaluation begins, following education, donor advocate meetings, and informed consent. While most agreed that collecting living donor data is important, they highlighted the administrative burden on transplant centers, the variation in how donors present and are evaluated, and differences across programs in how multiple potential donors are managed. There was a recommendation for prioritizing long-term outcomes of actual donors over expanded non-donor data collection.

Require Patient Notification for Waitlist Status Changes

Transplant Coordinators Committee

Sentiment: 5 strongly support, 6 support, 3 neutral/abstain, 3 oppose, 0 strongly oppose

- Comments: Attendees discussed the proposal to notify patients of waitlist status changes, focusing on both transparency and administrative burden. Several asked for clarification on what constitutes a status change—whether it includes only active/inactive changes or also shifts in score or priority. While many supported transparency and emphasized the importance of patients being informed, concerns were raised about the burden for centers, especially when patients fluctuate between active and inactive frequently or when temporary inactivation occurs. Some noted past discussions of this issue in 2012 and 2016, highlighting the need to balance patient involvement with practical implementation. Many centers reported they already provide verbal notification documented in the medical record, with some assuming this was already required. There was broad support for allowing flexibility in notification methods, including patient portals, phone calls, in-person discussions, and electronic messages, rather than mandating written letters, which could cause delays and confusion. Some attendees recommended making this a best practice rather than a regulatory requirement and suggested collecting data on administrative burden if implemented. Others emphasized that documentation of communication in the EMR should be sufficient for compliance. Overall, there was agreement on the importance of keeping patients informed, but concerns remain about feasibility, administrative workload, and whether written notification should be mandatory.

Establish Comprehensive Multi-Organ Allocation Policy

Ad Hoc Multi-Organ Transplantation Committee

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

- Comments: Several comments emphasized the need for flexibility when donor circumstances change. Questions were raised about whether a match run must be rerun if an organ initially considered ineligible improves, and whether provisions exist for donor instability or family time constraints. OPOs stressed that real-world scenarios could create the appearance of non-compliance unless clear mechanisms for case-specific exceptions are included. Kidney-pancreas (KP) and pancreas-alone (P) transplantation drew particular focus. Multiple attendees noted that only about 10% of pancreata are usable, and that the majority are transplanted as SPK (simultaneous pancreas-kidney). Concerns were expressed that the proposed policy may further reduce SPK numbers, increase wait times, and exacerbate delays in allocation. Attendees emphasized that SPK candidates face high mortality, lack the safety net options available to heart-kidney (H-K) and liver-kidney (L-K) candidates, and should not lose priority relative to other multi-organ groups. Some suggested adding stringency to H-K and L-K eligibility to limit overuse and protect SPK opportunities. There was also a call to better align pancreas prioritization with kidney candidates who are highly sensitized (cPRA 100%), as current criteria disadvantage pancreas candidates despite their dual status as kidney patients. Allocation tables were another area of debate. Several argued that donor characteristics such as age, diabetes status, and BMI should be used to prioritize allocation appropriately, avoiding unsuitable donors for pancreas/KP candidates while prioritizing young, non-diabetic donors for SPK. Some objected to the KDPI cutoff and age criteria, arguing they were misaligned with clinical practice. Others noted that pediatric DCD donors were not included in the tables and asked why. Beyond organ-specific issues, participants highlighted broader concerns about education, implementation, and system efficiency. Transplant centers and OPOs will need education to understand and explain the system, particularly for multi-visceral candidates. There were worries about slowing allocation, increased cold ischemia time, last-minute switching between allocations, and overall inefficiency. Suggestions included pre-implementation simulations of allocation scenarios in the OPTN system to test the logic of the new tables. While some institutions expressed support for the proposed order of priority, others opposed it, particularly in how candidate groups were ranked within the multi-organ allocation tables. Hospitals advocated for preserving flexibility, ensuring fairness, and protecting disadvantaged groups, including pediatric candidates, long-wait kidney-alone candidates, and highly sensitized pancreas recipients. Overall, attendees agreed that the proposal represents important progress toward standardization, fairness, and clarity in multi-organ allocation. However, they stressed the importance of monitoring post-implementation outcomes, protecting vulnerable groups such as SPK and pediatric candidates, ensuring OPOs can operate within real-world constraints, and preventing further reductions in pancreas utilization.

Updates

Councillor Update

- Comments: None

OPTN Patient Affairs Committee Update

- Comments: An attendee thanked the presenter for highlighting and continuing the Patient Portal concept, which was first proposed by the Patient Affairs Committee in 2016.

OPTN Executive Update

- Comments: Attendees raised questions about the recent increase in the OPTN registration fee and the broader budget and governance structure. The registration fee increase is intended to support policy development, implementation, and monitoring related to organ allocation and patient safety. It does not cover modernization efforts, which are funded separately. The fee had not been raised previously because OPTN was required to first use its reserve account. Concerns remain about how new appropriations will be distributed across the multi-vendor contract and how much of the new budget directly supports OPTN operations. Concerns were also expressed about board and committee diversity. Attendees noted limited representation of women and non-white members, and a reduction in the pediatric patient/caregiver voice despite the presence of pediatric providers. It was emphasized that representation should reflect not only the waitlist but also organ failure demographics, since many minority patients and pediatric patients face barriers before reaching the waitlist. Calls were made for broader participation in future elections to ensure more balanced representation. Finally, clarification was requested on how the OPTN Board's AOOS (Allocation Out of Sequence) workgroup coordinates with the MPSC (Membership and Professional Standards Committee). It was explained that MPSC members work directly with the AOOS workgroup and that their coordination is ongoing, with MPSC's specific responsibilities defined in the bylaws, though some roles are still being determined.

HRSA OPTN Modernization Update

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