The American Society of Transplantation (AST) responded to six items the OPTN released for public comment on August 27, 2025. The AST submitted the responses below through the OPTN website on September 30, 2025, after receiving input from the AST's communities of practice, OPTN Policy Committee, and Board of Directors.

1. Establish Comprehensive Multi-Organ Allocation Policy

The American Society of Transplantation (AST) offers the following comments in response to the proposal, "Establish Comprehensive Multi-Organ Allocation Policy." The AST strongly supports the goal of standardizing multi-organ allocation. Efforts to standardize multi-organ allocation across the transplant system are needed to balance equity and efficiency when allocating organs; however, the AST has some concerns with the approach and policy changes outlined in this proposal.

The AST is concerned that kidney alone and kidney-pancreas (KP) candidates, including pediatric kidney candidates, may be disadvantaged by this proposal. Preferential allocation of high-quality kidneys to multi-organ candidates may result in allocation of kidneys to candidates with potential for renal recovery (low net utility); this might be mitigated by more stringent requirements regarding renal function at the time of organ offer (i.e. lower eGFR) and demonstrate continued need for kidney transplantation closer to the time of organ offer. Similarly, allocation of high-quality kidneys to multi-organ candidates may result in lower graft survival (lower net utility) from these organs compared to allocation to kidney-alone candidates; this could be mitigated with policy requirements that monitor kidney transplant outcomes after multi-organ transplant to promote responsible candidate selection for multi-organ transplantation.

KP candidates differ from other multi-organ transplant candidates in that the primary organ is usually the kidney, and pancreas-alone transplant is rarely performed. A policy that reduces priority for KP candidates relative to other multi-organ candidates may result in longer wait times for KP candidates, progression of underlying diabetes and kidney related disease, dialysis access complications, and removal from the waiting list for pancreas and kidney-alone transplant. Missed opportunities to capture the benefits of pancreas transplantation for these patients threaten net utility and justice. Kidney and KP candidates face long wait times for transplantation, and although dialysis may be an option, with it comes significant personal, community, and healthcare burdens. These burdens are magnified for already marginalized candidates, candidates with social/financial stressors, and candidates with a low probability of finding a suitable organ donor. Any policy which potentially lowers priority for these candidates or allows them to be passed over in favor of other candidates for whom kidney transplantation is not the primary need is a threat to justice/fairness for these populations. Additionally, pancreas utilization is highest when the pancreas goes with the kidney. The AST is concerned that highly sensitized KP candidates will not have sufficient access to a KP, only the kidney alone, based on the proposed allocation changes. A possible adjustment to explore would be to start the allocation with the high CPRA, zero-antigen mismatches, pediatric, or prior living donors for kidney alone, followed by KP, and then make multi-organ allocation offers.

The AST also recommends that pediatric kidney candidates should be prioritized before pancreas and KP classifications in the proposed allocation tables for 11-17 years old donation after brain death (DBD) donors with a kidney donor profile index (KDPI) 0-34% and DBD donors aged <11 with KDPI 35-85%. Many pediatric appropriate kidneys are allocated to lower priority candidates currently, especially in regions where there are high rates of diabetes necessitating high rates of KP transplants. Combined with the high rates of declines for KP recipients, this

leads to missed opportunities for young candidates. The AST highly recommends that pediatric candidates should be prioritized for pediatric donor organs over adult KP recipients even when the KDPI is not ideal (KDPI 35% to 85%) as these kidneys will recover and last a long time for these pediatric recipients. Prioritizing pediatric recipients for small donors would also improve their access.

Regarding pediatric liver-kidney transplants, the AST is concerned that the kidney would not be automatically allocated with the liver to these patients. Children have naïve immune systems and form donor specific antibodies (DSA) at a much higher rate than adults. One of the benefits of allocating the liver with the kidney from the same donor to children is that the liver will absorb some of the DSA allowing the kidney to last longer.

The AST recommends that at least one kidney from each donor should be allocated to a kidney alone or KP candidate. Currently, only high-CPRA (100%), zero-antigen mismatched, pediatric, or prior living donors are given any priority from these multi-organ donors.

Additionally, appropriate education regarding this policy change should be shared broadly with the transplant community. More attention needs to be provided for how OPOs and transplant centers are to handle rapid donor cases where time is extremely limited for pre-recovery allocation planning. Additional clarity on how allocation should proceed in response to intra-operative declines or necessary reallocations would also be beneficial. E.g., if heart-kidney is allocated to a potential transplant recipient, the other organs have also been allocated, and the heart is ultimately deemed unsuitable for transplant- what is the expectation for reallocating the kidney?

Finally, it is crucial that the OPTN closely monitor the impacts of these changes as outlined in the proposal. The AST suggests that the OPTN consider a defined time frame to return to these policy changes with a plan to address any concerning trends observed during post-implementation monitoring and respond with additional changes in policy. Prospectively defined parameters for pausing or adjusting the proposed policies would help to promote transparency and trust from observers concerned about threats to net utility and justice. The AST recommends that the OPTN consider monitoring the following in addition to what is outlined in the proposal:

- Monitor pancreas non-utilization from these multi-organ donors. It should be very low (or close to zero) - at minimum no higher than current rate from similar donors. Also monitor how many potential KP offers became pancreas transplant alone offers due to multi-organ allocation.
- Monitor kidney function and kidney graft survival long-term in multi-organ recipients. If kidney function at 3-months, 12-months, and 2- and 3-years is inferior to kidney alone and/or KP recipients, consider allocations changes to maximize utilization and benefit.
- Monitor utilization of safety net listing for kidney after heart, lung, or liver transplant. This should increase, not decrease over time. If it decreases, it could be inferred that these patients are receiving undue priority as compared to kidney and KP patients.
- For every multi-organ donor where a kidney alone or KP candidate did not get top priority to the kidney, monitor the outcome of this candidate. How long from the ‘multi-organ transplant miss' to when they are transplanted? What was the difference in KDPI between multi-organ transplant miss and actual transplant? One possible solution to consider is adopting policy that prohibits a kidney alone or KP candidate from being

bypassed more than once due to prioritization of multi-organ potential transplant recipients.

- Monitor the re-transplant rate for kidney after heart-kidney, heart-lung, and heart-liver transplants. For this proposal to meet its goals, the multi-organ survival of patients and grafts should be equivalent or better for multi-organ than single kidney. If it turns out that multi-organ kidneys fail early and require another transplant, this would further exacerbate moving kidneys alone away from pure end stage renal diseased candidates. If this is the case, these changes will yield lost organs, life-years, and patients.
- The OPTN should pursue the development of models that include the outcomes of multi-organ recipients in the ongoing evaluation of transplant program performance.

2. Update and Improve Efficiency in Living Donor Data Collection

The American Society of Transplantation (AST) offers the following comments in response to the proposal, "Update and Improve Efficiency in Living Donor Data Collection." The AST strongly supports the broader goal of long-term living donor data collection and safety considerations but has concerns with the approach outlined in this proposal and does not believe it will satisfactorily address this goal.

The current proposal seeks to remove the two-year follow-up while retaining the one-year follow-up of living donors by the recovery hospital. The AST believes that this measure could unintentionally affect the relationship between donors and their providers as it might be perceived by some stakeholders as diluted responsibility. Transplant centers have close relationships with the donors, and it is this trust that leads to better adherence and outcomes. Complications from living donation like hypertension, end stage renal disease, steatotic liver disease, or cirrhosis are long term adverse events which need long term medical follow-up by transplant centers. As such, although yearly questionnaires administered by the Scientific Registry of Transplant Recipients (SRTR) will be helpful in expanding our understanding of living donors' long-term outcomes, they are not an adequate substitute. Resource constraints and burdens associated with data collection are well understood, and a registry by SRTR may relieve some of those burdens; however, the cost may be high attrition rates, leaving the data uninterpretable. Accordingly, the AST suggests keeping the two-year follow-up as a responsibility of transplant centers. The AST encourages efforts and resource allocation for integration of electronic health records to facilitate automatic data transmission. The AST also believes that a means to improve donor outcomes is emphasizing a focus and strengthening of the relationships between living donors and the transplant centers.

The living donor non-donation form is extensive and provides means to document the evaluation and outcome of the potential living donor; however, the form does not present a clear pathway to better understand and address barriers to donation. The AST recommends limiting this form's focus to demographics and reasons for not proceeding with donation. All protected health information should be removed to eliminate any concerns about personal information saved in a centralized repository and possible breaches. Obtaining information to complete the living donor non-donation form could also be strengthened with a clear informed consent process for these individuals. The AST suggests that the policy requires the first appointment with the transplant hospital to initiate the living donor evaluation process must include education about data collection requirements, their importance, and an informed consent process that makes it clear that participation in the data collection process is voluntary.

Additionally, the AST is also concerned that potential living donors who withdraw from the process may decline continued contact from the transplant center and be hesitant to share information regarding their decision. While unintended, the potential donor may perceive this follow-up contact as undue pressure. Instead of transplant hospitals collecting this information after a decision that the individual will not be a living donor, an alternative would be to gather this information directly from these individuals through a web-based portal or USPS mail. These concerns about the living donor non-donation form are amplified by the added burden that it will place on living donor teams at these transplant hospitals considering the required training, resources, and staff time allocation that will be necessary to comply with requirements.

3. Require Patient Notification for Waitlist Status Changes

The American Society of Transplantation (AST) generally supports the proposal, "Require Patient Notification for Waitlist Status Changes." This notification is vital information that should be communicated as part of patient's plan of care. These proposed changes will support patients' active participation in their own care, particularly in situations where their listing status changes due to reasons the patient may be able to resolve (e.g., substance use, suboptimal nutrition status, insurance issues).

The AST believes that transplant centers should have flexibility in how this information is communicated to patients and recommends that written documentation of the communication in the patient's chart is acceptable to comply with these policy requirements. This communication may be in the form of a written letter, a message in the patient's electronic medical record, an encrypted email, or a conversation with the patient either in person or on the telephone. Additionally, notification of patient status change by written letter alone may not be timely in all cases and could introduce an element of confusion when changes occur quickly. Based on the potential frequency of these changes, particularly for hospitalized and critically ill-patients, we recommend that chart documentation with patient notification (or caregiver notification if the patient is unable to receive and comprehend the notification) is sufficient to empower patients and support transparency. Additionally, use of electronic medical records and encrypted emails should be allowed considering patients who move, change mailing addresses, but do not update the transplant program of this change. Documentation in the medical record of a conversation with the patient or caregiver should also be an acceptable method of notification.

These waitlist status change notifications should at least include the specific reasons prompting the change to inactive status and information to contact the transplant program to discuss the patient's waitlist status and potential next steps.

It will take programs time as they work to implement practices to meet these expectations in a consistent manner. To support transplant programs in this endeavor, the AST recommends the following:

- Reasonable implementation timelines to allow for systems adjustments and staff training
- Development of organ-specific educational materials using standardized, patient-friendly language
- Resources to support the integration of this process into each transplant program's quality assessment and performance improvement (QAPI) initiatives, with routine tracking and reporting of communication efforts and outcomes.

Finally, the AST recommends excluding the notification requirement in the case of patient death as this is entirely unnecessary and can cause the patient's family additional and unnecessary anguish.

4. Require West Nile Virus Seasonal Testing for all Donors

The American Society of Transplantation (AST) supports the concept behind the proposal, "Require West Nile Virus Seasonal Testing for all Donors," but is concerned with the proposed policy changes. Specifically, the AST is concerned with the practical considerations of adhering to these requirements, anticipated unintended consequences, and unclear goals and metrics to evaluate the success of these policy changes.

The proposal does not thoroughly address practical considerations regarding the time necessary to obtain deceased donor West Nile Virus (WNV) nucleic acid test (NAT) results. Although the proposed policy states that these results must be available prior to implantation of the organ, the AST is concerned that this requirement will lead to delays that yield increased costs, increased cold ischemic time, and increased non-utilization rates. Obtaining timely WNV NAT test results will be particularly challenging for organ procurement organizations (OPOs) and living donor recovery hospitals that outsource this testing. Regardless of where donor testing is performed, these proposed changes are anticipated to present OPOs challenges during rapid deceased donor cases where waiting for test results is not an option. Additionally, WNV NAT results may not be possible for live donor workups in the setting of critically ill intended recipients. In consideration of these rapid donor scenarios and to allow donation to proceed without delay, the AST recommends the addition of policy language to accommodate scenarios when urgency and an inability to secure WNV NAT results prior to donor recovery can be documented.

The AST also recommends that the OPTN develop supporting resources to address the possibility of false positive results and instances where retesting is advisable or may be necessary; e.g., if a result is presumed to be a false positive. Considering the prevalence of WNV in the donor population, the AST is concerned that increased testing will result in more false-positives than true-positives results, and that this will lead to a net detrimental impact on organ utilization.

To fully evaluate the impact of these proposed changes, the post-implementation policy evaluation stands to be more clearly defined. The AST requests more detail on the anticipated impact of the policy and what findings would indicate a successful policy. The AST recommends modifying the monitoring plan to address the concerns outlined in this response- possible organ non-use and waitlist death because of delayed, equivocal, or false positive WNV NAT testing results.

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

The American Society of Transplantation (AST) supports the guidance document updates reviewed in the retrospective public comment document, "Modify Guidance for Pediatric Heart Exception Requests to Address Temporary Mechanical Circulatory Support Equipment Shortage." In addition to what is outlined, the AST recommends an ongoing, periodic evaluation of the status of this shortage. To perform this evaluation efficiently and consistently, the AST suggests that the OPTN consider criteria to determine when there is an appropriate supply of

these devices that would prompt the expiration of these updates to be scheduled. One factor that would be important to examine is geographical differences in access to these needed devices. Finally, with these evaluations, the OPTN would also be well suited to provide regular public updates on the device shortage problem and progress being made.

6. 2025 Histocompatibility HLA Table Update

The American Society of Transplantation (AST) supports the proposal, “2025 Histocompatibility HLA Table Update.”