Proposal: Clarify Requirements for Reporting a Potential Disease Transmission

The ASTS appreciates the opportunity to comment on this proposal from the OPTN Ad Hoc Disease Transmission Advisory Committee. We support this proposal in concept, and offer the following comments:

- **Do you support the proposed definition of an unexpected transmission event? Do you agree with the time frame in which an event should no longer be considered expected?**

  The OPTN proposes defining an unexpected transmission event as a pathogen, disease, or malignancy that was not known in the donor at the time of cross-clamp. The time of donor cross-clamp was chosen as it provides a consistent reference point. By this definition cultures drawn from the donor before cross clamp, but reported after cross clamp, would be considered an unexpected transmission event. The definition and time frame are reasonable. However, as the proposal is currently written, there remains lack of clarity about application to lung transplantation particularly for positive respiratory cultures that are drawn before cross clamp but reported after cross clamp. Would an unexpected transmission be reportable for lung recipients only if it is contributing to illness, i.e. 'sick' lung recipient?

- **Does the definition of sick lung recipient clarify when reporting should occur?**

  The new definition does provide some clarity though it still leaves substantial room for interpretation based on the clinical judgement of the team. We foresee that this subjectivity will continue to cause confusion and lead to variability in reporting. Is it possible to define this further? If not, monitoring and feedback post-implementation might be helpful to fine-tune the definition.

- **Do the reporting requirements for non-sick lung recipients reflect the appropriate level of reporting and avoid over-and under-reporting?**

  We support the concept of being more selective in reporting for non-sick lung recipients. Would a positive respiratory culture drawn before cross clamp, but resulted after cross clamp, be reportable for a non-sick lung recipient? This scenario should be clarified further in the policy language in 15.5.A.

Comments:

The ASTS supports the proposed definition of an unexpected transmission event and feels the time frame in which an event should no longer be considered expected is appropriate. We feel that standardization of this definition will lead to improvement in compliance of reporting both expected and unexpected transmission events.

We are concerned that the proposed definition for ‘sick lung recipient’ remains subjective although it does represent an improvement over the current state. We recommend clarification in the policy language for reporting of donor derived cultures in the setting of ‘non-sick’ lung recipients.

Proposal: [Continuous Distribution of Pancreata Update, Winter 2025]

Summary

Thank you for the opportunity to provide feedback on the latest iteration of OPTN request for feedback on the *Continuous Distribution of Pancreata Update.* We continue to be generally supportive of the concept of a continuous allocation system. We are gratified to see this latest expression of the OPTN's commitment to dealing with the innumerable pragmatic operational issues in kidney and pancreas allocation under a CAS and overall are supportive of the focus on operational items that provide evidence that a transition to a CAS will be actionable and safe. We are supportive of the ongoing focus on efficiency in allocation. We point out that the allocation system has seen major changes, and consequently disruptions, over the last few years, and we advocate strongly for an operational philosophy in the design of CAS for all organs that specifically aims to avoid massive changes in allocation patterns at the outset. We appreciate the malleability of CAS and expect that post-implementation monitoring will be vigorous and course corrections frequent. We are hopeful that the fundamental strategic pillar of increasing the number of transplants performed while maintaining quality outcomes guides future adjustments of the CAS.

We are supportive of the concept of a medical urgency system for pancreas, in part to keep pancreas aligned with other organ-specific medical urgency policy approaches. We support the use of the Kidney medical urgency criteria for KP candidates. We support the quantified and standardized approach to gauging hypoglycemic unawareness and support the primacy of the impaired awareness of hypoglycemia as a marker for medical urgency in the majority of candidates receiving such a designation.

We are concerned that proposed MOT allocation schemes continue to have the potential to impair access for vulnerable populations of SOT candidates. Examples include pediatric patients and highly sensitized adult kidney-alone candidates. We would request that clarification be provided within the CD of pancreata policy framework on the allocation of organs to MOT versus SOT candidates.

Overall recommendation: Support

How effectively might the proposed qualifying pathways identify medically urgent candidates? Do you have suggestions for modifying the proposed pathways for medically urgent candidates?

ASTS supports the validated and quantified approach to measuring impaired awareness of hypoglycemia (IAH) outlined in the proposal. We feel that IAH should be the basis of declared medical urgency in most candidates granted such status.

1). We are concerned that **diabetic ketoacidosis** (DKA) is often a marker of intentional or non-intentional non-adherence to insulin regimens, and as such are a marker of increased risk of non-adherence with medical regimens post-transplant. We would urge that a future Pancreas Review

Board receive guidance regarding this issue and the potential adverse outcomes that may ensue with an overreliance on DKA as a medical urgency criterion, particularly if not carefully vetted by the center prior to requesting medical urgency status.

2). We are concerned that **pancreatic exocrine insufficiency** is often of tangential importance to the overall state of health of these complex patients and is often amenable to mitigation with readily available oral supplements. We acknowledge, however, that some patients have problematic PEI that is refractory to available agents and can create significant barriers to homeostasis. We would urge that a future Pancreas Review Board view PEI as a possible, but likely uncommonly utilized pathway to medical urgency.

3). We are aware that severe **Cardiac Autonomic Neuropathy** (CAN) is a predictor of poor post-transplant outcomes. While transplantation and achievement of a euglycemic milieu can ameliorate CAN, this requires significant time. We caution that candidates with severe CAN may thus predictably have poorer outcomes than those without severe CAN and would anticipate that this would be carefully vetted at the center and at the Pancreas Review Board level and would likely be infrequently employed as a trigger for assignment of medical urgency status. We would also urge the OPTN to engage in post-implementation monitoring to ensure that outcomes of such patients (nationally aggregated) are acceptable and that the unanticipated possible effect of fostering performance of futile transplants is not being observed in follow up monitoring.

Do you believe the proposed pathways for medically urgent pancreas candidates will help transplant programs and the future Pancreas review board easily identify medically urgent candidates?

Yes, with the caveats and concerns enumerated above. We have additional concerns regarding the protection of vulnerable populations. We are concerned that proposed MOT allocation schemes continue to have the potential to impair access for vulnerable populations of SOT candidates. Examples include pediatric patients and highly sensitized adult kidney-alone candidates. We would request that clarification be provided within the CD of pancreata policy framework on the allocation of organs to MOT versus SOT candidates.

Do you see any challenges for the proposed documentation requirements described for the potential qualifying pathways? Do you see benefits? How could the proposed documentation requirements be made easier?

We favor limiting the data submission requirements to those few candidates for which centers are requesting medical urgency from the Pancreas Review Board. We are concerned that documentation of IAH is much easier to obtain and submit in candidates on continuous glucose monitoring and recognize that it is conceivable that that cohort has better access to care than an analogous cohort not utilizing CGM. We would urge post-implementation analysis to ensure that applications for, and granting of, medical urgency for pancreas does not inadvertently disadvantage

patients without access to CGM.

Proposal: [Escalation of Status for Time on Left Ventricular Assist Device]

The ASTS appreciates the opportunity to comment on this proposal from the OPTN Heart Transplantation Committee. **We support this proposal and offer the following comments**:

The appropriateness of the proposed changes in context of the following:

- **Does clinical evidence support the need to give greater prioritization to candidates who have waited an extended period of time for a transplant?**
  - Yes; the ASTS Thoracic Committee recognizes the association between time on device and device related complications. However, we believe consideration to the time-period before status upgrade is granted should be shortened to < 3-5 years, balancing concerns and risks regarding "time on device" versus risks with transplantation.
- **Should stable, non-hospitalized candidates be given the same priority as candidates who experienced stroke, infection, or device malfunction?**
  - No; the ASTS Thoracic Committee recognizes the importance of providing a faster route to transplantation for those patients experiencing device related complications. This is supported by the evidence cited by the OPTN Heart Transplantation Committee in the proposal.
- **From the perspective of patients, donors, and their families and caregivers, is the tradeoff between potentially transplanting fewer sicker patients versus transplanting more patients before they get sicker appropriate?**
  - Yes; the ASTS Thoracic Committee recognizes the tradeoff between transplantation of a "sick" patient on temporary MCS and a stable patient with a more technically challenging dissection due to the presence of an LVAD. The presence of an LVAD poses technical challenges during reoperative sternotomy, but these are greatly mitigated in stable outpatients. The current proposal gives surgeons the ability to have "less sick" candidates transplanted more quickly while still "stable."

- **Should the Committee wait until after the allocation changes associated with the Amend Adult Heart Status 2 Mechanical Device Requirements have been implemented and monitoring results are available before making the proposed changes?**
  - No; the ASTS Thoracic Committee does not believe the changes being considered will overlap substantially with the "amend adult heart status 2 mechanical device requirements" policy and would encourage the OPTN Heart Transplantation Committee to move forward with policy changes simultaneously.
- **Should the Committee include the proposed 'step-down' provision granting status 2 and 3 eligibility after seven- and five-years following device implant, respectively, or**

wait for monitoring results to determine effectiveness before shortening the timeframes?

- The ASTS Thoracic Committee believes that a shorter time-period before status upgrade is more appropriate. The ASTS Thoracic Committee urges the OPTN Heart Transplantation Committee to consider shorter wait-times before status upgrade (on the order of 3-5 years).

Policy: **Establish Comprehensive Multi-Organ Allocation Policy: Request for Feedback**

Executive Summary/General Comments:
The ASTS strongly supports efforts to standardize organ allocation order across match runs and develop a standardized approach to allocation for multi-organ transplant candidates. We recognize the challenges inherent in this effort, given the absence of a current standard to guide OPOs regarding which match run is completed first and the variability in determining the appropriate order for the match run based on specific donor characteristics. This proposal has identified specific donors which would be eligible for organs offered through this proposed standard approach, which would be inclusive of approximately 96% of the donors currently allocated to and used in multi-organ recipients.

Donor organs which do not meet the prespecified criteria would be allocated according to OPO preference on which match run order and then to both single organ and multiorgan recipients who appear on those match runs, in the order they appear for whichever organs are not yet allocated. The ASTS recognizes the ambiguities inherent in lung allocation regarding the lung continuous allocation system score which will be finalized and adopted to prioritize lung within this framework. We are uncertain how the allocation of pediatric donor organs (age <11) will occur within this framework. Will they be allocated to pediatric recipients first, including multi-organ and single organ recipients in order, or to all multi-organ first including adults and children? We would like to see more clarity in the proposed policy on this point but are otherwise supportive of this effort.

Overall recommendation: We propose that ASTS offer support for this proposal.

Questions for the Community:
1. Does the ASTS support the standardization of allocation order across match runs?
Yes. Current practice permits potential geographic inequities in organ allocation to multi-visceral and other recipients driven by variability in individual OPO practice patterns. Match runs throughout the nation should reflect transplant community consensus and balance honoring the precious gift made possibly by donor families, utility for candidates, and individual justice in parsing allocation for single organ and multi-organ candidates.

2. Do the proposed allocation tables cover appropriate donor groups?
Generally, yes given this covers 96% of the offers currently used for multi-organ patients. What is not entirely clear is how the allocation for donors under age 11 would work, given this is not likely to be suitable for adult recipients. Will these donors be offered to only to pediatric multi-organ recipients? We urge more clarity on this element of the proposal and recommend that pediatric SOT patients be highly prioritized in the schema.

3. Do the proposed allocation tables include appropriate candidate classifications?
Yes, recognizing that Lung CAS threshold is not yet finalized. We also note that allocation to multiorgan candidates will need to be carefully considered as each organ-specific allocation system moves to continuous distribution architectures in the future.

4. Do the proposed allocation tables appropriately balance the needs of different candidate groups and promote equity in access to transplant among multi- and single-organ candidates?
Yes, we agree with the proposed balance between multi-organ and single organ and recognize that there will inevitably be some disagreement in the community over how to optimize the prioritization of SOT and MOT candidates. We support a standardized and evidence-based system that attempts to balance competing needs and meets a community consensus on validity and equity.

5. In addition to all other organs following the primary organ on the heart, lung, and liver matches, should multi-organ offers be available from the intestine, kidney, and pancreas match runs?
We support a framework in which the primary organs on which allocation is based are heart, lung, and liver, as specified in the proposal. However, the policy should allow for variances or flexibility to be developed for individual unique patient cases (edge-cases). Centers and OPOs should work together on those to allow flexibility. We estimate that those types of edge-cases would be exceedingly rare (fewer than 5 cases a year in the nation).

6. Does the proposed policy appropriately prioritize pediatric candidates?
Yes. Pediatric MOT candidates seem to be prioritized and should have the highest access to MOT. Pediatric SOT should follow Pediatric MOT on match runs, and Adults should follow. However, there is a lack of clarity on allocation sequence if the age < 11 will be allocated to 1). multi-organ pediatrics, then pediatric single organ, then adults after that, or if they will go to 2). all multi-organs (children and adults) followed by single organ pediatric and then single organ adult. We are in support of route 1.

7. Does the community support the approach for incorporating the lung composite allocation score into the multi-organ allocation tables?
We do support having a workgroup perform an analysis to determine an appropriate recommendation. We believe the CAS of the patients currently accepting combined lung + other organs as well as the wait-list mortality of these candidates under the current system could be considered. We also agree with feedback from the OPO that it is not beneficial to spend excessive time trying to allocate multi-organ offers to lung candidates with a CAS score down to 25 and feel that a higher lung allocation score threshold should be utilized.

8. What potential barriers to operationalization/implementation challenges does the community anticipate?
No barriers per se. However, education and discussion with transplant programs and OPOs on the upcoming changes are critical to ensure smooth implementation. Discussion should occur at the OPTN Regional meetings to both educate the community and to provide community feedback to the OPTN Committees and Board. Materials to educate transplant professionals on the new scheme should be a part of the policy implementation bundle, so that transplant programs are equipped to educate patients and determine how best to counsel them on their options given their clinical conditions.

9. Does the proposed policy allow sufficient flexibility to maximize organ utilization?
The ASTS believes that medical urgency, fairness, and utility are appropriately balanced. We anticipate there will be some bumps in the road in implementation of this policy if approved. However, standardization should provide more uniformity in access so that similar candidates in different locales have similar expectations of priority on the waiting list, and similar access to organs.

Key prioritization decisions
10. In all multi-organ allocation tables, are Kidney Classifications 1-4 (CPRA equal to 100%) candidates appropriately prioritized relative to the other organ classifications?
Yes. Please note that table 4 (which is where the list for table 6 comes from) is hard to follow and could benefit from adding a numeric ranking column on the left side of the table. Additionally, in all multi-organ allocation tables, are Kidney Classifications 1-4 (CPRA equal to 100%) candidates appropriately prioritized relative to the other organ classifications? (see Figure 6, pg. 28)

11. In all multi-organ allocation tables, are Kidney Classification 5 (prior living donor within 250NM) candidates appropriately prioritized relative to the other organ classifications?
We agree with the high priority assigned for prior living kidney donors.

12. In the table for DBD donors age 18-69 with KDPI of 0-34%, are Pancreas/Kidney-Pancreas Classifications 1-4 (CPRA greater than or equal to 80% and all candidates within 250NM), Heart Classifications 5-6 (Adult Status 3 and Pediatric Status 1B within 250NM), and Kidney Classifications 6 (registered prior to 18 years within 250NM) and 7 (medically urgent within 250NM) appropriately prioritized?
Yes. In general, we agree with the prioritization algorithm. However, in Figure 7. pediatric candidates (KI class 6) should be prioritized above adult P or KP class 3 (CPRA> 80%, nation) and 4 (within 250 nm).

13. In the tables for DBD donors aged 11-17 with KDPI of 34%, should Kidney Classification 6 (registered prior to 18 years within 250NM) be placed above Pancreas/Kidney-Pancreas Classification 1 (CPRA greater than 80% within 250NM), between Pancreas/Kidney-Pancreas Classification 3 (CPRA greater than or equal to 80%, nation) and 4 (all candidates within 250NM), or below Pancreas/Kidney Pancreas Classification 4?
See above.

14. In the table for DBD donors aged 11-17 with KDPI of 0-34%, should Kidney Classification 6 (registered prior to 18 years within 250NM) be placed above Pancreas/Kidney-Pancreas Classification 1 (CPRA greater than or equal to 80% within 250NM), between Pancreas/Kidney Pancreas Classification 3 (CPRA greater than or equal to 80%, nation) and 4 (all candidates within 250NM), or below Pancreas/Kidney-Pancreas Classification 4?
See above.

15. In the table for DBD donors aged <11 with KDPI of 35-85%, should Kidney Classifications 7-14 (CPRA of 98% or greater; or 0-ABDR mismatch within 250NM; or 0-ABDR mismatch pediatric candidates, national) be included in the table?
Pediatric candidates should be prioritized above adult MOT candidates.

Some additional specific comments for the committee to consider include the following:

1. Pediatric priority – A child with PRA > 80 has major access issues that impacts survival – and for that reason Peds > 80% PRA within a 250 nm should be prioritized ahead of KP allocation for adult donors KDPI 0-35 and all pediatric donors.

2. Pediatric donor misclassification restricts pediatric recipient access to many pediatric donor organs – using KDPI for pediatric donors is not appropriate and KDPI should be eliminated as an allocation cutoff for pediatric donors. (Nazarian SM, Peng AW, Duggirala B, et al. The kidney allocation system does not appropriately stratify risk of pediatric donor kidneys: Implications for pediatric recipients. *Am J Transplant*. 2018;18:574–579. https://doi.org/10.1111/ajt.14462). We recommend that all pediatric donors be prioritized for pediatric patients in 500 or 250 nm before allocation to unsensitized KP candidates or multiorgan candidates.

3. Unintended consequences of post clamp kidney offers to sensitized kidney alone recipients upon MOT recipients. A potential impact of national allocation of kidneys from KDPI 35-80 to kidney alone candidates with PRA 80-99 ahead of multiorgan recipients like a liver recipient with MELD 31 could result in the MOT team finding out later that the kidneys were accepted ahead of the MOT liver kidney recipient and create unnecessary confusion and angst within the community. To avoid this, we recommend 1) narrowing the prioritization of highly sensitized kidney candidates (for example PRA ≥ 90 and only local candidates) ahead of MOT candidates, or 2) prioritizing MOT recipients ahead of the kidney alone (PRA 80-99). In addition, we recommend serious consideration to requiring that kidney alone offers that are prioritized ahead of MOT must be definitively accepted prior to the procurement OR.

Proposal: [Modify Lung Donor Data Collection]

The ASTS appreciates the opportunity to comment on the work of the OPTN Lung Transplantation Committee. **The ASTS Thoracic Committee generally supports the proposed changes** with the caveat of including the known limitations of the GLI pTLC equations as a disclaimer until externally validated in a larger, diverse population or a more inclusive equation is created; and of concern for PIP as an imperfect measure of compliance that would be improved with serial documentations and documentation of plateau pressure.

1. **Will this new and updated data collection provide transplant programs with useful, granular information for making decisions about potential lung donors**

   The ASTS Thoracic Committee believes that adding additional data collection fields for smoking, specifically the ability to collect more granular data about cigarette, vaping and marijuana use, will allow transplant providers to make more informed decisions donor selection. The committee is concerned that inclusion of peak inspiratory pressure (PIP) will give providers incomplete information on lung compliance. Plateau pressures are a better measure of compliance. We would recommend either collecting data regarding both peak and plateau pressures, or plateau pressures only. In addition, compliance might change in the donor with time. We would recommend updating the recorded peak and/or plateau pressures periodically- possibly every 24 hrs.

2. **Do OPOs foresee challenges or burden related to this data collection?**

   The ASTS Thoracic Committee recognizes that there may be possible burdens placed on data collectors to facilitate the collection of additional information, however the value of this information to transplant programs outweighs potential challenges. The changes might in fact decrease burden by decreasing communication between the OPO and accepting center (specifically by listing testing as complete, pending, etc.)

3. **Could the data fields, response options, or data definition be clearer?**

   No; the ASTS Thoracic Committee agrees that the data fields, response options and data definitions are clear and require no modification.

4. **Does the community support use of the Global Lung Function Initiative (GLI) calculation to predict Total Lung Capacity?**

   The ASTS Thoracic Committee recognizes the limitations of the use of the GLI calculation of predicted total lung capacity (pTLC). As described within the proposal there are several limitations to this formula to include its development in an all-European cohort, which does not necessarily reflect a more racially and ethnically diverse American population. Therefore, we conditionally agree with the OPTN's use of this equation to calculate pTLC until a more inclusive equation is developed or if this equation is validated against a more diverse cohort in the future. The ASTS

Thoracic Committee agrees with OPTN member suggestions that displaying a disclaimer to this equation can help bring awareness to its limitations.

5. **Will lung transplant programs use the proposed addition to lung offer filters?**
   Yes, the ASTS Thoracic Committee believes that transplant programs will use these additional filters.

6. **Do OPOs and transplant programs think the proposed Diagnostic Test Status data collection will increase efficiency and decrease back and forth regarding the availability of lung donor testing?**
   Yes, the ASTS Thoracic Committee believes the modification of the data field to include the status of the testing, and reason for non-completion of certain tests will allow for enhanced communication and therefore decrease back and forth.

7. **Do patients and donor family members support proposed data collection changes to streamline communications between transplant programs and OPOs to place organs more efficiently?**
   The ASTS thoracic committee would suspect patients, as well as donor family members, would support the proposed enhanced data collection and streamlined communication.

Policy: Monitor Ongoing eGFR Modification Policy Requirements
Position: Support with Amendments

On behalf of the American Society for Transplant Surgeons, we would like to express our sincere appreciation for the ongoing efforts of the Minority Affairs Committee (MAC) to improve equity in access to transplantation and for the opportunity to provide comment on this critical issue. Addressing systemic inequities, including the historic utilization of race- based eGFR calculations, is critical to ensuring a just and fair transplantation system. **We support the intent of this proposal, and the recommendations put forward for its operationalization.**

However, the need for this policy modification highlights significant shortcomings in the initial implementation of the changes to Policy 3.7D. These changes were enacted under intense external pressures, without sufficient operational planning, clarity, education or support for transplant programs. While enacting this change was ethically the right thing to do for patients, the resulting policy – in particular the post-public comment modifications made by the Committee and Board – imposed a significant administrative and financial burden for programs under a strict timeline. Had a more deliberate approach been taken— by engaging stakeholders to fully consider the practical implications, issuing clearer initial guidance, and providing adequate education and resources prior to implementation, we would not be in the position of revisiting this policy today.

While we support the notification and documentation requirements put forth, we strongly oppose that transplant programs be required to retroactively meet these obligations for all candidates registered on the waiting list on or after January 4, 2024. Imposing such a requirement to mitigate the prior lack of proactive planning places undue burden on transplant programs, diverting resources from daily patient care and other equally important quality improvement efforts.

Further, holding transplant programs accountable to a standard that was not defined at initial policy public comment, approval, and implementation is fundamentally unreasonable. Established regulatory and policy frameworks avoid retroactive enforcement due to the undue burden placed on those operating in good faith under previous guidance. Policy changes of this nature should prioritize prospective application to ensure fairness, feasibility, and sustainability.

It is worth noting the potential impact of the proposed retroactive data entry proposed in this policy. Approximately 43,000 candidates are listed in this country annually. This proposal would require significant transplant coordinator workflow for each of those listed candidates. If we assume that the stipulated retroactive requirements will take approximately 30 minutes per patient, then collectively this proposal will burden programs with an additional 21,500 hours of coordinator work. While we are fully committed to advancing access and equity, we are mindful of the significant opportunity costs of those additional documentation hours and

would prefer to spend those resources to evaluate, list, and transplant underserved patients rather than meet an unreasonable, retroactively applied data requirement.

We would appreciate additional information about the unmet need that the retroactive component of this policy proposal is designed to meet. What data have been analyzed to determine any potential benefit accruing to vulnerable populations from this very costly portion of the policy proposal? Was that analyzed by the Committee in developing this component of the proposal?

Finally, we would point out that, particularly with the widespread use of expedited organ allocation, many of the patients listed since January 2024 have already been transplanted. Therefore, the retroactive component of this policy proposal will be impossible to comply with for those patients. In effect, this makes the policy impossible for centers to be in compliance with, and higher performing centers with higher transplant rates will be disproportionately negatively impacted by this component of the proposed policy.

We respectfully request that the committee reconsider imposing a retroactive enforcement provision of this proposal that will undoubtedly create an unworkable compliance expectation. We urge the committee to adopt a forward-looking approach focused on prospective measures that enhance clarity, equity, and operational feasibility with clear, well-communicated guidance and the necessary resources to support successful implementation from a defined future point onward.

We fully support the intent of the proposal and would strongly support the policy with the adoption of the proposed revision. Again, we thank the Committee and the OPTN for the opportunity to contribute to the optimization of this policy proposal and look forward to partnering with you on implementation.

Proposal: [Updates to National Liver Review Board Guidance (NLRB) & Further Alignment with Liver Imaging Reporting and Data System (LI-RADS®)]

The ASTS appreciates the opportunity to comment on this proposal from the OPTN Liver and Intestinal Organ Transplantation Committee. **We strongly support this proposal and offer the following comments:**

- **Do you agree with the proposed guidance and score recommendations for each condition listed? If not, please elaborate.**
    - The ASTS Liver Oncology Task Force has reviewed the proposed guidance and score recommendations and agrees with the recommendations for each condition listed. At this time, we do not have additional conditions to add.

      As a point of clarification, an inconsistency was noted in the guidance statement regarding HEHE tumors, as a previous version of the guidance was included in the public comment document. This will be corrected by OPTN. To clarify, patients with limited extrahepatic disease would not be excluded from eligibility for the exception, while macrovascular disease would be considered a relative contraindication.

- **Are there other exception requests related to liver cancers or tumors that should be addressed by the Adult Transplant Oncology Review Board and associated guidance document?**
    - The ASTS Liver Oncology Task Force does not have additional suggestions for other tumors or cancers to be addressed at this time.

      However, we recognize that guidance for liver transplant eligibility and associated MELD exceptions for metastatic colorectal cancer to the liver (mCRM) and intrahepatic cholangiocarcinoma (iCCA) will require ongoing review and likely revision as more data emerges. We recommend continued evaluation of outcomes and evolving criteria to ensure evidence-based decision-making in transplant oncology.

- **Are there other exception requests related to the Adult MELD Exception Review Board and associated guidance that should be addressed in the guidance document?**
    - The ASTS Transplant Oncology Task Force will defer to colleagues with more specific expertise regarding conditions not related to liver cancer for recommendations to the OPTN in this response.

- **Do you agree with the addition of contrast-enhanced ultrasound (CEUS) as an optional imaging option to provide a pathway to automatic standard HCC exception approval in Policy 9.5.I?**
    - The ASTS Liver Oncology Task Force supports the incorporation of contrast-enhanced ultrasound (CEUS) as an adjunct to cross-sectional imaging for the diagnosis of HCC. While its use in this context may be infrequent, it aligns with the expanding role of CEUS

in liver imaging and represents a valuable additional tool for accurately diagnosing HCC.

- **Do pediatric practitioners incorporate LI-RADS 5 criteria into case management? If not, what system or categories should be used to classify pediatric HCC?**
    - The current LI-RADS criteria are not directly applicable to pediatric patients due to significant limitations in accuracy. Pediatric HCC often lacks the typical imaging features seen in adults, making standard LI-RADS classifications unreliable. Recognizing this gap, a dedicated Pediatric LI-RADS working group is actively refining guidelines specifically tailored to pediatric liver tumor imaging.

      LI-RADS was originally designed for adults at high risk of HCC due to cirrhosis, a condition far less common in pediatric patients, leading to poor specificity when applied to children. Additionally, there is limited data on pediatric HCC imaging characteristics, further complicating the direct application of adult-based criteria. While LI-RADS features such as arterial phase enhancement and washout may still help inform interpretation, they should be used cautiously and always within the broader clinical context.

      When imaging pediatric patients with suspected HCC, clinical history remains a key factor in guiding interpretation. Ultrasound (including contrast-enhanced ultrasound, CEUS) is often the first-line imaging modality, with CT or MRI used for further evaluation depending on clinical suspicion. Multiphasic contrast-enhanced imaging is essential for CT/MRI to accurately assess the lesion's dynamic enhancement characteristics. It may be worth noting in the guidelines that for pediatrics, specifically nearly all (or all) pediatric liver tumor patients get a biopsy given the relevant other tumors in the differential diagnosis (hepatoblastoma, angiosarcoma, lymphoma, etc.) and lack of cirrhosis, so the imaging fidelity is important but not as critical as for adult candidates.

- **How would this facilitate patients or families discussing exception priority with medical providers for adult or pediatric patients?**
    - The ASTS Liver Oncology Task Force supports the proposed guidelines and standardized MELD exceptions for liver tumors and cancers, as they will significantly facilitate discussions between patients, families, and medical providers regarding transplant priority for both adult and pediatric patients.

      By providing clear, consistent criteria, these guidelines will help ensure greater transparency in decision-making, improve patient and family understanding of transplant eligibility, and support equitable access to liver transplantation for oncology patients.