

## ASTS Responses to UNOS Proposals Open for Public Comment

October 2, 2017

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### 1. Enhancing Liver Distribution

ASTS represents the majority of the surgeons performing liver transplantation in the United States. Addressing geographic disparities in access to liver transplantation has been both a priority and difficult proposition for policymakers. It is noteworthy that the opportunity to provide successful liver transplantation to appropriate recipients continues to be limited by the supply of appropriate organs for transplantation. ASTS recognizes that our members hold a range of views and have not reached a consensus on how to address disparities involving organ access. To optimize organ sharing, we support allocation policies that effectively reduce disparities and promote the interests of transplant programs attempting to best serve their patients. Pressured change based on concerns of federal regulatory bodies is likely to result in significant discomfort in the transplant community, as well as potential serious public trust and relations issues. Therefore, ASTS supports continued discussion as to how to effect optimal change based on quantitative data and values graduated change with frequent and careful evaluation of outcomes and the impact on patient access.

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### 2. Improving En Bloc Kidney Allocation

ASTS supports the kidney committee proposal to establish policy for organ procurement organizations (OPOs) on when to allocate en bloc kidneys.

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### 3. Improving Dual Kidney Allocation

ASTS supports this proposal which will provide direction on which kidneys must be offered as duals, when an OPO can offer dual kidneys, and how to place them efficiently. ASTS thanks the committee for their consideration of the feedback provided during the earlier public comment period and for taking this first step which includes the opt-in component for transplant centers.

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June 2-6, 2018  
Seattle, Washington

#### **4. Deceased Donor Initiated KPD Chains**

ASTS supports the proposal to permit the use of deceased donor kidneys to initiate KPD chains. We appreciate the concerns expressed about potential unintended consequences related to blood type O, pediatric, and minority populations and therefore recommend that careful monitoring be mandated in whichever model is ultimately adopted. While there was a strong opinion that the "List Exchange Chain" was the preferred model, ASTS recognizes that different models may fit different programs and encourages the committee to examine all scenarios further during their deliberations.

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#### **5. Living Donation By Persons With Certain Fatal Diseases**

This white paper seeks to outline policy changes that would support living donation from individuals with certain fatal diseases. ASTS believes donation from such individuals is ethically appropriate based on the principle of autonomy. ASTS appreciates the work of the ethics committee on this topic and agrees there are currently barriers within policy that could limit a transplant center's ability to participate in these types of living donation scenarios. Specifically, the requirements in 18.6 - Reporting of Living Donor Adverse Events - could result in unnecessary regulatory scrutiny for the transplant center. Furthermore, it will be incumbent upon the transplant community to educate all stakeholders, including patients and their families, on the particulars involved with these types of donations to prevent any misconception or deterioration of public trust in the organ donation and transplantation system.

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#### **6. Review Of HLA Tables**

ASTS supports the goal of this proposal to update the policy's nomenclature in all equivalency tables and encourages the committee to take into account feedback submitted from ASHI.

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#### **7. Revise Transplant Fellowship Training Program Approval Bylaws**

ASTS is pleased to provide comments on the proposed bylaws revisions related to fellowship training programs. We agree with the decision to remove bylaws language regarding OPTN validation of training which was not occurring in practice and appreciate the recognition of ASTS' role as the leading Society advancing surgical care in transplantation. ASTS is committed to defining and promoting training through its accreditation of abdominal transplant surgery fellowship training programs. Ongoing iterative changes/improvements to program and fellow requirements ensure a system of continuous improvement within the program.

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#### **8. Guidance To Increase NonA1 And NonA1B Kidneys For Type B Candidates**

ASTS supports the committee's efforts to create guidance for kidney transplant programs performing non-A1/non-A1B (A2/A2B) transplants. While the document can be a useful tool for transplant centers, ASTS cautions that guidance documents often become de facto policy by payers. Therefore, we encourage the committee to include specific language affirming the goal

to create resources for transplant centers and not to develop detailed policy adding to the already cumbersome regulatory burdens in transplant.

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### **9. Improving The Efficiency Of Organ Placement**

ASTS supports the intent of this proposal to streamline the organ placement process. At the same time, we want to be mindful of continued and burdensome policy requirements that the community continues to place upon itself. The committee notes that 90% of cases already report within the proposed 30 minute window yet does not provide analysis on the 10% that do not. It would be helpful to understand if there are common characteristics among this group or organ specific variances. We think it is important to acknowledge there are busy centers that could face multiple challenges in meeting shorter timelines. We suggest the committee better understand why 10% of programs use more than 30 minutes and consider the impact of an increased number of "provisional yes" placeholders which is a potential unintended consequence of the proposal.

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### **10. Broaden Pancreas Allocation Across Compatible ABO Blood Types**

ASTS supports this proposal to increase the number of pancreatic transplants and reduce organ discard rates by incorporating new blood type compatibility standards.

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### **11. Guidance On Benefits Of Pancreas After Kidney Transplant**

ASTS supports the work of the committee to create a guidance document to inform the community on the benefits of PAK for certain candidates. However, since this borders on the practice of medicine, it should stand only as guidance.

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### **12. Revise Pediatric Emergency Membership Exception Pathway**

ASTS supports this proposal regarding suggested modifications to the emergency membership exception pathways for pediatric heart and liver transplant programs.

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### **13. Guidance On Congenital Heart Disease Exception Requests**

ASTS supports the work of the committee to develop a guidance document for the regional review boards to outline objective criteria to standardize adult congenital heart disease (ACHD) exception requests. We support the points outlined in comments submitted by the Society of Thoracic Surgeons (STS) and share the concern regarding over-reach of guidance documents that can be used by payers and others as de facto policy.