American Society of Transplant Surgeons

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June 12, 2013

John Roberts, MD
President
Organ Procurement and Transplantation Network (OPTN)
United Network for Organ Sharing (UNOS)
700 North 4th Street
Richmond, VA 23219

Re: Six proposals out for public comment through June 14, 2013

Dear. Dr. Roberts,

The American Society of Transplant Surgeons (ASTS) has reviewed and considered the following six proposals out for public comment through June 14, 2013. Below is the Society's position on each proposal.

Proposal #1: Proposal to Add Serum Sodium to the MELD Score (Liver and Intestinal Organ Transplantation Committee)

ASTS **supports** this proposal and suggests including language to acknowledge that while the effect of glucose may make subtle changes in the sodium value, an adjustment is not a mandatory aspect going forward. The overall impact is small, making the formula adjustment simple and requiring minimal programming.

Proposal #2: Proposed Changes to the OPTN Bylaws Governing Histocompatibility Laboratories (Histocompatibility Committee)

ASTS **supports the overarching goal of this proposal** to update the existing OPTN Bylaws governing histocompatibility laboratories but would defer to the American Society for Histocompatibiltiy & Immunogenentics (ASHI) for specific concerns. It is our understanding that ASHI has submitted comments regarding the proposal and we suggest that OPTN review and successfully resolve these concerns before finalizing a policy proposal for consideration by the board.

Proposal #3: Proposed Update to the HLA Equivalency Tables in Appendix 3A (Policy 3.0) (Histocompatibility Committee)

ASTS **supports** this proposal as written.

Proposal #4: Proposal to Clarify Requirements for Independent Donor Advocates at Living Kidney Donor Recovery Centers (Living Donor Committee)

ASTS **supports the overall concept of this proposal but does not support** this proposal as written. The ASTS has reviewed the policy proposal to clarify the requirements for Independent Donor Advocates (IDA) at living kidney donor recovery centers. The ASTS is in full support of the concept of an IDA as outlined in the bylaws and approved in 2007. These requirements state that an IDA;

1. Not be involved with the potential recipient evaluation
2. Be independent of the decision to transplant the potential recipient
3. Be a knowledgeable advocate for the potential donor.

It is understood that recent OPTN monitoring has detected a very low compliance rate with these requirements, and the proposed policy is, in part, designed to help clarify and bring consistency to IDA policy and procedures at transplant centers. It is also realized that the language in the proposed policy is essentially taken from language codified in CMS policy outlining conditions for participation of transplant centers (42 C.F.R. s.s. 482.68 - 482.104 and 42 C.F.R. s. 488.61). Further, it is understood that these requirements are Federal law, and transplant centers are responsible for meeting these requirements as a part of the conditions of participation (CoP). However, both the policies as outlined in the CoP and the proposed OPTN policy leave a fair amount of uncertainty as to specific requirements of the IDA. The specific areas of concern are outlined below:

1. Better definition is needed of the relationship of the IDA with the transplant program. The interpretive guidelines established for CMS site visits indicate that the IDA "should function independently from the transplant team", and "must not be involved in the transplantation activities on a routine basis." This seems to go beyond the spirit of the concept of the IDA – in that the individual or team is not involved in the direct care of the *recipient*. For example, a liver transplant social worker who may share a responsibility of serving as the IDA for kidney donors would not be allowed under these interpretive guidelines. The burden of hiring extra personnel to ensure that this position is truly an independent role needs to be considered in the costs of the proposed policy, if the intent of the proposed OPTN policy is to follow the lead of CMS. Specifically, ASTS does not think that OPTN should be overly prescriptive as to ***who*** should be the IDA. Rather, it should be clarified further in the policy language the true characteristics that will define "function independently from the transplant candidate's team" (12.4.2.1) that will serve as the basis for Department of Evaluation and Quality (DEQ) audits.

2. The requirement that the IDA "demonstrate knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressures on the potential living donor's decision to donate" (12.4.2.3) is also somewhat vague and questions arise about how this will be monitored. Given that there is no current certification process for IDA's or widely accepted training course, how will IDA's fill any gaps in knowledge, and more importantly how will this be measured? This appears to be an area where many IDA's, despite meeting the donor advocacy part of their role, may be found to be out of compliance depending on how DEQ establishes the audit and measures of compliance. In addition, if off site training is needed or other mechanisms of online training are needed, there will likely be an associated cost and this needs to be taken into consideration.
3. In proposed policy 12.4.2.4, the requirement to "discuss the surgical procedure as well as medical risks" should be better defined. Certainly it makes sense that an IDA have some basic fund of knowledge, but details about the procedure or medical risks may very well be outside the scope of the IDA role or abilities. ASTS strongly believes that the IDA ***should not*** be expected nor charged with discussing details of the surgical procedure as it is not an area of expertise for them. Again, it would be helpful to have a more specific expectation of level of knowledge outlined in the proposal, and the concept that the IDA can refer the potential donor to the proper individuals to address their specific medical or surgical questions should be better emphasized.

It is certainly appreciated that defining this relatively new position of an IDA in policy is challenging. However, creating a policy that will likely still lead to a large number of centers flagged for being out of compliance is problematic. Additional confusion arises when the OPTN and CMS policy language is not in harmony. Transplant centers have been challenged to develop IDA policies already, and many center's policies and procedures follow the intent of the original IDA requirements as defined in 2007. The current policy should continue to try to support those initial requirements, and more clearly outline expectations where it is felt more specificity is needed. Alternatively, the DEQ plan for auditing needs to be defined up front so transplant centers can determine if this proposed policy is acceptable in its current form. Without the above clarifications, the ASTS cannot support the policy as written.

Proposal #5: Proposal to Change Pediatric Heart Allocation Policy (Thoracic Organ Transplantation and Pediatric Transplantation Committee)

ASTS **supports** this proposal.

Proposal #6: Proposal to Redefine the Role of the Vice-President of the Board of Directors (Executive Committee)

ASTS **supports** this proposal.

Thank you for the opportunity to comment on these proposals. Please do not hesitate to contact me or Kim Gifford, ASTS Executive Director, if you have any questions or require additional information.

Sincerely yours,

Alan N. Langnas, D.O.
President