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December 20, 2011

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

Dear. Dr. Lake,

The American Society of Transplant Surgeons (ASTS) has reviewed and considered the following fourteen proposals out for public comment through December 23, 2011. Below is the Society's position on each proposal.

Proposal 1: Kidney Transplantation Committee: Proposal to Clarify Requirements for Waiting Time Modification Requests.

ASTS **supports** this proposal seeking to add clarification to waiting time modification requests.

Proposal 2: Liver and Intestinal Organ Transplantation Committee: Proposal to Extend the "Share 15" Regional Distribution Policy to "Share 15 National"

ASTS **supports** this proposal as it is likely that broader sharing will decrease waitlist mortality.

Proposal 3: Liver and Intestinal Organ Transplantation Committee: Proposal For Regional Distribution of Livers for Critically III Candidates.

ASTS **supports** this proposal as it is consistent with the intent to increase access for patients with the greatest medical urgency and decrease geographic disparity. Specifically, ASTS supports regional sharing for candidates with MELD/PELD scores of 35 or higher. Based on the available modeling, the impact of incorporating a sharing threshold is modest, and predicting behavior post policy change is at best an approximation. Consequently, we do not propose incorporating a Sharing Threshold but support rigorous monitoring of the impact of the policy change post implementation.

Proposal 4: Thoracic Organ Transplantation Committee: Plain Language Modifications to the Adult and Pediatric Heart Allocation Policies, Including the Requirement of Transplant Programs to Report in UNet a Change of Criterion or Status within Twenty-Four Hours of that Change.

ASTS **supports** this proposal.

Proposal 5: Ad Hoc International Relations and Ethics Committees: Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens), Which Include Changes to the Non-Resident Alien Transplant Audit Trigger Policy and Related Definitions.

ASTS is concerned with the level of investigative authority given the Ad Hoc International Relations Committee in this proposal. The proposal references the committee's desire "to collect information to determine the extent to which patients are traveling to the US for purposes of deceased donor transplantation and whether these practices undermine the ability of the US to provide transplant services for its own population." Given that NOTA requires the OPTN to base allocation policies on medical criteria and not residency status, we believe this proposal supports data collection for research purposes only and is, therefore, unwarranted. Additionally, it places a burden on transplant centers to ascertain the citizenship/residency status of potential recipients. Transplant centers lack the expertise to verify such status, and doing so stands to interfere with the physician-patient relationship by placing care-givers in the situation of challenging the documentation of patients. Finally, the vague proposal regarding a public report on transplantation of non-citizens/non-residents on a center-specific level leaves open the possibility that a transplant center will be forced to make a decision between providing the best care for its patients without regard to their residency and a public suggestion that they are giving domestic organs to foreign recipients, information likely to be sensationalized by media.

Proposal 6: Histocompatibility Committee: Proposed Update to the Calculated PRA (CPRA).

ASTS **supports** this proposal.

Proposal 7: Histocompatibility Committee: Revision of the UNOS Bylaws, the OPTN Bylaws and the OPTN Policies that Govern HLA Laboratories.

ASTS **supports** this proposal revising standards for HLA laboratories.

Proposal 8: Living Donor Committee: Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors.

ASTS objects to the changes that were made by the OPTN Living Donor Committee to the *Evaluation of the Living Kidney Donor – a Consensus Document from the AST/ASTS/NATCO/UNOS Joint Societies Work Group* (JSWG). While some of the changes can be perceived as minor revisions, others such as changing the word "should" to "must" may be interpreted more stringently than intended by the JSWG. ASTS maintains that the document should be accepted as submitted without revision.

Proposal 9: Living Donor Committee: Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-Up.

ASTS **opposes** the addition of a ninety percent threshold for living donor follow-up given the expanded reporting requirements. ASTS agrees that follow-up of living donors is important but in the absence of additional funding, the suggested compliance rate of ninety percent will be difficult to achieve at most transplant centers. Further, because the rule lacks a provision allowing patients to opt out of the testing necessary for the follow-up, it violates the fundamental patient autonomy ethical principle. Centers are not able – nor should they be able – to compel patients to return for testing. If this rule survives, which we believe it should not, the 90% threshold should be limited to requirement that transplant centers demonstrate they contacted and offered these follow-up tests to donors, and if the donors refused or were not responsive to the contact, documentation of that should satisfy the rule. ASTS supports a funded study of living donor follow-up to be performed at selected centers to further explore living donor follow-up and is in the process of applying for a grant via the CMS Healthcare Innovation Challenge to establish a pilot study.

Proposal 10: Living Donor Committee: Proposal To Establish Requirements for the Medical Evaluation of Living Kidney Donors.

ASTS objects to the changes that were made by the OPTN Living Donor Committee to the *Evaluation of the Living Kidney Donor – a Consensus Document from the AST/ASTS/NATCO/UNOS Joint Societies Work Group* (JSWG) including, but not limited to, the following:

1. The JSWG provided a list of relative contraindications to kidney donation that highlighted areas of potential controversy and provided a referenced basis for transplant centers to make local decisions. The OPTN Living Donor Committee subsequently requested the list of relative contraindications be included and noted that a "Kidney Recovery Hospital should consider excluding all donors who meet any of the following criteria." The difference between the words relative contraindications and should consider excluding may be interpreted more stringently in the negative than intended by the JSWG. The OPTN Living Donor Committee also removed an important modifier that the JSWG had attached to the decision-making process which we believe should be

included as submitted: "The impact of the above co-morbidities on the donor's future health is dependent upon age of onset, gender, access to healthcare, ethnicity, and family history as well as other criteria. An aggregate of relative contraindications in a given individual may also preclude donation."

2. The removal of the bullet points addressing the evaluation for coronary artery disease as suggested by the American College of Physician and pulmonary function tests for selected smokers as suggested by the American College of Anesthesiology and American Lung Association.
3. The addition of clinical nurse specialist or advanced practice nurse as sufficient for the psychosocial evaluation. Personnel who perform the psychosocial evaluation should have experience in both transplantation and psychosocial/mental health issues.
4. The addition of the CDC MMWR report on HIV testing. The consensus conference in Baltimore in 2011 voted against this recommendation and there is currently wide debate on the proposed PHS Guideline for Reducing HIV/HBV/HCV Transmission.
5. The absolute contraindication <18 years of age for donors. The JSWG has provided exceptions based on guidelines from the American Academy of Pediatrics (Minors as Living Kidney Donors. Pediatrics 2008; 122:454-461)

Proposal 11: Organ Procurement Organization (OPO) Committee: Proposal to Eliminate the Use of an "Alternate" Label when Transporting Organs on Mechanical Preservation Machines and to Require the OPTN Distributed Standardized Label Organ Procurement Organization (OPO) Committee.

ASTS **supports** this proposal as a patient safety measure.

Proposal 12: Organ Procurement Organization (OPO) Committee: Proposal to Change the Term "Consent" to "Authorization" Throughout Policy When Used in Reference to Organ Donation.

ASTS **supports** this proposal, with the caveat that a legal review should be undertaken prior to implementation to assure that this language change would not interfere with any of the states' first-person consent laws.

Proposal 13: Organ Procurement Organization (OPO) Committee: Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions.

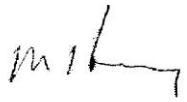
ASTS **supports** this proposal as it may improve consistency of reporting across OPO's.

Proposal 14: Policy Oversight Committee (POC): Proposal to Clarify and Improve Variance Policies.

ASTS **supports** this proposal as an effort to clarify policies and processes associated with variances.

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.

Best regards,



Mitchell L. Henry, MD
President