

August 31, 2009

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

Dear Dr. Wynn,

The Council and Executive Committee of the American Society of Transplant Surgeons (ASTS) on behalf of its constituency have reviewed and considered the following seven proposals that have been distributed by OPTN/UNOS in July for public comment through September 14. Below are the stated positions of the ASTS on these proposals.

A. To include non-directed living donors and donor chains in kidney paired donation pilot program.

The ASTS is **supportive** of this proposal as the use of open/closed chains has been successfully utilized and significantly increases the number of transplants that can be performed. However, the question as to what standards will be applied for the selection of a recipient of an undirected live donor kidney must be addressed. Consideration must be given to determine who covers the costs of donor work-ups (including altruistic donor work-ups) when the recipient has not been identified. Additionally, donor costs will vary according to public/private payers, and donors costs will need to be standardized nationally before full implementation of this system can be realized.

B. To improve the ABO verification process for living donors.

ASTS **supports** this proposal as it standardizes the deceased and living donor ABO verification processes.

C. Proposed guidance for the medical evaluation of living liver donors.

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ASTS **does not support** this proposal. While ASTS recognizes this proposal as guidelines only, the Society maintains that establishing these standards is beyond the scope of the OPTN/UNOS mission. Although the ASTS has some reservations about some details within this guidance document, we recognize the charge put to the OPTN by HRSA to develop these documents. The ASTS continues to encourage the OPTN and Government to emphasize that these guidance proposals in no way represent standards by which programs are to be judged for compliance or credentialing purposes. Development of living donor standards should be done collaboratively with professional society involvement at every stage of their development.

D. OPTN notification requirements for OPOs, transplant hospitals and histo-compatibility labs when faced with an adverse action taken by regulatory agencies.

ASTS **supports** this proposal to decrease the reporting burden by decreasing the submission requirements to include only those documents pertinent to the final adverse action taken by the regulatory agency. Additionally, ASTS agrees that increasing the allotted time to notify OPTN of final adverse actions from five to ten days is reasonable.

E. To change the OPTN/UNOS bylaws to reconcile discrepancies in patient volume for full and conditional program approval when qualifying kidney, liver and pancreas primary transplant physicians.

ASTS **supports** this proposal to standardize the pathway for conditional approval of the primary physician experience with the requirements for full approval.

F. To add language to the OPTN/UNOS bylaws requiring transplant center OPO members to follow state law regarding anatomical gifts.

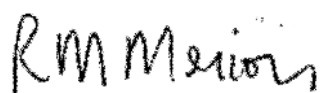
ASTS **supports** this proposal as an important step toward clarifying the obligation of members to abide by respective state laws regarding anatomical gifts. Specifically, this proposal prohibits the same physician from declaring a patient's death and participating in the removal or transplant of organs from that decedent.

G. To change requirements for labeling and packaging organs procured by visiting transplant center teams and for OPO labeling of tissue typing materials.

ASTS **supports** this proposal to standardize packaging and labeling of donor organs.

Thank you for the opportunity to address these proposals. ASTS would be pleased to participate in any further definition or revision of one or all of these potential policies.

Yours sincerely,

A handwritten signature in black ink, appearing to read "R M Merion".

Robert M. Merion, MD
President