August 7, 2009

Velma Scantlebury, MD
Chair
Advisory Committee on Organ Transplantation
U.S. Department of Health and Human Services
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane
Parklawn Building, Room 12-105
Rockville, MD 20857

Dear Dr. Scantlebury,

On behalf of the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST), we are writing to highlight three issues of concern to the transplant community that we request be considered by the Advisory Committee on Organ Transplantation. It is our desire that by addressing these issues, ACOT will help to bring greater awareness of these issues and that potential solutions can be communicated to HHS Secretary Kathleen Sebelius.

Islet Transplantation:

Pancreatic islet transplantation is a promising therapy for the more than 1 million Americans who suffer from juvenile diabetes. Unfortunately, current Medicare policies related to the organ acquisition cost center have resulted in a requirement for organ procurement organizations to impose financially untenable standard acquisition charges for pancreatic tissue used for islet transplantation. We believe that the Centers for Medicare and Medicaid (CMS) has the administrative discretion to revise its policies to address this serious problem, although they have not done so to date. Sadly, this situation has led to a near halt in research and innovation in pancreatic islet transplantation, as the number of recoveries has dropped to near zero.

The ASTS and AST along with several other relevant organizations developed a white paper (attached), wrote several letters to the HHS Secretary (most recent letters attached), and met

with CMS officials on numerous occasions to discuss our concerns and appeal for a change to the current policy.

We ask that ACOT provide a formal recommendation to Secretary Sebelius to have CMS revert to its prior policy of Medicare reimbursement of pancreatic tissue recovery costs for islet cells using a revenue offset methodology. Specifically, the incremental direct costs involved can be recouped by charging research centers an amount that reflects the relatively low surgical, transportation, perfusion and other direct costs involved, thereby averting cost shifting to the solid organ cost centers.

Separate Performance Metrics for Use by OPTN and CMS:

We are concerned that Program Specific Reports (PSRs) as reported by the Scientific Registry of Transplant Recipients (SRTR) are being increasingly used for purposes different than those for which they were originally intended. The ASTS sent a letter to the Organ Procurement and Transplantation Network (OPTN) and the SRTR detailing these concerns and outlining recommendations (attached).

We ask that ACOT provide a formal recommendation to Secretary Sebelius to instruct the Division of Transplantation at HRSA to require the SRTR to develop a performance metric more appropriate for program certification purposes for use by CMS in evaluating transplant center outcomes, in contrast to the existing metrics that are used by the OPTN for quality improvement.

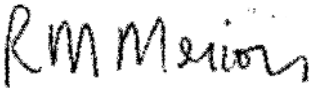
Conflicting Transplant Center and Organ Procurement Organization (OPO) Regulations:

There are elements of the Medicare conditions of participation for transplant programs and OPOs that are in conflict. OPO outcome measures standards require OPOs to maximize the number of organs transplanted per donor and OPOs risk de-certification if these transplant rates are lower than expected within several categories of deceased donors, such as standard criteria donors, expanded criteria donors, and donors after cardiac death. In contrast, transplant centers are required to meet outcome requirements related to patient death and graft failure. Transplant centers with higher than expected deaths or graft failures risk losing their Medicare certification to perform solid organ transplants. Although the risk-adjustment methodology used by the SRTR is good, it is widely acknowledged to be imperfect. This has created an increasing amount of tension in the transplant community between OPOs, which are charged to maximize the transplantation of recovered deceased donor organs, and transplant programs, which must consider the best interests of their patients in accepting organs for transplant while remaining cognizant of the need to produce acceptable post-transplant outcomes.

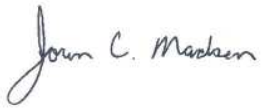
We ask that ACOT advise Secretary Sebelius of these incongruent policies and request that CMS work with the transplant community to resolve these conflicting goals for OPO and transplant programs.

Thank you for your consideration. We would be happy to attend and participate in an upcoming ACOT meeting or meet with you individually to answer any questions or provide additional information. Please contact Katrina Crist, ASTS Executive Director, at 703-414-7870 or katrina.crist@asts.org to make arrangements.

Sincerely,



Robert M. Merion, MD
ASTS President



Joren C. Madsen, MD, DPhil
AST President

CC: Patricia Stroup, ACOT
Executive Secretary