



American Society of Transplant Surgeons

July 7, 2009

Barry Straube, MD  
Director & Chief Clinical Officer  
Office of Clinical Standards and Quality  
Centers for Medicare and Medicaid Services  
7500 Security Blvd, Mail Stop S3-02-01  
Baltimore, MD 21244

Dear Dr. Straube:

On behalf of the American Society of Transplant Surgeons, I am writing to thank you and your colleagues at CMS for meeting with us on June 24 to discuss a number of issues of concern to the transplant community.

We greatly appreciate your ongoing interest in addressing the Medicare policies that have resulted in financially unsustainable standard acquisition charges for pancreatic tissue used for islet research. We continue to believe that CMS has the administrative discretion to revise current policies to address this serious and ongoing problem, by reclassifying pancreatic tissue used for islet research in the same manner as other types of donor tissues.

In this regard, we note that there is no statutory or regulatory authority that precludes CMS from treating the indirect or the direct costs of retrieving pancreatic tissue like the costs associated with retrieving other types of tissue. With respect to indirect costs, the Intent to Transplant Ruling (CMS-1543-R, December 21, 2006) does not explicitly apply to pancreatic tissue obtained for islet research and historically has not been applied to other types of tissues. Also, the identified incremental direct costs involved can be recovered 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.

We also look forward to final resolution of the issues that we raised with respect to Medicare payment for the "standard" backbench codes. We look forward to receiving any available CMS data regarding the allowances for these services that have been established by Medicare Part B contractors, and hope to work with you to establish an appropriate mechanism for recovery of the costs involved. These issues were discussed with other CMS staff in part after your departure from the meeting. We presume you've been briefed on this, and we will follow up with you soon.

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Finally, we regret that the shortness of time precluded a discussion of the conflicting policies reflected in the OPO and transplant program conditions of participation. In this regard, we note that while the OPO conditions of participation create an incentive for OPOs to recover and facilitate the transplantation as many organs as possible, the outcomes requirements for transplant programs create a dilemma for transplant programs that are trying to maximize the appropriate utilization of all donated organs while maintaining expected outcomes that are derived from incompletely risk-adjusted models. We look forward to continued discussion with you regarding how these conflicting goals can be harmonized.

Once again, thank you for your time and effort. We appreciate your engagement with these issues, your passionate advocacy on behalf of CMS beneficiaries, and your candor. We look forward to a continued productive working relationship with you and your colleagues at CMS.

Sincerely yours,

A handwritten signature in black ink that reads "R M Merion". The letters are cursive and fluid, with the first and last names being more prominent than the middle initial.

Robert M. Merion, MD  
President