



November 8, 2010

Richard Durbin, MBA
Director, Division of Transplantation
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Durbin,

The field of transplantation is dependent on the data collected and published under the Scientific Registry of Transplant Recipients (SRTR) contract. With the recent HRSA contract awarded to Minneapolis Medical Research Foundation (MMRF), the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) look forward to good collaborative effort and open dialogue as was experienced with the previous contractor. We would, however, like to highlight several issues of concern to our members and their transplant centers.

First, there needs to be clarity regarding the statistical methods that are being used after the transition to "flag" programs for review. More specifically, if there is a change in the observed versus expected outcomes in the program specific report (PSR), it must be clear to the transplant center whether the change is real or is related to a change in the statistical models used in creating the report. We understand that there is a transition process in place and propose that a provision for comparison between the PSRs defined by the previous and current contractor be included in this process and that the results of this comparison are shared with the transplant community.

The ASTS and AST are on record with our concerns regarding the manner in which CMS and many private payors use SRTR-generated PSR data and will continue to advocate for change in that arena (see ASTS letter to UNOS attached). In the interim, we request that there be transparency to all involved concerning the process by which the Organ Procurement and Transplantation Network (OPTN) and/or SRTR data are provided to Centers for Medicare & Medicaid Services (CMS) contractors to generate CMS reports. We believe it is essential to permit the existing CMS contractor to continue to have access to the primary data from the OPTN.

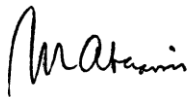
The SRTR is charged with performing the analyses that measure the efficiency and fairness of transplantation based on policy and methods developed by the OPTN. As part of this work, the ASTS and AST request that the major U.S. transplantation societies have representation on steering committees within SRTR that manage the blending of clinical activities with statistical reporting. We

believe this would enhance the transparency of the analysis process and benefit transplant candidates, transplant recipients and professionals in the field.

We also request confirmation that timely access to data and analyses will continue with the new contractor. In addition to data requests from OPTN committees and government agencies, the transplant community, including researchers and the general public, previously have had an efficient way to request and receive data from the SRTR. It is crucial that this access be maintained under the new contract without the addition of burdensome fees for data access. To maintain the integrity of scientific research, the contractor needs to clarify any changes in the data quality, data analysis and interpretation of the data to the scientific community.

Properly and consistently reflecting outcomes in our members' institutions is a shared goal of all stakeholders since these data are used by CMS to identify underperforming centers and by payors for identifying "centers of excellence." Thank you for the opportunity to present our members' concerns. We would be pleased to work with HRSA during this and future transitions to help disseminate information and improve communication concerning the process with the transplant community.

Sincerely,



Michael M. Abecassis, MD, MBA
ASTS President



Maryl R. Johnson, MD
AST President

Enc: Letter to UNOS on PSRs