April 5, 2013

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW - Room 445-G
Washington, DC 20201

Re: Medicare and Medicaid Programs; Part II – Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction, CMS-3267-P

Dear Ms. Tavenner:

The American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) are pleased to have the opportunity to submit comments on the Proposed Rule entitled, "Medicare and Medicaid Programs; Part II – Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction" published in the *Federal Register* on February 7, 2013 (the "Proposed Rule"). ASTS is a medical specialty society comprising more than 2,000 transplant surgeons, physicians, scientists, advanced transplant providers and allied health professionals dedicated to excellence in transplant surgery through education and research with respect to all aspects of organ donation and transplantation. The efforts of ASTS members save lives and enhance the quality of life of patients with end stage organ failure. The American Society of Transplantation (AST) is an international organization of transplant professionals who are dedicated to advancing the field of transplantation and improving patient care by promoting research, education, advocacy and organ donation. The Society comprises nearly 3,200 transplant physicians, surgeons, scientists and allied health professionals.

The Proposed Rule would eliminate or modify certain Transplant Center Conditions of Participation (CoPs) that CMS identified as administratively burdensome, confusing or duplicative. In particular:

- CMS is proposing to eliminate the requirement that a transplant center notify CMS of changes to its transplant program that are already reported to CMS through the Scientific Registry of

Transplant Recipients (SRTR) and other sources. For example, CMS is no longer requiring a transplant center to report changes in its outcomes that may impact the center's compliance with the outcomes requirements in the Conditions of Participation (CoPs), since this data is routinely reported to CMS by the SRTR and other sources.

- The Proposed Rule would eliminate the current automatic 3-year re-approval cycle, enabling CMS to focus survey attention where it is most needed.

- CMS is proposing to clarify that the mitigating factors process may occur at any time and to add an additional illustration of mitigating circumstances that may be considered, to ensure that transplant centers are aware that their establishment and completion of a clear regimen of quality improvement may be considered in the mitigating circumstances analysis.

- CMS is proposing to clarify that adult and pediatric outcomes will be reviewed separately for all programs that request Medicare approval to perform both adult and pediatric transplants, including lung transplant programs.

- CMS is proposing to eliminate language from the current CoPs requiring that a specified number of transplants be performed "during the time frame reported in the most recent SRTR center-specific report" since the SRTR uses a "rolling" time frame and this language is therefore confusing.

ASTS and AST strongly support all these proposals. We believe that these proposals constitute a needed step in eliminating the duplication and administrative burdens endemic to the current regulation of transplant centers both by CMS through its certification requirements and by HRSA through the Organ Procurement and Transplantation Network (OPTN).

ASTS and AST strongly urge CMS to continue to work with the OPTN to identify and eliminate additional duplicative or overlapping requirements. In particular, we strongly believe that CMS and OPTN requirements pertaining to transplant center safety and quality should be consolidated to the extent practicable; that on-site surveys should be conducted only when substandard outcomes are detected and documented; that surveys should be conducted at the same time by both agencies to reduce the administrative burden on affected centers; that survey personnel should be coordinated to ensure that clinical review is conducted by those with substantive expertise in transplantation; and that reports of deficiencies by the two agencies should be internally consistent and consistent with each other.

While it is unclear to us why there should be any differences in the requirements imposed by the OPTN and those imposed by CMS, we certainly believe that if there are any differences, these differences should be justified based on some unique expertise of that agency or by that agency's role in the oversight process. We would be delighted to work with CMS and the OPTN to achieve these laudable

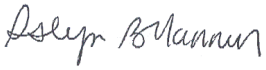
objectives. Please feel free to contact Kim Gifford or Susan Nelson if you have any questions or need further information.

Kimberly A. Gifford, MBA
ASTS Executive Director/CEO
ASTS National Office
2461 S. Clark Street, Suite 640
Arlington, VA 22202
PH: 703 414-1609
Email: *kim.gifford@asts.org*

Susan J. Nelson, CAE
AST Executive Vice President
AST National Office
15000 Commerce Parkway, Suite C
Mt. Laurel, NJ 08054
PH: 856 642-4438
Email: *snelson@ahint.com*

In the interim, we strongly support the Proposed Rule as a needed step in the right direction and thank you for your consideration of our comments.

Sincerely yours,



Kim M. Olthoff, MD
ASTS President

Roslyn B. Mannon, MD
AST President