Dear Ms. Verma:

The American Society of Transplant Surgeons (ASTS) is pleased to have the opportunity to comment on the 2018 IPPS Proposed Rule, released by CMS on April 18. ASTS is a medical specialty society representing approximately 1,800 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through leadership, advocacy, education, and training.

General Comments

Preliminarily, we wish to comment on a number of important CMS proposals that are included in the Proposed Rule but that do not raise transplant-specific issues.

- ASTS appreciates CMS’ efforts to apply a socioeconomic adjustment in conjunction with the Hospital Readmissions Reduction Program, in accordance with the 21st Century Cures Act. We recognize that efforts to develop a robust and reliable socioeconomic adjuster are in their infancy; however, we believe that it is critical that all of CMS’ value-based payment programs recognize the extraordinary impact of socioeconomic status on health care outcomes. For this reason, we encourage CMS to focus substantial research on this area, and to apply validated socioeconomic adjustments to other programs, including the Quality Payment Programs developed by CMS pursuant to the legislative mandate set forth in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).
We appreciate and support the de-regulatory bent reflected in the Proposed Rule. For example, we support the Proposed Rule’s proposal to make it easier for hospitals to meet Meaningful Use requirements by shortening the required reporting period from a year to a continuous 90 day period; to reduce the number electronic clinical quality measures that hospitals must report for FY 2019 and to shorten the data reporting period.

Transplant-Specific Comments

Our remaining comments address issues of unique applicability to transplantation. First, we note that the Proposed Rule recognizes that, under the IMPACT Act, CMS is specifically required to consider the removal of transplant admissions from being considered “readmissions” for the purpose of implementing the Hospital Readmissions Reduction Program (HRRP); however, the Proposed Rule does not include any provisions that would modify the HRRP exclusions policy for transplantation-related readmissions. In the field of transplantation, readmissions are not infrequent, and the health and well-being of organ recipients may depend upon expeditious readmission, especially where there are signs that immunosuppression may be compromised. High readmission rates in the case of transplanted patients are not indicative of poor quality, and, in fact, may improve both long and short term outcomes.

**Recommendation:** We strongly support the excluding readmissions of transplanted patients from the Hospital Readmission Reduction Program. We would be pleased to work with you to develop appropriate exclusion specifications in this area.

Second, the Proposed Rule indicates that CMS is considering adding a new hospital quality measure related to informed consent for hospital-performed elective procedures, but is proposing to exclude “highly specialized” procedures, such as organ transplantation, “because they typically use unique informed consent processes.” In fact, the informed consent process for both transplant recipients and living donors is already highly regulated under regulations setting forth the Medicare conditions of participation for Transplant Centers and under the rules of the Organ Procurement and Transplantation Network (OPTN). Additional regulations, if not identical to existing language would likely lead to confusion and malignment of purpose.

**Recommendation:** ASTS strongly supports the exclusion of transplantation from any new informed consent quality measures that may apply to hospital procedures, since the informed consent process both for transplant recipients and for organ donors is already highly regulated and since the types of information that must be disclosed to both transplant recipients and living donors are unique to transplantation.

Third, CMS is proposing to modify the requirement that provider termination notices and provider-initiated withdrawals from Medicare participation be published in local newspapers. Specifically, regardless of whether a termination is initiated by CMS or provider withdrawal, CMS is proposing to allow more flexibility regarding how notice may be provided to the public. It is unclear whether, and to what extent, CMS intends this change to be applicable to Transplant Centers. However, the type and extent of public notice – and notice to waitlisted patients – are specifically addressed both under Medicare...
conditions of participation for Transplant Centers and under OPTN rules. Another layer of regulatory requirements for Transplant Centers may lead to conflicting interpretations and misalignment of policy.

Recommendation: We recommend that CMS clarify that the notice requirements applicable to Transplant Centers in the event of termination of Medicare participation are governed exclusively by OPTN rules and by Transplant Center conditions of participation requirements.

ASTS appreciates the opportunity to comment on the Proposed Rule. If you have any questions regarding these comments, please do not hesitate to contact ASTS’ Executive Director, Kim Gifford, at kim.gifford@asts.org.

Sincerely yours,

Jean C. Emond, MD
President
American Society of Transplant Surgeons