September 27, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS-1713-P Medicare Program; ESRD Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

Dear Administrator Verma:

On behalf of the American Society of Transplantation (AST), we are pleased to have this opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) on the ESRD Prospective Payment system and its connection to kidney transplantation in response to the Request for Information (RFI) included in the Proposed Rule. The AST is an organization of more than 4,000 transplant professionals dedicated to advancing the field of transplantation and improving patient care by promoting research, education, advocacy, organ donation, and service to the community.

Upon review, we feel there is not sufficient detail nor emphasis given regarding post-transplant care (or wait list management). It seems as though transplant is an end point rather than a treatment phase in the life of a patient with chronic kidney disease.

As patient benefit, societal benefit, and utility are closely tied to how long the transplanted organ lasts, it is very important that incentives are aligned with keeping transplant recipients healthy and with functioning grafts.

Premature transplant failure necessitating a return to dialysis is counter to the proposal, and as such resources, incentives and policies need to be carefully developed to acknowledge the importance and complexity of post- transplant care.

We also suggest that acute kidney injury (AKI) payments be competitive with ESRD payments. Transplant recipients often have AKI early after transplant surgery and require dialysis support until transplant function is established. Currently, outpatient dialysis centers can receive payment for

patients that are dialyzed for the diagnosis of AKI, but unfortunately, most centers are not dialyzing these patients. We suspect that this is because the dialysis centers do not want to give up a chronic spot to an acute patient that may only require treatment for a limited time. The chronic ESRD patient is a guaranteed bundled payment patient. Physicians typically see the patient weekly for 4 weeks. If a patient is only in the unit one week as an acute patient, the reimbursement is much less and therefore, the units tend to not want these patients in the chronic chairs.

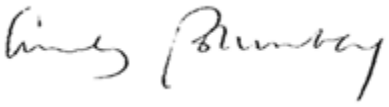
Finally, we wish to share our concern regarding the deadline for the four voluntary models to be released by CMMI stemming from the July 10 Executive Order. The January 1, 2020 deadline does not allow adequate time for kidney transplant programs to appropriately consider and commit to these models. We ask that this enrollment deadline be extended to allow for transplant programs to carefully consider and commit to these opportunities.

In summary, we wish to point out:

- Transplant is a phase in the life of chronic kidney disease patient. Transplantation is not a cure for CKD and transplant patients require ongoing complex care to maximize the longevity of their transplant.
- Transplant candidates on the waiting list require ongoing education to ensure that they understand and consider all opportunities for transplantation including living donation.
- Most transplant candidates require active medical management to ensure that they can safely undergo transplantation and that scarcely available kidneys are not wasted.
- Transplant candidates and recipients are among the most complex patient population and require highly specialized integrated care.
- The emphasis should be on maximizing access to transplantation and long-term outcomes, rather than short-term post-transplant outcomes.

We appreciate the opportunity to submit these comments and would be pleased to work with CMS to expand upon these thoughts. If you have any questions or if we can be of any further assistance, please contact our Executive Director, Shandie Covington, at scovington@myast.org.

Sincerely,



Emily A. Blumberg, MD, FAST
President