



Nonprofit Kidney Care Alliance

September 27, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW, Room 445-G
Washington, D.C. 20201

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage [CMS-1717-P]

Dear Administrator Verma:

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer our comments and recommendations regarding the Centers for Medicare and Medicaid Services' (CMS) Outpatient Prospective Payment System proposed rule, specifically related to the request for information (RFI) on Organ Procurement Organizations. NKCA represents six nonprofit dialysis providers: Centers for Dialysis Care; Dialysis Centers of Lincoln; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; Northwest Kidney Centers; and The Rogosin Institute. Collectively, we serve more than 21,000 patients at more than 300 facilities in 30 states. In an effort to keep patients off dialysis, we also serve more than 5,700 patients with chronic kidney disease (CKD) with the goal of avoiding, or at least delaying, the onset of end-stage renal disease (ESRD).

We are pleased to see the Administration continue to take on kidney disease in a more comprehensive way through the Advancing American Kidney Health (AAKH) initiative. We believe that by identifying patients with CKD earlier, counseling them on their treatment options along with CKD education, patients are able to consider transplant options and make decisions early. By doing so, they can get on a wait list sooner, thereby increasing their prospects of receiving a pre-emptive transplant, and improving their preparedness whenever they receive transplant. It is critical that all of the policies announced in the AAKH be carefully but comprehensively rolled out since they are dependent on one another for success. For instance, while the policies outlined in both the mandatory ESRD Treatment Choices (ETC) and voluntary kidney models are intended to expand access to transplant, without access to additional organs, these goals may not be attainable in the near term. Thus, we encourage CMS and other relevant agencies carrying out these policies do so strategically, with close coordination and stakeholder input from all those involved in the kidney industry. Each kidney stakeholder, from the patient to the dialysis provider, nephrologist, transplant surgeon or OPO, plays a role in transplantation and must be a part of these initiatives as they are implemented. We offer our

comments accordingly and stand ready to assist as the agency continues to analyze this issue in further rulemaking.

OPO Conditions for Coverage

NKCA believes the current OPO measures would benefit from further updates to ensure such measures are reliable and hold OPOs appropriately accountable. While we are not advocating a specific measure to be used, any new measures considered should be outcomes based and encourage OPOs to work collaboratively with other providers of kidney care, including transplant centers, dialysis providers, and nephrologists to always strive to provide the best care options for patients and strive for increased utilization of kidneys. As we look to advance new policies in kidney disease, it is critical that each component of care, including OPOs, are reviewed and updated standards set so that everyone in the industry is working towards common goals. As previously mentioned, we cannot move forward in one area, without the proper organ supply and support from OPOs.

Transplant Centers Conditions of Participation

NKCA was pleased to see that CMS recently finalized its *Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care*. NKCA and other stakeholders have long advocated for changes surrounding the requirements in the Conditions of Participation § 482.82 that require transplant centers to submit data, clinical experience, and outcomes for transplant program re-approval in order to address some of the unintended consequences that have been observed as transplant centers fearing penalties associated with lower outcomes, have become too risk averse, particularly in regards to the use of less than optimal organs. We appreciate CMS finalizing this rule and encourage a transparent process to examine transplant center CoPs in the future.

Conclusion

Thank you for the opportunity to comment on the RFI related to OPOs and transplant centers. We look forward to further discussion and rulemaking in this area. The NKCA appreciates the opportunity to provide input to ensure the rule's impact continues to support increasing the amount of transplantable organs as the optimal therapy for patients with kidney disease. We would be pleased to discuss any of these suggestions in greater detail at any time. If you have any questions, please feel free to contact Martin Corry at 202-580-7707 or info@nonprofitkidneycare.org.

Sincerely,



Martin Corry
Executive Director