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Nonprofit Kidney Care Alliance

September 2, 2016

Andrew Slavitt
Acting 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: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems…Transplant Outcome Measures and Documentation Requirements (CMS-1656-P)

Dear Administrator Slavitt:

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) Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule, and specifically its updates to Transplant Outcome Measures and Documentation Requirements. NKCA represents five nonprofit dialysis providers: Centers for Dialysis Care; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; Northwest Kidney Centers; and The Rogosin Institute. Collectively, we serve over 20,000 patients at more than 280 clinics in 30 states. Consistent with our belief that we can do more to keep patients *off dialysis*, we also serve more than 4,500 patients with chronic kidney disease with the goal of avoiding, or at least delaying, onset of end stage renal disease (ESRD).

NKCA believes that transplant is the optimal therapy for patients with kidney failure in order to improve life expectancy, increase quality of life, and reduce the number of people who need dialysis. We believe there is a great deal of work to do in order to increase access to pre-emptive transplants, lower the current organ discard rate, and promote policies that do not inadvertently penalize transplant centers for utilization of high risk organs. Over the past several months our member companies have engaged with the Administration on increasing access to transplant and have made our own commitments to this at the White House Organ Summit in June of this year. We believe that by counseling patients early 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 the wait list sooner, making them more likely to receive a pre-emptive transplant.

To this end, we are pleased to have the opportunity to provide the following comments on the transplant provisions in the Proposed Rule.

Revisions to Organ Transplant Performance Thresholds

CMS proposes to increase the performance threshold for organ transplant from 1.5 to 1.85 based on its determination that as overall national outcomes have improved since its 2007 changes, the ratio used

based on the risk-adjusted national average has led to difficulties maintaining compliance with the lower threshold. CMS proposes this threshold for all organs and for both graft and patient survival, intending to restore the CMS tolerance limit level allowed under the original 2007 rule. This is consistent with the revised guidelines which were sent to State Survey Agency Directors in May of this year. The intention for this change is to increase beneficiary outcomes while also increasing access, which CMS has asked for comment. We appreciate and support CMS analyzing outcomes and performance under the threshold in order to take steps to accommodate the increase in positive transplant outcomes and to not inhibit transplant centers from providing access to transplant to beneficiaries or donors who may be considered higher risk. We believe a change is necessary as we are seeing an increase in organs being refused by transplant programs since these lower thresholds were established. We agree with CMS that this policy has made transplant centers risk-averse, an unintended consequence causing centers to become more selective of patients and organs in order to stay in compliance.

In addition, for kidney transplant, a recent study[1] examining the association between transplant center performance and survival benefit of transplantation versus dialysis, shows transplant centers with lower performance still have superior outcomes compared to patients remaining on dialysis. This evidence suggests that even in a lower performing center, transplant still sees greater survival outcomes than patients on dialysis on the wait list. We believe CMS should acknowledge this and reduce barriers limiting transplant centers in this and future rulemaking.

We believe the best way of doing this, and restoring the 2007 impact, includes two steps: 1) raising the threshold minimum for all organs' patient and graft survival to 1.85, and 2) increasing thresholds further for those thresholds CMS has indicated would be greater than 1.85, based on their 2007 restoration estimate.

We support CMS' recommendation to raise the threshold to a minimum of 1.85 for all organs and for both graft and patient survival. Increasing the minimum threshold would allow transplant centers to perform transplants on higher risk patients that could still benefit from a transplant. By allowing patients who may be older or less healthy to have greater access to transplant, health outcomes and quality of life will likely increase and program costs will decrease over time for the patient. While we appreciate CMS' step forward, we fear it may only impact a few transplant programs who's threshold currently falls between 1.5 and 1.85, and would not provide enough of a change to increase access in a meaningful way. We encourage CMS to consider a higher threshold to encourage the use of high risk kidneys when appropriate and decrease the rate of organ discards overall.

We do believe, however, that for those thresholds that have an estimated rate to restore the 2007 effective impact greater than 1.85, such as for kidney graft survival, CMS should make that change to during the current rulemaking to provide greater access. For instance, based on CMS' data to restore the 2007 effective impact, the threshold for adult kidney graft survival would be 2.02. We believe increasing the threshold to this rate now would more accurately reflect the change for graft survival and provide much greater access to transplant than simply raising it to the 1.85 minimum.

[1] Schold et al, CJASN, October, 2014

We appreciate CMS indicating they will continue to make appropriate modifications through rulemaking in the future as outcomes continue to change. We believe it is necessary for CMS to alter policies to accommodate the safe transplant of organs and not penalize transplant centers for utilizing as many organs as appropriate.

Changes to the Conditions for Coverage for Organ Procurement Organizations (OPOs)
NKCA member companies operate and work with OPOs across the country and play an important role in providing transplantation to the maximum number of recipients. These OPOs work closely with the Organ Procurement and Transplantation Network (OPTN) in order to maintain compliance and report necessary outcomes. Because of the close relationship between OPOs, OPTN, and CMS, we are pleased to see CMS propose changes that promote consistency in requirements between OPTN and CMS. We support these changes that will ultimately allow for more transplantable organs and clear requirements between the two organizations. In particular we believe that the proposed changes to the "eligible death" definition, the aggregate donor yield metric, and transport documentation are necessary updates to reflect advances in technology and promote greater utilization of organs.

Transplant Technical Correction and Other Proposed Revisions
NKCA appreciates CMS being vigilant to address needed technical corrections and clarifications and supports the proposed changes in the rule including extending and clarifying the due date for a mitigating factor request and clarifying guidance to System Improvement Agreements (SIAs). These changes are helpful for transplant centers and OPOs to have clear information in order to appropriately provide transplant to patients.

Conclusion
Thank you for the opportunity to comment on the transplant provisions of the HOPPS Proposed Rule. 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