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University of Michigan Epidemiology and Cost Center dialysisdata@umich.edu

Re: Vascular Access and Access to Kidney Transplant Measures

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the development of quality measures to evaluate dialysis facilities performance in improving the care of patients. NKF is America's largest and oldest health organization dedicated to the awareness, prevention, and treatment of kidney disease for hundreds of thousands of healthcare professionals, millions of patients and their families, and tens of millions of people at risk. NKF has a network of 40,000 patient and family members as part of our constituent council membership and reaches tens of thousands more patients through our programs and education materials. In addition, NKF has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI). We work with volunteers to offer the scientific, clinical and kidney patient perspective on what needs to be done to prevent kidney disease, delay progression, and better treat kidney disease and kidney failure. We offer the following comments on the proposed modifications of the vascular access measures and the development of transplant waitlist measures.

End-Stage Renal Disease Vascular Access Measure Development

Hemodialysis Vascular Access: Long-term Catheter Rate

NKF supports the addition of measure exclusions that are supported by the data (hospice, metastatic cancer, end stage liver disease and coma or anoxic brain injury). The implicit exclusions for peritoneal dialysis and age less than 18 years are sound.NKF recognizes a number of other potential exclusions are not feasible with

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the current data collection methodology.We encourage CMS to consider the impact of the proposed exclusions as well as explore additional exclusions in the future.

Adjusted percentage of adult hemodialysis patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.

The NKF supports this measure, which is modified by the identical exclusions of the aforementioned catheter measure and adds data-driven risk adjustments. The functioning AVF is superior to other access types, but AVF have a high primary failure rate. An area of controversy is how to best individualize care to match the optimal access to a specific patient. A KDOQI vascular access guideline update, under development, will address the current evidence base for access selection and management, which may better characterize the role of the AV graft.

End-Stage Renal Disease Access to Kidney Transplantation Measure Development

Percentage of Prevalent Patients Waitlisted (PPPW)

NKF is very supportive of improving patient education about kidney transplantation and increasing the number of patients that are referred for transplant. We encourage CMS to further pursue the data collection necessary to develop measures in these areas. Of the transplant measures proposed, NKF believes the overall kidney transplant waitlist measure, the percentage of prevalent patients waitlisted (PPPW) is the most meaningful for patients. Dialysis facilities can help support patients in maintaining their active status on the waitlist for routine antibody and other periodic testing. This measure would incentivize greater care coordination by the dialysis facility with the transplant center. Many transplant centers have dialysis outreach programs to better educate facility staff and patients about the transplant process and the patient and dialysis facility role in the process. However, gaps in patients getting waitlisted remain. Patients continue to report that they were not fully informed about transplant or were provided misinformation that led them not to not pursue transplant. Holding dialysis facilities accountable for ensuring their patient population is knowledgeable about transplant and supporting patients to maintain their status on the waitlist will help address this current gap in care. However, we note concerns with the limited exclusions. Some patients under age 75 may not be eligible for transplantation due to other clinical reasons. In addition, in

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some cases even the most informed and educated patient may ultimately choose not to pursue a transplant. Limited, but additional exclusions to account for these circumstances should be evaluated. Ultimately, the decision on whether a patient is listed for a transplant is made by the transplant center that evaluated the patient (and the patient's desire for a transplant). These are complex decisions that take into account many factors and vary by transplant center and geographic region, which would make nationwide comparisons of waitlist percentages difficult to interpret. The effect of this variance in transplantation policy on dialysis facility performance on this measure should be considered prior to implementation.

Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients NKF appreciates the intent of this measure to ensure that patients are waitlisted as early as possible after starting dialysis, if they were not already waitlisted. However, we are concerned this measure is limited in terms of actionability by the dialysis center as the ultimate decision on waitlist status is made by the transplant center and the patient. As we highlight above, dialysis facilities have a role in educating patients about transplant and supporting their active listing. However, incident dialysis patients, who were not listed before starting dialysis, may be more complex and have comorbidities that make them ineligible for the waitlist during the first year. While it is the responsibility of the dialysis facility to work to improve the health and functional status of dialysis patients during the first year, much of the final decision is beyond their control. In addition, dialysis units involved in preeducation and care coordination in the transition of advanced CKD to ESRD would not be recognized for pre-emptively having patients on the waitlist. To better improve earlier wait listing, NKF instead encourages CMS to reconvene the TEP and explore measure development to evaluate transplant referrals and patient education within the first 12 months of initiating dialysis.

Sincerely,

Joseph Vassalotti

Joseph Vassalotti, MD Chief Medical Officer