February 3, 2016

University of Michigan Kidney Epidemiology and Cost Center
1415 Washington Heights
Suite 3645 SPHI
Ann Arbor, MI 48109
diagnosisdata@umich.edu

Re: End-Stage Renal Disease Access to Kidney Transplantation Measure Development

To Whom It May Concern:

On behalf of the American Nephrology Nurses Association (ANNA), I appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) and University of Michigan Kidney Epidemiology and Cost Center’s (UM-KECC) proposed draft End-Stage Renal Disease (ESRD) Access to Kidney Transplantation measures.

ANNA promotes excellence in and appreciation of nephrology nursing so that we can make a positive difference for people with kidney disease. Established as a nonprofit organization in 1969, ANNA has a membership of approximately 10,000 registered nurses in almost 100 local chapters across the United States. We are the only professional association that represents nurses who work in all areas of nephrology, including hemodialysis, chronic kidney disease, peritoneal dialysis, acute care, and transplantation. Most of our members work in freestanding dialysis facilities, hospital outpatient units, and hospital inpatient dialysis units.

ANNA develops and updates standards of clinical practice, educates practitioners, stimulates and supports research, disseminates knowledge and new ideas, promotes interdisciplinary communication and cooperation, and monitors and addresses issues encompassing the breadth of practice of nephrology nursing.

Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients

ANNA appreciates the efforts of CMS and UM-KECC to increase access to kidney transplantation for individuals with kidney failure. We believe that a successful kidney transplant is the best treatment option for these individuals. People who undergo successful kidney transplants have improved outcomes compared to individuals remaining on dialysis, as measured by mortality, morbidity, cardiovascular complications, and quality of life. ANNA is supportive of all efforts to ensure the equitable placement of transplanted organs to reduce and/or eliminate disparities.
However, ANNA has some questions about the rationale for the standardized first kidney transplant waitlist ratio for incident dialysis patients (SWR) measure specifications. It is not clear why UM-KECC has chosen to include patients on the kidney or kidney-pancreas transplant waitlist who received a living donor transplant within the first year after initiation of dialysis, while excluding deceased donor transplants and patients who are listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis.

One of the overarching goals of nephrology practitioners is to ensure patients are included on the kidney or kidney-pancreas waitlist prior to beginning dialysis. ANNA has concerns with the plan for this measure to exclude patients who are waitlisted prior to beginning dialysis. ANNA also believes it may be difficult for dialysis facilities to determine which of their patients were placed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis, which may inadvertently exclude some patients from analysis.

Additionally, ANNA encourages CMS and UM-KECC to consider excluding from the SWR measure those dialysis patients over 70 years of age, as the 70+ patient population is less likely to be referred and accepted for kidney transplantation as compared to younger patients.

The SWR measure, as currently drafted, indicates it will measure patients who received a living donor transplant within one year after initiating dialysis or who are placed on the deceased donor waitlist after starting dialysis. The majority of transplant centers place all accepted patients on the deceased donor kidney transplant waitlist, including those with a potential living donor. Since this is the standard practice, there always will be patients who fit both categories, and could be counted twice. To ensure accurate analysis, ANNA urges CMS and UM-KECC to give further consideration to these issues in how this measure may best be implemented.

As development of the SWR measure continues, we encourage CMS and UM-KECC to take into account the variability of each transplant center’s acceptance criteria for transplant candidates and the weight given to the urgency or medical need for a transplant. ANNA urges CMS and UM-KECC to consider that not all referred patients will be eligible for transplantation and also to clarify how patients who are enrolled at more than one transplant center will be identified and accurately counted in this measure.

**Percentage of Prevalent Patients Waitlisted**

ANNA is supportive of the development of a measure for referral for transplant for incident patients. Research studies have shown that earlier transplantation results in positive patient outcomes and decreases the unnecessary utilization of limited health care resources. While we appreciate UM-KECC’s efforts to assess ongoing placement on the kidney or kidney-pancreas transplant waitlist among prevalent dialysis patients, ANNA has several concerns about using the percentage of prevalent patients waitlisted (PPPW) measure as a quality measure for dialysis facilities.
Transplantation is a multi-step process that involves many variables, including not only referral by a health care practitioner, but also evaluation and approval by a transplant team. The length of time a patient waits before receiving a kidney or kidney-pancreas transplant varies greatly, partially dependent on organ availability as well as the length of time it takes to complete the patient evaluation. Often, patients are referred and begin “work-up,” but remain in this process for an extended period of time prior to inclusion on the waitlist and/or determination that the individual is not a suitable transplant candidate. Although dialysis facilities have little to no control over the steps of the transplant process, under the proposed measure, a dialysis facility could be held responsible for the delay of a patient’s transplant evaluation. We request CMS and UM-KECC clarify how those patients who are referred to transplant centers by dialysis units but are delayed in their work-up or are deemed not suitable candidates will be excluded by the measure.

ANNA also has concerns that the proposed measure fails to appropriately account for patients who are included on the waitlist and subsequently removed from the list without a transplant. In developing the finalized PPPW measure, ANNA encourages CMS and UM-KECC to address patients who fit within this category.

Additional concerns revolve around transplant evaluations that may result in the identification of barriers to kidney transplantation, including active drug and/or alcohol abuse, noncompliance with medical treatment, active illnesses that would compromise the success of a transplant, obesity, or insufficient social support. Patients are often required to overcome such barriers to be considered an appropriate candidate for kidney transplantation, and would be excluded from the kidney or kidney-pancreas waitlist until such barriers are resolved. ANNA has concerns that under the proposed measure, dialysis facilities would be “penalized” until patients resolve such conditions and are placed on the kidney or kidney-pancreas waitlist. ANNA encourages CMS and UM-KECC to adjust the measure to ensure such delays in listing after referral do not result in penalties for dialysis facilities.

It also is imperative that dialysis facilities are notified when its patients are added to the waitlist. Nephrology nurses provide education and support for transplantation to the patient, their family and support systems, and the community. Nurses are uniquely qualified health care professionals who can educate patients on their transplant status and guide a patient through the transplant process. Dialysis patients often mistakenly believe that they are on the kidney or kidney-pancreas waitlist, when in fact they are still undergoing the process of evaluation and have not received final approval from the transplant team. The dialysis facility or unit plays a significant and meaningful role in periodically verifying the patient’s transplant status.

While the current standard of practice (and transplant center regulations) require the transplant center to transmit the updated waitlist information to the patient, nephrologist, and dialysis facility, in many circumstances, the dialysis facility is not notified when one of its patients is added to or removed from the waitlist. Ensuring the kidney transplant centers
transmit up-to-date waitlist information to dialysis facilities would allow clear communication with patients regarding their status.

Finally, we encourage UM-KECC and CMS to consider the development of quality measures that measure the frequency with which transplant education is provided to patients who may be eligible for kidney or kidney-pancreas transplantation.

**Conclusion**

ANNA greatly appreciates the opportunity to share our comments on measures related to the ESRD patient’s access to kidney or kidney-pancreas transplant. As the leading professional association representing nephrology nurses, we look forward to continuing to work with you on these important issues. Should you have any questions, please contact me or have your staff contact our Health Policy Consultant, Kara Gainer (Kara.Gainer@dbr.com or 202-230-5649). We thank you for your consideration.

Sincerely,

Cindy Richards, BSN, RN, CNN
President, 2015-2016