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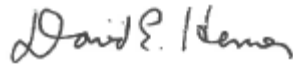
University of Michigan Kidney Epidemiology and Cost Center (UM-KECC)

Re: Practitioner-Level Measures in the Area of Access to Kidney Transplantation for Dialysis Patients and Facility-Level Measures in the Area of Modality Education for Dialysis Patients: Contract Name: Kidney Disease Quality Measure Development, Maintenance, and Support. Contract Number 75FCMC18D0041, Task Order Number 75FCMC18F0001

To Whom It May Concern:

The National Forum of ESRD Networks appreciates the opportunity to comment on the five proposed measures in access to kidney transplantation for dialysis patients and facility-level measures in the area of modality education for dialysis patients. Keeping in mind the Department of Health and Human Services' objectives for the Meaningful Measures Initiative 2.0 as a component of the CMS Quality Measurement Action Plan, we have highlighted our comments on those changes that can be anticipated to affect quality of care and access to ESRD treatment with a commitment to person-centered care and equity in care. Below are our comments. Thank you for your consideration.

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Co-Chair, Forum Kidney Patient Advisory Council

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1. Hemodialysis Vascular Access: Standardized Fistula Rate (SFR)

The Forum's Kidney Patient Advisory Council (KPAC) and Medical Advisory Council (MAC) acknowledge the goal of this new measure "to evaluate facility performance in increasing fistula use in the incident population in order to reduce the heightened risks patients face due to bacteremia and infection related hospitalizations." We also appreciate the high rate of over 80% of incident dialysis patients beginning treatment with a tunneled catheter, and that an arteriovenous fistula (AVF) may be preferred to AV graft in select patients "under favorable circumstances." Although this measure is aimed at dialysis facilities, the dialysis facility staff and providers do not usually impact the dialysis access that is in use for incident dialysis patients. The access in use for incident patients is mainly under the influence of the nephrologist caring for dialysis patients before they begin dialysis and the education and care the patient receives pre-ESRD. Even in the best of circumstances, a dialysis facility and the nephrologist taking care of the patient when she/he initiates dialysis will require at least several months in order to complete education, surgical referral, and follow-up in order for the patient to have a mature, functioning AVF for dialysis.

We do agree that reduction in catheter use in hemodialysis patients overall is beneficial to most dialysis patients and that nephrologists play an important role in helping to educate and refer patients for appropriate vascular access. We acknowledge the exclusions of patients on peritoneal dialysis, patients under hospice care, patients with metastatic cancer, patients with end stage liver disease, and patients with coma or anoxic brain injury in the past 12 months. Of note, CMS/CMMI did modify the Optimal Start Quality Measure for the voluntary Kidney Care Choices Models to REMOVE the restriction that only < 10% of incident dialysis patients could begin treatment with an AVG acknowledging the importance of "Catheter Last" rather than "Fistula First."

Both the KPAC and MAC of the National Forum of ESRD Networks expressed concern that patient choice is not incorporated into this measure, and in keeping with the Meaningful Measures Initiative concept of patient-centered measures that are meaningful to patients, we believe that patient choice can and should be incorporated into this measure. We believe that the life goals of patients need to be taken into account when considering which type of vascular access to pursue. At a certain age or time in a patient's life, she/he just may not wish to go through the process of evaluation or await the maturation of an AVF and/or associated multiple revisions in some cases or for valid clinical reasons may not wish to pursue an AVF. Furthermore, patients who have been on dialysis many years and have had many vascular access surgeries may be suffering and choose not to pursue any more vascular surgery. We healthcare providers and payers all should respect our patients'/beneficiaries' life goals and choices.

Also, when considering patient-centered care that safeguards the public, we believe that patients who have exhausted all possible sites for potential AVF placement should be excluded from this measure. In addition, we believe that patients who have suffered significant complications from AVF or AVG placement in the past, including steal syndrome affecting the partial or complete use of a limb, should be excluded from this measure. In many of these cases, further attempts of AVF placement may jeopardize the health of our patients, and we don't believe CMS should incentivize facilities to pursue further potentially harmful interventions for these patients. Keeping our patients safe is one of our primary goals, and we also feel that avoiding unnecessary or potentially dangerous vascular access surgeries in some patients is best for certain beneficiaries and should be taken into account in the measure. For example, patients with severe cardiovascular disease, for whom the risk of undergoing AV access surgery exceeds the possible benefit, should be excluded from this measure. In addition, there are patients in whom the vascular surgeon has determined there are no viable vessels for AV access. In these patients, attempting to place AV access may lead to unnecessary and preventable harm.

There are also many patients with medical or psychiatric contraindications to having AV access used on dialysis, such as some patients with schizophrenia or other psychiatric disorder in which use of an AV access on dialysis could potentially be dangerous. In these patients, a catheter may be the safest option.

In general, we believe that well informed patient choice is critical when considering placement of AV accesses. The appropriate access needs to be individualized for each patient based on both patient choice and the safest option. The 2020 KDOQI Vascular Access guidelines also focus on choosing the most appropriate vascular access for each patient.

Recommendations:

- We recommend that CMS implement claims-based exclusions for history of steal syndrome (often affecting the partial or complete use of a limb), severe congestive heart failure, severe hematologic disorders placing patient at risk for bleeding diathesis, severe psychiatric illness, limited life expectancy, or other conditions in which the risk of surgery to place AVF, or use of AVF on dialysis, is deemed to be unacceptable by their physician.
- We recommend excluding patients who have exhausted all potential sites for AVF or AVG placement, or in whom there are no viable vessels for AVF placement. We believe that facilities can report such patients in EQRS (formerly known as CROWNWeb) if a checkbox to indicate such patients is added.
- We recommend excluding patients with advanced age as evidence suggests these patients may benefit equally from AVG as AVF use on dialysis.
- We recommend excluding patients with complex multi-morbid conditions or those whose main goal is palliative dialysis therapy.
- We recommend excluding from the denominator patients who refuse consideration of AVF placement or use, despite >2 attempts spanning a 3-month period at education on the risks of catheters and benefits of AVF by their nephrologist and RN. Educational attempts should be documented by having the patients sign forms indicating that they have been informed and decline that option after repeated education has been completed. The patient's declination should be indicated by documentation in EQRS. We believe that facilities can report such patients in EQRS if a checkbox to indicate patient refusal is added.
- For such patients who would be excluded from the denominator due to the patient's informed decision not to have an AV access, we also recommend requiring facilities to continue attempts at education on the risks of catheters and benefits of AVF or AVG by their nephrologist and RN at least annually. This ongoing education attempt could be indicated by additional checkbox in EQRS.
- We believe including the above exclusions would help achieve the goal of making these measures more patient-centered and meaningful and would help to safeguard the health of ESRD patients.
- Our recommendations align with the updated KDOQI Vascular Access Guidelines, which emphasize that a patient's access needs stem from the creation of an individualized ESKD life plan. Rather than a "fistula first, catheter last" approach, the guideline reflects that the "right" vascular access is different for every patient.

2. Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standard Waitlist Ratio (FYSWR)

Percentage of Prevalent Patients Waitlisted (PPPW):

In the Forum's previous comments concerning the PPS 2019 proposed rule, we concurred with the CMS statement concerning "...shared accountability between dialysis facilities and transplant centers"

in enabling patients receiving dialysis to be placed on a kidney or kidney-pancreas waitlist. We agree that dialysis facilities can work with transplant centers to coordinate care so that patients can traverse the many steps between transplant referral and waitlisting, including starting the transplant evaluation and undergoing the multiple tests and consultations necessary to complete the evaluation. We also believe that practitioners have a vital role in this responsibility. We remain concerned about adopting these as clinical rather than reporting measures. When the TEP recommended the PPPW become a clinical measure, the effect of the new kidney allocation system (KAS) on waitlisting was not known. Since KAS started in December 2014, it has been shown that clinician behavior has changed, resulting in reduced rates of waitlisting (Zhang X, Melanson TA, Plantinga LC, Basu M, Pastan SO, Mohan S, Howard DH, Hockenberry JM, Garber MD, Patzer RE Racial/ethnic disparities in waitlisting for deceased donor kidney transplantation 1 year after implementation of the new national kidney allocation system. *Am J Transplant.* 2018 Aug; 18(8): 1936-1946). This may be due to the fact that under the new KAS, waiting time starts at dialysis initiation, which eliminates the benefit of early waitlisting for deceased donor transplantation and has appropriately caused providers to wait until a patient has spent several years on dialysis prior to making a transplant referral. Another concern remains the fact that it can take many months for transplant centers to complete the transplant evaluation, and there is geographic inequity in the distribution of transplant centers; areas of the country with fewer transplant centers have been shown to have less access to renal transplantation (Patzner RE, Plantinga L, Krisher J, Pastan SO. Dialysis facility and network factors associated with low kidney transplantation rates among United States dialysis facilities. *Am J Transplant.* 2014 Jul; 14(7): 1562-72).

In addition, there are many reasons why a patient may not be eligible for transplantation and may not be waitlisted; transplant eligibility varies by transplant center and geographic region, factors which are outside of the control of the dialysis practitioner. Many low-income patients with limited family support, with depression, or other barriers to obtaining complex care may struggle with completing the additional visits required for achieving a complete workup to achieve waitlisted status. If CMS is concerned that improved referral rates are not translating into higher rate of waitlisting in certain Networks or regions within a given Network, this should be referred to the appropriate Network for further inquiry. We are also concerned that these measures will exclude patients who received a kidney transplant for the months after they receive the transplant. Receiving a kidney transplant is the ultimate goal of having patients waitlisted, and we don't believe that practitioners should lose credit for a reduced waitlisting prevalence once the patient has been transplanted. After all, one of the payment incentives for the voluntary Kidney Care Choices models is the Transplant Bonus which is only paid once the patient receives a transplant as that transplant remains functioning for up to three years.

Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW):

The Forum recognizes the importance of patients being actively waitlisted prior to receiving a kidney transplant and that the active listing rate may be a more clinically relevant measure of access to transplant than overall waitlisting, that includes inactively listed patients. It is possible for transplant centers to increase their waitlisting rates by listing patients inactive. However, the transplant center must also responsibly manage their waiting lists to avoid high waitlist mortality rates.

First Year Standard Waitlist Ratio (FYSWR):

The Forum believes that one year is probably too short of a timeframe to expect most patients to be referred to a transplant center and to complete the multiple steps required to be placed on the waitlist. In one study in the Southeast, only 33.7% of patients were referred for transplant within one year of starting dialysis, and of those patients only 48.3% started the evaluation at a transplant center within the following six months (Patzner RE, McPherson L, Wang Z, Plantinga LC, Paul S, Ellis M, DuBay DA, Wolf J, Reeves-Daniel A, Jones H, Zayas C, Mulloy L, Pastan SO. Dialysis facility referral and

start of evaluation for kidney transplantation among patients treated with dialysis in the southeastern United States. *Am J Transplant.* 2020; 20(8): 2113-2125). We recognize the 2014 KAS change, which changed the listing start date to dialysis start, resulted in a drop in waitlisting due in part to the lack of urgency to get a patient on the waitlist early; most practitioners are aware that the average wait time to receive an offer will be many years. Unfortunately, this results in patients potentially missing out on getting evaluated earlier for living donor transplant or for early offers.

All three measures—Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standard Waitlist Ratio (FYSWR)—contain exclusion criteria including patients >75 years old, patients residing in a skilled nursing facility, and patients on hospice, but the measures do not exclude patients with severe cardiovascular disease, patients with severe pulmonary disease or other comorbidities, such as obesity, untreated psychiatric illness, or frailty that are considered by transplant centers when they evaluate potential recipients. This is especially true as transplant centers are being measured on their waitlist mortality as mentioned above, and centers may be hesitant to list patients with these issues. If we want to get these patients listed, it will clearly take more than one year to optimize them for transplant.

The Forum's KPAC members are interested to see the ESRD Treatment Choices model implemented, seeing how nephrologists and dialysis facilities work together to improve the outcome of kidney transplantation. Hopefully, this will create best practices that can be shared throughout the community and allow development of better quality measures in the future that incentivize equality for all patients to have access to transplantation across multiple care settings. The Forum/KPAC look forward to working with CMS to offer perspectives from both patients and professionals as these models are implemented and tested.

Recommendations:

- We recommend that these measures be reporting measures only until we have a better understanding of a medically appropriate target for waitlisting rates under the current KAS.
- We reiterate our recommendation that referral rates are more appropriate than waitlisting rates as an appropriate metric, although we acknowledge the challenges in data acquisition.
- We recommend including patients who receive a kidney transplant during the measurement year in the numerator as equal to being on the waitlist for the 12 months following the kidney transplant.
- We recommend the adoption of a measure that specifically measures whether patients have received education concerning transplantation as a modality.