March 30, 2022

Jonathan Segal, MD
University of Michigan Kidney Epidemiology and Cost Center (UM-KECC)
1415 Washington Heights, Suite 3645 SPHI
Ann Arbor, MI 48109-2029

RE: Spring 2022 Renal Measures

Dear Dr. Segal:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease.

RPA appreciates the opportunity to provide comments on the Renal Measures developed by UM-KECC. RPA believes these measures as proposed are flawed and therefore not a reliable indicator of quality. The measures largely focus on aspects of the patient's status that are beyond the control of the nephrology practitioner or dialysis facility. Therefore, we believe there is a high risk of unintended adverse consequences should these measures be adopted as written.

RPA's specific concerns on both the provider and facility level measures are outlined below.

Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR)
Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW)
Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

RPA recognizes the critical importance of improving transplantation rates for patients with ESRD. As evidenced by our 2011 provider-level measure on Transplant Referral, we have long advocated for referral to a transplant center and initiation of the waitlist evaluation process, but do not support the attribution of successful or unsuccessful waitlisting to the nephrologists, dialysis facilities, individual practitioners, or group practices. Waitlisting is a decision made by the transplant center and is beyond the control of any of the providers targeted in these measures. Therefore, RPA strongly objects to attributing successful/unsuccessful placement on a transplant waitlist to dialysis facilities, individual clinicians or practitioner group practices and believe this is an unacceptable structural flaw with these measures. The transplant center decides whether a patient is placed on a waitlist, not the facility, practitioner, or group practice.

Furthermore, RPA has concerns regarding the measures' failure to address variation in transplant center eligibility criteria. Criteria indicating a patient is "not eligible" for transplantation can differ by location, and the degree to which these factors influence waitlist placement must be accounted for in any measure to be a valid representation of waitlisting.

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Finally, RPA is concerned about the of these measures for small providers as reliability data has not been provided.

Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMOSR)
RPA does not support the Standardized Modality Switch Ratio (SMoSR) Measure as written, due to concerns about the premise of the measure. UM-KECC indicates that the basic premise of the measure is that patients who consent to changing their treatment modality from in-center to home do so because of iterative education efforts and effective decision support by the dialysis facility, which can help patients select a modality that is best aligned with their personal goals and values. However, the use of modality switch rates as a proxy for proper patient education will incentivize switching in-center patients to home dialysis, but there is no mechanism for the measure to discern whether such conversions are the result of the "iterative education efforts and effective decision support" that the developer envisions. Indeed, the measure offers no insight whatsoever into degree or quality of education and training the patient received in preparation for the switch, or if patients are instead being subjected to a modality for which they haven't, in fact, received adequate education or training. The measure may even inadvertently infringe on patient choice; any home dialysis-related measure, particularly when tied to financial incentives, must be approached with considerable caution to ensure that patients who should not or do not want to receive home dialysis are not inadvertently pressured or even coerced into selecting a home modality.

Facility-Level Standardized Fistula Rate for Incident Patients (ISFR)
RPA believes that effective and appropriate vascular access placement is one of the most important clinical considerations for patients making decisions about dialysis facilities. However, we do not believe that narrowing the target population of the prior, all-patient iteration of the Standardized Fistula Rate Measure (SFR, previously NQF #2977) effectively addresses the issues that led to its loss of NQF endorsement. The NQF Renal Standing Committee rejected the prior SFR measure because they believed it was effectively "topped out" at 64% for all patients for whom an AV fistula is clinically appropriate. As the new measure defines an incident patient as one who began maintenance hemodialysis within the prior twelve months, we believe UM-KECC's logic is flawed. Rather than supporting the premise of the measure, fistula rates climbing from less than 20% at dialysis initiation to greater than 60% within twelve months supports the notion that dialysis facilities are already placing fistulas in nearly all clinically appropriate new patients, once under their care, such that by the end of the first year of dialysis the population approaches that "topped out" AV fistula rate identified by NQF. Therefore, we do not believe the measure will not meaningfully increase fistula rates, and may lead to the creation of fistulas in patients such as those who are medically frail or otherwise not good candidates for such a procedure.

As always, RPA welcomes the opportunity to work collaboratively to improve the quality of care provided to the nation's kidney patients. Any questions or comments regarding this correspondence should be directed to Amy Beckrich, RPA's Interim Executive Director, at 301-468-3515 or abeckrich@renalmd.org.

Sincerely,

Timothy Pflederer, MD
President

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TO: University of Michigan Kidney Epidemiology and Cost Center Renal Measures Team
DA: March 30, 2022
RE: Public Comment: Spring 2022 Renal Measures

Dear UM-KECC Team:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to offer commentary on the five proposed transplantation, vascular access, and modality education measures put forth by the Centers for Medicare and Medicaid Services (CMS)/University of Michigan Kidney Epidemiology and Cost Center (UM-KECC):

- Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR)
- Facility-Level Standardized Fistula Rate for Incident Patients (ISFR)
- Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR)
- Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW)
- Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

ASN offers comment on all five measures under review. However, ASN expresses its disappointment that the public was not alerted to the March 30 comment period deadline until March 17, leaving little time for stakeholders to review these complex measures and develop a response. Due to the complexity and significance of the issues addressed by these measures, ASN recommends adoption of these measures be delayed and the comment period extended to gather further input.

Based on our abbreviated review, ASN is concerned by several aspects of the measures:

- Focus on incident maintenance dialysis populations with “stand alone” measures that are independent of measures targeting patients in other stages of kidney diseases such as non-dialysis advanced chronic kidney disease and prevalent dialysis. This siloed focus disadvantages kidney care providers who have

provided high quality care for people with advanced CKD, including referral for home dialysis and pre-emptive transplantation
- Reliance on CMS-2728 data (End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration) for any risk adjustment including transplant measures
- Attribution of measures to the dialysis facilities
- Lack of consideration of social determinants of health that may influence the measures and have implications for health equity
- Focus on dialysis unit-specific measures, without consideration of advanced CKD care and nephrologist-led care

Below are comments about the specific measures:

Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR)

The stated goal of the SMoSR measure is to incentivize high quality modality education. However, ASN does not understand how or why the developer arrived at the modality switch rates as a valid proxy for high quality patient engagement and education about modality options. The measure does not indicate the degree or quality of education and training the patient received in preparation for a modality switch, and the measure may even infringe on the patient-physician relationship. If a dialysis facility or organization is responsible for a metric around dialysis modality switch, that may place the facility inappropriately at odds with conversations and achieved decisions between the patient, the patient's care partners and the nephrology clinician. While ASN acknowledges that education can be improved for many individuals with advanced chronic kidney disease, we feel strongly that a nephrologist-led care team working with the patient must be at the core of deciding dialysis modality. ASN notes that this measure discounts any prior conversations and education that may have occurred among the nephrology clinician, the patient, and the patient's carepartners. This is extraordinarily non-patient centered and, inadvertently may incentivize initiation with hemodialysis prior to a modality change. A measure that focuses on modality switches as opposed to receipt of proper patient education and that is attributed to the facility results in a high risk for conflict between informed patient preferences, pre-existing decisions, and dialysis facility incentives.

ASN generally supports CMS's ESRD Treatment Choices (ETC) Model handling of modality switches, wherein the home dialysis rate is aggregated across dialysis facilities under the same legal entity/parent organization within the same Hospital Referral Region, although ASN continues to have concerns about how transfers among organizations are accounted for. We believe that this HRR approach is fairer, better acknowledges the existing business structure that many larger organizations have developed around home dialysis, and is more easily deciphered by patients, physicians, and providers.

Ironically, the proposed measure will actually penalize facilities that have a higher incident home dialysis rate. If a facility serves a population that already has a high home dialysis rate (e.g., 20% Home Dialysis in the service area), then more patients who are likely to desire home dialysis are already performing home dialysis as their initial dialysis modality than facility service areas where fewer (e.g., 10%) maintenance dialysis patients are performing home dialysis. Often times, facilities are involved in preparing patients for home dialysis prior to dialysis initiation. This puts the facility at risk for doing poorly with the metric, despite providing high quality care.

Lastly, the "less than thirty days" exclusion in this measure also concerns ASN, since some patients may decide to transition at less than thirty days for valid reasons, although understandably a facility may less often be responsible for home dialysis transitions during the first weeks a patient is receiving in-center dialysis. Additionally, given that individual facilities are relatively small, ASN shares concerns regarding the reliability of the proposed metric for most dialysis facilities. We feel strongly that this proposed metric should be completely reconsidered.

Facility-Level Standardized Fistula Rate for Incident Patients (ISFR)

ASN agrees that vascular access is an important clinical consideration for patients and supports the hypothesis that some facilities are better than other facilities at optimizing the longevity of hemodialysis fistulas and grafts as well as at facilitating creation of fistulas and grafts. ASN also continues its support of CMS's Long-Term Catheter Rate Measure (NQF #2978) in the ESRD QIP to maintain prevalent central venous catheter use at a small portion of the dialysis population. However, ASN does not believe that narrowing the target population of the prior, all-patient iteration of the Standardized Fistula Rate Measure (SFR, previously NQF #2977) to incident dialysis patients makes for an appropriate metric or that this change addresses the issues that led to its loss of NQF endorsement in 2020.

Inherently, the proposed fistula measure is unchanged from the prevalent measure, applying the existing measure to an incident population. ASN does believe attributing performance on this measure to the dialysis facility is appropriate. As a nephrologists' society, ASN considers optimizing vascular access among incident dialysis patients an appropriate focus for a measure for physicians and physician groups, but the proposed measure is misdirected at dialysis facilities. A well-thought-out vascular access plan is patient-centered, and clinician led. Dialysis facilities who meet patients for the first time should not be primarily responsible for vascular access plans. Rather, this should be done under the direction of the patient's whole kidney care team, in which the patient and their nephrologist work closely with the providers placing access, such as the surgeon or interventionalist.

Of note, there are patients for whom timely AVF placement is not feasible and AV graft (AVG) is a reasonable, safer alternative to a catheter. AVG placement should be considered in the numerator.

Finally, this measure encourages dialysis facilities to cherry pick patients with existing arteriovenous fistulas, potentially marginalizing patients with other types of access. This is not patient-centered and does not promote equity.

Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR)
Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW)
Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

While ASN is supportive of these measures for ensuring and promoting equitable access to kidney transplantation, it is important to recognize that the actual waitlisting of patients and whether they are active or inactive on the waitlist is beyond the control of dialysis units or individual nephrologists as currently structured (attached is ASN's response to **CMS-3409-NC: Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities** in which the flaws of the current waitlisting program are examined in depth). In order for these measures to be valid assessments of quality of care, it is imperative that the following information be easily and readily accessible to referring physicians and dialysis units:

1. Waitlisting criteria at transplant centers including absolute AND relative contraindications.
2. Clear information on the reasons for declining a patient for listing by transplant centers so that nephrologists can determine if patients would benefit from referral to a different transplant center.
3. Active status on the waitlist needs to be made clearly available to nephrologists and dialysis facilities so that centers and dialysis facilities are immediately aware of when (and why) patients are inactivated on the list. If physicians are going to be held accountable for this, they need to be aware of the status and what needs to be done to be re-activate those patients on the waitlist.
4. "Internal holds" placed on a patient by the transplant center while leaving the patient as active on the waitlist. Differences in how transplant centers use this practice can adversely impact the measure and access to transplant for patients who are on extended periods of internal hold unbeknownst to them.

In light of this, the implementation of these measures should be accompanied by easy and timely access to the status of the patient in the evaluation process, reasons for not listing a patient, and waitlist status. In addition, the only way to shed light on whether transplant centers are inappropriately using "internal hold" for patients is to share organ offer data with nephrologists and dialysis facilities which would help identify patients who are on internal hold instead of being inactivated. The Health Resources and Services Administration (HRSA) and the Organ Procurement and Transplantation Network (OPTN) need to provide access to waitlist data, information on steps to transplantation from centers, and organ offer data in a manner that is timely, easily accessible, and actionable.

ASN appreciates the opportunity to provide comments on the five proposed transplantation, vascular access, and modality education measures put forth by the UM-KECC team. To discuss the contents of this memorandum, please contact ASN Regulatory and Quality Officer David L. White at dwhite@asn-online.org or call (202) 640-4635.

Sincerely,

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NATIONAL KIDNEY FOUNDATION®

March 30, 2022

Re: Kidney Disease Quality Measure Development, Maintenance, and Support;
Contract Number: 75FCMC18D0041, Task Order Number: 75FCMC18F0001

Dear Dr. Messana,

The National Kidney Foundation (NKF) thanks the University of Michigan Kidney Epidemiology Cost Center (UM-KECC) for the opportunity to provide comments on the following measures:

- Effective Availability and Utilization of Home Dialysis Modalities, Standardized Fistula Ratio (SFR)
- Effective Availability and Utilization of Home Dialysis Modalities, Standardized Modality Switch Ratio (SMoSR)
- Practitioner Level Measurement of Effective Access to Kidney Transplantation

Standardized Fistula Ratio

NKF has grave concerns about prioritizing the development of a facility-level measure of standardized fistula ratio (SFR) for incident dialysis patients. As UM-KECC acknowledges, the Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline for Vascular Access: 2019 Update, focuses on vascular access choice and the creation of an ESKD Life Plan centered on the patient's "current and anticipated medical and life circumstances and preferences." A measure based on AVF as the sole means of vascular access is not sufficiently patient-centered. We share similar concerns with the existing SFR measure used in the Quality Incentive Program (QIP), which we communicate to CMS annually during the public comment period for the ESRD rule.

There are numerous reasons, some clinical and some based on patient preferences, that lead to patients choosing not to go through the process of evaluation or maturation of an AV fistula. Further vascular surgery may not align with patients' preferences for care, for example for patients who have been on dialysis for many years and have had multiple vascular access surgeries or patients who are able to dialyze safely with a catheter and, though educated on the benefits of a permanent vascular access, prefer it.

We understand the data points that UM-KECC raises in the measure description, namely that, under favorable circumstances, AV fistulas used in incident patients result in fewer long term vascular access events than an AV graft. NKF has supported a solution for the QIP in which CMS simply relies on the Hemodialysis Vascular Access: Long-Term Catheter Rate rather than incentivizing any specific vascular access. The long-term catheter rate measure encourages the facility to pursue a permanent vascular access for most patients, while allowing some flexibility for patients for whom it is appropriate to continue on dialysis with a catheter. In addition, to better account for patient preferences, the long-

term catheter rate measure method could reduce the cherry-picking that is a common and destructive unintended tradeoff of the SFR measure.

In general, NKF supports the prioritization of measure concepts other than specific vascular access measures, which we are unsure will provide benefits that outweigh the consequences of further incentivization of fistulas.

If the development of vascular access measures is necessary, we ask UM-KECC to consider how to create measures with sufficient adaptability to the preferences of the dialysis population. For example, a SFR measure should include claims-based adjustments for severe steal syndrome affecting the partial or complete use of a limb, severe congestive heart failure, severe psychiatric illness, limited life expectancy, or other conditions in which the risk of surgery to place AV access, or use of AV access on dialysis, is deemed to be unacceptable by the physician.

Standardized Modality Switch Ratio (SMoSR)

Considerations of how to measure concepts in home dialysis access, retention, and safety are of the utmost importance as the Administration pursues policies that grow the U.S. home dialysis census. Measurement of modality switches from in-center to home dialysis is not, in and of itself, a priority for NKF, particularly given that a new home dialysis quality measure would presumably be one of the first home-focused quality measures to be added to the QIP. The measure is too narrowly focused, failing to account for switches to home modalities, especially switches to home hemodialysis (HHD) that occur after the first year of dialysis. Given the extraordinary strain the dialysis system is under as the COVID-19 pandemic continues, it is likely the modality switch measure will capture switches that are not a function of the facility's quality, but rather delays in getting patients prepared to go home. Finally, as the dialysis industry changes, both in the context of Innovation Center kidney models and industry mergers to consolidate nephrology and dialysis practice, the Administration's focus should be on measures that incentivize preparation among late-stage dialysis patients for a "home first" strategy, rather than on what is now, but will not always be, the practical reality of starting patients on in-center dialysis and subsequently switching them to a home modality after dialysis initiation.

NKF has defined five domains of home dialysis quality outlined as follows. While we do not oppose the SMoSR measure, we ask UM-KECC to prioritize the development the quality measures in these domains.

Home Dialysis Access

> A home dialysis access measure can be modified for use in the QIP from the ETC model. The home dialysis access domain should also include patient-reported assessments of whether the individual was given a choice of modality, meaningful education on those choices and whether they are being treated with the modality they prefer. A home dialysis access domain could also include an assessment of the percentage of eligible patients who declare a

preference for home dialysis who are successfully trained in a timely manner. Backlogs in home training are themselves a barrier to access.

Clinical Care

Measures in the clinical care domain should account for residual kidney function (RKF), incentivizing nephrologists and providers to incorporate RKF into the dialysis prescription and dosing. Current practice is better in PD than in HHD, where overtreatment and loss of residual function are common. We appreciate CMS' adjustments to Kt/V for home patients and ask CMS to continue to decrease reliance on this measure for home patients in favor of a complete spectrum of lab values and assessment of how the patient feels and functions. Even with adjustment, Kt/V can still be punitive for home patients whose facilities will not exercise the flexibility they are allowed under the QIP.

Other concepts that should be captured in the clinical domain are:

- Intensive hemodialysis
- Volume status
- Blood pressure control

Safety

The current safety domain need only include a measure of peritonitis to evaluate safety across dialysis settings.

Retention

Measures in the retention domain will by definition get at the quality of home training, one of the most important factors in a person's ability to be successful on home dialysis. Retention measures will also elucidate the steps the facility is taking to anticipate and manage patient and care partner burnout. A measure of short-term retention on home dialysis is not useful and may be actively harmful. The goal should be to support patients through their first year on home dialysis, which can be very challenging, but after which many patients will experience substantial improvements in their quality of life.

Quality of Life (QoL)

The patient-centered outcome that matters to home dialysis patients, in fact, all dialysis patients, is quality of life (QoL). Nephrologists and dialysis facilities can and should be responsible for some elements of a patient's QoL. We acknowledge that quality of life is unique to each individual, is affected by processes outside of dialysis, and does not necessarily correlate with quality of care and therefore that developing accountabilities

associated with QoL may be challenging. As a preliminary step, facilities could report an individual's Activities of Daily Living (ADLs), which are much more closely related to an individual's quality of life. There are also existing mechanisms that could be deployed to encourage nephrologists and providers to focus on QoL, for example better leveraging the Kidney Disease Quality of Life (KDQOL) tool that dialysis facilities must already administer to dialysis patients under the existing Conditions for Coverage, the development of the Plan of Care and the ESKD Life Plan.

Practitioner Level Measurement of Effective Access to Kidney Transplantation

NKF supports the UM-KECC in its endeavor to create and implement a practitioner-level measurement of effective access to kidney transplantation. Kidney transplantation is the optimal treatment modality for most End-Stage Kidney Disease (ESKD) patients, yet there are few clinician-level quality measures incentives to encourage it. Too many individuals with kidney failure are disregarded and left behind to die on dialysis. We believe that dialysis centers and nephrologists who deliver care to ESKD patients should be accountable and measured for their role in the transplantation process.

Patient access to the deceased donor waitlist has not increased in two decades and has fallen in socially vulnerable populations, despite policy efforts to increase waitlisting. CMS regulations at § 494.90(d) require dialysis facilities to educate dialysis patients about transplantation. The Quality Incentive Program ties 2% of Medicare reimbursement to dialysis facility performance on a set of quality measures including Percent of Prevalent Patients Waitlisted (PPPW). The ESRD Treatment Choices (ETC) model holds 30% of Medicare-enrolled nephrologists and dialysis facilities accountable for performance on waitlisting

While transplant centers are the ultimate entity with the power to waitlist a patient, it is appropriate to hold nephrologists and dialysis centers accountable for their role in ensuring that a patient is waitlisted. This measure should also be included under the Merit-Based Incentive Payment System (MIPS). Finally, to ensure coordination across the range of stakeholders in the transplant system, we encourage CMS to develop similar waitlisting measures for transplant centers.

The absence of a practitioner-level measurement is a disservice to ESKD patients and may contribute to health inequities. We acknowledge that access to the transplant system is not a surrogate for the outcome of transplantation, but when patients enter the transplant system, they often receive more support in finding a living donor and participating in kidney paired donation (KPD) than they do from their dialysis center and nephrologist. NKF strongly advocates for implementing measures that will change clinical behaviors to influence improved patient access to transplantation.

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NKF thanks UM-KECC for the opportunity to comment on quality measurements under consideration. We welcome the opportunity to collaborate and would be pleased to discuss these comments. Please contact Morgan Reid, Director of Transplant Policy and Strategy (morgan.reid@kidney.org) or Miriam Godwin, Health Policy Director (miriam.godwin@kidney.org).

Sincerely,

Kevin Longino
CEO and Transplant Patient

Paul M. Palevsky, MD
President

FORUM OF END STAGE RENAL DISEASE NETWORKS

March 30, 2022

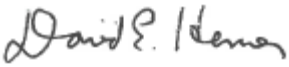
University of Michigan Kidney Epidemiology and Cost Center (UM-KECC)

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:

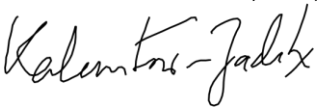
The National Forum of ESRD Networks appreciates the opportunity to comment on the five proposed measures in access to kidney transplantation for dialysis patients and facility-level measures in the area of modality education for dialysis patients. Keeping in mind the Department of Health and Human Services' 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.

David E. Henner, DO



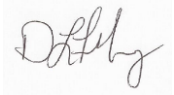
President, Forum of ESRD Networks

Kam Kalantar-Zadeh, MD, MPH, PhD



Chair, Forum Medical Advisory Council

Derek Forfang



Co-Chair, Forum Kidney Patient Advisory Council

Dawn Edwards

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 (Patzer 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 (Patzer 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.

TO: University of Michigan Kidney Epidemiology and Cost Center Renal Measures Team

DA: March 30, 2022

RE: Public Comment: Spring 2022 Renal Measures

Dear UM-KECC Team:

Kidney Care Partners (KCP) is a non-profit coalition of more than thirty organizations comprising the full spectrum of stakeholders related to dialysis care—patients and advocates, dialysis professionals, physicians, nurses, researchers, therapeutic innovators, transplant coordinators, and manufacturers. KCP is committed to advancing policies that improve the quality of care and life for individuals at every stage along with chronic kidney and end stage renal disease care continuum, from prevention to dialysis, transplant, and post-transplant care. We appreciate the opportunity to provide comments on the five proposed transplantation, vascular access, and modality education measures put forth by the Centers for Medicare and Medicaid Services (CMS)/University of Michigan Kidney Epidemiology and Cost Center (UM-KECC):

- Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR)
- Facility-Level Hemodialysis Vascular Access: Standardized Fistula Rate (SFR)
- Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR)
- Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW)
- Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

We offer comment on all five measures under review. However, we note with considerable dismay that the public was not alerted to the March 30 comment period deadline until March 17, leaving little time for stakeholders to review these complex measures and develop a response. This is particularly an issue with multi-member organizations and coalitions that must achieve consensus among its constituents on such comment letters; we urge CMS and UM-KECC to notify its stakeholders of these important matters in a timelier manner.

Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMOSR)

KCP does not support the Standardized Modality Switch Ratio (SMoSR) Measure. UM-KECC indicates that the basic premise of the measure is that patients who consent to changing their treatment modality from in-center to home do so as a result of iterative education efforts and effective decision support by the dialysis facility, which can help patients select a modality that is best aligned with their personal goals and values. It was also noted that the Technical Expert Panel (TEP) that convened in Spring 2021 to offer feedback on a draft modality switch measure had broad consensus that: 1) home dialysis rates are very low in the US; 2) a quality measure to monitor facility performance on home dialysis would be useful to patients, providers, and other stakeholders; and 3) there must be greater emphasis on effective and on-going education by both nephrologists and the facility care team to allow more patients to make a more informed modality choice. The TEP also recognized that a majority of switches to home dialysis occur within the first year of beginning chronic dialysis.

While KCP agrees with all of the TEP's above conclusions, we remain unsure how the developer arrived at modality switch rates as a valid proxy for proper patient education. If, as stated, the goal is to incentivize improved modality education, this measure misses the mark. Certainly the measure will incentivize switching in-center patients to home dialysis, but there is no mechanism for the measure to discern

whether such conversions are the result of the "iterative education efforts and effective decision support" that the developer envisions. Indeed, the measure offers no insight whatsoever into degree or quality of education and training the patient received in preparation for the switch and may even inadvertently infringe on patient choice; any home dialysis-related measure, particularly when tied to financial incentives, must be approached with considerable caution to ensure that patients who should not or do not want to receive home dialysis are not pressured or even coerced into selecting a home modality. We note that our sister organization, the Kidney Care Quality Alliance (KCQA) has developed a home dialysis measure set that is currently being considered for National Quality Forum (NQF) endorsement. The paired measure set was developed and designed to promote steady, deliberate performance improvement over time by addressing *both* sides of the home dialysis utilization equation—uptake and retention. The set pairs a "core" Home Dialysis Rate Measure with a "guardrail" Home Dialysis Retention Measure to counterbalance unopposed incentivization of home prescription and minimize risk of unchecked home dialysis growth. The retention measure will also allow providers to more readily assess the success of their efforts to create a *sustainable* home program through appropriate patient education, preparation, and support, and to apply targeted quality improvement interventions as needed.

We are also concerned that the SMoSR requires use of a complicated and rather confusing two-part regression model connected through an estimated "mixture structure" to account for the many facilities that do not offer home dialysis ("zero-patient facilities"). We believe this issue is more effectively addressed in the KCQA measures, which have adopted the approach deployed in CMS's ESRD Treatment Choices (ETC) Model, wherein the home dialysis rate is aggregated across dialysis facilities under the same legal entity/parent organization within the same Hospital Referral Region. We believe that this HRR approach is fair and respects the existing business structure many organizations have developed around home dialysis, and is more easily deciphered by both patients and providers.

Further, we note that while UM-KECC reports that the TEP supported the basic construct of the SMoSR, KCP staff attended the TEP calls and made note of the following reservations expressed by members, which were considerable:

- The measure addresses only a small subset of patients—incident patients who switched from in-center to home dialysis within the first year of treatment; the TEP voiced concern that the measure would thus ultimately do little to "move the marker" on overall home dialysis utilization within facilities and across dialysis organizations.
- Likewise, TEP members argued that as there is significant room for improvement in home dialysis utilization in *established* patients, the measure should also address *prevalent* patients. With the exclusion of this population, the measure misses a significant opportunity to drive performance improvement.
- Because the measure only gives "credit" for incident patients specifically who *switch* from in-center to a home modality, there was considerable concern that implementation of the SMoSR in a penalty-based program would create a perverse incentive to, paradoxically, *start* new patients on *in-center dialysis* so as to allow for a subsequent modality "switch" to home, for which credit could be received.

Finally, as a matter of process, we note that stratification of reliability scores by facility size was not detailed; we are thus unable to discern how widely reliability varies across the spectrum of facility sizes. We are concerned that the reliability for small facilities might be substantially lower than the overall IUR, as has often been the case with other UM-KECC standardized measures. Without evidence to the contrary, KCP is thus concerned the SMoSR reliability may be unacceptably low for small facilities, effectively rendering the metric meaningless for use in performance measurement in this group of

providers. KCP believes it is incumbent on UM-KECC and CMS to demonstrate reliability for all facilities by providing data by facility size. Similarly, as with CMS's other standardized ratio measures (e.g., the SMR, SHR, SRR, STrR), KCP again strongly recommends that ratio measures be avoided in favor of risk-adjusted rates or year-over-year normalized rates.

Facility-Level Standardized Fistula Rate for Incident Patients (ISFR)

KCP does not support the Standardized Fistula Rate for Incident Patients (ISFR) Measure. KCP maintains that vascular access is one of the most important clinical considerations for patients making decisions about dialysis facilities, and we continue our strong support of CMS's Long-Term Catheter Rate Measure (NQF #2978) in the ESRD QIP to reduce catheter use. However, we do not believe that merely narrowing the target population of the prior, all-patient iteration of the Standardized Fistula Rate Measure (SFR, previously NQF #2977) effectively addresses the issues that led to its loss of NQF endorsement in 2020.

As UM-KECC notes in its request for comments, the SFR's loss of endorsement was precipitated by KDOQI's then-recent downgrading of the evidence supporting fistulas as the preferred access type, in favor of catheter avoidance and individualized ESKD Lifeplans. To support the premise for this new, incident-only measure, UM-KECC now counters that the same guidelines do suggest that under favorable circumstances an AV fistula is preferred to an AV graft in incident patients due to fewer long-term vascular access events (e.g., thrombosis, loss of primary patency, interventions) and because "blood stream infection rates are the lowest in incident patients with AV fistula compared to long-term catheters." We note, however, that the KDOQI guideline *explicitly* indicates there is inadequate evidence to make a recommendation on choice of AV fistula vs AV graft for incident vascular access based on associations with infections; thus, here again, the KDOQI statement focuses on catheter reduction and takes no stance on the superiority of fistulas over grafts in this regard.

UM-KECC also indicates that the Incident SFR was developed to focus on the subset of dialysis patients that evidence suggests may benefit the most during a time of intense vascular access creation, noting that while greater than 80% of incident dialysis patients begin treatment with a tunneled catheter, AV fistula rates exceed 60% by twelve months after dialysis initiation. Here we note that NQF's Renal Standing Committee also rejected the prior SFR because they believed the measures was effectively "topped out" at 64% for all patients for whom an AV fistula is clinically appropriate. As the new measure defines an incident patient as one who began maintenance hemodialysis within the prior twelve months, we believe UM-KECC's logic here is flawed. Rather than supporting the premise of the measure, fistula rates climbing from less than 20% at dialysis initiation to greater than 60% within twelve months supports that dialysis facilities are *already* placing fistulas in nearly all clinically appropriate new patients, once under their care, such that by the end of the first year of dialysis the population approaches that "topped out" AV fistula rate identified by NQF.

We also note that performance scores from measure testing were not provided with the materials, making it impossible to determine whether the incident fistula rate obtained from this measure is consistent with the cited "greater than 60%" value in the supporting documents; we urge UM-KECC to make this information available to stakeholders for review. Likewise, stratification of reliability scores by facility size was not detailed; we are thus unable to discern how widely reliability varies across the spectrum of facility sizes. We are concerned that the reliability for small facilities might be substantially lower than the overall IUR, as has often been the case with other CMS standardized measures. Without evidence to the contrary, KCP is thus concerned the ISFR reliability may be unacceptably low for small facilities, effectively rendering the metric meaningless for use in performance measurement in this group of providers. KCP believes it is incumbent on CMS and KECC to demonstrate reliability for *all* facilities by providing data by facility size.

Taking all of the above into consideration, we do not believe limiting the SFR population to incident patients effectively addresses the previously identified issues with the original measure. We maintain that catheter avoidance is the appropriate focus for vascular access in both the incident and prevalent dialysis populations, and we believe the Standardized Fistula Rate for Incident Patients is an unnecessary solution to a problem already being effectively addressed by the existing vascular access measure.

Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR)
Practitioner/Group-Level Percentage Of Prevalent Patients Waitlisted (PPPW)
Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution of successful or unsuccessful waitlisting to dialysis facilities, individual practitioners, or group practices and thus cannot support these measures. KCP believes that while a referral to a transplant center and initiation or even completion of the waitlist evaluation process might be appropriate measures for these levels of analysis that could be used in CMS's quality programs, the newly proposed practitioner/group level Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standardized Waitlist Ratio (FYSWR) measures are not. Waitlisting per se is a decision made by the transplant center and is beyond the locus of control of any of the providers targeted in these measures. In reviewing these measures, we offer the following comments:

I. Overarching Concerns

Several of KCP's concerns apply to all three proposed transplant access measures:

i. **Attribution.** As above, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to dialysis facilities, individual clinicians or practitioner group practices and believe this is a fatal structural flaw with these measures. The transplant center decides whether a patient is placed on a waitlist, not the facility, practitioner, or group practice. KCP patient members who are transplant recipients have noted there are many obstacles and delays in the evaluation process with multiple parties that have nothing to do with the facility or practitioner—e.g., one patient noted their private pay insurance changed the locations where they could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a practitioner/group practice each month through the PPPW, aPPPW, and FYSWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle", which states that measures' attribution models should fairly and accurately assign accountability.[1] KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued. For instance, KCQA has developed a dialysis facility-level Transplant Access Measure Set that will be submitted to NQF for endorsement consideration later this year. The set pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who were referred by the facility within the preceding three years. Because the KCQA waitlisting measure denominator is limited to those patients who were deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than metrics such as the PPPW; this construct will also provide a counterbalance to the referral measure, curbing the tendency to indiscriminately refer patients who are not appropriate transplant

[1] NQF. Attribution: Principles and Approaches. Final Report. December 2016. http://www.qualityforum.org/ProjectDescription.aspx?projectID=80808..

candidates, preventing unnecessary patient and transplant center burden. The same approach could be applied at the practitioner/group level.

ii. **Variation in Transplant Center Eligibility Criteria.** We also note that criteria indicating a patient is "not eligible" for transplantation can differ by location—one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply eligibility exclusions differently or have additional or different criteria. The degree to which these biological factors influence waitlist placement must be accounted for in any model for the measure to be a valid representation of waitlisting.

iii. **Stratification of Reliability Results by Group Size and Performance Scores Absent.** We also note that performance scores from measure testing were not provided with the materials for any of the transplant access measures; we urge UM-KECC to make this information available to stakeholders for review. Likewise, UM-KECC has provided no stratification of reliability scores by provider size for the measures; we are thus unable to discern how widely reliability varies across the spectrum of practitioner/group practice sizes. We are concerned that the reliability for small providers might be substantially lower than the overall IURs, as has been the case, for instance, with other CMS standardized ratio measures. This is of particular concern with the FYSWR, for which empiric testing has yielded an overall IUR of only 0.64—interpreted as "moderate" reliability by statistical convention.[2] To illustrate our concern, the Standardized Transfusion Ratio for Dialysis Facilities (STrR) measure (NQF 2979) also was found to have an overall IUR of 0.60; however, the IUR was only 0.3 ("poor" reliability) for small facilities (defined by CMS as <=46 patients for the STrR). Without evidence to the contrary, KCP is concerned that FYSWR reliability is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this subset of providers. KCP believes it is incumbent on CMS and KECC to demonstrate reliability for all providers by stratifying data by practice size.

II. Percentage of Prevalent Patients Waitlisted In Active Status (aPPPW)

KCP had identified two concerns specific to the aPPPW measure:

i. **Rate vs. Ratio.** Notwithstanding our concerns described above, consistent with our comments on other standardized ratio measures (e.g., SHR, SMR), KCP prefers normalized rates or year-over-year improvement in rates instead of a standardized ratio. We believe comprehension, transparency, and utility to all stakeholders is superior with a scientifically valid rate methodology.

ii. Active Status Data. We also note that a patient's status on the waitlist (active/inactive) can change frequently within the transplant centers and can be notoriously difficult to track. We believe this reality will seriously compromise the measure's validity and render the information it provides flawed, at best—and potentially harmful, should patients and providers act on the assumption of accuracy.

Finally, KCP underscores the importance of patient choice in transplant access, and we would urge CMS and UM-KECC to adjust for patient preference in any such measure. We note, for instance, that patient groups are considering options for establishing their right to accept donor kidneys not classified as "pristine," should they choose, with research supporting that such organs provide a survival benefit over dialysis or waiting for a low-KDPI kidney. We believe that such rapidly evolving issues may have a

[2] Landis J, Koch G. The measurement of observer agreement for categorical data. Biometrics. 1977;33:159-174.

considerable impact on transplant access. We encourage CMS and KECC to consider innovative approaches to performance measurement that address matters of vital importance to people living with kidney disease

KCP again thanks you for the opportunity to comment on this these measures. If you have any questions, please do not hesitate to contact Lisa McGonigal, MD, MPH (lmcgon@msn.com).

Sincerely,

Kidney Care Partners

Akebia Therapeutics, Inc.
American Kidney Fund, Inc.
American Nephrology Nurses Association
American Society of Nephrology
American Society of Pediatric Nephrology
Ardelyx
AstraZeneca
Atlantic Dialysis Management Services, LLC
Baxter International, Inc.
Cara Therapeutics, Inc.
Centers for Dialysis Care
CorMedix Inc.
DaVita, Inc.
Dialysis Patient Citizens, Inc.
Dialysis Vascular Access Coalition
DialyzeDirect
Fresenius Medical Care North America
Greenfield Health Systems
Kidney Care Council
North American Transplant Coordinators Organization
Nephrology Nursing Certification Commission
Otsuka America Pharmaceutical, Inc.
Renal Healthcare Association (formerly NRAA)
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare, Inc.
U.S. Renal Care, Inc.
Vertex Pharmaceuticals
Vifor Pharma Ltd.