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August 31, 2021

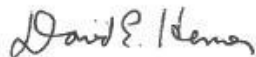
Chiquita Brooks-LaSure, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1749-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: CMS-1749-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease (ESRD) Quality Incentive Program, and ESRD Treatment Choices Model

Dear Ms. Brooks-LaSure,

The National Forum of ESRD Networks appreciates the opportunity to comment on the proposed changes in CMS-1749-P. We have primarily focused our comments to those sections of the proposed rule that specifically relate to the renal dialysis services furnished and the ESRD Quality Incentive Program (QIP) along with the ESRD Treatment Choices (ETC) model published in the Federal Register on July 9, 2021. 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. We are aware of the continued importance of the QIP and ETC model in the Advancing American Kidney Health (AAKH) initiative. We have limited our comments to those sections of the proposed rule that pertain to the ESRD QIP and proposed changes to the ETC model and limited sections of the PPS that could be anticipated to impact quality of care and access to equitable treatment for all beneficiaries. Below are our comments.

Thank you for your consideration.



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Chair, Forum Medical Advisory Council



Derek Forfang  
Co-Chair, Forum Kidney Patient Advisory Council



Dawn Edwards  
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**1. Inclusion of calcimimetics in the ESRD PPS base rate:** In the CY 2021 ESRD PPS Final Rule, CMS incorporated an adjustment of \$9.93 for the inclusion of calcimimetics in the ESRD-PPS bundled payment. We acknowledge the proposal in the CY 2022 ESRD PPS Proposed Rule to increase the ESRD PPS base rate to \$255.55 reflecting the productivity adjusted market basket of 1.01% without any additional adjustment for calcimimetics. As the Forum’s Kidney Patient Advisory Council (KPAC) and Medical Advisory Council (MAC) understand, only 20 to 30% of dialysis patients take calcimimetics and these are especially vulnerable patients such as Black American patients, dual-eligible patients, and those with a dialysis vintage longer than 3 years since their first dialysis therapy initiation. The KPAC and MAC first is concerned with cherry picking and lemon dropping, looking for patients who may not need these drugs or treat secondary hyperparathyroidism in a different way e.g. vitamin D, phosphate binders and surgery as dialysis companies will be focused on cost and those for-profit companies on maintaining profits. We are also concerned that patients with kidney failure will not have equal access to the medications that best work for them individually. With intravenous (IV) medications having a substantially higher cost than medications taken by mouth (PO), this may lead many dialysis facilities to utilize the lowest cost medication option. Some members of MAC and KPAC have noted that upon expansion of the bundle payment to account for adjustments for inclusion of calcimimetics, some dialysis organizations appear to have placed more stringent criteria for eligibility of the patient for intravenous versus oral form of this medications, which may be related to higher costs of intravenous medication compared to the oral form. We feel strongly that patients need to have shared decision making with their physician to ensure the medication prescribed works best for them, considering side effects and what is most effective and best tolerated. Lastly the KPAC and MAC are concerned with the payment increase to the patient’s out of pocket cost due to the bundle increase. Although the increase is small, we need to keep financial burden to our patient population in consideration. Because of kidney disease and co-morbidities, we suspect the number of patients unable to work is high. Providing for medication costs and kidney friendly foods and basic human needs can be difficult. These costs add up and lead to stress, hardship and impact our wellbeing. We hope CMS will keep this in mind and not increase the cost to patients.

**Recommendations:**

- Continue to monitor the usage of calcimimetics
- Monitor for disparities in access for vulnerable populations
- Emphasize the importance of shared decision making

**2. Transitional Add-on Payment for New and Innovative Equipment and Supplies (TPNIES):** The Forum’s KPAC and MAC support and applaud CMS on the creation of the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES). We also support the substantial clinical improvement (SCI) criteria as the basis of TPNIES eligibility. We agree that products that qualify for the payment adjustment should be “truly innovative” and emphasize the need for CMS to assess data on patient preferences, patient-reported outcomes, and other patient-centered data when evaluating SCI. We encourage CMS highly weight reducing patient and care partner burden, improved communication with the care team and improved safety for patients by lower rates of severe adverse events in their considerations. We also feel it is especially important to consider improving current symptoms and managing symptom burden of dialysis treatments and have

treatments that fit better with patients' lives and improve their health-related quality of life. We feel taking these concerns into consideration would decrease the high levels of patient and care-partner burnout and issues that currently cause home hemodialysis and peritoneal dialysis patients to transition back to in-center hemodialysis after only few years of home treatments. The high rate of failure to keep patients on home modalities works against the goals of the Administration and the benefits patients receive by improved outcomes by utilizing these home modalities.

**Recommendations:**

- Suggest using the most appropriate evidence to evaluate the submissions
- Collect feedback from patients concerning the value of the innovations being considered

**3. Reduce regulatory burden, lower costs and enhance overall care:** As we have previously noted, we gratefully acknowledge the ongoing commitment to maintain a meaningful Quality Payment Program for ESRD and have previously commented that the ESRD QIP is in the vanguard of the CMS initiatives for this endeavor to build value-based care in our healthcare system.

We wish to emphasize that reduction in the regulatory burden and the unique burden of maintaining multiple different reporting requirements each intended to insure the same quality of care and incentivize excellence, will enhance the ability of all providers to work with the ESRD networks to fulfill their work on behalf of CMS and of the patients, to further enhance quality. Additionally, we wish to emphasize that this central task of the ESRD networks is critically dependent on reliable, accurate, and timely data. Optimizing the parsimonious collection of data to serve multiple purposes will enable achievement of the highest fidelity of the data and allow for timely interventions. We have learned from our experience with dealing with the COVID-19 pandemic, the importance of data to meet both acute and continuing challenges to the safe, effective, and unbiased care of ESRD patients. Such data is also key to identifying disparities in the delivery of care and sources of such disparity, and informing prospective measures to correct these disparities and their impact on patient outcomes. Good data is central to an honest effort to achieve the goals of the AAKH initiative on health equity.

**Recommendations:**

- We urge CMS to be cognizant of the unfunded regulatory burden on dialysis facilities to track and monitor these many measures, especially independent and hospital-based facilities because they do not often have data managers, or the individuals working for large dialysis organizations that can assist with these functions. The burden for compliance often results in taking dialysis staff away from critical direct patient care activities to perform this extra work.
- We recommend aligning measures in the QIP with those in DFR, DFC, Core Survey, Network QIAs and the Advancing American Kidney Health initiative to the extent possible. Although the data sources for most of these programs are the same, the burden on facility staff to enter this data into EQRS, and to track all of the measures is quite significant.
- We acknowledge the RFI in the CY2022 ESRD PPS Proposed Rule following our recommendation last year that CMS continue to explore ways to support improving HIE infrastructure and EHR data sharing to reduce the burden on facilities, and to improve the care coordination for dialysis patients throughout the U.S.

**4. Performance Score Certificate Modification:** The Forum’s KPAC and MAC have reservations concerning the current PSC, compared to the format utilized prior to last year’s PPS Final Rule, which simplified the language and presentation of the PSC by removing individual measure performance results and national comparisons. Members of the KPAC are concerned that by simplifying the PSC, patients and caregivers that remain interested would have significantly less useful information to understand their facility’s performance in different areas. This appears to run contrary to the objectives of the Meaningful Measures Initiative by reducing rather than enhancing transparency. The current PSC does not provide the data that patients need to make informed decisions concerning their options for care.

**Recommendations:**

- We recommend modifying the PSC as it had been PREVIOUSLY reported

**5. Measures for PY 2022:** We are grateful for the proposal to extend the reporting period for facilities to report September-December 2020 ESRD QIP data under the ECE policy due to CMS operational issues with EQRS, formerly known as CROWNWeb. These prevented submission of data from November 1, 2020- July 11, 2021. The new submission deadline will be September 1, 2021. We also gratefully acknowledge the suppression of measures for scoring and payment adjustment for performance year 2020 (payment year 2022) due to the PHE to include the SHR, SRR and ICH CAHPS and the decision to not score or reduce payment to any facility in PY 2022. We do concur with the 4 Measure Suppression Factors identified in the proposed rule.

**Recommendations:**

- We support these proposals to include adoption of the 4 measure suppression factors.

**6. Measures for PY 2024 and PY2025:**

**a. Standardized Arteriovenous Fistula Rate Clinical Measure, Long-Term Catheter Rate Clinical Measure:** 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 patients 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.

Both the Kidney Patient Advisory Council (KPAC) and Medical Advisory Council (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 arteriovenous (AV) fistula (AVF) and/or associated multiple revisions in some cases, or for valid clinical reasons may not wish to pursue an AV access including AVF or AV graft (AVG). 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 that have exhausted all possible sites for potential AVF or AVG placement be excluded from these measures. In addition, we believe that patients that 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 or AVG placement may jeopardize the health of our patients, and we don't believe the 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, in patients with severe cardiovascular disease, in whom the risk of undergoing AV access surgery exceeds the possible benefit, patients 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 to beneficiaries. 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 recently released KDOQI guidelines also focus on choosing the most appropriate vascular access for each patient.

### **Recommendations:**

- We recommend excluding patients from the denominator that have exhausted most to all potential sites for AVF or AVG placement, or in whom there are no viable vessels for AVF or AVG placement from these measures. We believe that facilities can report such patients in EQRS (formerly known as CROWNWeb) if a checkbox to indicate such patients was added.
- We recommend excluding patients from the denominator that have suffered severe steal syndrome affecting the partial or complete use of a limb. We also recommend excluding patients with conditions such as severe congestive heart failure, severe psychiatric illness, 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 their Physician. We believe that facilities can report such patients in EQRS if a checkbox to indicate such patients was added.
- We recommend excluding patients from the denominator that refuse consideration of AVF or AVG placement or use, despite >2 attempts spanning a 3-month period at education on the risks of catheters and benefits of AVF or AVG 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 patients 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 was added.

- For such patients that would be excluded from the denominator due to the patients 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.

**b. Dialysis Adequacy measures in hemodialysis patients:** We noted that Kt/V of 1.2 or higher in maintenance hemodialysis patients will continue to serve as a required metric as in prior years. The current rule for current and future payment years is that facilities must report the following data for that clinical month, for each qualifying patient:

- Hemodialysis Kt/V, value and date
- Peritoneal dialysis Kt/V, value and date

The Forum's Board of Directors along with its KPAC and MAC remain concerned that appropriate monitoring and reporting of the residual kidney function (RKF) of the native or transplanted kidney that is routinely pursued in peritoneal dialysis patients, is also needed for hemodialysis patients with substantial RKF, e.g. urine volume >500 ml/day or Kru (residual kidney urea clearance) >3 ml/min. In patients with substantial RKF, insisting on achieving target hemodialysis Kt/V of 1.2 may be unnecessary and may cause harm by accelerating loss of residual renal function of the native and transplanted kidneys. We noted the discrepancy between peritoneal dialysis adequacy reporting requirements, where inclusion of RKF is pursued and acceptable, as opposed to those hemodialysis patients who have substantial RKF and in whom longer dialysis may be prescribed to achieve target hemodialysis Kt/V regardless of their residual kidney function.

**Recommendations:**

- We remain concerned that a strict single target of Kt/V of equal or greater than 1.2 without accounting for RKF 1) does not allow for inclusion of the important contribution of patient's native kidneys, 2) results in forcing patients with substantial residual kidney function to stay unnecessarily longer on dialysis and to cause harm due to unnecessarily prolonged dialysis therapy, 3) puts at a disadvantage those patients with who prefer to preserve their residual kidney functions longer while undergoing hemodialysis, and 4) may lead to acceleration of the loss of residual kidney function, which may be associated with worse outcomes. And therefore, use of exclusive HD Kt/V without accounting for RKF will adversely impact hemodialysis patients and their outcome.

- Additionally, we feel that the perceived contrast between PD and HD dialysis adequacy requirements and reporting could cause confusion, in that in PD patients RKF is an important metric whereas in HD patients it does not appear to be so.
- With regard to hemodialysis, the strict single target of  $\text{spKt/V} \geq 1.2$  does not account for the important contribution of patient's native kidneys in the form of the residual renal function. The target disadvantages patients who wish to preserve their residual kidney function longer and may lead to the acceleration of the loss of residual renal function. While we recognize the patient centeredness and outcomes advantages of this more individualized approach, we acknowledge that for hemodialysis patients, a consensus on which targets will lead most consistently to optimal outcomes has not been as well defined compared to PD patients. We recognize that a judicious evaluation of the available observational data, might inform specific targets to insure optimal outcomes. We would endorse establishment of a technical expert panel (TEP) that included a significant patient input, to explore the current evidence and make specific recommendations that recognize that incident dialysis patients, patients with a recently failed kidney transplants, and prevalent patients with significant residual native renal function might benefit from different  $\text{spKt/V}$  corrected for residual function thresholds or other appropriate measure of dialysis adequacy.

c. **Standardized Transfusion Ratio (STrR) Clinical Measure:** We acknowledge the continued inclusion of the STrR Clinical Measure as a Reporting Measure. We do remain concerned that this is not the most optimal measure of anemia management at the level of dialysis facility given the plethora of clinical conditions that can lead to the need for a blood transfusion completely unrelated to care provided within the facility. We all hope that current progress in the management of anemia in the CKD population to include those patients receiving dialysis will ultimately reduce the percentage of patients that we currently classify as ESA hyporesponsive which does come under the purview of care rendered in the facility.

**Recommendations:**

- We continue to support the change of the STrR Clinical Measure to a Reporting Measure
- Since we acknowledge the statutory requirement for an anemia measure in the QIP, we suggest replacing this measure with a measure of % of prevalent patients (on hemodialysis for > 90 days) treated with ESAs with Hgb 9.0-12.0 g/dL This would be a more direct measure of anemia management in dialysis facilities than transfusion rates. The KPAC has expressed concern that the current STrR measure may have the unintended consequence of causing harm to patients by incentivizing facilities to avoid transfusing patients suffering from anemia, where transfusions may be clinically indicated. According to both USRDS (*USRDS 2017 Annual Data Report ESRD Chapter 2- Anemia*) and DOPPS (*US-DOPPS Practice Monitor, April 2018*), there has been a substantial increase in the prevalent % of dialysis patients in US with Hgb<10 g/dL since 2011, when the ESRD PPS (Bundled payment system) and FDA black box warnings against targeting higher Hgb levels were released. According to USRDS, "Among ESA-treated patients on dialysis  $\geq 90$  days, the percentage with Hgb <10 g/dL increased from 7% in 2007 to 26% in 2015". Due to these concerns, the KPAC recommends replacing the current STrR measure with Hgb measure (% of prevalent patients treated with ESAs with Hgb 9.5-12.5 g/dL) as above.

**d. National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure:** The NHSN Dialysis Event Reporting Measure will remain part of the Safety Measure Domain of the QIP for PY 2021 and beyond. It has previously been brought to the attention of the Forum that the current NHSN reporting requirements include contaminants as BSI and require noting “contaminants” as the source of the BSI. The issue is that contamination is not a source of infection, since it’s not an infection, so this is erroneous. We are concerned as this has the unintended consequence of leading to an inappropriate increase in a given facilities’ BSI rate and could have an adverse impact on the final TPS. There is also the possibility that national BSI data rates could be impacted. Furthermore, we are concerned that many dialysis facilities may avoid drawing blood cultures in dialysis patients with possible symptoms of infections in attempts to avoid negative consequences of having BSI counted against them. This could have unintended consequences of failing to identify and treat infections early on, which could be harmful to patients. Instead, we should encourage dialysis facilities to be more proactive identifying and treating infections earlier on. In addition, if dialysis facilities aren’t proactive about drawing blood cultures, patients may instead go to ERs where contamination of blood cultures is more likely. Although the intention of the BSI measure is to improve patient care, there is risk of it leading to poorer care to dialysis patients by avoiding tests in attempts to avoid negative consequences of BSI counted against facility. Furthermore, we are concerned that many dialysis facilities may avoid drawing blood cultures in dialysis patients with possible symptoms of infections in attempts to avoid negative consequences of having BSI counted against them. This could have unintended consequences of failing to identify and treat infections early on, which could be harmful to patients. Instead, we should encourage dialysis facilities to be more proactive identifying and treating infections earlier on. In addition, if dialysis facilities aren’t proactive about drawing blood cultures, patients may instead go to ERs where contamination of blood cultures is more likely. Although the intention of the BSI measure is to improve patient care, there is risk of it leading to poorer care to dialysis patients by avoiding tests in attempts to avoid negative consequences of BSI counted against facility. We feel that hospital based facilities could see a disproportionate adverse impact since these facilities have better access to BSI data from the respective hospital. The possibility of a contaminated blood culture obtained at the time of admission is felt to be greater than OP facilities.

We also believe that dialysis facilities have much more direct control over preventing access-related BSI, than total BSI. Many BSI originate from sources which are unrelated to dialysis, including cyst infections in patients with Polycystic Kidney Disease, pneumonia, wound infections related to diabetes or Peripheral Vascular Disease, etc.

**Recommendations:**

- We recommend excluding BSI events from the numerator of BSI measure if the facility indicates contamination as the source of BSI as per the NHSN Protocol. This would accomplish keeping the NHSN Protocol for reporting BSI in place without penalizing facilities for appropriately reporting contaminants (which are not actually infections).



- We recommend replacing BSI measure with Access-Related BSI since facilities have more direct control over preventing Access-related infections than other sources of BSI, and therefore this would be a much more meaningful measure for dialysis facilities.
- Since Access-related BSI are reported in NHSN similar to BSI, this measure can be calculated in same way as BSI using the same data source. However, as above would exclude Access-related BSI events when contamination is indicated as the source of infection in NHSN.

**e. Clinical Depression and Follow-Up Reporting Measure:** The Kidney Patient Advisory Council feels the current reporting measure on depression does not incentivize the needed follow-up for patients struggling with emotional and mental issues. We know that patients with crippling anxiety or severe depression may need to be referred to a mental health provider outside the facility. Although, for some patient's behavioral health support can be provided by dialysis facility social workers. We feel both antidepressants and therapy should be prescribed by mental health providers, and neither nephrologists nor dialysis facilities should be accountable for these treatments. We believe that a clinical measure is better suited, given the high prevalence of depression in the dialysis patient community and the potential for care to be referred or provided within the facility

**Recommendations:**

- This measure should be changed to a clinical measure

**f. In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration:** The Kidney Patient Advisory Council feels ICH CAHPS is administered too frequently. The frequency of administration does not allow a facility time to create or share an action plan, so patients do not see the results which discourage patient participation.

The KPAC recommends the survey be administered no more frequently than every 9 months.

We feel the survey does not reflect elements of care that are meaningful. ICH CAHPS was developed in 2004 and endorsed by NQF in 2005 and so is out of date.

Also, ICH CAHPS is not suitable for home dialysis patients. This becomes increasingly important considering the goals of the Administration and kidney community to significantly increase home dialysis.

The KPAC recommends an updated patient-reported measure that is designed to report the views and preferences that are more person centered, that also includes home and in-center patients. The KPAC recommends the PROMs highlighted in the summary of the End Stage Renal Disease Patient Reported Outcomes TEP from 2017 that address treatments and care reflecting patient life goals and patient choices be incorporated.

**Recommendations:**

- Decrease the frequency of administration to no greater every 9 months
- Develop an updated patient-reported measure
- From the patient perspective, the survey could be simplified to 5-10 questions which capture patient experience and provide information to providers to encourage conversations between providers and patients to improve care and be more patient-centered. For example: Do you feel

respected? Do you feel heard by your care team? Do you feel safe? If you have chronic pain, do you feel it's being managed well? Do you fear retaliation by your care team if you speak up? Do you understand your treatment choices? (in-center hemodialysis, home dialysis both PD and home hemodialysis, and transplantation) Does your care team respond to your needs timely? These questions would be effective and could be used across all modalities of care.

- CMS should consider sharing patient comments with providers to facilitate constructive improvements

**g. Standardized Hospitalization Ratio Clinical Measure:** This measure was initially adopted in the CY 2017 PPS Final Rule, is reported on the DFC website and one of the quality measures used in the ETC model. It is an NQF endorsed, all cause, risk adjusted standardized rate of hospitalizations during a 1-year observation period. It currently incorporates 210 comorbidities into the risk adjustment. The weight of the measure was increased from 8.25% to 14% of the TPS in the CY 2019 ESRD PPS Final Rule. On November 20, 2020, the NQF renewed its endorsement and endorsed updating the 210 individual prevalent comorbidities into 90 condition groups (AHRQ). It would only use Medicare claims with the addition of Medicare Advantage patients, a MA indicator and consideration for time spent in a SNF. These changes were supported by the MAP.

**Recommendations:**

- We support the proposed updating of this important clinical measure

**7. Requests for Information (RFIs) on Topics Relevant to ESRD QIP:**

**a. Closing the Health Equity Gap in CMS Quality Programs:**

We acknowledge the commitment that the CMS has demonstrated by including an RFI in this year's proposed rule to close the health equity gap in their quality programs and, in particular, to make this endeavor more comprehensive and actionable for dialysis facilities, providers and patients. We also agree that these disparities manifest themselves in multiple groups of patients to include race, ethnicity, disability, LGBTQ+ and socio-economic. The Equity Plan adopted by CMS focuses on increasing both the understanding and awareness of disparities, developing and disseminating solutions to achieve health equity and implementing sustainable actions in the achievement of these goals. The CMS is now soliciting input on the stratification of quality measures through the use of Dual Eligibility within and across facilities along with race and ethnicity. They also requested comment on current facility data collection practices and the development of an ESRD Facility Equity Score.

**Recommendations:**

- The KPAC remains concerned about how the CMS will collect and analyze this data to ensure it is correct. The KPAC has had lengthy discussions on this topic. The information on the health equity gaps in care, access, and outcomes has been captured and remains unchanged for decades as we have seen in the USRDS Annual Report, for example. We support and agree with CMS looking deeper into health equity gaps by stratifying data, but only if action is taken on the findings to reduce these gaps in care and address health equity and inequality in our kidney patient

community. Also, the KPAC feels very strongly that underserved patient communities should not be risk adjusted. Looking at offering additional needed resources is the best way to achieve improvement. We feel all patients deserve to receive the same standards of high-quality care and equal access to it.

**b. COVID-19 Vaccination Measures:**

The ACIP recommendations indicated that ESRD patients would be offered the COVID-19 vaccine based on their high-risk status. On March 25, 2021, the Administration announced a new partnership with dialysis facilities to provide COVID-19 vaccinations directly to people receiving dialysis and HCP in dialysis facilities. The CMS is seeking public comment on the potential inclusion of both adding COVID-19 vaccination among HCP and for patients in ESRD facilities as new measures to the ESRD QIP measure set in the next rule making cycle.

**Recommendations:**

- Our KPAC and MAC support the proposal to add these as new measures to the ESRD QIP measure set in the next rule making cycle
- We also support the inclusion of other vaccinations to the ESRD QIP measure set to include Influenza, PCV13, PPSV23 and Hepatitis B.

**8. End-Stage Renal Disease Treatment Choices Model (ETC) Proposed Changes:**

**a. Performance Payment Adjustment (PPA) Beneficiary Attribution for LD Transplants:**

- Current: Pre-emptive LDT attributed to the MC with the plurality of claims from the start of the MY and the month of the transplant
- Unintended consequence is that a Pre-emptive LDT may be attributed to the nephrologist who manages their transplant, not the MC who has seen them through the living donor transplant process
- Proposed: Pre-emptive LDT attributed to MC submitting majority of claims 365 days prior to the transplant

**Recommendations:**

- We support this proposed change

**b. Home Dialysis Rate Calculation:**

- Current: for both MC and facilities, numerator includes number of dialysis treatments BYs during MY in which attributed beneficiaries received dialysis at home + 0.5 x self-dialysis in-center
- Proposed: Addition of nocturnal in-center dialysis for facilities NOT owned whole or in part by LDO and MC
  - ETC LDO – legal entity owns 500+ ESRD facilities
  - 0.5 x nocturnal in-center dialysis

**Recommendations:**

- Our KPAC supports this proposed modification to include nocturnal in-center hemodialysis in the Home Dialysis Rate Calculation, however, does not believe that there should be any exclusion based on ownership. This is about patient choice and not dialysis facility ownership.

**c. PPA Transplant Rate Beneficiary Exclusion:**

Proposed: Exclude beneficiaries (ESRD and Pre-emptive LDT) with a diagnosis of or receiving chemotherapy or radiation for vital solid organ cancers from the denominator for the MY using Medicare claims

**Recommendations:**

We support this proposed modification

**d. PPA Achievement Benchmarking Methodology:**

- Proposed: Increase achievement benchmarks by 10% over CGA rates every 2 years beginning MY3 (2022) using a formula as follows:
  - %-tile rate x 1.1 (MY3/4), x 1.2 (MY 5/6), x 1.3 (MY7/8), x 1.4 (MY9/10)
- Proposed: Stratify achievement benchmarks based on proportion (> 50% or < 50%) of attributed beneficiaries who are dual-eligibles or receiving Low Income Subsidy (LIS)

**Recommendations:**

- We support both the proposed modification to increase the achievement benchmarks by 10% over CGA rates every 2 years beginning with MY3 and to stratify the achievement benchmarks based on the proportion of attributed beneficiaries who are dual-eligible or receiving the LIS.

**e. PPA Improvement Benchmarking Methodology:**

- Proposed: Add 1 beneficiary month to the numerator of the home dialysis rate and the transplant rate for the BY rate for an ETC participant's aggregation group BY when that rate is 0 (cannot receive an improvement score if the home dialysis rate or transplant rate was 0 in the BY)
- Proposed: Introduction of the Health Equity Incentive (0.5 points) to the Improvement Scoring methodology for beneficiaries who are dual-eligible or receiving the LIS (home &/or transplant rate > 5%).

**Recommendations:**

- We support both the proposal to add one beneficiary month to the numerator of the home dialysis rate and the transplant rate for the BY rate for an ETC participant's aggregation group BY rate when that rate is 0 and the proposal to introduce a Health Equity Incentive to the Improvement Scoring methodology for beneficiaries who are dual-eligible or receiving the LIS.

**f. PPA Modality Performance Score (MPS):**

- Current MPS:

$MPS = 2 \times ((\text{Higher of home dialysis achievement or improvement score}) + (\text{Higher of transplant achievement or improvement score}))$

- Proposed MPS:

$MPS = 2 \times (((\text{Higher of home dialysis achievement or (improvement + Health Equity Bonus*)}) + ((\text{Higher of transplant achievement or (improvement + Health Equity Bonus*)}))$

\* Health Equity Incentive applied to the home dialysis or transplant improvement score only if earned and provided that the ETC participant is NOT ineligible (Low volume)

**Recommendations:**

- We support the changes incorporated in the proposed Modality Performance Score.

**g. PPA Reports and Data Sharing:**

Attribution is currently done retrospectively at the end of the MY for each month based on the beneficiary's receipt of services that month. Both Home dialysis and transplant rates are used to calculate an MPS followed by a PPA to adjust the PPS/MCP every 6 months with the first PPA period 7/1/2022-12/31/2022. CMS is supposed to notify each ETC Participant of their attributed beneficiaries, MPS, and PPA not less than 1 month prior to the start of the PPA period.

**Recommendations:**

- We support the proposal to establish a regulatory requirement for CMS to share attributed beneficiaries names, MBIs, DOB, DE status, LIS status, number of months each beneficiary attributed, received home dialysis, self-dialysis nocturnal IC dialysis, on transplant waitlist, and number months since LDT, along with aggregate data to include performance scores, and Health Equity Incentive aggregation group scores vs. ETC Participants scores.
- We also support the proposal to use a web-based platform with notification via the ETC listserv/model website with the provider having completed a "ETC Data Sharing Agreement" on an annual basis
- We agree with the expected uses to include request targeted review of the MPS calculation, care management/coordination and QI

**h. Medicare Waivers:**

- Proposed: Allow the provision of KDE via telehealth
  - Some beneficiaries may not have reliable transportation, especially those impacted by the PHE, but may have access to technology allowing telehealth
  - Fear of in-person encounter for KDE even after deemed "safe"
  - Waive the geographic and site of service requirements
  - Must maintain "interactive telecommunications system" (NO audio only)

**Recommendations:**

- We support this proposal

- KDE Coinsurance Waivers
  - Permit MC to reduce or waive 20% coinsurance for KDE *without secondary insurance*
  - CMS will make a anti-kickback statute safe harbor available
  - Medicare considered paying 100% of the amount for these services but rejected due to negative impact on savings estimates

**Recommendations:**

- We support these proposals.

**i. Requests for Information (RFIs) on Topics Relevant to ETC Model:**

- **PD Catheter Placement:**
  - Key barriers to increased placement of PD catheters?
  - How can CMS promote more timely placement of PD catheters?
  - Should CMMI test Advance Payment “structures” to address barriers as part of the ETC model? Why and how?

**Recommendations:**

- We support these proposals.
- We would recommend that CMS consider gathering data from the ESRD network projects examining barriers to home therapies including barriers to PD catheters and to identify common themes and best practices that have improved PD catheter acquisition rates and overcome barriers.

**9. Requests for Information (RFIs) on Topics Relevant to ESRD PPS:**

- **Modifying the site-of-service for AKI treatments**

**Recommendations:**

- The Medical Advisory Council of the Forum and the Kidney Patient Advisory Council acknowledge the increasing numbers of individuals with AKI during the COVID pandemic. In order to lessen the burden on in-center dialysis facilities for provision of this care, and to have an option available to patients that might improve their overall outcomes and experience of care, we would argue that home dialysis modalities might be for some patients with AKI an optimal treatment option.
- The advantages for initiating patients with AKI on home therapies might include the documented benefit for renal recovery with more controlled ultrafiltration rates achievable with PD and the increased likelihood that if a patient is initiated on home therapies for AKI, should they progress to ESRD, they are much more likely to stay with the home modality.
- We would urge that Medicare consider supporting reimbursement to allow for home dialysis therapies for patients with AKI.

Thank you for your consideration.