FORUM OF END STAGE RENAL DISEASE NETWORKS

September 4, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1732-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1732-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program

Dear Ms. Verma,

The Forum of ESRD Networks appreciates the opportunity to comment on the proposed changes in CMS-1732-P. We will be limiting our comments to those sections of the proposed rule that specifically relate to the renal dialysis services furnished and the End Stage Renal Disease Quality Incentive Program published in the Federal Register on July 13, 2020. Keeping in mind the Department of Health and Human Services objectives for the Meaningful Measures Initiative as a component of the CMS Strategic Goals, Quality Priorities and associated Meaningful Measure areas, we have focused our comments on those changes that can be anticipated to affect quality of care and access to ESRD treatment. We are aware of the continued importance of the QIP in the Advancing American Kidney Health initiative. We will be limiting our comments to those sections of the proposed rule that pertain to the ESRD QIP 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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1. Inclusion of calcimimetics in the ESRD PPS base rate: CMS is proposing the methodology for modifying the ESRD PPS base rate to include calcimimetics in the ESRDPPS bundled payment. Using the proposed methodology based on the latest available data, CMS is proposing to add $12.06 to the ESRD PPS base rate beginning in CY 2021.

As the Kidney Patient Advisory Council (KPAC) understands only 20 to 30% of dialysis patients take calcimimetics and these are especially vulnerable patients such as African American, dual-eligible patients, and those with a dialysis vintage over 3 years. The KPAC 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 will not have equal access to the medications that best work for them individually. With IV medications having a higher cost than medications taken by mouth leading facilities to utilize the lowest cost medication. 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 is 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.

2. Transitional Add-on Payment for New and Innovative Equipment and Supplies (TPNIES): The Kidney Patient Advisory Council supports and applauds 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 of dialysis treatments and have treatments that fit better with our lives and improve our overall quality of life. We feel taking these concerns into consideration would decrease the high levels of patient burnout and issues that currently cause home hemodialysis and peritoneal dialysis patients to transition back to in-center dialysis in the first few years of treatment. 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.

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 move our healthcare system from volume to value.

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 are encouraged that CMS will be moving to utilizing a single system (EQRS) to track and report data for all of these programs.
- We recommend 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 US.

4. Performance Score Certificate Modification: The Kidney Patient Advisory Committee (KPAC) has 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.

Recommendations:

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

5. Data Validation: The Forum acknowledges the proposal to modify NHSN dialysis event validation to require the submission of 20 records for any 2 quarters of the entire calendar year in PY2023 and beyond. The final paragraph in the CY2021 Proposed Rule is as follows:
"We believe the reduction in patient records still provides an adequate sample size for the validation and reduces overall facility burden. A recent estimation analysis conducted by the CDC supports our belief that a review of 20 charts per facility across a specified validation timeline that are acquired by randomly selecting approximately 300 facilities would continue to meet the medical record selection criteria outlined in the NHSN Dialysis Validation methodology. This would meet the CDC's recommended sample estimate to achieve the 95 percent confidence level precision and 1 percent margin of error, while also reducing facility burden."

Recommendations:

- We support this proposal

6. **Measures for PY 2022 and PY2023:**

a. Standardized 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 and Medical Advisory Council 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 AV fistula and/or associated multiple revisions in some cases, or for valid clinical reasons may not wish to pursue an AV access. 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 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 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 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 CROWNWeb 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 patient's declination should be indicated by documentation in CROWNWeb. We believe that facilities can report such patients in CROWNWeb 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 CROWNWeb.
- 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. **Ultrafiltration Rate reporting measure:** The Forum of ESRD Networks received feedback from several dialysis facilities that found the requirement to report all required data elements for UFR in CROWNWeb for all hemodialysis sessions during the week of the monthly Kt/V draw submitted for that clinical month for each eligible patient, a very difficult measure to meet each month. This was due to the requirement that all data on all patients be included for facility to obtain credit for reporting each month. We gratefully acknowledge the change proposed in the reporting of this measure in the CY 2021 Proposed Rule from number of months successfully reporting data to number of patient-months successfully reporting data.

Recommendations:

- We support the proposed change in the numerator

c. **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

Our Board of Directors and Kidney Patient Advisory Council remain concerned that appropriate monitoring and reporting of the residual kidney function (RKF) that is routinely pursued in peritoneal dialysis patients, is also needed for hemodialysis patients with substantial residual kidney function, 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 1.2 may be unnecessary and may cause harm by accelerating loss of residual kidney function. 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, 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.
- We recommend that in HD patients with Kru > 3 ml/min, Kt/V values for HD patients for January 2021 be reported with the inclusion of residual kidney function similar to that in PD patients thereby aligning adequacy concepts for the two modalities.

d. **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 ≥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.

e. Percentage of Prevalent Patients Waitlisted (PPPW) Clinical Measure: In our comments concerning the PPS 2019 proposed rule, we acknowledged the proposal to include the PPPW Clinical Measure in the new Care Coordination Measure Domain for PY 2022 with a weight of 4% of the TPS, with an accompanying reduction in the respective weights of the SRR and SHR to 12% each. We certainly 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 remain concerned about adopting this as a clinical rather than a reporting measure. 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 facilities. 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. We also remain concerned about adopting the PPPW as a clinical rather than a reporting measure in the QIP given the lack of current NQF endorsement of this new measure. If the 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.

The Forum's KPAC are interested to see the ESRD Treatment Choices model rolled out. 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 the PPPW be a reporting measure only until we have a better understanding of a medically appropriate target for waitlisting rates under the current KAS.

- We reiterate our feeling that referral rates are more appropriate than waitlisting rates as an appropriate metric for the QIP although we acknowledge the challenges in data acquisition
- Consider the adoption of a measure that specifically encompasses education concerning transplantation as a modality

f. **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. 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.

g. 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

h. **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
- Develop a meaningful survey for home therapy patients

Thank you for your consideration.