FORUM OF END STAGE RENAL DISEASE NETWORKS

August 22, 2022

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1768-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1768-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 Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

Dear Administrator Brooks-LaSure:

The National Forum of ESRD Networks appreciates the opportunity to comment on the proposed changes in CMS-1768-P. We have primarily focused our comments on 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 June 28, 2022. 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.

Following are our comments.

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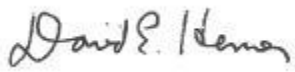
Thank you for your consideration,



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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 $264.09 reflecting updated wage-index budget neutrality adjustment and the rebased productivity adjusted market basket without any additional adjustment for calcimimetics. The Forum's Kidney Patient Advisory Council (KPAC) and Medical Advisory Council (MAC) would like to respectfully reiterate that 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 are both concerned that lack of any adjustment for oral calcimimetic therapy may lead to the treatment of secondary hyperparathyroidism with either pro-calcemic alternative therapies (e.g., activated vitamin D) or earlier referral for surgical interventions that may carry increased risk for adverse outcome as dialysis companies focus 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. 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. Request for Information about Addressing Issues of Payment for New Drugs after Transitional Drug Add-on Payment Adjustment (TDAPA) Period Ends: The Forum's MAC was pleased to see the novel therapy for CKD-associated Pruritis (CKDaP), difelikefalin, approved for TDAPA coverage as of 4/1/2022. The Forum recognizes that CKDaP affects a large proportion of our ESRD population and is associated with a pronounced decline in sleep as well as overall quality of life. We are, however, concerned that once the 2-year TDAPA period has ended, this unique therapy will be included in the ESRD PPS bundled payment without planned modification of the base rate resulting is lack of access to those most in need of such treatment.

Recommendation:

- Consider adjustment to ESRD PPS bundled payment base rate to help accommodate for the use of difelikefalin once TDAPA coverage concludes on 3/31/2024.

3. TDAPA Definition of Oral-only Drugs: The Forum noted the proposal slated to take effect on 1/1/2025 to change the definition of "oral-only drugs" from a focus on mode of action to end action effect "in the treatment or management of a condition or condition associated with ESRD." When considering this change in definition, the Forum MAC did note a concern for future classes of drugs

(such as the newer anemia treatment referred to as "HIF stabilizers") and their availability to patients if excluded from TDAPA. While we recognize that there is still much to be learned from this specific class of drug, the opportunity to treat anemia of CKD (and other diseases associated with ESRD) with non-injectable drugs should someday lead to lower cost and decreased side effect risk. The Forum also has concerns regarding how such future limitations on oral-only drugs could have adverse effects on our home dialysis population; peritoneal dialysis patients are unable to provide themselves with intravenous iron replacement at home and often must travel to dialysis clinics. Newer oral therapies could have a dramatic impact for those with limited time and resources.

Recommendation:

- Consider further review of proposed changes to "oral-only drug" definition and how such restrictions could affect optimization of patient access to care.

4. 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 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
- For the purposes of supporting innovation to improve patient care and safety, the Forum would like to offer its support for all 3 applications for CY 2023 to include the CloudCath PD Drain Set Monitoring System, the SunWrap System for hemostasis following AV fistula needle removal, and the Theranova 400/500 dialyzers for expanded dialysis.

5. 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 ensure 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 who 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 AAKH 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 these measures is quite significant.

6. Performance Score Certificate Modification: The Forum's KPAC and MAC have reservations concerning the current PSC, compared to the format utilized prior to the ESRD PPS 2021 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 who 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.

7. Measures for PY 2023: We are grateful for the proposal to suppress the SHR, SRR, ICH CAHPS, LTC Rate, PPPW, and the Kt/V Dialysis Adequacy Comprehensive clinical measures for performance year 2021 (Payment Year 2023) under the Measure Suppression Policy adopted in the ESRD PPS 2022 Final Rule due to the ongoing impacts of the public health emergency related to COVID-19. Since CMS operational issues with EQRS, formerly known as CROWNWeb, prevented submission of data from November 1, 2020- July 11, 2021, we would ask that CMS consider the suppression of all measures for scoring and payment adjustment for performance year 2021 (payment year 2023). The Forum is concerned that suppressing the 6 proposed measures will lead to excessive weight attributed to the remaining measures. In such an environment, a facility performing high quality of care in areas of the proposed suppressed measures, but poorly on even a few of the remaining measures, could be unfairly penalized with a low TPS, resulting in loss of critical revenue needed to stay operational in its efforts to serve the vulnerable local ESRD population. We acknowledge that the proposed payment penalties will be significantly reduced for PY 2023, however we would like to reiterate our recommendation to not score or reduce payment to any facility in PY 2023.

Recommendations:

- We recommend that no facility be scored or have payment reduced for performance year 2021 (payment year 2023)

8. **Measures for PY 2024:**

a. Standardized Hospitalization Ratio and Standardized Readmission Ratio Clinical Measures: The SHR was initially adopted in the CY 2017 PPS Final Rule, is reported on the DFC website, and is one of the quality measures used in the ETC model. As it is used in the ESRD QIP measure set, it is a ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that would be expected given the characteristics of the facility's patients and the national mean for facilities. It is an NQF-endorsed, all-cause, risk-adjusted standardized rate of hospitalizations during a 1-year observation period. We supported the updating of this measure in the CY2022 ESRD PPS Proposed Rule. The SRR was initially adopted in the CY 2015 PPS Final Rule. It is the ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day hospital readmissions. These two measures are the highest weighted measures in the calculation of a facility's TPS. These measures are calculated as a ratio, however they can be expressed as a rate. Hospitalization and readmission rates vary across facilities even after adjustment for patient characteristics, suggesting that hospitalizations and readmissions might be influenced by facility practices. The proposal in the CY 2023 ESRD PPS Proposed Rule is to change the scoring methodology such that a facility's results are expressed as a rate in the performance period compared directly to its rate in the baseline period. These measures would be referred to as the Risk-Standardized Hospitalization Rate (RSHR) and the Risk-Standardized Readmission Rate (RSRR). It was noted that this proposed change would more closely align the ESRD QIP methodology with the DFC Star Rating methodology.

Recommendations:

- We support the proposed technical updates to these measures.

9. Measures for 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 Forum KPAC and MAC 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 who have exhausted all possible sites for potential AVF or AVG placement be excluded from these measures. 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 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, for 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. 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 from the denominator patients who 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 from the denominator patients who 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 from the denominator patients who 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 EQRS. We believe that facilities can report such patients in EQRS if a checkbox to indicate patient refusal was 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 an 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 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 outcomes.
- 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 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 spKt/V corrected for residual function thresholds or other appropriate measure of dialysis adequacy.

- In summary, the Forum would like to endorse the use of residual kidney function (RKF) when calculating spKt/V in the hemodialysis population and would otherwise recommend against adopting added weight to the dialysis adequacy measure if RKF is not added out of concern for patient kidney health and the disproportionate impact it has on smaller dialysis facilities.

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 who we currently classify as ESA hyporesponsive which does come under the purview of care rendered in the facility. It is our experience, however, that even those patients with ESA hyporesponsiveness rarely require blood transfusion. Rather, the large majority of dialysis patients requiring blood transfusion either have gastrointestinal bleeding or prolonged, complicated hospitalizations, neither of which are affected by the quality of dialysis facility anemia management.

Recommendations:

- We continue to recommend that the STrR remain 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 percentage of dialysis patients in the 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.

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 facility's 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 in 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 the 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 the 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 KPAC 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 patients) behavioral health support can be provided by dialysis facility social workers. We feel both antidepressants and other forms of 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 KPAC 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 discourages 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 patient reported outcome measures (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, such questions could include:

    - 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 (dialysis modalities, conservative care, or transplantation)?
    - Does your care team respond to your needs in a timely manner?

    These questions would be effective and could be used across all modalities of care.
- Develop a meaningful survey for home therapy patients
- CMS should consider sharing patient comments with providers to facilitate constructive improvements

g. Hypercalcemia Reporting Measure: We have taken note of the proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025. The measure would be relocated from the Clinical Care domain with a current weight of 3% to the new Reporting domain with a weight of 1.67%.

Recommendations:

- We support the proposed conversion of this clinical measure to a reporting measure.

h. COVID-19 HCP Vaccination reporting measure: We note the proposal to include a COVID-19 HCP Vaccination reporting measure in the PY 2025 ESRD QIP measure set. The proposal would place this in the new Reporting domain with an individual measure weight of 1.67% equal to the other five reporting measures to be included in this new domain. Our KPAC and MAC supported the inclusion of this measure in the RFI in the ESRD PPS CY 2022 Proposed Rule.

Recommendations:

- We support the inclusion of this new reporting measure for PY 2025.

10. Measures for PY2026: No new measures are proposed for PY2026 (performance period CY2024, baseline CY2022) and if adopted, the STrR would remain a clinical measure and the Hypercalcemia and COVID-19 HCP Vaccination measures would be included as reporting measures. The measure domains and weighting along with scoring would be unchanged.

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

a. Quality Indicators for Home Dialysis Patients

Public comments solicited

1. Strategies to monitor and assess quality of care delivered to patients who receive dialysis at home
2. How to support more equitable access to home dialysis

Recommendations:

- The Forum would like to recommend consideration of a metric that monitors modality change/transition from in-center to home dialysis. We feel that such a metric would be a good way to capture efforts indicating that ongoing education is being offered to prevalent in-center patients. Given the disproportionate degree of patients of minority background who receive in-center dialysis, we feel that documentation of in-center to home transitions could be a good surrogate marker of efforts to improve at-risk patient treatment options.
- The Forum would also like to recommend consideration for home dialysis measures focused on PROM, including an experience of care survey. As the KPAC described above, we would support an updated patient-reported measure that is designed to report the views and preferences that are more person-centered, that also include home and in-center patients. The KPAC recommends the patient reported outcome measures (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. Such a measure could utilize the total eligible patients who receive education on home dialysis modalities each year in the numerator divided by the total number of home-dialysis eligible patients in the denominator.

b. Potential Future Inclusion of Two Social Drivers of Health Measures

Public comments solicited

1. Adding a new measure, **Screening for Social Drivers of Health to the ESRD QIP measures**, in the next rulemaking cycle
2. Assess proportion of a facility's patients screened for 1 or more HRSNs in the five core domains
   Allow for future measures focusing on developing an action plan to address these HRSNs
3. Adding a new measure, **Screen Positive Rate for Social Drivers of Health**, in future rulemaking
   Assess proportion of a facility's patients who screen positive for HRSNs in the five core domains

Recommendations:

- The Forum agrees with the premise of screening for social drivers of health but has concerns about the burden of documentation in dialysis units already overwhelmed with staffing shortages. We would recommend against adding these as measures to the QIP.

c. Principles for Measuring Healthcare Quality Disparities Across 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, LGBQT+ 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. 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 in 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.

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

a. Performance Payment Adjustment (PPA) Achievement Scoring Methodology
Proposed: An ETC participant's aggregation group MUST have a home dialysis/transplant rate > 0 to receive an achievement score.

Recommendations:

- We support this proposed change.

b. Kidney Disease Education Provision and Waivers
Proposed:

1. Clinical staff may not be leased/provided by related entity.
2. KDE furnished by clinical staff cannot "market" specific ESRD facility/chain.

Recommendations:

- The Forum very much appreciates the proposal to allow the provision of KDE to occur via telehealth after completion of the PHE as well as the waiver of geographic and site of service requirements. We do have concerns regarding how the KDE anti-kickback statute could affect more rural/underserved areas where there may be just a single LDO providing care and how this could limit access to KDE care for these more underserved areas. The Forum would recommend allowing education services using staff or other resources furnished under a contractual arrangement with an ESRD facility or other entity in order to ensure adequate access to care for more underserved areas.

c. Publication of Participant Performance

Data to be disseminated would include, but would not be limited to, patient de-identified results of patient experience of care and quality of life surveys, patient de-identified measure results calculated based upon claims, medical records, and other data sources.

Aggregate results for the home dialysis rate (home, self or nocturnal) and transplant rate (LD, pre-emptive LD) for each aggregation group.

Identify all ESRD facilities or MC in the aggregation group for the MY.

Results posted on the ETC Model website AFTER finalized and targeted review requests resolved.

Recommendations:

- We support this proposed modification.

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

a. Add-on Payment Adjustment after the TDAPA Period Ends

1. Is this needed and why?
2. What criteria should be used?

Recommendations:

- TDAPA supports payment and patient access to new therapies introduced to the ESRD PPS. The Forum appreciates CMS' raising of the topic of potential payment adjustments for the post-TDAPA period given an ongoing desire to encourage life-altering drug and biologic innovation while also maintaining a focus on improving equitable access to care. The Forum supports the creation of an add-on payment adjustment for drugs in existing functional categories. We recognize that this would likely require the extension of the TDAPA period beyond two years in order to ensure a thorough review of utilization of drug in the ESRD population as well as up-to-date cost assessment (via Medicare reimbursement as well as facility cost). We would also encourage an annual review in clinical outcomes data in order to ensure the appropriateness of ongoing support for such medications and biologics in an effort for ongoing cost-containment.