FORUM OF END STAGE RENAL DISEASE NETWORKS

September 27, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, D.C. 20201

Re: CMS-1713-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, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

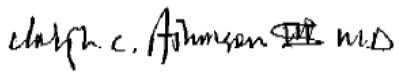
Dear Ms. Verma,

The Forum of ESRD Networks appreciates the opportunity to comment on the proposed changes in CMS-1731-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 August 6, 2019. 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 narrowly on those changes that can be anticipated to affect quality of care and access to ESRD treatment. We would like to acknowledge the creation of a technical expert panel (TEP) convened by Acumen, LLC in 2018 to discuss options for improving data collection on composite rate (CR) items and services provided by the End Stage Renal Disease (ESRD) Prospective Payment System (PPS). CR items and services comprise the essential components of dialysis treatment, including all drugs, laboratory tests and supplies necessary to administer the treatment. The TEP also explored the selection of new risk adjusters for the ESRD PPS payment model and we are pleased that this process will continue in 2019. We are aware of the continued importance of the QIP in the concurrent

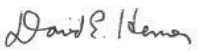
release of the Advancing American Kidney Health initiative. We will be limiting our comments to those sections of the proposed rule that pertain to the ESRD QIP. In reviewing the proposed changes, we considered how each measure would help to answer the question "How will the patient do?"

Below are our comments.

Thank you for your consideration,



Ralph Atkinson III, MD
President, Forum of ESRD Networks



David Henner, DO
Chair, Forum Medical Advisory Council

Derek Forfang
Chair, Forum Kidney Patient Advisory Council

1. 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 whom don't often have data managers, or individuals working for the corporation 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, and Core Survey 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 recommend utilizing a single website (perhaps 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.

2. 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.

3. Data Validation: The Forum acknowledges the proposal to continue the CROWNWeb Data Validation as noted to solicit 10 records from 300 facilities within 60 days of the request and the NHSN dialysis event validation study with the modification to increase to 300 facilities in PY2022 requiring 20 records for the first two quarters of the measurement year within 60 days of the request and beyond.

Recommendations:

- We support this proposal.

4. Extraordinary Circumstances Exception Policy: The Forum acknowledges the proposal to modify the Extraordinary Circumstances Exception Policy for PY 2022 and beyond to allow a facility to reject an ECE granted by CMS under certain circumstances.

Recommendations:

- We support this proposed modification.

5. Payment Reductions: We wish to acknowledge the re-estimation of the payment reductions under the ESRD QIP to correct an error in the way the weights were redistributed when estimating the PY 2022 payment reductions for the CY 2019 ESRD PPS final rule (83 FR 57060) and in accordance with the proposed policy changes described earlier, including the proposed changes to the scoring methodology for the NHSN Dialysis Event reporting measure and the proposed conversion of the STrR measure from a clinical measure to a reporting measure. We acknowledge that this also includes updating the payment reduction estimates using newly available data for the PPPW clinical measure and the Ultrafiltration reporting measure and more recent data for the other measures in the ESRD QIP measure set.

6. Measures for PY 2022 and PY 2023:

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 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 maturation of an AV fistula, or pursuing 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 anymore 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 harm to beneficiaries, that could be preventable. 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 patient choice is critical when considering placement of AV accesses in patients, and the appropriate access needs to be individualized for each patient based on both patient choices, and the safest option for each patient. According to the chair of the updated KDOQI guidelines on vascular access, the new KDOQI guidelines will 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 suggest excluding patients from the denominator that have suffered severe steal syndrome affecting the partial or complete use of a limb. We also suggest 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 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 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 refusal forms after repeated education completed, and the refusal 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 refusal of 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 Guideline, which emphasizes 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: Although this is currently a 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. In some cases, an issue with EMR not transmitting a single data element on a single patient resulted in facility not getting credit for reporting on this measure for the entire month. One of the required data elements is the HD Kt/V Date. If a patient had all other data but not a Kt/V on one patient resulted in CROWNWeb, the facility would get no credit for reporting this measure for the month. For the Kt/V measure, the QIP measure includes looking both at CROWNWeb data and Claims data for the month for Kt/V result. However, for the UFR measure, the Kt/V reported in Claims is not counted, so if the facility did do a Kt/V on a patient, but for some reason the Kt/V result was not in CROWNWeb, then the facility would receive no credit for the reporting measure for the month.

For several other reporting measures, including Depression Screening (and in past, Pain reporting), there is a dashboard in CROWNWeb to help facilities identify patients missing data for the measure. This is very useful to help facilities be successful for the reporting measure. For UFR measure, there is no dashboard in CROWNWeb, and the only way a facility may know that a single data element is missing on a single patient is to search through every patient, every month, which is very time consuming, and takes clinical staff away from vital patient care.

Recommendations:

- Change numerator requirement to include all required data elements for ultrafiltration rate in CROWNWeb for all hemodialysis sessions during the week of the monthly Kt/V draw submitted for that clinical month for **90%** of eligible patients.
- For HD Kt/V Date, include either date for Kt/V result in CROWNWeb, **or Kt/V date of Kt/V reported in Claim for the month.**
- Create dashboard for CROWNWeb including patients with any of the required 5 data elements missing for all patients to be included in UFR measure each month, for each facility, to help facilities more easily track UFR measure for reporting.
- Reduce the weight of this reporting measure.

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 BOD and KPAC 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 are concerned that a strict single target of Kt/V of equal or greater than 1.2 without accounting for RKF will: 1) not allow for inclusion of the important contribution of patient's native kidneys, 2) result in forcing patients with substantial residual kidney function to stay unnecessarily longer on dialysis, and 3) put 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 Kt/V values for HD patients for January 2020 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 proposal to modify the STrR Clinical Measure to a Reporting Measure for Payment Year 2020 among the 3 options that were discussed in the PPS 2020 Proposed Rule. 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 support the proposal to change the STrR Clinical Measure to a Reporting Measure for Payment Year 2020.
- 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 9.5-12.5 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 consequences of causing harm to patients by incentivizing facilities for avoiding 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. 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

waitlisiting in certain Networks or regions within a given Network, this should be referred to the appropriate Network for further inquiry

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 that this could have the unintended consequence of leading to an inappropriate increase in a given facilities' BSI rate with 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 PKD, pneumonia, wound infections related to diabetes or PVD, 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.