FORUM OF END STAGE RENAL DISEASE NETWORKS

August 28, 2017

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-1674-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 to the ESRD Prospective Payment System for CY 2018, as well as updates to renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI) and requirements for the ESRD Quality Incentive Program (QIP), including for payment years (PYs) 2019 through 2021 published in the Federal Register on July 5, 2017. Keeping in mind the Department of Health and Human Services goals of advancing the national quality strategy of better healthcare for individuals, better care for populations and communities, and lower costs by promoting value-based purchasing, we have focused our comments narrowly on those changes that can be anticipated to affect quality of care and access to ESRD treatment. 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,

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President, Forum of ESRD Networks

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1. Acute Kidney Injury: Our Kidney Patient Advisory Council (KPAC) is concerned about the possibility for unintended consequences resulting from the inclusion of patients with AKI in the QIP using the current metrics that exist. In addition, there was concern expressed that the facility staff need to distinguish between patients receiving dialysis for AKI and those with ESRD as there are unique differences in the approach to care for these two populations. An important distinction is that renal recovery and the treatment of the acute illness provoking the AKI are goals of care unique to this group. Given the association of AKI with sepsis, this is a population of patients that would potentially be uniquely impacted by appropriate antimicrobial stewardship. In the PPS 2017 final rule we were pleased to see the acknowledgment of the need for a particularly close patient-physician relationship in support of the monitoring to ensure the successful outcome of these patients. The Forum feels that at the present time, none of the current QIP measures are appropriate for AKI-D patients. We believe that future measures should focus on monitoring for recovery of kidney function (process measures) but that much more study would be needed before any outcome (morbidity, mortality, recovery of renal function, etc.) measure would be appropriate.

Recommendations:

- Supportive material will likely need to be developed to address the unique needs of this population remaining cognizant of the fact that many will recover kidney function and become independent of the need for dialysis, while ensuring a smooth transition to ESRD care for those who do not recover function.
- We suggest monitoring for the recovery of residual kidney function no less than monthly, including timed urine volume as well as creatinine and urea clearance by native kidney.
- Measures concerning Care Coordination seem uniquely suited to this group of patients
- Given the fact that these patients virtually all require catheter based dialysis, the facility catheter metrics intended for ESRD patients should not be adversely impacted

2. **Accounting for Social Risk Factors in the ESRD QIP:** The Forum acknowledges the importance of analyzing the impact of social risk factors and if warranted using risk adjustment in the ESRD QIP, one of the longest standing value-based purchasing programs. Our KPAC is concerned about unintended consequences impacting the quality of or access to care by how one chooses to define determinants of social risk. The work of facilities to deliver the highest standard of care to patients with the highest social risk needs to be acknowledged, encouraged and rewarded.

Recommendations:

- Ensure that these patients continue to receive the highest standards of care using the current and future QIP metrics
- Acknowledge the challenges of the current systems in use for capturing data for these metrics as we attempt to integrate additional data

3. **Performance Score Certificate Modification:** The KPAC has reservations concerning the proposal to simplify the language and presentation of the Performance Score Certificate by removing individual measure performance results and national comparisons.

Recommendations:

- We recommend continuing the PSC as it has been reported

4. **Data Validation:** The Forum acknowledges the proposal to continue the Data Validation pilot and the NHSN dialysis event validation study with the modification to include both high performing facilities and facilities at risk of underreporting for PY 2020 and beyond.

Recommendations:

- We support this proposal

5. **Extraordinary Circumstances Exception Policy:** The Forum acknowledges the proposal to modify the Extraordinary Circumstances Exception Policy for PY 2020 and beyond to allow submission of the signed form by the CEO or designated personnel, allow consideration of a difficulty due to an unresolved issue with a CMS data system and consideration of a facility's operations significantly affected beyond the control of the facility.

Recommendations:

- We support these proposed modifications

6. **Measures:**

a. **Standardized Fistula Rate Clinical Measure, Long-Term Catheter Rate Clinical Measure:** We acknowledge the proposal to incorporate risk adjustment for the Standardized Fistula Rate Clinical Measure along with including all hemodialysis patients, exclusion for life expectancy and the definition for the numerator of the use of 2 needles. We also acknowledge the similar inclusion of all hemodialysis patients and exclusion for life expectancy for the Long-Term Catheter Rate Clinical Measure along with the numerator being 90+ days with or without an AVF or AVG and that "missing" VAT would be included in the numerator and denominator. We are concerned that CROWNWeb will be used as the data source for both numerator and one of the data sources for the denominator along with claims and the 2728. It is not clear how "life expectancy" will be calculated.

Recommendations:

- We suggest that based on the proposal to use CROWNWeb as the primary data source for numerator and denominator, consideration be given to delaying modification of these clinical measures as proposed

b. **Revision of the STrR Clinical Measure:** We acknowledge the proposed changes in this metric's specifications to align more closely with that endorsed by the NQF in 2016.

Recommendations:

- We support the proposed modifications to this measure

c. **Ultrafiltration Rate reporting measure:** We previously noted the proposal in the PPS 2017 rule include this as a reporting measure for PY 2020 using the percentage of patient-months for patients with an ultrafiltration rate greater than 13 ml/kg/hr. The NQF endorsed Avoidance of Utilization of High Ultrafiltration Rate (>/= 13 ml/kh/hr) (NQF #2701) assesses the percentage of patient-months for patients with an ultrafiltration rate greater than or equal to 13 ml/kg/hr. The current rule for PY 2020 and future payment years is that facilities must report the following data to

CROWNWeb for all hemodialysis sessions during the week of the monthly Kt/V draw submitted to CROWNWeb for that clinical month, for each qualifying patient:

- HD Kt/V Date
- Post-Dialysis Weight
- Pre-Dialysis Weight
- Delivered Minutes of BUN Hemodialysis
- Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting month

Our KPAC remains concerned that this measure may lead to conflict between the patient and care team at the facility by fostering the sense of loss of patient autonomy along with the potential to impact hospitalization rates.

Recommendations:

- We are concerned that a strict single measure of Ultrafiltration of greater than 13 ml/kg/hr will: 1) not allow for shared decision making with the individual patient, 2) result in cherry-picking of patients who are unable to modify their interdialytic fluid gains, and 3) favor patients with higher BMI. And therefore, one single threshold of UF rate will differentially impact patients on the basis of their size, BMI, sex and ability of restrict fluid intake.
- Additionally, we feel that this threshold for UF rates be considered only for those patients with prescribed dialysis times of less than 240 minutes per treatment.
- We recommend that ultrafiltration rates for January 2018 be due on or before March 31, 2018 rather than February 28, 2018, to align with the reporting of all other clinical values for January 2018 and avoid confusion.

d. Clinical Depression Screening: Our KPAC previously supported the continuation of the inclusion of this a reporting measure for PY 2020 and does so for 2021

Recommendations:

- We are concerned that clinical depression be separated from fatigue and fear
- A significant concern is the lack of availability of adequate services in many communities to treat these patients following diagnosis and identification
- Consideration for migrating this to a Clinical Measure
- Consideration for incorporating of this metric as a Clinical Quality Measures Collaborative

e. **Hypercalcemia Clinical Measure:** Our KPAC remains concerned that this metric is challenging in that many patients continue to experience difficulties with access to medications and the health outcomes related to surgery for hyperparathyroidism and hypercalcemia.

Recommendations:

- We recommend consideration for removal of this measure from the QIP although do acknowledge the statutory requirements that are specific to the inclusion of this metric

f. **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 2018 be reported with the inclusion of residual kidney function similar to that in PD patients thereby aligning adequacy concepts for the two modalities.

7. **Request for Information on Medicare Flexibilities and Efficiencies:** We acknowledge the importance of this RFI and feel that it is so broad that the current comment period does not allow adequate time for a thoughtful response

Recommendations:

- We would like the opportunity to comment at a future date given the overarching nature of this RFI