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September 9, 2018

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Re: CMS-1691-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) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS

Dear Ms. Verma,

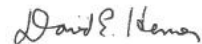
The Forum of ESRD Networks appreciates the opportunity to comment on the proposed changes in CMS-1691-P. We will be limiting our comments to those sections of the proposed rule that specifically relate to the renal dialysis services furnished and the End Stage Renal Disease Quality Incentive Program published in the Federal Register on July 18, 2018. 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 gratefully acknowledge the embrace of "Patients over paperwork" and took note of the several objectives listed in the Proposed Rule under the Meaningful Measures Initiative. 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,



Donald A. Molony, 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 noted above, we gratefully acknowledge the 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. The commitment of all of the providers who work diligently to improve patient outcomes and the overall experience of care in ESRD is further demonstrated by the active participation of many facilities across the United States in no less than 37 of the End Stage Renal Disease Seamless Care Organizations, one of the CMMI advanced alternative payment models. These ESCOs must meet the requirements of the ESRD QIP, in addition to demonstrating acceptable outcomes in other measures unique to the ESCO. Of interest, several of these measures are now proposed to become part the ESRD QIP for PY 2021 and beyond in this year's proposed rule. We will be offering comments below concerning three of these measures proposed for inclusion in the ESRD QIP. Our concerns really echo those objectives so eloquently outlined for the Meaningful Measures Initiative in this year's proposed rule. We also were encouraged to see the complimentary proposal for the revised QIP Measure Removal Factors in this year's proposed rule.

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 QIP with those in DFR, DFC, and Core Survey. 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. Acute Kidney Injury: Although this year's proposed rule did not specifically mention future inclusion of patients with AKI in the QIP, our Kidney Patient Advisory Council (KPAC) is concerned about the possibility for unintended consequences resulting from this using the current metrics that exist. In addition, there was expressed concern that the facility staff need to distinguish between patients receiving dialysis with AKI and those with ESRD as there are unique differences in the approach to care for these two populations. This is a population of patients that would potentially be uniquely impacted by appropriate antimicrobial stewardship. We see the provision of care to these individuals in the OP facility as an opportunity to learn more concerning the possibility and likelihood of recovery of function. In the PPS 2017 final rule we were pleased to see the acknowledgment of the need for a close patient-physician relationship as being critical for the successful outcome of these patients especially as it related to adequate monitoring.

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 becoming

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 renal function no less than monthly
- 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 should not be adversely impacted

3. Accounting for Social Risk Factors in the ESRD QIP: The Forum acknowledges the importance of attempting to account for social risk factors using risk adjustment in The ESRD QIP as this represents the most mature program in the CMS Quality Payment Program. Our KPAC is concerned about the unintended consequence of impacting the quality of care that would be defined by these determinants of social risk. The work of facilities to continue to deliver the highest standard of care to these patients needs to be acknowledged, encouraged and rewarded.

Recommendations:

- Insure 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

4. Performance Score Certificate Modification: The Kidney Patient Advisory Committee (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. Members of the KPAC are concerned that by simplifying the PSC as proposed, 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 continuing the PSC as it had been PREVIOUSLY reported

5. 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 150 facilities in PY 2021 and 300 facilities in PY2022 requiring 20 records for the first two quarters of the measurement year within 60 days of the request.

Recommendations:

- We support this proposal

6. Extraordinary Circumstances Exception Policy: The Forum acknowledges the proposal to modify the Extraordinary Circumstances Exception Policy for PY 2020 and beyond to allow an exception to the November 1st attestation deadline

Recommendations:

- We support these proposed modifications

7. 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.

Both the KPAC and MAC expressed concern that patient choice is not incorporated into either of these two measures, 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 both of these measures. 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.

Recommendations:

- We continue to remain concerned that CROWNWeb is the primary data source for numerator and denominator
- We recommend excluding patients from the denominator that have exhausted all potential sites 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 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 included 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.

b. 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 (\geq 13 ml/kg/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 may lead to conflict between the patient and care team at the facility in 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.

c. 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. We are concerned that clinical depression be separated from fatigue and fear. A significant concern remains the lack of availability of adequate services in many communities to treat these patients following diagnosis and identification.

Recommendations:

- Consideration for migrating this to a Clinical Measure
- Consideration for incorporating of this metric as a Clinical Quality Measures Collaborative

d. 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 acknowledge the statutory requirements that are specific to the inclusion of this metric, although would suggest consideration for a further reduction from the proposed weight of 3% in the TPS.

e. **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 2019 be reported with the inclusion of residual kidney function similar to that in PD patients thereby aligning adequacy concepts for the two modalities.

f. **STrR Clinical Measure:** We are concerned with the proposal to significantly increase the overall weighting of the STrR measure to 22% of the TPS, as we feel that this may result in the unintended consequence of posing an access-to-care barrier for those patients whose anemia is either ESA resistant or not medically appropriate for treatment with an ESA.

Recommendations:

- We suggest that the Network MRBs be provided with data from facilities within the jurisdiction of a given Network that have disproportionately high transfusion rate, particularly below the Achievement threshold. This would enable the Network MRB members to accomplish peer-to-peer non-confrontational mentoring to review best practices and provide assistance with the removal of barriers to improvement
- We recommend reducing weight of STrR measure from 22% to 12% (equal to SRR and SHR measures) and consider increasing the current weight of ICH CAHP and Depression Reporting measures..

- Since we acknowledge the statutory requirement for an anemia measure in the QIP, we suggest replacing this measure with 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 STTrR 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 STTrR measure with Hgb measure (% of prevalent patients treated with ESAs with Hgb 9.5-12.5 g/dL) as above, and if the STTrR measure remains, reducing its weight from 22% to 12% as above.

g. Percentage of Prevalent Patients Waitlisted (PPPW) Clinical Measure: We acknowledge 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 concur with the CMS 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 are 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 is 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 waitlisting 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

h. Medication Reconciliation for Patients Receiving Care at Dialysis Facilities Reporting

Measure: We acknowledge the proposal to include the Medication Reconciliation Reporting Measure in the new Safety Measure Domain for PY 2022 with a weight of 4% of the TPS, with an accompanying reduction in the respective weights of the NHSN BSI clinical measure to 8% and the NHSN Dialysis Event measure to 3%. We concur with the CMS concerning the numerous medications, multiple prescribers and frequent changes that occur for patients receiving dialysis. This is an NQF endorsed measure and the Forum did actively participate in the KCQA measure development process for this metric.

Recommendations:

- We support this proposed measure

i. Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)

Clinical Measure: We acknowledge the proposal to include the SWR Clinical Measure in the new Care Coordination Measure Domain for PY 2024, as we noted above for the proposed PPPW clinical measure. We certainly concur with the CMS 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 are concerned about adopting this as a clinical rather than a reporting measure. When the TEP recommended the SWR 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 is 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.

We also have a unique concern about the exclusion of patient's waitlisted prior to the start of dialysis as this may be a disincentive to those nephrologists actively attempting to enable preemptive transplantation as a viable alternative to dialysis.

Recommendations:

- We recommend that the SWR be a reporting measure only until we have a better understanding of a medically appropriate target for waitlisting rates under the current KAS.
- If the current proposed measure is included in the Final Rule, we recommend removing the exclusion of patients who were waitlisted prior to the start of dialysis for the reasons stated above.

j. 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 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.