FORUM OF END STAGE RENAL DISEASE NETWORKS

August 25, 2015

Andrew Slavitt
Acting 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-1628-P: Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program

Dear Mr. Slavitt,

The Forum of ESRD Networks appreciates the opportunity to comment on the proposed changes to the ESRD Prospective Payment System for CY 2016 and the Quality Incentive Program for updates to programmatic policies for the PY 2017-2018 QIP and new quality measures for PY 2019 published in the Federal Register on July 1, 2015. 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?" Attached are our comments regarding specific measures, performance period and standards, scoring methodology, and data validation.

Thank you for your consideration,

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1. Measures:

a. Anemia Management: While we supported the removal of the topped out measure for Hemoglobin > 12 g/dL, as previously noted, we also supported the proposal of the TEP convened by Arbor Research at the behest of CMS to consider reintroduction of a hemoglobin floor and are concerned that there are no plans to include this for successive PYs. We had supported the prior proposal to consider inclusion of a Patient Informed Consent for Anemia Treatment and again note its absence from proposed QIP rulemaking. We would like to reiterate that in prior comments developed by our Kidney Patient Advisory Council, the patient voice of the Forum, with assistance from members of the Medical Advisory Council constituted of Network Medical Review Board Chairs, and submitted to Arbor during May 2013 on the proposals from the TEP for inclusion in future QIP rulemaking, a specific issue with the Patient Informed Consent for Anemia Treatment was the need to include quality of life data. This was to avoid the unintended consequence of further discouraging use of erythrocyte stimulating agents leading to the potential for further increases in the transfusion rate. We were supportive of the TEP recommendation to include a Standardized Transfusion Ratio (STrR) and are pleased to see that this will included as a clinical measure for PY 2018 (Additional comments as noted below).

Recommendations:

- We continue to support consideration for the inclusion of the Patient Informed Consent for Anemia Treatment clinical measure but recommend that quality of life data be included.
- We suggest consideration for the TEP recommendation to revisit inclusion of a hemoglobin floor

b. Dialysis Adequacy: We acknowledge the proposal to replace the four individual dialysis adequacy measures (1. Hemodialysis Adequacy: Minimum delivered hemodialysis dose; 2. Peritoneal Dialysis Adequacy: Delivered dose above minimum; 3. Pediatric Hemodialysis Adequacy: minimum spKt/V; and 4. Pediatric Peritoneal Dialysis Adequacy) with a single comprehensive Dialysis Adequacy clinical measure. As we have noted in prior comments, however there remain several unresolved concerns. These comments are being placed in the context of the proposed criteria for removal of a topped out measure and do raise some concern. Although the proposed single Dialysis Adequacy clinical measure fulfills the criteria for removal based on a truncated coefficient of variation (TCV) of < 0.10, the 75^{th} and 90^{th} percentile of performance remain statistically distinguishable, therefore the two conditions for removal of a measure are not met. As noted by CMS, a measure was considered topped out if the 75th percentile, or 25th for measures where lower percentiles indicate better performance, was statistically indistinguishable from the 90th (or 10th) percentile **and** second, the truncated coefficient of variation (TCV) was less than or equal to 0.10. Therefore, we reiterate our recommendation that residual renal function should be considered in the reporting of the Kt/V for hemodialysis (both in-center hemodialysis and home hemodialysis) as it has been for peritoneal dialysis. Our recommendation reflects the most recent KDOQI Guidelines for Hemodialysis Adequacy. We are concerned that unless residual renal function is included in hemodialysis dose calculations, patients with significant residual renal function may be coerced into unnecessary prescription or modality changes because of the misperception, based on measurement of delivered Kt/V alone, that their total clearance is insufficient. Patients with the cardiorenal syndrome may be particularly disadvantaged. To protect patients against inadequate dialysis, we recommend that residual renal function be included in Kt/V calculation only if the urine collection used to measure it was performed within the previous 90 days, as recommended by KDOQI. Residual renal function can be substantial early in ESRD, and

particularly for a patient whose fistula has not yet fully developed and who gains little weight between treatments, taking residual function into account in the prescription can result in a meaningful difference in dialysis time. The requirement to exclude residual renal function from reported Kt/V presents those facilities which choose to measure residual renal function with a dilemma: either accept a QIP penalty for supposedly (but not really) inadequate dialysis, or coerce the patient to accept a medically unnecessary prolongation of treatment time. This hardly sounds like patient-centered care, and we suggest that as written, the proposed Rule fails fairly to answer the question "How did the patient do?" It will pose a particular burden for those facilities receiving large numbers of new patients in which the physician and nursing staff are assiduous enough to order urine collections. Finally, we point out that excluding Kt/V values exceeding 2.5 for patients receiving thrice weekly in-center nocturnal HD may not be appropriate, because many patients treated in this way achieve such values. We ask that this exclusion be removed for this cohort of patients.

Recommendations:

- We support the proposal to consolidate these individual measures to a single comprehensive measure
- Inclusion of residual renal function in dose calculations in hemodialysis dose calculations only if the urine collection used to measure it was performed with in the previous 90 days.
- Do not exclude Kt/V values exceeding 2.5 for patients receiving thrice weekly in-center nocturnal HD
- Consider a weekly Kt/V average

c. Vascular Access Type: As we have noted in prior comments, while we embrace the concept of "fistula first", we would like CMS to consider also adopting "catheter last" by assigning a higher value to a graft than to a central venous catheter present for more than 90 days. It is of interest that the TCV for Catheter Use remains $\leq$ 0.01 although the 25th and 10th percentile of performance does remain statistically distinguishable. Despite this, we concur with CMS that continued inclusion of this clinical measure will set a high standard of care for dialysis facilities, however this gives us even more reason to continue to reiterate our recommendation noted above concerning the inclusion of grafts in the Vascular Access Type (VAT) measure topic.

Recommendations:

- Consider assigning a higher value to a graft than to a central venous catheter present for more than 90 days.

d. Bone Mineral Metabolism Management: Although hypercalcemia is an NQF endorsed measure (NQF # 1454), it is of interest that as with Adequacy and Catheter Use, the TCV is $\leq$ 0.01, although the 25th and 10th percentile of performance do remain statistically distinguishable. The potential for individual facilities to bias this metric and its relevance to patient care elevated to the level of a clinical measure in the QIP remains in question at this time. In your own words, "The Hypercalcemia clinical measure is not an outcome-based measure." We acknowledge the statutory requirement in PAMA to require the Secretary to adopt measures in the ESRD QIP (outcomes based, to the extent feasible) that are specific to the conditions treated with oral-only drugs for CY 2016 and subsequent years. Perhaps the inclusion of a suite of laboratory values as a single reporting measure (e.g. calcium, phosphorus and parathyroid hormone) would be more appropriate until the data supports use of these biochemical measures in the realm of performance improvement.

Recommendations:

- We support removal of the hypercalcemia clinical measure and the revision of the Bone Mineral Metabolism reporting measure to include measurement of calcium, phosphorus and parathyroid hormone.

e. Patient Safety (NHSN): For the PY 2018 Subdomains, this will be included as the sole measure under the Safety Subdomain and will have a higher weight (20%) than any other single clinical measure with the exception of the ICH CAHPS which will have an equivalent weight. As we noted in prior comments, the National Quality Forum had endorsed a measure assessing the number of HD patients with positive blood cultures over a specified time period (NQF #1460) and we were in favor of considering the incorporation of this as a clinical measure in future years. We are pleased to see that the proposed rule for PY 2019 continues to limit this clinical measure to in-center hemodialysis patients.

Recommendations:

- We support continuing to limit this clinical measure to in-center HD patients.

f. Patient-Centered Experience (ICH CAHPS): The Forum acknowledges the importance of patient-centered experience as both a component of the National Quality Strategy and a potential measure of the quality of patient care. Indeed, this is congruent with our expressed philosophy guiding our approach to the proposed rule in evaluating each metric continually asking the question, "How did the patient do?" In previously submitted comments concerning the CMS Star Ratings System, The Forum's Kidney Patient Advisory Council noted that the type of feedback solicited by the ICH CAHPS would be of greater utility to informing patient choices than the majority of what is included in the Star Ratings System. We previously noted the migration of this metric to a clinical measure in the Patient and Family Engagement/Care Coordination Subdomain for PY 2018. We also noted that this will have an individual weight of 20% of this Clinical Measure Domain score being paired with the Standardized Readmission Ratio having an individual weight of 10% comprising the 30% given to this Subdomain. The ICH CAHPS is the highest weighted single Clinical Measure Domain along with the NSHN. We support the proposal that facilities will be eligible to receive a score on the ICH CAHPS measure if they treat 30 or more survey eligible patients during the eligibility period and the proposal to reinstate the ICH CAHPS attestation beginning with PY 2017 to allow facilities to attest in CROWNWeb that they did not treat enough eligible patients during the eligibility period defined as the CY prior to the performance period, to receive a score on the ICH CAHPS measure and thereby avoid receiving a score for this measure.

Recommendations:

- We support the proposal to reinstate the ICH CAHPS attestation beginning with PY 2017 to allow facilities to attest in CROWNWeb that they did not treat enough eligible patients during the eligibility period to receive a score on the ICH CAHPS measure and thereby avoid receiving a score for this measure.
- We recommend that CMS consider adding a question concerning a patient's fear of possible retaliation for completing the survey.
- Consider the burden placed on patients in completing the survey given its current length as evidenced by low return rates at certain facilities

g. Standardized Readmission Ratio (SRR): Our Kidney Patient Advisory Council and Medical Advisory Council had endorsed the TEP recommendations concerning the SRR in 2013. We applaud CMS for the methodical and detailed description of this clinical measure in the PPS 2015 final rule. There are, however, significant concerns that remain. These include some inconsistencies with the dialysis facility risk adjusted Standardized Mortality Ratio and the Standardized Hospitalization Ratio for Admissions measure to include among others lack of exclusion of patients with an incomplete claims history from the SRR. Despite the explanations offered in the rule to discount the impact of physician level admitting patterns, we believe that this remains of paramount importance along with concern about regional and geographic practice patterns. A final concern is the ability of an individual facility to actually see the patient for a treatment prior to readmission as readmission occurs in a substantial percentage of patients before return to the facility. In the words of CMS: "We believe that outcome measures proposed and adopted for the ESRD QIP properly risk adjust for patients with severe illnesses, but we remain concerned that misperceptions to the contrary might negatively impact access to dialysis therapy." We acknowledge the inclusion of this measure under the Patient and Family Engagement/Care Coordination Subdomain for PY 2018 and note that this will have an individual weight of 10%. Needless to say, until communication systems between hospitals and dialysis facilities are in place with the addition of functional interoperability for cohesive and reliable health information exchange, facilities will face significant challenges in achieving meaningful positive change for beneficiaries with ESRD. The onset of Integrated Care will accelerate this process in a positive manner.

Recommendations:

- We support the proposal in the PPS 2015 final rule and reiterated in the current proposed rule to publish the methodology this year to study the impact of adopting both the SRR and Standardized Transfusion Ratio clinical measures on access to care.
- We gratefully acknowledge the commitment of HHS to Advancing Health Information Exchange through the publications and efforts of the Office of the National Coordinator for Health Information Technology as articulated in the current proposed rule.

h. Standardized Transfusion Ratio (STrR): We concur with the concerns expressed in prior rules that the removal of the Hemoglobin less than 10 g/dL clinical measure from the ESRD QIP measure set could result in the underutilization of ESAs to manage anemia in ESRD patients, with the result that these patients have lower achieved hemoglobin levels and more frequently need red-blood-cell transfusions and that patients with ESRD who are eligible to receive a kidney transplant and are transfused risk becoming sensitized to the donor pool, thereby making it less likely that a transplant will be successful. These views were expressed in our comments on Anemia Management as noted above in prior comments developed by our Kidney Patient Advisory Council and submitted to Arbor during May 2013 on the proposals from the TEP for inclusion in future QIP rulemaking. To the extent that this measure to be included for PY 2018 and PY 2019 under the Clinical Care Subdomain reflects the recommendations of the TEP, we support its inclusion.

Recommendations:

- We only support the inclusion of the STrR for PY 2018 and PY2019 as a Clinical Measure Domain under the Clinical Care Subdomain to the extent that it reflects the recommendations from the TEP.

i. Pain Assessment and Follow-Up: We note the proposal to modify the new Pain Assessment and Follow-Up Reporting Measure for PY 2018 for Pain Assessment and Follow-Up in that if a facility treats no eligible patients in one of the two six-month periods, then that facility's score will be based solely on the percentage of eligible patients treated in the other six month period for which the facility reports one of six conditions.

Recommendations:

- We support the proposed modification to scoring facility performance on the Pain Assessment and Follow-Up Reporting Measure for PY 2018.

j. Ultrafiltration Rate reporting measure: We note the proposal to include as a reporting measure for PY 2019 the percentage of patient-months for patients with an ultrafiltration rate greater than 13 ml/kg/hr. Although measures are under consideration, there are no current NQF endorsed measures or measures adopted by a consensus organization on ultrafiltration rates. Under the current authority permitted by statute, the CMS proposal is that facilities must report an ultrafiltration rate for each qualifying patient at least once per month in CROWNWeb. Qualifying patients for this proposed measure are defined as patients 18 years of age or older, on hemodialysis, and who are assigned to the same facility for at least the full calendar month (for example, if a patient is admitted to a facility during the middle of a month, the facility will not be required to report for that patient for that month). We further propose that facilities will be granted a one month period following the calendar month to enter this data. For example, we would require a facility to report ultrafiltration rates for January 2017 on or before February 28, 2017. Facilities would be scored on whether they successfully report the required data within the timeframe provided, not on the values reported.

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 recommend that if implement that this threshold for UF rates be considered only for those patients with prescribe dialysis times of less than 240 minutes per treatment.
- We recommend that ultrafiltration rates for January 2017 be due on or before March 31, 2017 rather than February 28, 2017, to align with the reporting of all other clinical values for January 2017 and avoid confusion.

k. Full-Season Influenza Vaccination reporting measure: We concur with CMS that encouraging closer evaluation of patients' influenza vaccination status in the dialysis facility will increase the number of patients with ESRD who receive an influenza vaccination and increase influenza vaccination rates in this population, which will in turn improve patient health and well-being. The proposed rule states that for PY 2019 and future payment years, we propose that facilities must report one of the following conditions in CROWNWeb once per performance period, for each qualifying patient (defined below):

1. If the patient received an influenza vaccination:
   a. Influenza Vaccination Date
   b. Where Influenza Vaccination Received: (1) Documented at facility; (2)

Documented outside facility; or (3) Patient self-reported outside facility

2. If the patient did not receive an influenza vaccination:
a. Reason:
i. Already vaccinated this flu season
ii. Medical Reason: Allergic or adverse reaction
iii. Other medical reason
iv. Declined
v. Other reason

For this measure, a qualifying patient would be defined as a patient aged six months or older as of October 1 who has been on chronic dialysis for 30 or more days in a facility at any point between October 1 and March 31. This measure would include in-center hemodialysis, peritoneal dialysis, and home dialysis patients. We would require that facilities report the data on or before May 15 following the performance period for that year. We believe this reporting deadline will ensure that facilities have sufficient time to collect and enter data for all qualifying patients following the influenza season, and aligns this reporting effort with that of the NHSN Healthcare Personnel Influenza Vaccination reporting measure finalized in the CY 2015 ESRD PPS final rule for PY 2018.

Recommendations:

- We support the inclusion of the Full-Season Influenza Vaccination reporting measure

2. Other Measures Under Development: Given the rapidly evolving complexity of the QIP and the dependence of data capture and reporting on a fully functional CROWNWeb, we support the consideration of delaying incorporation of other measures until this is no longer a concern. We endorse the critical importance of care-coordination, cost reduction and population health but would like to see NQF or equivalent endorsed measures before considering these for inclusion as future clinical measures.).

Recommendations:

- Continue a dialogue with the community as to how measures will be used in the future.
- In light of the statutory requirements in the recently enacted MACRA, align all of these measures with physician measures to enable dual accountability and harmonization when possible

3. Data Validation: In prior comments, we emphasized the central role of ESRD Networks in the CMS quality infrastructure with respect to measurement, collection and validation of the various metrics by which ESRD facilities are currently evaluated and noted that we were pleased that CMS was considering procuring the services of a data validation contractor who would be tasked with validating a national sample of facilities' records as they report data under the ESRD QIP. We supported the proposal not to penalize facilities for the first year of data validation in CY 2013 and supported the extension of the pilot in CY 2014 and CY 2015 with a reduction in the number of records and facilities to sample approximately 10 records from 300 facilities with compensation for the submission of requested records given the financial constraints that facilities in all Networks currently face. We support the proposal to continue this Validation Pilot in CY 2016 with the proviso to comply within 60 days to avoid a deduction to the facility's TPS. We supported the proposed methodology for validation of data submitted to the CDC's NHSN Dialysis Event Module

in the PPS 2015 proposed rule and were pleased that this was to include an estimation of the associated costs and burden to facilities participating in an NHSN validation program. We would expect that CMS would also compensate these 9 facilities in CY 2016 since they will face the same penalty for failure to comply within 60 days resulting in a deduction to their individual facility's TPS.

Recommendations:

- We support the extension of the pilot as proposed with compensation to the selected facilities and the imposition of a penalty for failure to comply.
- We support the decision not to penalize facilities during the ongoing pilot phase
- We support the proposal for the pilot for validating data concerning the NHSN Dialysis Event Module including an estimation of costs and burden to facilities with appropriate compensation and the imposition of a penalty for failure to comply.

4. Performance Period and Standards: In prior comments, we encouraged the use of methodologies that recognized changes in performance over time and advocated the use of the most recently available data as comparison data. The principles of CQI emphasize the importance of real-time data collection and reporting to assess the effectiveness of quality improvement efforts. We do note that the Adult and Pediatric HD Kt/V performance standards are lower than the corresponding performance standards for PY 2017. Finally, we note the proposal for consideration in future rulemaking to increasing the achievement threshold from the 15th percentile to the 25th percentile of national performance during the baseline period.

Recommendations:

- We support the proposal to utilize CY 2016 as the Performance Period employing CY 2014 for PY 2018 for calculation of Performance Standards, Achievement Thresholds and Benchmarks, although are concerned that the SRR and STrR clinical measures will be using CY 2013 data as this contradicts the principle of utilizing real-time data collection and reporting to assess the effectiveness of quality improvement efforts. This raises the issue of whether these measures are appropriate for use as clinical measures at this time.
- We concur with the proposal to utilize CY 2015 for setting the performance standard, achievement threshold and benchmark for the ICH CAHPS clinical measure with CY 2016 as the performance period as this is the first year that complete data will be available for this measure
- Due to the fidelity of the data, we recommend CMS reconsider using the PY 2017 data rather than the estimated PY 2018 data where these values are lower than PY 2017 as noted for the Adult and Pediatric HD Kt/V.

5. Scoring Methodology: We note that for the ICH CAHPS clinical measure for PY 2018, the performance standard will be set to zero for the purposes of determining the minimum TPS as the CMS is not able to establish a numerical value for the performance standard through the rulemaking process before the beginning of the PY 2018 performance period. We also note the language added to the current proposed rule for PY 2018, that a facility will not receive a payment reduction if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if: (i) it performs at the performance standard for each clinical measure; (ii) it received zero points for each clinical measure that does not have a numerical value for the performance standard established through rulemaking before the beginning of the PY 2018 performance period;

and (iii) it receives the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2016 reporting measures.

Recommendations:

- We support each of these 2 proposals

6. Revising the Small Facility Adjuster for All Clinical Measures: We acknowledge the proposal to modify the Small Facility Adjuster (SFA) beginning with PY 2017 to ensure that any error in measure rates due to a small number of cases will not adversely affect facility payment. As noted in the proposed rule and supporting documentation, the purpose of the SFA is to correct for the measure estimated below the national average level, which is likely due to the random variation because of a small facility size. Facility scores for some of the previously adopted outcome measures were not normally distributed and the within facility standard error does not capture the spread of data. In addition, it has been challenging for facilities to calculate pooled within facility standard errors. The proposed calculation does not rely upon a within facility standard error.

Recommendations:

- We support this proposal

7. Sub-Regulatory Measure Maintenance in the ESRD QIP: The Forum acknowledges the current process for drafting a CMS ESRD Measures Manual to include the ESRD QIP measure specifications and technical information on quality indicators that facilities report for other CMS ESRD programs. This appears to have the potential to harmonize these now disparate quality indicators and measures. The plan to release the manual at least 6 months prior to the beginning of the applicable reporting period is also acknowledged.

Recommendations:

- We support these proposals