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August 21, 2018

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Room 314G
Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

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 Administrator Verma:

The National Kidney Foundation appreciates the opportunity to comment on the proposed changes to the end-stage renal disease (ESRD) prospective payment system (PPS), including policies that will govern coverage and payment for renal dialysis services delivered to individuals with acute kidney injury (AKI), and the quality incentive program (QIP) for payment years 2021-2024. The National Kidney Foundation is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI). This year we are dividing our comments into three separate letters in hopes to make it easier to review our recommendation on each section of the rule. This letter responds to proposed changes within the ESRD QIP. Two additional letters will reflect our comments regarding proposed changes to the PPS and the request for comment on questions regarding home dialysis and transplantation. Our recommendations on the proposed QIP include the following:

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- The National Kidney Foundation reiterates our support for evaluating the impact that social risk factors have on measuring dialysis facility performance and suggest CMS, broaden its analysis of social risk factors to include mental health status. We also recommend CMS consider a reward-based incentive for facilities that improve outcomes in populations with social risk factors.
- We generally support the factors for retiring measures but recommend that CMS continue to require reporting of retired measures in CROWNWeb, when they are retired due to topped out performance, for a period of at least three years.
- We are concerned about the removal of the pain assessment and follow up measure and encourages CMS to explore new measure development in pain management.
- We recommend CMS consider performance gaps and clinician and patient input when determining weights for measures. We also request that CMS share the weighting considerations and methodology used to arrive at the proposed weighting scheme for PY 2021 and beyond.
- We continue to oppose the use of a pooled dialysis adequacy measurement and encourage CMS to return to the individual adequacy measures or construct a composite measure where each individual measure is evaluated and then rolled up to one score.
- We support adding the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities reporting measure to the QIP.
- We oppose including the Percentage of Prevalent Patients Waitlisted (PPPW) Clinical Measure in the QIP.
- We suggest improvements to several measures that will continue in the QIP from 2021 to 2022.
- We oppose including the New Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients Clinical Measure in the QIP.
- We reiterate our concern about the lack of information sharing between hospitals and dialysis facilities and recommend hospitals specifically be required to share discharge information with dialysis facilities and nephrologists. We also recommend that hospitals

be required to report blood stream infections directly to the National Healthcare Safety Network (NHSN) or to the dialysis facility.

- We reiterate our request that CMS revise the Performance Score Certificate (PCS) that was finalized in last year's rule in order to provide a document that is more meaningful to patients.
- We reiterate our recommendations for improving the PCS, the five-star rating and Dialysis Facility Compare to make these more useful and transparent tools that can assist patients in making decisions about the quality of care dialysis facilities deliver.

A. 2021 QIP Proposed Changes

i. Meaningful Measures

The National Kidney Foundation appreciates the development of the meaningful measures objectives, quality priorities and their application across all value-based purchasing programs. We agree with these priorities and their application to the QIP, because they align with many of areas patients have highlighted as important factors they consider when evaluating the quality of care their dialysis center provides. For example, in 2016 working with a CMS contractor at the University of Michigan we asked patients how important certain factors were in determining the quality of care a dialysis facility provides. In the area of *Making Care Safer by Reducing Harm Caused in the Delivery of Care* 89% of 471 ESRD patients or families ranked safety as *Very Important* and 86% ranked facility cleanliness as *Very Important* as well. Following closely, ranked at 75% or higher, were satisfaction with care delivered, attentiveness of the staff and feeling comfortable enough with the staff to speak up when the patient or family member has concerns. All which align with the priority of *Strengthening Patient and Family Engagement as Partners in their Care*.

We also appreciate that the Meaningful Measures Initiative calls for alignment across programs. This is critically important for dialysis patients who see multiple health care providers and are frequently hospitalized. Ensuring accountability for patients' total health is the responsibility of many parties and alignment of measures across care settings will help to ensure each healthcare provider is accountable for communicating and coordinating better care for patients on dialysis. We thank the agency for the commitment to prioritize areas that are most meaningful to patients.

ii. Accounting for Social Risk Factors

The National Kidney Foundation appreciates that CMS continues to explore opportunities to protect beneficiaries' access to high quality care by considering ways to account for social risk factors in measures. We reiterate our support and comments on last year's proposed rule for evaluating the impact that social risk factors have on measuring dialysis facility performance.

The Office of the Assistant Secretary for Planning and Evaluation's (ASPE) 2016 report on Social Risk Factors Performance Under Medicare's Value Based Purchasing Programs found that among facilities serving a high proportion of patients with social risk factors such as high dual, disability, or African American populations were more likely to receive penalties under the QIP, while facilities having a high portion of Hispanic populations, patients residing in low income areas or rural areas were less likely to receive penalties. However, as ASPE notes measures added to the QIP such as the standardized readmission, standardized transfusion and standardized hospitalization measures could show greater variation in performance on those measures and on the QIP scores. We offer some recommendations and consideration as CMS explores how to account for social risk factors in measures used within the QIP and Dialysis Facility Compare (DFC) Star Ratings.

Stratifying performance reporting, for each dialysis facility, on clinical quality measures by social risk factors known to influence performance on the measures may help illuminate disparities in outcomes within a dialysis facility. This allows facilities to identify the impact social risk factors have on measure development and to develop strategies to improve outcomes in those groups and close any gaps they may have within the facility. Stratifying reporting on performance to highlight differences in performance between dialysis facilities based on the proportion of patients served may highlight facilities that need greater support to improve outcomes for their patients. CMS should provide support through quality improvement activities to help facilities with lower quality performance and high proportions of patients with social risk factors. The ESRD Networks would be well positioned to work with facilities on these projects. We agree with the ASPE report that such evaluation of new quality measures in the QIP should include the impact social risk factors have on performance, but we can't recommend adjustment at this time due to the potential unintended consequence of masking poor performance and because we believe risk adjustment may discourage additional effort to address improvement where feasible.

Since the QIP is a penalty-based program the National Kidney Foundation is concerned

that as new measures are brought into the QIP where social risk factors impact performance this could discourage facilities from accepting patients with social risk factors and could also discourage opening or maintaining facilities in areas where patients with these risk factors reside. As a result of this concern, we suggest CMS consider a reward-based incentive for facilities that improve outcomes in populations with social risk factors. This would help to drive resources towards facilities that serve a high number of patients with social risk factors and encourage innovative solutions to reducing disparities. Should a reward-based program not be effective in closing gaps on certain measures then consideration of adjusting certain measures for social risk factors may be appropriate.

While the ASPE report highlighted dual status as the strongest predictor of disparate outcomes, we question why this might be as many individuals with dual Medicare and Medicaid coverage have access to social services that patients who fall just outside of eligibility for Medicaid may not. For example, in many states Medicaid beneficiaries have coverage for transportation. Also, those who are eligible for Medicaid are likely eligible for other community programs to include nutritional programs. Instead, we suggest it is likely a combination of underlying social risk factors that lead to the duals population being the greatest risk predictor. To better illuminate which factors are driving differential performance and thus allow for more targeted interventions, we suggest CMS may need to evaluate additional data points on social risk factors such as mental health status and income ranges.

iii. Factors for Removing Measures

The National Kidney Foundation generally agrees with the proposed factors for removal and again appreciates that they align with factors in other programs. However, we suggest that CMS continue to require reporting of retired measures in CROWNWeb, when they are retired due to topped out performance, for a period of at least three years to monitor any unintended changes in performance. This would be like the process used in MIPS that allows 3 years of rule making before retiring topped out measures.

iv. Removal of measures

The National Kidney Foundation encourages CMS to continue require reporting for a period of at least three years the following measures the agency proposes to remove: 1) pain assessment and follow up; 2) healthcare personnel influenza vaccination; 3) anemia reporting measures. In regards, to the serum phosphorus reporting measure, also proposed for removal, we encourage CMS to maintain this measure as a reporting measure in the QIP until such a time that a better measure of bone and mineral

metabolism can be developed that accounts for the balance of phosphorus, PTH, and serum calcium.

While CMS is proposing to retire the pain assessment and follow up measure, we reiterate the importance to patients of having a properly trained health care worker (we recommend a technician, nurse, or physician or advanced practitioner) to ask at every treatment whether the patient is experiencing pain, to have the patient rate their pain, and for the nurse, physician, or advanced practitioner to try and assess the root cause. We further agree that the pain, its source, and recommended treatment be documented in the patients care plan and that a referral to a specialist be made when appropriate. Just because the pain reporting measure has high performance does not indicate absence of a gap in addressing pain in dialysis patients. We encourage CMS to retain this measure in CROWNWeb and explore future measure development as this is an important and meaningful topic for patients.

v. Measure Weights

The National Kidney Foundation has concerns with changes to the proposed measure weights. Most notably the significant increase in the weight for the Standardized Transfusion Ratio measure. While anemia management is a critically important clinician outcome measure, we are concerned by the heavy weighting of this measure. Particularly, given the coding and validity concerns with the measure. Often dialysis facilities are not able to capture the information about blood transfusions because they occur in the hospital setting outside the dialysis facilities' control.

We also do not believe so much weight should be given to one measure unless there is a significant performance gap, the measure has met National Quality Forum (NQF) standards for reliability and validity, and there is agreement among clinicians and patients that the measure addresses a critical opportunity to advance quality improvement. The National Kidney Foundation requests that CMS consider these factors for weighting measures, provide information on performance gaps for each measure, and share the rationale for the entire weighting methodology for years 2021 and beyond in the final rule.

vi. Concern with Kt/V Dialysis Adequacy Comprehensive Measure

The National Kidney Foundation continues to oppose the use of a pooled dialysis adequacy measurement and encourages CMS to return to the individual adequacy measures or construct a composite measure where each individual measure is evaluated and then rolled up to one score. In last year's final rule CMS stated each individual

measure and population was evaluated, however the measure as specified consolidates the entire population of patients, including pediatrics, adult PD patients, and hemodialysis patients receiving four or less treatments per week into one denominator with a single score calculated for the measure. This distorts the measure and no longer aligns it with the KDOQI guidelines for dialysis adequacy – which recommends separate adequacy targets for hemodialysis vs. peritoneal dialysis. As the NQF renal standing committee also pointed out, the evidence for the Kt/V targets for the hemodialysis population is based on three times per week dialysis not four. This masks performance of adequacy for home dialysis patients.

We also disagree with CMS's previous assertion that including the pediatric population into a pooled measure is more beneficial than having a separate measure. The pooled measure does not accomplish the goal of ensuring pediatric patients receive adequate dialysis as the measure does not allow for evaluating this patient population separately from the adult population.

B. Proposed Measures Beginning in 2022

- i. The National Kidney Foundation supports adding the *Medication Reconciliation for Patients Receiving Care at Dialysis Facilities* reporting measure to the QIP. Ensuring that the dialysis facility has the most accurate record of all medications including prescription and over the counter medications and herbal supplements is of critical importance to patient safety and outcomes.
- ii. The National Kidney Foundation opposes including the *Percentage of Prevalent Patients Waitlisted (PPPW) Clinical Measure* in the QIP. While we greatly appreciate the Administration and Agency's focus on transplantation and agree that a robust goal and action for increasing transplantation is necessary, we have many concerns with including this measure in the QIP. In a separate letter, responding to the *Solicitation for Information on Transplant and Modality Requirements* from the proposed rule, we share our recommendations on opportunities to increase transplantation. Our concern with the PPPW measure is that the ultimate decision on whether to place a patient on the waitlist is made by the transplant center. These are complex decisions that take into account many factors and vary by transplant centers even within the same geographic region, which would make nationwide comparisons of waitlist percentages difficult to interpret. In addition, the NQF renal standing committee has also issued similar concerns about the measure and has not recommended it for endorsement.

However, we do agree that dialysis facilities have a role in educating patients about

transplant, helping likely candidates receive an evaluation by the transplant center, and in keeping patients healthy enough to remain active on the wait list. CMS needs to work with the kidney community to develop a transplant measure that is more actionable by the dialysis facility. As an organization with representation and leadership from dialysis and transplant patients and professionals the National Kidney Foundation would be pleased to work with CMS to help inform the development of such a measure.

In the interim, we suggest that the PPPW measure may more appropriately apply to a nephrologist participating in the Merit Based Incentive Payment System (MIPS) as the nephrologist, who receives a monthly capitated payment (MCP), has accountability for managing ESRD patients and coordinating care, a leading role in evaluating patients for referral to a transplant center, and assisting patients in getting on the waitlist. However, we caution that still the decision to waitlist or not remains in the hands of transplant centers that have varying, including financial, criteria for wait-listing. Exclusions need to account for circumstances that cause a patient to not be able to be placed on the waitlist due to factors, like income, that are beyond the nephrologist's control.

iii. 2022 Remaining measures continuing from 2021

The table below highlights the National Kidney Foundations recommendations regarding the 10 measures proposed to remain in the QIP from 2021 to 2022.

Continuing Measures 2021	NKF Recommendations
In-Center Hemodialysis CAHPS Survey	We support this measure as it is important for dialysis patients, who spend a considerable amount of their time in the dialysis facility, to be satisfied with the attention and time they receive from the facility staff and to feel safe and comfortable in their surroundings. We remain concerned with the length of the survey and the frequency it is administered. If only a few questions from the survey are to be used in the QIP perhaps it would not be unreasonable to shorten the survey to focus on those items or to administer the survey in two parts once per year.
Standardized Readmission Ratio	We support the measure but remain concerned about the effect of the measure on patient access to care. CMS had planned a study on evaluating the effect this measure has on patient access to care and we inquire about when the study will be completed, and the results released. We also appreciate that CMS has remove any overlap between this

	<p>measure and the Standardized Hospitalization Ratio that would have penalized facilities twice. In order, for this measure to be more actionable by dialysis facilities and drive forward quality improvement, hospitals need to be required to share key discharge information directly with dialysis facilities. Dialysis facilities report challenges in accessing hospital discharge data as it relates to medication changes and plans of care post discharge.</p>
Standardized Hospitalization Ratio	<p>NKF supports holding dialysis facilities accountable for preventing hospitalizations. However, we continue to believe this measure needs to be better risk stratified for causes that are actionable by the nephrology care team.</p>
Standardized Transfusion Ratio	<p>The National Kidney Foundation remains concerned that a StR alone does not counter-act the potential to under-treat anemia and sets a low bar for an outcome measure. While avoidance of transfusions is important, particularly among patients waiting for a kidney transplant, we are concerned the unintended consequence of this measure is resulting in inadequate anemia management. In addition, a transfusion avoidance measure does not consider patients' quality of life or the cardiovascular risks associated with low hemoglobin levels. The National Kidney Foundation encourages CMS to pursue a low hemoglobin level to better protect patient safety. The KDOQI Anemia Management guidelines recommend a low hemoglobin range of 9.0 g/dl -10.0 g/dl.</p>
Hypercalcemia	<p>While the National Kidney Foundation understands that CMS is required by The Protecting Access to Medicare Act of 2014 (PAMA) to include quality measures related to conditions that are treated with oral only medications, NKF recommends removing hypercalcemia as a clinical measure and instead using it as a reporting measure. While hypercalcemia is potentially an important modifiable marker associated with mortality, this measure is unlikely to drive additional improvements in outcomes. Therefore, we believe reverting it to a reporting measure is the most feasible approach to fulfilling the requirements of PAMA while ensuring the QIP more highly values measures that drive improvement in patient outcomes.</p>
Ultrafiltration Reporting Measure	<p>The National Kidney Foundation does not see the value in a reporting measure of ultrafiltration, particularly when there is an NQF endorsed clinical measure that if implemented would</p>

be more meaningful to patient outcomes. We encourage CMS to implement the NQF# 2701: Avoidance of Utilization of High Ultrafiltration Rate (≥ 13 ml/kg/hour), which has been supported for endorsement by the NQF renal standing committee. The KDOQI hemodialysis adequacy clinical practice guidelines, do not include a target for UFR and instead recommend minimizing UFR as best possible to maximize hemodynamic stability and tolerability of the hemodialysis procedure. This is because the supporting evidence for a specific target is limited.¹ One retrospective study (not cited in the evidence for this measure) suggests an increased risk for individuals with heart failure with a UFR between 10-14 ml/h/kg, but improvements in outcomes for individuals without heart failure with a UFR in that range.² While this remains an area of active investigation and debate with the recognition that prospective randomized clinical trials are needed to more clearly define an appropriate target, NKF supports using the NQF #2701 in the QIP. However, we note implementing the measure is not without challenges that will require efforts from dialysis providers, dialysis facility staff, physicians and patients to overcome. Successfully meeting the measure will require patient participation and adherence to the dialysis prescription and fluid restrictions. The KCQA measure includes a total treatment time greater than 240 minutes which excludes patients that dialyze for less time than the average patient to better recognize the individual patient needs and desires.

NHSN Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure. The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving

The National Kidney Foundation continues to have concerns with maintaining both the NHSN Dialysis Event Reporting Measure and the NHSN bloodstream infection (BSI) in hemodialysis, clinical measure. We appreciate that CMS has increased the number of records it will review for its data validation study and we hope this will assist CMS in fixing the underlying challenges with the NHSN BSI clinical measure to ensure its validity. We also urge CMS to institute a system where hospitals are required to report BSI either directly to

¹ National Kidney Foundation. KDOQI clinical practice guideline for hemodialysis adequacy: 2015 update. *Am J Kidney Dis.* 2015;66(5):884-930.

² Flythe, Jennifer E., et al. Rapid Fluid Removal During Dialysis is Associated With Cardiovascular Morbidity and Mortality. *Kidney Int.* 2011;79(2):250-257.

hemodialysis at outpatient hemodialysis centers.	NHSN or directly to dialysis facilities, so they can appropriately report on the measures. We do not believe that including a reporting measure within the patient safety domain will solve the underlying challenge of receiving information on BSIs from hospitals and only dilutes the value of a BSI measure
NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to CDC	See above
Hemodialysis Vascular Access: Standardized Fistula Rate	NKF supports this measure
Hemodialysis Vascular Access: Long-Term Catheter Rate	NKF supports this measure
Clinical Depression Screening and Follow-Up	The National Kidney Foundation encourages CMS to modify the depression screening measure to require that the same methodology for detecting depression be used across dialysis facilities, or at a minimum require that the methodology for how depression was detected be reported. Dialysis facility social workers are equipped and trained to employ strategies to improve symptoms of depression by providing education and counseling. However, persistent or severe depression needs to be referred to a mental health practitioner for further diagnosis and treatment. This measure must not hold the dialysis facility or nephrologist accountable for counseling or prescribing anti-depressant medications to patients, since these are both outside the scope of practice of nephrologists. Therefore, we encourage CMS to include in the measure documentation of appropriate referral to treatment for persistent depression that cannot be addressed by social support provided by dialysis facility social workers.

C. Proposed New Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients Clinical Measure for Payment Year 2024

The National Kidney Foundation opposes including this measure in the QIP. We appreciate the intent of this measure to ensure that patients are waitlisted as early as possible after

starting dialysis, if they were not already waitlisted. However, we are concerned this measure is limited in terms of actionability by the dialysis center as the ultimate decision on waitlist status is made by the transplant center and the patient. Dialysis facilities have a role in educating patients about transplant and supporting their active listing. However, incident dialysis patients who were not listed before starting dialysis may be more complex and have comorbidities that make them ineligible for the waitlist during the first year. While it is the responsibility of the dialysis facility to work to improve the health and functional status of dialysis patients during the first year, much of the final decision, regarding acceptance to a transplant list, is beyond their control. In addition, dialysis units involved in pre-education and care coordination in the transition of advanced CKD to ESRD would not be recognized for patients who have received a pre-emptive transplant, which could further create a perceived incentive to start someone on dialysis earlier.

D. Efforts to Advance Health Information Technology

The National Kidney Foundation reiterates our concern about the lack of information sharing between hospitals and dialysis facilities. In our comments on last year's proposed rule, in response to the CMS request for information on opportunities to advance health information technology, we recommended CMS require hospitals to share discharge summaries with the patient's nephrologist or dialysis facility, when they are known to the hospital, within 48 hours. There is evidence that an additional nephrology visit and early intervention following a hospital admission could reduce the risk of readmissions.^{3,4} Proper care coordination with patients' nephrologists and dialysis facilities can also help hospitals avoid readmissions within 30 days of discharge. We reiterate our recommendation that CMS require hospitals to share information about patients discharge plans directly with the nephrologist and/or dialysis facility. Additionally, hospitals should be reporting bloodstream infections in dialysis patients directly to NHSN or the dialysis facility to improve the accuracy of the NHSN bloodstream infection clinical measure.

E. Transparency and Beneficiary Choice

The National Kidney Foundation recommends revisions to the public reporting of the QIP performance via the Performance Score Certificate (PSC) and reiterates our request to improve DFC. Without changes patients will continue to underutilize DFC and not have the opportunity to make informed decisions about where to receive care.

³ Erickson, Kevin F., et al. Physician Visits and 30-Day Hospital Readmissions in Patients Receiving Hemodialysis, *JASN*, 25: 2014.

⁴ Chan, Kevin E. Association between repeat hospitalization and early intervention in dialysis patients following hospital discharge, *Kidney International* (2009) 76, 331–341.

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The changes to PSC that were finalized last year have over simplified the certificate so much that it has little affect in providing patients with a solid understanding of how their dialysis facility is performing. We suggest CMS, at minimum, include the measures that are used to calculate the performance score and a note that some measures are weighted higher than others. Using the star ratings for the QIP as opposed to a separate rating on DFC would provide a visual portrayal of performance given that some beneficiaries have low health literacy and health numeracy. It would also help remove the confusion that patients have with the two separate scoring systems.

For the DFC website we continue to recommend that CMS work with the broader patient community to develop a website that is customizable by patients and families and allows them to select quality factors that are most important to them. We recommend that CMS either use the QIP measures and scores on DFC, or substantially differentiate DFC by including indicators of quality that patients value most (safety/infections, cleanliness, patients' satisfaction with the care received, staff attentiveness). The National Kidney Foundation has conducted patient surveys on this topic and have shared the results with CMS and its contractors. We would be happy to further discuss the results and work with CMS to improve public reporting of dialysis facility quality.

Right now neither the QIP PCS nor DFC is helping achieve the Administration's goal of providing transparent information to assist beneficiaries in making decisions about where they receive care.

The National Kidney Foundation appreciates the opportunity to comment on upcoming changes to the QIP and would be happy to meet with CMS to further discuss our recommendations. For questions, please contact Tonya Saffer, Vice President for Health Policy at tonya.saffer@kidney.org or 202.244.7900 x 717.

Sincerely,

Kevin Longino

Kevin Longino
CEO and Kidney Patient

Michael Choi

Michael Choi, MD
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