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August 19, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Room 445–G
Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1651-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and 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 Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model

Dear Acting Administrator Slavitt:

The National Kidney Foundation (NKF) 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 2018-2020. NKF is America's largest and long-established health organization dedicated to the awareness, prevention, and treatment of kidney disease for hundreds of thousands of healthcare professionals, millions of patients and their families, and tens of millions of people at risk. In addition, NKF is the founding sponsor of the Kidney Disease Improving Global Outcomes (KDIGO) initiative and has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD) and related complications since 1997 through the NKF Kidney Disease

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Outcomes Quality Initiative (KDOQI). We commend the agency for its commitment to ensuring dialysis patients have access to affordable, high quality care. While we are supportive of several items in the proposed rule, we encourage the agency to make additional modifications in order to realize its vision of improving quality and lowering costs, while protecting access to care. NKF's comments focus on those areas of the proposed rule most critical to patient access to high quality care.

I. Proposed Changes to the ESRD PPS

a. Payment for hemodialysis more than three-times per week

NKF is pleased that CMS seeks to have a better understanding and reliable source of data for the number of hemodialysis treatments patients receive each week. As more research and evidence supporting differing dialysis treatment schedules and use of home hemodialysis increases, the policy to allow dialysis facilities to report each treatment even when no additional reimbursement is being requested for those treatments is important to allow flexibility in personalized treatment plans and to incorporate any new evidence of improved care practices into care standards. While NKF encourages CMS to collect data on all dialysis treatments delivered, it is unclear as to why reimbursement needs to be changed to accomplish this goal. NKF questions why CMS could not instead issue guidance to the Medicare Administrative Contractors (MACs) to not deny or hold up claims where extra treatments are indicated, but are not being submitted for reimbursement, and to facilities to ensure they are recording every treatment and clearly indicating when reimbursement is not being requested.

Moreover, NKF appreciates CMS's specific clarification that this proposal continues to allow facilities to bill for extra treatments when medical justification is provided to the MACs. NKF believes this is an important existing policy that allows patients who have a medical need to be able to obtain extra treatments and for the facilities to be reimbursed for them.

b. Home Dialysis Training

NKF supports the CMS proposal to increase the home dialysis training

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adjuster to better align reimbursement with the cost of training as we have recommended in previous comments. NKF believes the training payment helps encourage home dialysis availability by covering the upfront investment needed to successfully initiate dialysis with home therapies or to transition those on in-center hemodialysis to home therapies. However, we do not support reductions to the base rate to facilitate a training adjuster as it undermines the intent to cover the upfront training costs, when the money is being removed from elsewhere in payment system. To improve access to home therapies the training payments should be additive.

As a point of clarification, when outlining the formula CMS uses for determining the increased training adjuster, CMS references that there are KDOQI guidelines on the nursing hours recommended to train patients. However, none of the KDOQI guidelines include recommendations related to the number of hours a nurse is involved in training patients for peritoneal or home hemodialysis and NKF is unaware of any conclusive evidence that would point to such a recommendation. As a result, NKF does support CMS efforts to monitor and better capture data to understand training practices, including when retraining is necessary. Allowing the flexibility for facilities to deliver retraining, when it is necessary, to ensure patients continue to dialyze safely at home is an important CMS policy and we support CMS efforts to better gather data to distinguish when a patient is receiving initial training versus retraining. However, we also note that training is and should be individualized and tailored to the patients' needs and learning aptitude and policies should remain flexible to ensure a patient-centered approach is attainable.

c. Coverage and Payment for Acute Kidney Injury

NKF is appreciative that CMS recognizes the differing treatment needs of AKI patients from those with ESRD throughout this proposed rule. NKF supports the CMS proposal to not apply the ESRD patient level adjusters to the AKI payment rates at this time. NKF also appreciates the flexibility and notes the importance in allowing reimbursement for dialysis

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treatments in excess of three times per week and separate billing for items and services that are outside of the ESRD PPS, including laboratory tests. The goal of dialysis for AKI patients is a return of renal function as quickly as possible and frequent monitoring of laboratory values is a critical component of this.

NKF agrees that most AKI patients will not use home dialysis, particularly home hemodialysis, since this modality takes time to initiate. However, there are patients for whom acute PD is used to treat AKI and a very small number of those patients are discharged to do PD at home after completing training. To allow for this relatively small number of patients to have the option to do PD at home, CMS should reimburse for the training of these patients, but that training should be an additive payment and not come out of the base rate.

While CMS has proposed to define an AKI patient as an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14)," in alignment with the authorizing statute, the Trade Protection Extension Act of 2015, the KDIGO clinical practice guidelines and KDOQI commentary on CKD evaluation and management recommends diagnosis of CKD when two laboratory values at least 90 days apart confirm a sustained reduction in eGFR.[1] While it is possible that some AKI patients will recover kidney function after being on renal replacement therapy for more than 90 days and flexibility in diagnosis should be left to the practitioner we do encourage CMS to monitor for any increase in the number of patients with prolonged diagnosis of AKI as an unintended result of potentially more favorable reimbursement.

While the clinical treatment of AKI patients receiving dialysis differs from that of ESRD patients, during the time that AKI patients are receiving dialysis in the outpatient facility they should still have the same rights as

[1] Inker, Leslie A, et al., KDOQI US Commentary on the 2012 KDIGO Clinical Practice Guideline for the Evaluation and Management of CKD, Am J Kidney , 63(5): 713 – 735.

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ESRD patients including access to a grievance process and be protected under the conditions for coverage (CfC). Additionally, access to a dietitian and a social worker are also necessary for AKI patients. However, the requirements for care planning and the modality information and evaluation requirements under the CfCs for AKI patients should not be the same as those for ESRD patients. It is not necessary for all AKI patients to be evaluated for vascular access, home dialysis, or transplant as the goal is to have recovery of renal function. Additionally, care planning for AKI patients is more likely to be necessary on a weekly basis rather than a monthly basis and Kt/V targets will be different than for ESRD patients. The CfCs should be modified to account for the differences in delivering care to AKI patients.

i. **Quality measures for AKI patients**
Given AKI patients are clinically different from those with ESRD the quality measures that apply to ESRD patients should not apply to AKI patients, until they are diagnosed with ESRD As we mentioned previously it is reasonable to expect most patients to be diagnosed after 90 days on dialysis, but there are instances where patients may recover renal function beyond the 90 day window and CMS should monitor whether there is any unintended incentive under this proposed rule to increase the length of time patients are diagnosed as AKI instead of ESRD.

NKF believes strongly that quality measures should be developed and used to ensure that patients with AKI receive high quality care and achieve the best possible clinical outcomes. Most notably a weekly Kt/V target of 3.9 when intermittent or extended dialysis is used has the highest level of evidence with a KDIGO guideline grade of 1A.[2] In addition, blood stream infection control measures should apply to AKI patients, but AKI patients should not be included in the same measure pool as ESRD patients given that AKI

[2] Palevsky, Paul, et al., KDOQI US Commentary on the 2012 KDIGO Clinical Practice Guideline for Acute Kidney Injury, Am J Kidney Dis. 61(5):649-672

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patients have a higher risk of infections and have additional complex complications. CMS should also seek to develop patient reported outcomes measures for this population, including assessments of patient satisfaction.

ii. **Monitoring the care of AKI patients**

NKF supports the CMS proposal to closely monitor the care of AKI patients. Much is still to be learned about their treatment and medication needs, the staff time involved in caring for them, and ultimately the costs associated with their care. In addition, we agree that the patient-practitioner relationship is critical in the care of these patients. Frequent assessment of patients is needed to ensure they receive the dose of dialysis prescribed so that prescriptions can be adjusted appropriately, which is strongly supported by the KDIGO AKI guidelines with a grade of 1B.[3]

d. Ongoing challenges in ESRD patients access to care

i. **Low/Volume Rural Facility Adjuster**

NKF continues to remain concerned that even with the addition of a rural facility adjuster that there remains an existing incentive for facilities within close approximation to one another to limit access to their facility in order to meet the requirements for the low volume adjuster, which unnecessarily increases healthcare costs, including co-pays for patients, and does not serve the policy intent of ensuring the viability of dialysis facilities to serve in areas where there is a sparse patient population. In addition, as facilities serve AKI patients some could be at risk of losing the low-volume facility adjuster even when dialyzing these patients temporarily. We encourage CMS to meet with the kidney community on solutions to protect patient access to care in a cost-effective manner.

ii. **Patient Adjusters**

NKF remains concerned that the patient adjusters do not serve the

[3] Ibid.

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intended policy purpose to protect high cost patients from the risk of under-treatment or access to care. Specifically, we believe the base age range of 70-79 is inappropriate as facilities would not receive a payment adjustment for this age group, but would increase payments by 7% for the 60-69 group. Similarly, we continue to question the rationale for CMS's use of both a body surface area and body mass index adjustment and encourage the agency to use a BMI adjustment for overweight and underweight patients to better account for costs of treatment, including differing staffing, treatment times, and medication needs.

iii. **Payment for new innovation**

NKF encourages CMS to work with the kidney community now to develop a proposed policy for incorporating new therapies into the PPS. It is important to have such a policy in place before any new therapies come to market in order to ensure patients have access immediately. NKF continues to favor an approach where new therapies are initially paid separately, without cost-sharing for the patient, before they are incorporated into the base rate to ensure experience and cost data are appropriately captured and accounted for.

II. ESRD QIP

a. Proposed changes to the hypercalcemia measure for payment year 2018

While NKF does not disagree that plasma in addition to serum calcium are acceptable tests and that including all patients in the denominator is more appropriate for a quality measure than only including those with laboratory values, we reiterate that the hypercalcemia measure as a whole is not impactful and should not be weighed as a clinical measure in the QIP when other measures are much more meaningful to patient care. While NKF 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

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reporting measure. Given that a clinical hypercalcemia measure is not a measure that will improve outcomes, 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.

b. NHSN Blood Stream Infection Measures

NKF strongly agrees with CMS that a clinical quality measure that holds dialysis facilities accountable for preventing blood stream infections should be a high priority for inclusion in the QIP. NKF is gravely concerned with the literature CMS cites in the proposed rule as showing 60-80 percent underreporting of bloodstream infections to the National Healthcare Safety Network (NHSN). However, we disagree with the solution CMS has proposed to add an event reporting measure in addition to the NHSN clinical measure and to create a safety domain for the two measures. As the literature concluded, underreporting of blood stream infections in dialysis patients was largely attributed to challenges in dialysis facilities reporting appear to be a result of inability to obtain information back from hospitals.[4,5] Simply giving dialysis facilities extra credit for reporting will not move the needle in ensuring all events are reported, or change the difficulties facilities have in getting the information from the hospitals. CMS needs to ensure hospitals are required to report this information to dialysis facilities in a timely manner. We encourage CMS to quickly rectify this challenge so that a valid, clinical measure that accomplishes the goal of preventing bloodstream infections in dialysis patients can be realized.

[4] Nguyen Duc B., et al. Completeness of Methicillin-Resistant Staphylococcus aureus Bloodstream Infection Reporting From Outpatient Hemodialysis Facilities to the National Healthcare Safety network, 2013. Infection Control & Hospital Epidemiology, http://journals.cambridge.org/abstract_S0899823X1500265.

[5] Thompson, Nicola D., et al., Evaluation of Manual and Automated Bloodstream Infection Surveillance in Outpatient Dialysis Centers. Infection Control & Hospital Epidemiology, Available on CJO 2016 doi: 10.1017/ice.2015.336.

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c. Measures for Payment Year 2020

i. Adding the Standardized Hospitalization Ratio

NKF supports holding dialysis facilities accountable for preventing hospitalizations that are actionable by the nephrology care team. NKF is pleased that CMS proposes to add additional comorbidities to risk adjust the measure as this moves the measure closer to the goal of ensuring the measure is actionable by the nephrology care team and will help to protect against unintended consequences that may impede access to care for more complex patients. We do raise concern that there may be overlap with the Standardized Readmissions Ratio (SRR), which would cause readmissions that occur within the 30 day window of an index hospitalization to be counted in both this measure and the SRR thereby penalizing facilities twice. NKF does not believe this is appropriate and encourages CMS to correct this in the measure specifications before the measurement year.

ii. Phosphorus Reporting Measure

While NKF is not opposed to the change in moving from a metabolism reporting measure to a phosphorus reporting measure we believe the more meaningful change would be to have a mineral metabolism composite measure that includes hypercalcemia, intact-PTH and phosphorus.

iii. Ultrafiltration Reporting Measure

NKF does not see the value in a reporting measure of ultrafiltration, particularly when there is an NQF endorsed clinical measure that if implemented would be more meaningful to patient outcomes. NKF encourages 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 NKF KDOQI hemodialysis adequacy clinical practice guidelines, do not include a target for UFR and instead recommend minimizing UFR as best possible in order to maximize

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hemodynamic stability and tolerability of the hemodialysis procedure. This is because the supporting evidence for a specific target is limited.[6] 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.[7] 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.

d. Continuation of 2019 measures in 2020

i. Dialysis Adequacy

NKF 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 lumps 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. As the National Quality Forum (NQF) renal standing

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

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

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committee pointed out the evidence for the Kt/V targets for the hemodialysis population is based on three times per week dialysis not four. NKF also disagrees with CMS's assertion in last year's final rule 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.

ii. Remaining 2019 Measures

NKF general supports the remaining measures finalized for payment year 2019, but offers the following the suggestions and comments on six of the 13 existing measures (for which we did not comment on elsewhere in this letter) that are proposed to continue to be included in the QIP that could be improved. Additionally, we encourage CMS to continue its work to engage dialysis patients to identify patient reported outcomes and measures that would be most meaningful to patients for inclusion in the QIP in future years.

Continuing Measures 2020	NKF Recommendations
Vascular Access Type Catheter >= 90 days And Vascular Access Type Fistula Vascular Access Type –Arteriovenous Fistula (AVF) Clinical Measure	NKF is pleased that CMS has submitted changes to the NQF Renal Standing Committee related to these measures that address our previous suggestions to modify the measure to address the small number of patients for whom a catheter may be the most appropriate vascular access when life expectancy is limited. We look forward to those new measures being proposed for the QIP when the NQF process is completed. NKF also continues to have concerns that credit for the fistula measure should only be given if the catheter has been removed. The presence of a catheter increases the risk for infection even if it is not in use. Related the catheter measure should include in the numerator all patients with a catheter in place for the reporting period, whether the hemodialysis catheter is in continuous use or not. We look forward to the completion of the NQF process that

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	may allow for the improved measures to be included in the QIP.
Standardized Readmission Ratio	NKF supports the measure, but remains concerned about the effect of the measure on patient access to care. NKF looks forward to the results of the study CMS has planned on evaluating the effect this measure has on patient access to care. We also request that CMS remove any overlap between this measure and the SHR that would penalize facilities twice.
Standardized Transfusion Ratio (StR)	NKF believes a transfusion avoidance measure should be stratified to appropriately capture blood transfusions that could have been prevented by the dialysis facility and exclude transfusions that result for acute or chronic medical conditions outside the scope of practice of the facility and nephrologist caring for the patient. For example, sickle cell anemia and anemia caused by hematologic malignancies should be excluded. NKF acknowledges that tracking blood transfusion data that are critical to understanding patient safety issues will be difficult for facilities since most blood transfusions are not provided in the dialysis setting. NKF continues to remain concerned that a StR alone does not completely counter-act the potential to under-treat anemia and permits for patients' hemoglobin levels to fall below the minimum range recommended in the KDOQI Anemia Management guidelines of 9.0 g/dl -10.0 g/dl. In addition, a transfusion avoidance measure does not take into account patients' quality of life or the cardiovascular risks associated with low hemoglobin levels.
Clinical Depression Screening and Follow-Up	NKF 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, NKF encourages CMS to include in the measure documentation of appropriate referral to treatment for

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	persistent depression that cannot be addressed by social support provided by dialysis facility social workers.

NKF greatly appreciates the opportunity to submit our comments on this proposed rule and for the attention and hard work by the staffs at the Center for Medicare and Center for Clinical Standards and Quality to ensure dialysis patients have access to high quality care.

Sincerely,

Kevin Longino
Kevin Longino
CEO

Jeffrey S. Berns
Jeffrey S. Berns, MD
President