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

Dear Acting Administrator Slavitt:

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the "Proposed Rule: End-Stage Renal Disease Prospective Payment System and Quality Incentive Program." NKF is America's largest and oldest 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 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 are focuses on those areas of the proposed rule most critical to patient access to high quality care.

Changes to the Prospective Payment System (PPS):

**I. Patient Case Mix Adjusters**

NKF has concerns that because of the data sources and methodology used, the payment for the patient level adjusters are not serving the policy intention of protecting access to care for beneficiaries who are perceived to be more costly. NKF's health professional membership, which includes nephrologists, nurses, advanced practitioners, dietitians, and social workers have stated that while age is not always a predictor of costs it is a legitimate proxy for higher costs associated with older patients. Similarly underweight patients and overweight patients also contribute to increased costs to the dialysis facility. However, the rationale for these higher costs is not necessarily always reflected in claims data and dialysis facility cost reports because these patients typically require more staff time devoted to them.

**a. Age**

For example, older patients are more susceptible to falls requiring greater facility staff assistance to obtain their weights and assist them in and out of the dialysis chair. Elderly patients are also more likely to have a catheter, which increases the risk of bloodstream infections requiring antibiotics, blood cultures, and more frequent hospitalizations. They also tend to have more comorbid conditions, which could require frequent adjustments in the dialysis prescription and closer surveillance of the multitude of medication they may be on.

Given this, it does not make sense that the age group of 70-79 would not have a payment adjustment while the 60-69 year old population would have a 7% payment adjustment.

**b. Body Surface Area (BSA) and Body Mass Index (BMI)**

An analysis by The Moran Company concluded that the BSA adjuster is canceling out the BMI adjuster in most cases for underweight patients. This is negating the policy intent of adjusting payment for patients who are underweight and more costly to the system. Like older patients, healthcare professionals attest that both underweight and overweight

patients require additional staff time devoted to their care and overweight patients may require the facility to provide additional equipment. For example, underweight patients may be more frail and susceptible to falls and require assistance getting around the facility. Many underweight patients are also malnourished and require additional staff resources to help them get closer to dietary goals. They also may require higher doses of medications and more medications. Patients with higher BMI also require additional staff time as well as additional equipment. Assistive devices to protect healthcare professionals' safety in moving larger, non-ambulatory patients may be required. Overweight patients may require additional time on dialysis and larger dialyzers to achieve optimal fluid removal. Larger dialysis chairs may also be required for those substantially overweight. In addition, some medications are dosed according to weight.

To ensure that the patient level adjusters are achieving the intended policy purpose of protecting these seemingly more costly patients from adverse selection, NKF recommends maintaining the current (2015) age adjuster, eliminating the BSA adjuster and applying a BMI adjuster only for underweight and adding a BMI adjuster for overweight patients (using the National Institutes of Health definition) for 2016, and working with the kidney community to develop new data sources for patient characteristics for which appropriate age and weight adjusters could be calculated from in future years.

## **II. Facility Adjusters**

- a. Low Volume Payment Adjuster (LVPA) and Rural Payment Adjuster  
NKF is pleased that CMS is considering ways to better align payment with higher costs for dialysis facilities that serve a critical need in geographically isolated communities. In last year's proposed rule, NKF recommended that CMS conduct an analysis to identify these critical access facilities and align policy in such a way that protects beneficiary access to these facilities. However, we remain concerned that even with the removal of grandfather status, for low-volume facilities that are within 25 miles of another commonly owned facility, and the change in geographic proximity to 5 miles that the incentive still remains for

commonly owned facilities to maintain low-volume status while having two or more facilities serving in close proximity to an uncommonly owned facility. For example, two commonly owned facilities could sit 10 miles from one another, but on either side of an uncommon facility causing all three facilities to potentially be low-volume. In this scenario, while patients have more choices of where to go for dialysis it also causes them to unnecessarily pay a higher coinsurance than they otherwise would if they had access to a facility that didn't qualify for a low-volume payment. It is also not serving the intended purpose of the LVPA to protect patient access to facilities that are low-volume because they serve a critical access need.

Rather than adding a rural payment adjuster – for which facilities could qualify for both the LVPA and the rural adjuster, CMS should instead consider using a tiered LVPA that would pay higher for rural facilities that are also low-volume, while still applying an adjustment (although of a lesser amount) to low-volume facilities that may be in closer proximity to other commonly owned dialysis facilities. Since rural status for facilities may be associated with higher costs, independently of the number of treatments they provide, CMS should consider adding a tier of the LVPA that would provide a payment adjustment for a higher range of treatments delivered for facilities with a rural designation. A simplified example of this tiered approach may look like the following:

1. Rural +  $\leq 4,000$  treatments 75% of the LVPA adjuster value
2. Rural + 4,001 – 6,000 treatments 50% of the LVPA adjuster value
3.  $< 4,000$  treatments 25% of the LVPA adjuster value

Geographic proximity rules may still be necessary with this approach. A tiered approach for the LVPA was recommended in the March 2013 Government Accountability Office (GAO) report. While NKF's recommendation differs from that recommendation because the tiered approach does not decrease as the facility size increases, it does address GAO's recommendation and MedPAC's recommendation in its 2014 report to Congress that the LVPA be targeted to protect access to

facilities that serve a critical need, some of these facilities may be larger than the current LVPA limits allow, but also serve a critical need in the community. This approach could serve as an interim solution until such a time that CMS is able to conduct further analysis to better identify facilities that are geographically isolated.

- b. While CMS did not propose to make changes to the home training payment adjuster, NKF reiterates our support for expanded patient access to home dialysis. The percentage of patients using home hemodialysis remains low at just under 2%. NKF notes that the upfront costs of beginning a home program may be one barrier to growth. We encourage CMS to monitor patient access to home dialysis and ensure that the payment for home training covers the costs of the nursing time involved. However, any necessary increases to the training adjuster should not come at the cost of removing funds to care for patients who chose to receive dialysis in-center.

### **III. ESRD PPS Drug Designation Process**

While we appreciate that CMS is considering the issue of payment for new medications, NKF has concerns with the proposed approach. NKF believes that new drugs and biologics should not be added to the bundle unless they are substantially similar to those drugs and medications already included. While we agree that drugs and biologics that are primarily related to treating dialysis patients should be included in the bundle, CMS should rely on utilization and cost data before incorporating them into the bundle. Therefore, when a product is not substantially similar to an existing product it should receive a transitional payment until utilization and cost data can be evaluated for inclusion into the bundled payment. If new products are immediately added to the bundle without additional payment this would curtail innovation in treatments for people on dialysis. In addition, we believe clinicians should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes. The proposed rule does not allow for this. KDIGO and KDOQI guidelines are often updated when evidence of improved therapies on patient outcomes are made available. This rigorous and evidence based process is extremely important in guiding widespread treatment decisions in nephrology. However, under this proposed rule reimbursement and contracting arrangements could instead

dictate utilization of a product before real world evidence on patient outcomes is ever generated.

NKF believes that a transitional payment should also apply to IV versions of phosphate binders and calcimemtics until utilization and cost data can be captured. Otherwise, the bundled payment could be improperly inflated by a higher costing IV version that is only benefitting a subset of patients, but all patients would be subjected to a higher coinsurance. Conversely, there could be superior benefit of the IV version that renders lower utilization of the oral versions. Again, allowing a transition period allows for proper data to be collected and evidence to be gathered on patient outcomes.

Proposed Changes to the Quality Incentive Program (QIP):

**IV. Proposal to Use the Hypercalcemia Measure as a Measure Specific to the Conditions Treated with Oral-Only Drugs**

While NKF understands that CMS is required by the 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 returning it to the bone and mineral metabolism reporting measure. Previously, NKF supported transforming the hypercalcemia measure into a clinical measure, but given the delay of including oral only drugs into the PPS until 2026 and that performance on the measure is very high and unlikely to see any additional improvement, we no longer see the need for this as a clinical measure.

NKF strongly encourages CMS work with experts in the kidney community to develop a composite phosphorus/calcium/PTH measure, as it would be much more likely to improve patient outcomes than any measure that evaluates just one of these parameters. NKF looks forward to contributing our expertise in this area to facilitate development of such a composite measure.

**V. Proposal to substitute 2017 Performance Standards if quality is lower**

NKF agrees that the QIP should encourage continuous improvement in quality and that performance standards should not be set below their performance in

previous years. NKF encourages CMS to use the previous year performance standard(s) moving forward if the updated calculation for performance standard(s) is lower than it was the prior year.

## VI. Proposed Requirements for the PY 2019 ESRD QIP

### a. Continuing 2018 measures

NKF supports continued use of the 2018 measures in 2019. However we reiterate our recommendations from last year on ways to improve some of these measures in the table below:

Measure	NKF Recommendations
<b>Vascular Access Type Catheter &gt;= 90 days</b>	CMS should modify the measure to exclude and/or consider risk adjustment in the measure for the small number of patients for whom a catheter may be the most appropriate vascular access, for example when life expectancy is limited, patients awaiting AV fistula maturation, and those scheduled to switch modalities such as receiving a living donor transplant or moving to peritoneal dialysis.
<b>National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Patients</b>	NKF appreciates that in the final 2015 rule CMS did not move forward with adding the Adjusted Ranking Metric (ARM) to this measure. NKF had requested greater clarity on the purpose of the ARM and believes that until more information about the ARM is available and the public has time to comment it should not be incorporated into this measure. NKF supports continuing this measure in 2019 without the ARM.
<b>Hypercalcemia</b>	For the reasons stated previously, we believe this measure should be returned to the mineral metabolism reporting measure and not be used as a clinical measure.
<b>Standardized Readmission Ratio</b>	NKF is pleased that CMS has added a grace period to exclude patients from the measure within 1-3 days of hospital discharge as this will allow those patients time to follow up with the dialysis facility. NKF also remains concerned about the measure on patient access and overall quality. NKF is pleased that CMS plans to move forward with a study on patient access in regards to this measure. Specifically, we request that CMS evaluate the combination effects of socioeconomic status and demographics to determine if they are influencing poor performance on the measure.
<b>Standardized Transfusion Ratio (StR)</b>	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

other reasons for transfusions. For example sickle cell anemia and anemia related to 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.

**In-Center Hemodialysis  
Consumer Assessment  
of Healthcare Providers  
and Systems (ICH  
CAHPS)**

While more studies are needed to evaluate whether patient satisfaction is associated with clinical outcomes, NKF believes 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 as it does require a considerable amount of time to complete and patients already spend a great deal of their time focused on dialysis. 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.

**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. It is important that this measure does not lead to the dialysis facility or nephrologist being held accountable for treating or prescribing medication to patients for depression as that is not an appropriate role for these practitioners. Therefore, NKF encourages CMS to include in the measure documentation of appropriate referral to treatment for persistent depression that cannot be addressed by social support provided by social workers.



b. New Measures for PY 2019

i. Dialysis Adequacy

NKF opposes the move from the current four dialysis adequacy measures to the singular measure “Minimum Kt/V for All Patients and All Modalities.” NKF could consider supporting a composite measure for the adult population if the calculation was conducted for each individual measure then rolled up into one score. However, the measure submitted pools the populations together and as the National Quality Forum (NQF) renal standing committee points out, for the hemodialysis population, includes people receiving dialysis three and four times a week when the evidence is based on three times per week. NKF also has concerns that incorporating pediatrics into the measure may mask performance in treating that population. This measure could also be improved if the upper limit thresholds were removed.

ii. Ultrafiltration Rate (UFR) Reporting Measure

NKF supports the use of an UFR measure in the QIP, but encourages CMS to implement the NQF# 2701: Avoidance of Utilization of High Ultrafiltration Rate ( $\geq 13$  ml/kg/hour), which has been supported for endorsement by the NQF renal standing committee. The NKF KDOQI hemodialysis adequacy draft guidelines (publication pending), do not include a target for UFR and instead recommend minimizing UFR as best possible in order to maximize hemodynamic stability and tolerability of the hemodialysis procedure. This is because the supporting evidence for a specific target is limited. One 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.<sup>1</sup> However, NKF believes the  $\geq 13$  ml/kg target for a quality measure of UFR has the most consensus among experts.

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<sup>1</sup> Flythe, Jennifer E., et al. Rapid Fluid Removal During Dialysis is Associated With Cardiovascular Morbidity and Mortality. *Kidney Int.* 2011;79(2):250-257.

Additionally, implementing the measure is not without challenges. Successfully meeting the measure will require patient participation and adherence to the dialysis prescription and fluid restrictions. The KCQA measure includes a time component of <240 minutes which excludes patients that dialyze for less time than the average patient to better recognize the individual patient needs and desires.

- iii. Proposed Full-Season Influenza Vaccination Reporting Measure  
NKF supports the Full-Season Influenza Vaccine measure in the QIP. We suggest CMS base the measure off of the NQF endorsed #0226 Influenza Immunization in the ESRD population rather than introduce an entirely new measure. In addition, we are concerned about the "offered but declined" portion of the measure and recommend it be removed. While patients may decline the vaccine initially, many more will accept if they are properly educated. The inclusion of this clause could actually result in lower immunization rates than if it were not included. Including the clause also dilutes the measure making it a process of care measure rather than actual measures of immunization rates.

## **VII. Advancing Health Information Exchange**

NKF appreciates the attention on the need for greater interoperability of electronic health records. Fragmentation of the health system contributes to poor communication between the health care professionals who care for the patient before dialysis initiation and the dialysis clinic staff. Improved electronic health information sharing should help to promote care coordination and overcome fragmentation during this vulnerable transition. Additionally, lack of communication between dialysis facilities and hospitals is a missed opportunity to reduce readmissions and improve medication reconciliation in the transition between the dialysis clinic and hospital setting.

Dialysis patients are hospitalized, on average, nearly twice a year for an average of 11 hospital days. In 2012, nearly 40% of dialysis patient discharges from all-cause hospitalization were followed by an unplanned readmission

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within 30 days.<sup>2</sup> Sharing health information is key to care coordination and patient safety, particularly discharge summaries, which include information about hospital diagnosis, antibiotic use, blood stream infections, red-blood cell transfusions, and modifications in dialysis prescription. Yet, there is little electronic information exchange from acute hospitals to dialysis clinics. Interoperability standards would create greater ease of information sharing.

Sincerely,

*Jeffrey Berns*

Jeffrey Berns, MD  
President

*Joseph Vassalotti*

Joseph Vassalotti, MD  
Chief Medical Officer

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<sup>2</sup> Saran R, Li Y, Robinson B, et al. US Renal Data System 2014 annual data report: epidemiology of kidney disease in the United States. Am J Kidney Dis. 2015;66(1)(suppl1):S1-S306.