National Kidney Foundation™

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

November 17, 2015

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: Response to the Request For Information Regarding Implementation of the Merit-based Incentive Payment System (MIPS), Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models

Dear Acting Administrator Slavitt:

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the Request for Information (RFI) Regarding Implementation of the Merit-based Incentive Payment System (MIPS), Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models. 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 has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI).

NKF believes the programs included in Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) have the opportunity to improve the quality of care patients receive. Each element of the program should reinforce one another and ensure alignment in quality across MIPS and alternative payment models (APMs) rather than simply be discrete activities with differing goals. All quality activities should encourage the closure of gaps in care for eligible professionals (EPs) and these gaps in care should ultimately determine which quality measures and clinical improvement activities physicians should participate in each year. With this principle in mind NKF has responded to

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targeted questions in the RFI and highlighted how kidney care could be improved through MACRA implementation.

I. MIPS

A. Quality Measures

i. Should we maintain the policy that measures cover a specified number of National Quality Strategy domains?

Yes, NKF believes that the National Quality Strategy (NQS) assesses the national gaps in care and identifies an overarching goal for where health care should focus to improve population outcomes. What should follow from that overarching strategy are the tactics to accomplishing those goals and prioritizing quality measures that are in line with accomplishing the NQS. The NQS establishes how the healthcare workforce can help move us towards the overarching goals of better care, healthier people and lower costs.

ii. Should we require that certain types of measures be reported? For example, should a minimum number of measures be outcomes-based? Should more weight be assigned to outcomes-based measures?

Quality measures should focus on gaps in care and ultimately outcomes. There are some conditions for which outcomes measures are not available and are not ready for development, but for which improvements in care processes have observational data that show improvement in outcomes. The use of process measures often serve as the first step in educating and transforming clinical practice to align with evidence based care. In addition, with chronic conditions, like CKD, certain outcomes like progression to end-stage renal disease (ESRD), may take several years to show results. CMS should continue to prioritize new process measures for areas where gaps in care in exist, but for which outcomes measures are not available. Process measures may also lead to the development of a body of evidence that can then be used to develop outcome measures.

CKD care is an example where substantial gaps in clinical care processes strongly associated with patient outcomes exist. In a study of primary care practitioners (PCP) and their practices in detecting CKD, it was noted that in adults with type-2 diabetes, who are at the highest risk for CKD, their CKD often went undiagnosed and unmanaged. The NKF KDOQI guidelines offer evidenced based strategies for PCPs to detect, diagnose, and manage CKD. The recommendations include testing at-risk populations for CKD by serum creatinine and urine albumin including those with diabetes, hypertension and age over 60 years to promote patient safety. In individuals with CKD, certain medications need to be dose adjusted or avoided entirely to protect patients from toxic side effects and acute

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kidney injury – which can result in temporary kidney failure requiring dialysis and faster progression to permanent kidney failure. Both over-the-counter and prescription nonsteroidal anti-inflammatory drugs are a class of commonly used medications that cause acute kidney injury in CKD. In addition, the guidelines recommend the use of certain blood pressure medications such as an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB) for CKD with albumin in the urine and hypertension. The guidelines also identify when a referral to a nephrologist is recommended. However, existing quality measures in PQRS do not address any of these areas. NKF and others are working on quality measures in these areas to encourage earlier CKD identification and management strategies associated with improved outcomes. These measures would address a substantial gap in the care of patients who often ask why they weren't told they had kidney disease before their kidneys failed.

iii. **How do we apply the quality performance category to MIPS EPs that are in specialties that may not have enough measures to meet our defined criteria? Should we maintain a Measure-Applicability Verification Process? If we customize the performance requirements for certain types of MIPS EPs, how should we go about identifying the MIPS EPs to whom specific requirements apply?**

NKF strongly encourages CMS to customize performance measure requirements and to establish a process to identify which provider types are reporting on which measures. EPs should also be required to select measures that will encourage them to address gaps in their own performance rather than select measures where they already perform at a high standard. This may require the agency to collect attestation that individual EPs and group practices have performed gap analyses on their own performance relative to the quality measures they have selected.

iv. **Apart from the cost measures noted above, are there additional cost or resource use measures (such as measures associated with services that are potentially harmful or over-used, including those identified by the Choosing Wisely initiative) that should be considered? If so, what data sources would be required to calculate the measures?**

Given that the Medicare program is responsible for covering nearly 90 percent of Americans with kidney failure, regardless of their age, CMS should explore the costs associated with patients who experience kidney failure and start dialysis without proper planning when they were under the care of a nephrologist at least 1 year prior to kidney failure. Many studies have shown that with proper nephrology care and preparation for renal replacement therapy patients can avoid hospitalizations and unnecessary

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procedures. The National Quality Forum (NQF) has endorsed measure 2594 *Optimal ESRD Starts* that measure nephrologists or health plans performance on ensuring that patients do not start hemodialysis with a catheter in place and are educated on all of their dialysis and transplant options prior to kidney failure. Applying this measure to nephrologists or practices that have 50 new ESRD patients seen within the previous year (as recommended by the measure developer) would certainly lower healthcare expenditures for increased hospitalizations and vascular access surgeries associated with improper dialysis planning. CMS could implement this measure and track changes in costs for new ESRD starts overtime, which could set a baseline for a cost/resource measure in the future.

v. **CMS has received stakeholder feedback encouraging us to align resource use measures with clinical quality measures. How could the MIPS methodology, which includes domains for clinical quality and resource use, be designed to achieve such alignment?**

Per our comments above, this could be done by using a clinical quality measure that has evidence behind it to support lower healthcare costs and then using claims data track lower hospitalizations and healthcare utilization related to the quality measure (i.e. for ESRD this may include vascular access placement costs, hospitalizations related to emergent dialysis starts, and bloodstream infections in those with catheters).
An approach where performance on clinical quality measures can also be tied to cost reductions by preventing adverse events and unnecessary surgeries and hospitalizations would be one way to ensure that cost and resource measures don't become the driver of clinical care trumping patient outcomes and access to care.

B. Clinical Improvement Activities

i. **In this RFI, we seek comment on other potential clinical practice improvement activities (and subcategories of activities), and on the criteria that should be applicable for all clinical practice improvement activities. We also seek comment on the following subcategories, in particular how measures or other demonstrations of activity may be validated and evaluated**

Per our comments on quality measures clinical improvement activities should align with the NQS and with known gaps in care for the Medicare population. EPs should be required to select at least one clinical improvement activity (CIA) that addresses gaps in

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their performance.

ii. **We also seek comment on the following subcategories, in particular how measures or other demonstrations of activity may be validated and evaluated:**

a. **A subcategory of Promoting Health Equity and Continuity, including (a) serving Medicaid beneficiaries, including individuals dually eligible for Medicaid and Medicare, (b)accepting new Medicaid beneficiaries, (c) participating in the network of plans in the Federally facilitated Marketplace or state exchanges, and (d) maintaining adequate equipment and other accommodations (for example, wheelchair access, accessible exam tables, lifts, scales, etc.) to provide comprehensive care for patients with disabilities.**
NKF agrees that paying for performance should also include serving vulnerable populations. Measures in this subcategory will encourage greater access to care for patients across multiple federal programs achieving national goals of equity and access to health care.

b. **A subcategory of Social and Community Involvement, such as measuring completed referrals to community and social services or evidence of partnerships and collaboration with the community and social services.**
Partnerships with community organizations and social services can help EPs achieve goals of improving patients' health and expanding capacity for EPs to focus on clinical care delivery. Community organizations and social services help patients receive the social support and education they need to overcome barriers to self-management of health and chronic conditions. NKF strongly agrees that this subcategory for measurement is important and will encourage EPs to ensure patients are linked to community resources that can help patients become an equal partner with the EP in their health care.

c. **A subcategory of Achieving Health Equity, as its own category or as a multiplier where the achievement of high quality in traditional areas is rewarded at a more favorable rate for EPs that achieve high quality for underserved populations, including persons with behavioral health conditions, racial and ethnic minorities, sexual and gender minorities, people with disabilities, and people living in rural areas, and people in HPSAs.**

NKF agrees that creating a subcategory to measure health equity could create

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incentives for EPs to think innovatively on how to improve outcomes for underserved populations. There have been many calls for risk-adjusting quality measures based on socioeconomic and demographic factors to ensure that practitioners are not penalized for caring for a population that has more difficulty achieving outcomes. However, there have been concerns that adjusting for these factors may mask inequities in care delivery. Creating a sub category for measurement in achieving health equity may serve as a better alternative to risk adjusting for certain populations.

iii. **What threshold or quantity of activities should be established under the clinical practice improvement activities performance category? For example, should performance in this category be based on completion of a specific number of clinical practice improvement activities, or, for some categories, a specific number of hours? If so, what is the minimum number of activities or hours that should be completed? How many activities or hours would be needed to earn the maximum possible score for the clinical practice improvement activities in each performance subcategory? Should the threshold or quantity of activities increase over time?**

NKF believes CIAs have the opportunity to transform clinical practice. Per our previous comments we believe participation in these activities should help EPs improve gaps in care. The past 20 years have seen significant increases in the production and dissemination of medial information and practice guidelines. New trends have heightened expectations that continued professional development programs will result in demonstrable improvements not only in clinical practice but also in patient outcomes at both individual and population levels. The new trend has "relied heavily on dissemination of scientific evidence to a more systematic and concerted effort to deliver educational interventions that improve clinical practice."

Clinical transformation involves assessing and continually improving the way patient care is delivered at all levels in a care delivery organization. It occurs when an organization rejects existing practice patterns that deliver inefficient or less effective results and embraces a common goal of patient safety, clinical outcomes and quality care through process redesign and IT implementation. By effectively blending people, processes and technology, clinical transformation occurs across facilities, departments and clinical fields of expertise. The MIPs program is well-positioned to make this a reality. CIAs should have metrics and assessments built into them that evaluate how participation in the activity has filled a gap in practice. EPs should be able to

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demonstrate that the activity filled a knowledge or practice gap that has led to process improvement and overtime a better outcome for patients.

NKF has been a leading provider in continuing medical education for kidney health for decades and has now created a curriculum and program to help implement practice transformation in primary care and nephrology to detect kidney disease early, improve patient safety, and avoid adverse events and outcomes associated with kidney disease. NKF would be pleased to discuss how this curriculum could also be implemented as a CIA.

iv. Should performance in this category be based on demonstrated availability of specific functions and capabilities?

In year one and year two EPs should be given credit for participation in CIAs that address gaps in their own practice. In future years the bar should be set higher where credit is provided for achievement of the metrics and assessments that should be built into CIAs, and eventually EPs should be held to improving outcomes through CIA. The CIAs should improve clinical processes that lead to improvement in patient outcomes. Measurement of the impact of the CIA should continue well after the activity has ended so data can be collected to show not only process improvement, but that the process improvement also led to improvements in outcomes. Through this process CIAs could also serve to provide an evidence base for which outcomes based quality measures could be developed and used in the quality measure component of MIPS. This creates a cycle for which participation in a CIA can also help the EP meet their quality measurement goals – better connecting each component of MIPS.

v. What types of global and population-based measures should be included under MIPS?

vi. How should we define these types of measures?

vii. What data sources are available, and what mechanisms exist to collect data on these types of measures?

Healthy People 2020 goals should serve as a resource and foundation for developing population based measures. NKF strongly encourages CMS to develop and implement a population health measure for all patients at risk of CKD – this includes individuals with diabetes, hypertension, of African American or Hispanic descent, a family history of kidney failure and adults over age 60 – to have a documented serum creatinine and urine albumin test annually, repeated once to confirm if signs of kidney disease are present. EHRs can and should collect this data. NFK points to a measure used by the

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Indian Health Services for testing for nephropathy in people for diabetes. This measure encourages appropriate detection of CKD using a serum creatinine and urine albumin to creatinine ratio. The measure could be used more broadly and apply not only to diabetic patients, but to those with the other aforementioned risk factors.
CMS has a vested interest in ensuring that CKD is detected and managed early. Medicare spends $87 billion annually to care for patients diagnosed with kidney disease, including nearly $29 billion for most of the 636,000 individuals with ESRD.[1] As CKD advances from stage 1-4, costs nearly double from one stage to the next.[2] Over 26 million people are living with CKD, yet only 10% are aware they have it.[3] NKF anticipates that Medicare is actually spending billions more on individuals with kidney disease that have not been diagnosed. In a recent clinical study, only 12% of PCPs were properly diagnosing CKD in their patients with diabetes who are at the highest risk of kidney disease. In addition, the study found that PCPs conducted a urine albumin to creatinine ratio and a serum creatinine to estimate kidney function in only about half of their diabetic patients. Earlier detection allows the introduction of patient education and medical management that can slow the progression of the kidney disease and reduce the associated co-morbidities, such as cardiovascular events, and drug toxicity for many individuals. PCPs acknowledge that kidney disease is under recognized and that patient outcomes could be improved with increased recognition, earlier treatment of CKD, and improved collaboration with nephrologists, however, the gap in appropriate diagnosis remains.

Diagnosis of CKD is associated with patient awareness (of CKD) leading to improved opportunities for patient engagement – a key component of the National Quality Strategy and Healthy People 2020. In addition, conversations and surveys of patients with kidney disease have shown that those with kidney failure would have welcomed the opportunity to modify their lifestyle had they understood they had kidney disease and known its risks prior.

NKF encourages CMS to incorporate a population health measure for proper CKD detection across EPs and to have a CKD CIA available to help EPs improve care and management of newly diagnosed CKD patients.

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[1] United States Renal Data System, 2014 Annual Data Report: Epidemiology of Kidney Disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2014.
[2] Honeycut t AA, Segel JE, Zhuo XH, Hoerger TJ, Imai K, Wi l l iams, D: Medical Costs of CKD in the Medicare Population. J Am Soc Nephrol 2013. 24.
[3] Tuot DS, Plantinga LC, Hsu CY, et al. Chronic kidney disease awareness among individuals with clinical markers of kidney dysfunction. Clin J Am Soc Nephrol. Aug 2011;6(8):1838-1844.

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viii. Are there additional or different criteria that the Committee should use for assessing PFPMs that are specialist models? What criteria would promote development of new specialist models?

NKF has been championing the creation of an Advanced Kidney Care Model. This model would partner primary care and nephrologists to identify kidney patients with CKD stage 4 who need to be under the care of a nephrologist. The model would encourage care coordination and cost-effective, patient-centered care that can help slow progression to ESRD, reduce adverse events, and help patients that do progress to ESRD properly prepare for transplant or dialysis. The payment under this model would be capitated to nephrologists and adjusted by specific quality metrics, including some of those we identified in our above comments. Incentive payments would be given to for timely identification of CKD, proper nephrology consultation, care management, and coordination. We believe the involvement of the PCP in this model incentivizes the nephrologist's participation because often by the time a patient is referred to a nephrologist there is little the nephrologist can do to help the patient plan for transplant or dialysis. This model seeks to reduce the 41% of the population that now start dialysis unprepared and without ever having been referred to a nephrologist. Lack of referral to a nephrologist results in excess hospitalization for initiation of kidney replacement therapy.[4]

ix. We are considering that proposed PFPMs should primarily be focused on the inclusion of participants in their design who have not had the opportunity to participate in another PFPM with CMS because such a model has not been designed to include their specialty.

NKF disagrees with this proposal, those already participating in an APM have experience that can elevate Physician Focused Payment Models (PFPMs) and improve patient outcomes. Those EPS should not be excluded from participation, or limited to just one model type. It is critically important that the development of new APMs continue to enhance patient care as well as encourage new participants.

x. For the Committee to comment and make recommendations on the merits of PFPMs proposed by stakeholders, we are considering a requirement that proposals include the same information that would be required for any model tested through the Innovation Center. For a list of the factors considered in the Innovation Center's

[4] Chan MR, et. al. Outcomes in patients with chronic kidney disease referred late to nephrologists: a meta-analysis. Am J Med. Dec 2007;120(12):1063-1070.

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model selection process.
NKF supports this proposal and agrees that criteria for APMs should align across all models to ensure clarity, transparency, and consistency. This will make it easier for EPs to participate and understand the expectations.

NKF appreciates the opportunity to comment on the implementation of MACRA and looks forward to future opportunities to contribute our expertise in shaping the MIPS program.

Sincerely,

Jeffrey S. Berns *Joseph Vassalotti*

Jeffrey S. Berns, MD
President

Joseph Vassalotti, MD
Chief Medical Officer