National Kidney Foundation™

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

September 8, 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: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 CMS-1631-P

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 offer the below comments in support of proposed changes and offer additional ways to improve the physician payment and quality programs to lead to better outcomes for kidney patients.

I. **Improved Payment for the Professional Work of Care Management Services**

NKF appreciates the Center for Medicare & Medicaid Services' (CMS) efforts to better account for the time and resources that are used for chronic care

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

management. Given that CKD is widely undetected and poorly managed before patients reach ESRD or die prematurely, NKF has been working to develop strategies to overcome known barriers in CKD detection and management. One of these barriers is inadequate reimbursement.[1] Paying properly for chronic care management allows for practitioners to transition from treating acute episodes to detecting chronic conditions early, in people with key risk factors, and working to prevent associated complications. Once diagnosed, patient care requires effort that extends outside of the face-to-face office visit – as CMS has recognized in this proposed rule. While many chronic conditions are associated with one another, management for each condition and the severity of the condition may require different resources and time and this should be reflected in the practitioner's reimbursement. For these reasons, NKF recommends that chronic care management codes be established for specific conditions. For conditions that are caused by other chronic conditions (disease multipliers) and conditions that become more severe and require more time and resources establishing add on codes is an appropriate option to overcome reimbursement barriers.

Medicare spends $87 billion annually to care for patients with kidney disease, including nearly $29 billion for most of the 636,000 individuals with ESRD.[2] Over 26 million people are living with CKD, yet only 10% are aware they have it[3] and another 73 million are at risk. Risk factors for kidney disease include diabetes, hypertension, age over 60, and a family history of kidney failure. A recent study published by researchers leading the Centers for Disease Control and Prevention's (CDC) CKD surveillance program shows that the burden of CKD is increasing and that over half of U.S. adults age 30-64 are likely to develop CKD.[4] Minority populations, particularly African Americans, are disproportionately affected. African Americans are three times more likely

[1] Greer, Raquel C., Challenges Perceived by Primary Care Providers to Educating Patients About Chronic Kidney Disease, J Ren Care. Dec 2012; 38(4): 174–181.
[2] 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.
[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.
[4] Hoeger, Thomas, et al. The Future Burden of CKD in the United States: A Simulation Model for the CDC CKD Initiative, Am J Kidney Dis. 2015;65(3):403-411.

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

than whites to progress to ESRD and start dialysis at a younger age, thus spending more of their lifetime on dialysis.[5] Mortality in earlier stage CKD among African Americans under age 65 is also higher compared to European Americans.[6] Additionally, CKD is a disease multiplier that leads to cardiovascular disease, bone disease and other chronic conditions. Intervention at the earliest stage is vital to improving outcomes, lowering health care costs, and improving patient experience.

In 2012, NKF commissioned a study to determine the amount of healthcare savings that could be identified if CKD was detected and managed before comorbidities arose. While the results are under review for publication, the conservative model showed a $4.3 billion reduction in Medicare spending on CKD over 10 years, with $0.2 billion saved in the second year after improved diagnosis and management. Similarly, the Centers for Disease Control and Prevention (CDC) showed that screening for CKD in people with hypertension and diabetes was cost effective.[7]

NKF and the American Diabetes Association found in a study of PCPs and their practices in detecting CKD that in adults living with type-2 diabetes, who are at the highest risk, CKD goes largely undiagnosed and unmanaged.[8] Presumably one might think this is simply a gap in education, but the PCPs participating in the study identified the importance of testing for CKD in their diabetic patients; regardless, their practices reflected otherwise. The NKF KDOQI guidelines offer evidenced based strategies for PCPs to detect, diagnose and manage CKD. The recommendations include screening at-risk populations for CKD including those with diabetes, hypertension and age over 60 as a matter of patient safety. In individuals with CKD, certain medications that are eliminated by the kidneys need to be dose adjusted or avoided entirely to protect patients from toxic side effects and acute kidney injury – which can result in temporary kidney failure requiring dialysis and faster progression to permanent kidney failure. In addition, the guidelines recommend patients receive

[5] Centers for Disease Control and Prevention, National Chronic Kidney Disease Fact Sheet 2014, http://www.cdc.gov/diabetes/pubs/pdf/kidney_Factsheet.pdf.
[6] Mehrotra, Rajnish et al., Racial Differences in Mortality Among Those with CKD, J Am Soc Nephrol. 2008 Jul; 19(7): 1403–1410.
[7] Hoerger TJ, et al. A health policy model of CKD: 2. The cost-effectiveness of microalbuminuria screening, Am J Kidney Dis. March 2010; 55(3):463-73.
[8] Szczech LA, et al. Primary Care Detection of Chronic Kidney Disease in Adults with Type-2 Diabetes: The ADD-CKD Study (Awareness, Detection and Drug Therapy in Type 2 Diabetes and Chronic Kidney Disease), PLOS One November 26, 2014.

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

a dietary education program tailored to the stage and severity of the CKD, and the use of 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.[9]

To ensure greater attention and awareness is placed on managing CKD early, NKF recommends that CMS work with the kidney community to develop CKD Chronic Care Management codes that reflect the time and resources needed to manage CKD at each stage and when comorbidities are present. If CMS were to develop disease specific management codes, then when CKD is secondary to another condition (such as diabetes) an add-on code for the CKD is appropriate. Creating tiers for add-on codes to reflect the severity of the disease aligns reimbursement with resources rendered.

A tiered management strategy for CKD is also supported by the literature.[10] Aligning reimbursement with this approach could improve early detection and management of CKD by primary care practitioners as well as appropriate referral and co-management with nephrology for patients who advance to later stages of CKD and are in need of more intensive interventions. Such referral has been associated with significant improvements in care and healthcare savings.[11, 12] Recognizing the potential for cost savings and improved outcomes, the United Kingdom is one country that has already taken action to improve detection of CKD by aligning financial incentives with detection in targeted risk populations.[13]

The below table illustrates what activities/services a tiered management and reimbursement strategy might include at different stages of CKD.

---

[9] Inker LA, Astor BC, Fox CH, et al. KDOQI US commentary on the 2012 KDIGO clinical practice guideline for the evaluation and management of CKD. Am J Kidney Dis. 2014;63:713-735.

[10] Wouters, Oliver J., et al. Early chronic kidney disease: diagnosis, management and models of care, Nature Reviews Nephrology 11, 491–502 (2015), published online June 9, 2015 http://www.nature.com/nrneph/journal/v11/n8/full/nrneph.2015.85.html.

[11] 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.

[12] Smart, NA, et al., Early referral to specialist nephrology services for preventing the progression to end-stage kidney disease, Cochrane Database Syst Rev. 2014 Jun 18;6: Accessed online June 19, 2015.

[13] Wouters, Oliver J., et al. Early chronic kidney disease: diagnosis, management and models of care, Nature Reviews Nephrology 11, 491–502 (2015), published online June 9, 2015 http://www.nature.com/nrneph/journal/v11/n8/full/nrneph.2015.85.html.

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

CKD Stages	Inputs	Billing Frequency
1-3	• Ordering and assessing quarterly lab data to determine progression • lipid management, • medication dose adjustment, • medication reconciliation, • blood pressure management, • lifestyle modification education, • dietary modification education/referral to dietitian and communication with dietitian, • patient education and communication with the patient's other health care providers about avoidance, when possible, of contrast induced media and prescription and over the counter non-steroidal anti-inflammatory drugs (NSAIDs)	No more than quarterly
CKD stage 4-5 (not yet on renal replacement therapy)	Nephrology/Primary Care Practitioner collaboration, treatment/management of anemia and bone disease • Dietary education/management • Education on renal replacement therapy options – including end of life decision making and advanced care planning • Preparation and coordination with vascular access surgeon or surgeon/interventional nephrologists/radiologist for placement of PD catheter if dialysis is chosen • Coordination with transplant	At least quarterly. For many patients with late stage 5 CKD these would be more frequent as part of routine visits.

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

	center if transplant is chosen (I deleted surgeon since others also involved) • Mental health assessment and coordination with specialist if warranted	

From a beneficiary perspective a disease specific care management approach also delivers more value to the patient as they are an integral part of care management. For CKD, this approach is likely to improve patient awareness of their CKD as well as help patients understand and take a more proactive role in managing their disease. Unfortunately, for chronic care management patients are currently subjected to a 20% coinsurance. Patients may unexpectedly receive a bill for these services and even with the best of information and the requirement that patients approve these services, some patients may not be prepared for this expense or understand what value they are receiving for these services. The CCM also puts patients in a difficult position of having to mediate, which of their practitioners is billing for the CCM services. Having specific disease CCMs may help resolve some of these challenges for patients as they are more likely to be better engaged in the management. However, NKF believes beneficiaries should not have a coinsurance for care management services as it is a barrier for patients to benefit from these important services.

II. Medicare Telehealth Services

NKF supports the proposal to add four home dialysis related codes (90963, 90964, 90965, and 90966) to the list of telehealth services. These codes reflect services that do not always require in-person care, such as nutrition adequacy assessments, growth and development assessment, and caregiver counseling for children, as well as, appropriate assessments and monitoring for the adult home dialysis population. NKF also is pleased with the clarification that nephrologists can use telehealth to communicate with their patients during the month, after the first in-person visit has occurred, and receive payment under the Monthly Capitated Payment (MCP) for doing so.

Telehealth services lessens the burden many rural patients and their caregivers have commuting long distances to see their health care providers. Patients are more likely to use these important services if they do not have to

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

commute to the nephrologists' offices. However, these patients and caregivers must still commute to a telehealth originating site. Permitting freestanding dialysis facilities and patients' homes, equipped with the proper technology, to serve as originating sites can help alleviate this burden. NKF also notes that currently, hospital based dialysis facilities may serve as an originating site, but freestanding facilities are not afforded the same opportunity. If equipped with the technology, there is no reason a dialysis facility or a patient's home cannot also serve as an originating telehealth site.

III. PQRS

a. Adult Kidney Disease: Referral to Hospice

NKF strongly supports inclusion of this measure in PQRS. Studies have indicated there is an underuse of hospice by dialysis patients leading to increased Medicare costs because dialysis patients at the end of life are more frequently hospitalized and often die in the hospital.[14] When patients choose to stop dialysis they should be referred to hospice care where they can receive palliative care in a setting designed to also facilitate psychological support and acceptance of death for the patient and their families. In addition, patients who are not eligible for hospice services may benefit from palliative care consultation for severe complex and difficult to manage pain, patient/family communication challenges or other issues.

b. Removal of hemodialysis and peritoneal dialysis adequacy measures

While NKF recognizes high performance on *Adult Kidney Disease: Hemodialysis Adequacy: Solute:* and *Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute:* we believe these measures should remain in PQRS as they are also in the ESRD Quality Incentive Program (QIP). Including the measures in both programs recognizes the importance of this core function as one of the means for prescribing and delivering quality dialysis care.

[14] Murray, Anne, et al. Use of Hospice in the United States Dialysis Population, *Clin J Am Soc Nephrol,* November 2006; (6): 1248-1255.

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

c. **Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial Venous (AV) Fistula**
As long as the ESRD QIP continues to measure AV Fistula use, NKF encourages CMS to retain this measure in PQRS as it is important that measures used to assess quality for a patient population are consistent across their healthcare providers. We believe that this measure has helped foster increased use of AV fistulas and decreased catheter placement, which is the goal of the CMS Fistula First Initiative. Given high performance on this measure and in recognition that an AV Graft may also be an appropriate access for patients, NKF believes for both PQRS and the ESRD QIP future vascular access quality measures should focus on reductions in catheter use. Catheters pose a significant risk of infections to patients and should only be used in limited circumstances.

d. **Additional measures needed to improve early CKD detection and care**
There remains only one measure in PQRS related to early detection and management of CKD, yet the measure is not adequate to ensure greater patient and practitioner awareness of CKD status. In addition, PQRS does not contain important safety and care coordination measures that can slow or prevent CKD progression, reduce comorbidities, prevent acute kidney injury and appropriately prepare patients for renal replacement therapy. For these reasons NKF recommends the following new measures be added to PQRS:

i. **Replace PQRS 119 Diabetes: Medical Attention for Nephropathy with the measure developed by the Indian Health Services for diabetic nephropathy.**
The Indian Health Services (HIS) measure for diabetic nephropathy is a more actionable measure to PQRS 119 as it provides CKD diagnostic and risk stratification information to the physician. The IHS measure is also consistent with the KDOQI U.S. commentary on the KDIGO guidelines for diagnosis of CKD, which highlight the preference for a documented eGFR and albumin to creatinine ratio (ACR). Documentation of both

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

eGFR and ACR indicates the severity of kidney damage and the risks for adverse outcomes including cardiovascular disease, progression to ESRD, acute kidney injury and death. This information is necessary for physicians to determine the best course of treatment for patients or to determine if nephrology referral is necessary. Recognition of impaired eGFR is the first step to promoting patient safety in those with CKD.[9]The IHS measure recognizes the importance of ACR in testing for kidney disease in diabetics to assess cardiovascular and ESRD progression risks.[15]

In addition, KDOQI guidelines for detecting CKD do not vary between diabetics and those with hypertension – the second leading cause of CKD. Given that the Hypertension: Urine Protein Test measure was removed from PQRS last year applying the IHS measure in people with hypertension, would also fill a current gap in quality measurement.

ii. Developing a patient safety measure for NSAID avoidance in patients with at least two eGFR values < 45 ml/min/1.73m^2 at least 90 days apart could reduce the occurrence of acute kidney injury (AKI) and prevent progression of CKD for many individuals.

More than 98 million NSAIDs prescriptions were filled in 2012 and NSAIDs.[16] Over-the-counter and prescription NSAIDs are frequently associated with community-acquired acute kidney injury (AKI), a strong risk factor for development and

[15] Resource and Patient Management System, Office of Information Technology (OIT) Division of Information Technology, IHS Clinical Reporting System, Selected Measures (Local) Report, Performance Measure List and Definitions, Diabetes: Nephropathy Assessment p. 20-22. Version 15.1 May 2015 http://www.ihs.gov/crs/documents/crsv14/GPRAMeasuresV140.pdf

[16] Delmas PD. Non-steroidal anti-inflammatory drugs and renal function. Br J Rheumatol 1995; 34 (suppl 1): 25–28.

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

progression of chronic kidney disease.[9, 17] A recent analysis showed that among the U.S. stratified random sample of 12,065 individuals in the cross-sectional National Health and Nutrition Examination Survey with estimated glomerular filtration rates between 15 and 50 mL/min/1.73m2, 5% reported using OTC NSAIDs regularly and 66.1% had used these agents for 1 year or longer.[18] A U.K. population study showed over 4000 fewer NSAID prescriptions following eGFR reporting (adjusted odds ratio 0.78). Furthermore, follow-up data confirmed that the 1511 individuals with eGFR < 60 mL/min/1.73m^2 experienced significant improvement in kidney function following withdrawal of NSAIDs. [19]

iii. Developing a care coordination measure for co-management of nephrology and primary care for patients with patients with two eGFR values < 30 ml/min/1.73m2 at least 90 days apart is an opportunity to improve outcomes and lower health care costs for those with stage 4/5 CKD, who are not receiving renal replacement therapy. Detection of CKD allows for collaborative care between primary care and nephrology practitioners. This is critical for patients with severe or difficult to manage disease. Extensive uncontrolled observational data demonstrate that outcomes improve when patients with progressive CKD are referred to a nephrologist in a timely fashion. Patients not referred to a nephrologist in advance of ESRD have a higher risk of morbidity and mortality and increased healthcare costs.[9]

The evidence that there are gaps in referral care for patients with progressive CKD is reflected by the Medical Evidence Form

[17] Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2012 clinical practice guideline for the evaluation and management of chronic kidney disease. Kidney Int Suppls. 2013;3:1-150.
[18] Plantinga L, Grubbs V, Sarkar U, et al, CDC CKD surveillance team. Nonsteroidal Anti-Inflammatory Drug Use Among Persons With Chronic Kidney Disease in the United States. Ann Fam Med. 2011; 9: 423-430.
[19] Wei L, Macdonald TM, Jennings C, Sheng X, Flynn RW, Murphy MJ. Estimated GFR reporting is associated with decreased nonsteroidal anti-inflammatory drug prescribing and increased renal function. Kidney Int. 2013;84(1):174-8

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

(CMS 2738) as virtually all U.S. citizens who are diagnosed with chronic kidney failure, administratively known as end-stage renal disease (ESRD) are eligible for Medicare. Based on CMS 2728 data collection, 41% of patients did not see a nephrologist before initiating dialysis in 2012.[20] To address suboptimal care in the transition to ESRD, the federal legislature created the stage 4 CKD education benefit was created by the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110-275) to promote improved management of advanced CKD, but this benefit has been significantly underused.

Approximately 100 observational trials have demonstrated improved outcomes for patients with early versus late nephrology referral, including improved survival, reduced duration of hospitalization, increased access to home dialysis, reduced use of hemodialysis catheters, and higher utilization of pre-emptive kidney transplantation. These differences persist after statistical adjustment for selection biases between the early and late referral population. Increasing access to nephrology services will improve outcomes for patients.[21, 22, 23, 24, 25, 26, 27]

---

[20] U.S. Renal Data System. USRDS 2014 Annual Data Report, NIDDK, NIH. 2014.

[21] Chan MR, Dall AT, Fletcher KE, Lu N, Trivedi H. Outcomes in patients with chronic kidney disease referred late to nephrologists: a meta-analysis. Am J Med. Dec 2007;120(12):1063-1070.

[22] Haley WE, Beckrich AL, Sayre J, et al. Improving Care Coordination Between Nephrology and Primary Care: A Quality Improvement Initiative Using the Renal Physicians Association Toolkit. Am J Kidney Dis. Aug 30 2014

[23] Jungers P, Massy ZA, Nguyen-Khoa T, et al. Longer duration of predialysis nephrological care is associated with improved long-term survival of dialysis patients. Nephrol Dial Transplant. Dec 2001;16(12):2357-2364.

[24] Kinchen KS, Sadler J, Fink N, et al. The timing of specialist evaluation in chronic kidney disease and mortality. Ann Intern Med. Sep 17 2002;137(6):479-486.

[25] Lin CL, Chuang FR, Wu CF, Yang CT. Early referral as an independent predictor of clinical outcome in end-stage renal disease on hemodialysis and continuous ambulatory peritoneal dialysis. Ren Fail. Sep 2004;26(5):531-537.

[26] Roderick P, Jones C, Drey N, et al. Late referral for end-stage renal disease: a region-wide survey in the south west of England. Nephrol Dial Transplant. Jul 2002;17(7):1252-1259.

[27] Winkelmayer WC, Owen WF, Jr., Levin R, Avorn J. A propensity analysis of late versus early nephrologist referral and mortality on dialysis. J Am Soc Nephrol. Feb 2003;14(2):486-492

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

NKF would welcome the opportunity to work with CMS on the development and implementation of these measures that could have a significant impact on outcomes for CKD patients.

IV. The Merit-based Incentive Payment System (MIPS)

NKF looks forward to implementation of MIPS and believes this offers CMS a significant opportunity to facilitate improvements in outcomes for Medicare beneficiaries, particularly those with chronic conditions. In our comments on chronic care management codes contained previously in this letter, we recommend CMS create CKD specific care management codes. Given the significant under-diagnosis and suboptimal management of CKD, the growing public health burden, and high costs associated with CKD, NKF believes strongly this is an area where significant opportunity exists to improve outcomes for beneficiaries and lower Medicare costs. Given this opportunity and as CMS moves forward with transforming physician payment to pay for value over volume, NKF offers the following comments on how CMS can further its goals to tie payment to value and lower health care costs by aligning incentives with improvements in CKD care.

a. Clinical practice improvement activities

Given the significant opportunity to improve outcomes and lower Medicare costs, NKF strongly recommends a clinical practice improvement activity to improve detection, diagnosis and management of CKD be used in MIPS. Such a program could also help accomplish key Healthy People 2020 goals. CKD represents a defined patient population in which there are evidence based clinical practice guidelines that can reduce adverse events, including heart attack and stroke. In a most recent study conducted by The Johns Hopkins University, testing for kidney disease – in those with the disease – may be a stronger risk predictor of heart attack and stroke than tobacco use, blood pressure, or high cholesterol.[28]

[28] Matsushita, Kunihiro, Estimated glomerular filtration rate and albuminuria for prediction of cardiovascular outcomes: a collaborative meta-analysis of individual participant data, Lancet Diabetes Endocrinol. Published online May 29, 2015, http://dx.doi.org/10.1016/S2213-8587(15)00040-6.

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

Similar to our recommendations, earlier in this letter, regarding creating specific chronic care management codes for CKD management, a CKD clinical improvement activity could also use a tiered approach dependent on CKD stage. It could include risk stratification to identify those at greatest risk of progressing to ESRD who are in need of more intensive care and address patient safety issues, such as medication dose adjustments, avoidance of nephrotoxic agents, and regular monitoring of kidney function and urine albumin. Along these lines, NKF has done considerable work to develop a program, CKD Intercept, which will transform primary care practice to improve diagnosis, management and patient awareness of CKD. Key aims of this program could be included in a CMS clinical practice improvement activity and be designed to meet 4 out of the 6 subcategories required by Medicare Access and CHIP Reauthorization Act (MACRA), as reflected in the table below.

CKD Clinical Improvement Activity Aims	MACRA Clinical Improvement Activity subcategories
Improve CKD diagnosis and risk stratification among patients being treated for diabetes and hypertension in primary care settings.	• *Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry.*
Improve adherence to CKD-related clinical guidelines and performance measures to reduce mortality, morbidity and costs associated with cardiovascular complications of CKD in both primary care and nephrology.	• *Patient safety and practice assessment, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification*
Increase clinician counseling about CKD, patient awareness of CKD, patient knowledge of self-management activities to improve CKD-related outcomes, and patient activation in applying self-management recommendations. Improving primary care physician diagnosis of CKD can increase patient awareness of CKD and its inherent risks. Providing feedback to clinicians regarding patient gaps in knowledge and understanding will improve clinician CKD-related	• *Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.*

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

counseling over time.	
Improve medication management among CKD patients including reduction of the prescription and use of NSAIDs and avoidance of contrast media– when possible. Improving documentation of CKD and current medications in the medical record can reduce the prescription and use of nephrotoxic drugs in people with CKD. Improved patient awareness of the necessity of NSAID and contrast media avoidance will result from improved CKD-related medication management	• *Patient safety and practice assessment, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification.* • *Care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth.*
Improve referral to nephrology for those CKD patients meeting an estimated glomerular filtration rate (eGFR) of less than 30 ml/min/1.73 m2. Improving referral to nephrology can result in increased adherence to advanced CKD treatment guidelines for patients with late stage CKD reducing emergent RRT starts and thereby decreasing related hospitalizations.	• *Care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth.*
Increase utilization of shared decision-making and advance care planning to reduce high costs associated with end-of-life care. Data suggest that elderly patients in high intensity health care environments may incur greater health care costs at end of life which may be a reflection of limited preparation and advance care planning. The Choosing Wisely campaign has recommended that a shared decision making process be encouraged between patients, their families, and their physicians before the initiation of dialysis.	• *Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.*

NKF would be pleased to work with CMS on the design of a CKD improvement activity to be included in MIPS.

b. Alternative Payment Models (APMs)
NKF believes APMs that hold practitioners accountable for quality improvement and lower health care costs provide a significant opportunity to improve CKD outcomes. However, there is need to ensure that these models include CKD related quality improvement activities and measures to ensure practitioners are devoting time and

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

attention to CKD. Per our recommendations on new measures to add to the PQRS program, NKF recommends CMS ensure that APMs include the IHS measure Diabetes: Nephropathy Assessment as well as CKD related objectives such as NSAID avoidance and nephrology co-management. In addition, we recommend that CMS incorporate practice transformation and clinical improvement activities for CKD into these models. These CKD measures and activities are particularly well-suited for models targeting primary care, such as primary care medical homes, Medicare shared savings programs, accountable care organizations, the Million Hearts Initiative model, as well as others.

In closing, NKF appreciates the opportunity to comment on the proposed rule. We are looking forward to the changes to better align healthcare quality and value with payment and strongly believe a focus to address CKD by removing reimbursement barriers to CKD diagnosis and management and establishing quality metrics and clinical improvement activities for CKD patients in stages 1-4 will significantly improve cardiovascular outcomes, mortality, morbidity and progression to ESRD for millions of Medicare beneficiaries living with CKD.

Sincerely,

Jeffrey Berns *Joseph Vassalotti*

Jeffrey Berns, MD
President

Joseph Vassalotti, MD
Chief Medical Officer