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August 18, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

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:

This letter addresses the questions in the proposed rule, CMS-1651-P, related to the care of patients with Chronic Kidney Disease (CKD) and Alternative Payment Models (APMs) and Advanced Alternative Payment Models (AAPMS). The National Kidney Foundation (NKF) appreciates CMS's interest in exploring how APMs could better improve the care of patients with CKD and those that progress to End-Stage Renal Disease (ESRD). NKF believes a comprehensive approach is needed to improve outcomes and lower costs of care for kidney patients and achieve the ideal spectrum of care for patients who often are not engaged in self-management and shared decision making until after their kidneys have failed. First, earlier detection and management of CKD by primary care practitioners is a critical gap in care in the U.S. that must be addressed. Second, improved management of CKD stages 4 and 5 by the nephrology care team is necessary to preserve kidney function, manage comorbidities, and better prepare and educate patients at greatest risk for progression to ESRD about renal replacement therapy options including dialysis, transplant, or comprehensive supportive care. Third, it is important to look beyond dialysis facilities to improve outcomes and care coordination for ESRD patients.

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NKF has summarized clear actionable steps CMMI could take to improve outcomes for CKD patients throughout the spectrum of their disease.

- Provide payment incentives within APMs/AAPMs, particularly primary care models, to detect and properly manage CKD stages 3b among those that are at highest risk (those with diabetes, hypertension and a family history of kidney failure, or who have documented evidence of CKD progression) and include CKD related performance measures into these models
- 2. Incorporate CKD practice transformation activities that are in in alignment with evidence based clinical practice guidelines for CKD treatment into primary care APMs
- 3. To ensure primary care APMs are accountable and incentivized for better, earlier CKD care and improved ESRD transitions, patients should remain aligned to their current primary care APM/AAPM for 6 -12 months after starting dialysis, if their dialysis facility is participating in the Comprehensive ESRD Care (CEC) initiative
- 4. To promote transplantation, transplant evaluation and surgical costs related to the transplant should be excluded from the financial benchmark for APMs, but rewarded.
- 5. Realign the financial incentives of nephrologists to encourage an enhanced focus on preserving kidney function and improving patient outcomes as well as greater accountability for appropriate transitions for those who do progress to ESRD. Nephrologists should be accountable for ESRD starts including, advanced vascular or peritoneal dialysis (PD) access placement and pre-emptive transplant. Consider rewarding nephrologists for pre-emptive transplants with a higher payment than they would receive during the year if the patient started dialysis.
- 6. Encourage APMs to partner with community based organizations with expertise in patient education and engagement to provide tools and resources to help patients in their communities better engage in self-management
- 7. Develop and pilot a patient-focused, CKD specific APM/AAPM that includes PCP detection and management of CKD stage 3b and nephrology practitioner care management of CKD 4/5 patients to realize lower costs and study additional improvements in patient outcomes. NKF has convened a multi-stakeholder workgroup of PCPs, nephrologists, advanced practitioners, a dietitian, and patients to develop a patient-focused payment model to submit to CMMI and the Physician-Focused Payment Model Technical Advisory Committee (PTAC). NKF is hosting this workgroup in collaboration with the Renal Physicians Association and Northwell Health.

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8. To improve the care of dialysis patients in the CEC model hospitals should be required to provide discharge information directly to dialysis facilities. In addition, ESCOs should be encouraged to collaborate with other health care providers such as PCPs, hospitals, and transplant centers.

Primary Care Models and APMs such as the Patient-Centered Medical Home, Accountable Care Organizations, Medicare Shared Savings Program participants, and the Comprehensive Primary Care (CPC) Initiatives are well positioned to drive large-scale improvements in earlier detection and care of CKD patients thereby improving outcomes for patients and substantially lowering health care costs. However the use of financial motivators, practice transformation activities, and appropriate quality metrics that address CKD care are necessary to include in these APMs to drive focus and action on a condition that is often missed and unaddressed.

Approximately 26 million adults have CKD, yet only 10% are aware they have it – 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. CKD has no distinguishable symptoms in its early stages and is often not diagnosed until complications occur or until the very late stages of the disease. Lack of awareness leaves little opportunity for patient self-management, and shared-decision making. To better understand the gaps in diagnosis of CKD, NKF and the American Diabetes Association partnered to conduct 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. Only a little over half of the practitioners in the study diagnosed CKD when it was present, and only 12 percent of practitioners used both serum creatinine and urine albumin to creatinine ratio (UACR) to detect for CKD in their patients. The study was also the first to show that detection of CKD by the PCP was strongly associated with patient awareness, which provides the opportunity for patient engagement. Patient engagement is a key goal of the National Quality Strategy and increasing patient awareness of CKD is a Healthy People 2020 objective that has seen no progress.² 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.

¹ 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.

² U.S. Department of Health and Human Services, Office of Disease and Health Promotion, Healthy People 2020, 2007-2012. www.healthypeople.gov.

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The Medicare program spends \$99 billion on the care of individuals diagnosed with CKD. This includes \$31 billion in spending on the care of ESRD patients.³ Earlier detection allows the introduction of low-cost patient education and medical management that can slow the progression of the kidney disease, reduce associated co-morbidities, limit cardiovascular events, and avoid drug toxicity for many individuals. While PCPs acknowledge that the significance of kidney disease is underappreciated and that patient outcomes could be improved with increased recognition, earlier treatment of CKD, and improved collaboration with nephrologists,⁴ the gaps in appropriate diagnosis and earlier care of CKD patients remain. Therefore, it is critical to provide education and other "motivators" to promote appropriate guideline driven care in those identified with CKD.⁵

For many of the Primary Care APMs, CMS relies on the Medicare Advantage (MA) risk adjustment model as a way to offset the costs of caring for complex patient populations and to protect against adverse selection of patients. However, while unintended, the model motivates healthcare practitioners to assess patients for health conditions they may have that are also undiagnosed. In previous years CKD stages 1-3 were included in the risk adjustment model, but were removed this year. Under the previous years' model, CKD diagnosis of stage 1-3 beneficiaries was higher among MA plans than it was among Medicare Fee-For-Service beneficiaries. Since APMs use the risk adjustment model and it has been associated with increased recognition of CKD, NKF recommends that CMS restore the risk adjustment for CKD 3a/b patients. The model already risk adjusts for patients with CKD 4 and 5, but evidence also shows that risk adjustment is appropriate for CKD 3 patients as the costs of caring for them is double the spending on the average Medicare beneficiary.⁶

As an alternative to using the MA risk adjustment model, CMS could provide CKD management payments to PCPs to care for CKD 3 patients contingent on ensuring their at-risk patient population is properly assessed for CKD. Since CKD is diagnosed using two simple tests, serum creatinine and UACR (a urine protein to creatinine ratio or a urine dipstick test for protein may

³ United States Renal Data System. 2015 USRDS 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, 2015.

⁴ Allen AS, Forman JP, Orav EJ, Bates DW, Denker BM, Sequist TD. Primary care management of chronic kidney disease. J Gen Intern Med. Apr 2011;26(4):386-392.

⁵ Tuot DS, Plantinga LC, Hsu CY, Powe NR. Is awareness of chronic kidney disease associated with evidence-based guideline-concordant outcomes? Am J Nephrol. 2012;35(2):191-197.

⁶ United States Renal Data System. 2015 USRDS 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, 2015.

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be used instead), there is little risk for inappropriate or over diagnosis as it can be verified through lab data. In fact, the Indian Health Services uses a performance measure in patients with diabetes that requires practitioners to have an estimated Glomerular Filtration Rate (eGFR) and urine albumin result on record for each diabetic patient. A similar quality measure could be used to evaluate proper detection of the highest risk patients – those with diabetes and hypertension.

Additionally, the new CPC Plus initiative, as a multi-payer model, provides a unique opportunity to also align other healthcare payers with earlier detection and management of CKD and produce even greater downstream savings to CMS, as there are many individuals with undiagnosed CKD who are not in the Medicare program. NKF is working with 10 different payors who encompass 20 million lives. These conversations have created the opportunity for as many as 2 million people with undiagnosed CKD to be identified.. Researchers leading the Centers for Disease Control and Prevention's (CDC) CKD surveillance program published findings from their simulation model that shows that the burden of CKD is increasing and that over half of U.S. adults age 30-64 are likely to develop CKD, further underscoring the need to include commercial payers and Medicaid programs in efforts to improve earlier CKD care.

Interventions actionable by the PCP

Ultimately the goal of management in CKD 3b patients is to prevent or delay progression and to lower risk of adverse events. In a recent study conducted by faculty at The Johns Hopkins University, testing for kidney disease was identified as being a stronger risk predictor of heart attack and stroke than tobacco use, high blood pressure or high cholesterol. While there is evidence that improving processes in the care delivery of CKD patients is associated with improved outcomes, research is still lacking to support the leap to outcomes-based measures as different patient populations progress at varying rates and the cause of kidney disease also affects progression. Therefore, using outcomes based measures ahead of studying process improvements could unfairly hold practitioners accountable for factors beyond their control. However, APMs offer the opportunity to drive process improvement and create data on the effect those process improvements have on outcomes, as is being done in the Million Hearts® Cardiovascular Disease (CVD) Risk Reduction Model.

Published earlier this year in the American Journal of Medicine, Practical Approach to Detection and Management of Chronic Kidney Disease for the Primary Care Clinician, provides a clear road

⁷ 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.

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map for how the KDIGO clinical practice guidelines for CKD evaluation and management can be implemented into primary care practice. The recommendations include screening at-risk populations for CKD, including those with diabetes and hypertension, 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 (AKI) – which can result in temporary kidney failure requiring dialysis and faster progression to permanent kidney failure. 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 is supported with a high level evidence to slow or prevent progression.⁸ In addition, the guidelines recommend patients receive a dietary education program tailored to the stage and severity of the CKD. Receipt of dietary education from a renal dietitian is a key component of providing patients with actionable strategies to help self-manage their CKD.

More than 98 million NSAIDs prescriptions were filled in 2012. Over-the-counter and prescription NSAIDs are frequently associated with community-acquired AKI, a strong risk factor for development and progression of CKD. 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 eGFR 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. 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/1.73m² experienced significant improvement in kidney function following withdrawal of NSAIDs. ^{9,10,11,12,13} Avoiding prescription use of NSAIDs and counseling patients on over-the-counter use is an important patient safety strategy and can empower patients to preserve their kidney function.

⁸ Vassalotti, Joseph A. et al., Practical Approach to Detection and Management of Chronic Kidney Disease for the Primary Care Clinician, Am J Med, February 2016; 129 (2): 153 - 162.e7.

⁹Delmas PD. Non-steroidal anti-inflammatory drugs and renal function. *Br J Rheumatol* 1995; 34 (suppl 1): 25–28 ¹⁰ 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.

¹¹ 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.

¹² 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.

¹³ 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.

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For patients that do progress to CKD stage 4 and 5, co-management between a PCP and nephrologist is strongly recommended and associated with lower healthcare costs. The evidence that there are gaps in referral care for patients with progressive CKD is reflected by the Medical Evidence Form (CMS 2728) as virtually all U.S. citizens who are diagnosed with ESRD are eligible for Medicare. Based on CMS 2728 data collection, 41% of patients did not see a nephrologist before initiating dialysis in 2012. Although CKD is a progressive disease; most of these individuals did not know they had it prior to their kidneys failing. This is a clear indication that the needs of a sizable segment of beneficiaries with a chronic disease are not being met, oftentimes not even acknowledged. Other studies have also shown that referral to a nephrologist prior to dialysis initiation leads to lower mortality and hospitalization. In addition, Medicare data suggests lower spending results for patients with CKD stage 4 when they visit a nephrologist 1-2 times per year.

Improvements in referral to nephrology allow nephrologists to act in time to preserve kidney function, manage comorbidities, and improve care transitions for those that do progress to ESRD. APMs that include both nephrologists and PCPs are in the best position to improve outcomes for kidney patients as presumably PCPs have improved opportunities to consult with nephrologists about their CKD 3b patients while still serving in the primary role in caring for these patients – referring their CKD care management to nephrology practitioners once the patient reaches CKD stage 4. This allows nephrologists to focus on the more difficult to manage CKD 4/5 patients and reduces referral of earlier CKD patients to specialty services leading to smarter spending. The shared accountability for improved quality and lower costs creates an added incentive for collaboration and coordination between PCPs and nephrologists.

CKD Quality Measures for Primary Care Practitioners

Performance measures in CKD are limited. The only measure in use by CMS (but not included in the measure set for ACOs and MSSPs) is an NCQA developed measure for diabetic nephropathy assessment. Unfortunately, that measure is not an indicator of appropriate detection and monitoring of kidney disease in patients with diabetes. The measure permits practitioners to forgo testing and diagnosis of CKD as long as the patient has been prescribed an ACE inhibitor or an ARB. As a result practitioners can be led to believe they have addressed CKD when in

¹⁴ 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.

¹⁵ United States Renal Data System. 2015 USRDS 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.

¹⁶ Avalere Health analysis of 2013 Medicare 5% claims data. Spending represents total payments in all settings for patients enrolled in fee-for-service.

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reality they may not be appropriately diagnosing CKD and monitoring their patient for progression. In contrast, the Indian Health Services (IHS) developed and uses a measure for diabetic nephropathy that requires an eGFR and UACR be documented annually (once within the reporting period). This measure is in better alignment with the NKF and American Diabetes Association clinical practice guidelines for assessing kidney disease in diabetes. The measure could also be used in patients with hypertension. While not endorsed by the National Quality Forum (NQF) because the IHS does not need NQF endorsement to implement measures in their own program, it is a readily available performance measure that can be used by APMs to assess appropriate detection and monitoring of CKD.

NKF is also in the process of developing two performance measures: (1) avoidance of NSAIDs and counseling patients against over-the-counter NSAID use for patients with an eGFR of less than 45 ml/min/1.73m² and (2) Nephrology consultation for patients with an eGFR less than 30 ml/min/1.73m² or eGFR less than 45 ml/min/1.73m² and severe proteinuria or albuminuria. Both measures could be used to assess the quality of CKD care delivered to patients. We expect these measures to be completed and ready for use by early 2018.

Together these three measures could serve as a core measure set to evaluate appropriate detection and care of CKD patients by primary care practitioners. However, given that PCPs recognize the importance of CKD, but on a large scale have not appropriately acted to address it, education and practice improvement is necessary to realize the goals of better, earlier CKD care.

Practice Transforming Activities and Education

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. NKF has been a leading provider of continuing medical education for kidney health for decades and has now created a curriculum and program to help implement practice transformation in primary care to detect kidney disease early, improve patient safety, and avoid adverse events and outcomes associated with kidney disease. NKF encourages CMS to incorporate CKD specific practice transformation into primary care APMs. This will help practitioners in those models improve earlier detection and management of CKD, thereby preventing complications and reducing costs associated with missed CKD.

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CKD is not ESRD and ESRD is not just dialysis

We must move away from a frame of mind of considering all CKD patients, even those in stage 4, as pre-dialysis patients. While most patients with ESRD do start dialysis after their kidneys fail, it has become the presumed choice of modality in the minds of many practitioners and policy makers, which has led to missed opportunities for pre-emptive transplants, and conversations about comprehensive conservative care – for those patients whose ideal or even acceptable quality of life is unlikely to be achieved through dialysis. As previously stated, not all patients will progress to ESRD. Many patients can remain in their CKD stage indefinitely, but there is also high mortality among stage 4 patients. Thus, the focus of nephrology care for patients that progress to Stage 4 is also on preserving kidney function, while addressing other comorbidities that occur in advanced CKD patients and improving quality of life and life expectancy. For patients who continue to progress and approach an imminent need for RRT the focus becomes on ensuring patients are educated about all of their options, including comprehensive conservative care, and feel confident in their ability to make the care choice that aligns with their personal goals, values and preferences. Nephrology practitioners should focus on ensuring the patient is properly prepared for that option when the time comes.

For patients wanting a transplant, preparation should begin around the time their eGFR reaches 20 ml/min/1.73m² as they are able to get on the transplant wait list and seek a living donor if they choose. For patients that choose or will ultimately need dialysis it is important to ensure a permanent access (vascular or PD) is placed in advance so they do not start dialysis with a hemodialysis catheter – and later need subsequent surgery to place a permanent access. However, we recognize for a limited number of patients (such as those with limited life expectancy) a catheter may be the appropriate access choice.

While the care described above represents the ideal patient journey through CKD, unfortunately it rarely occurs. The current reimbursement system rewards dialysis starts over other options such as transplantation and comprehensive conservative care. Current APMs such as the ACOs and MSSPs that operate in markets where there are End-stage Renal Disease Seamless Care Organizations (ESCOs) are not held accountable for proper ESRD transitions and in fact could be penalized for care improvements that are made to ensure optimal ESRD starts. This was worsened by changes in policy at the launch of the CEC. As a result of the challenges faced by smaller dialysis organizations to meet the patient number threshold to participate in the CEC, policy was changed so that CKD patients who may have been previously aligned to an ACO, MSSP or other APM are instead reassigned to an ESCO after starting dialysis in a facility that is participating in the CEC. This created an unintended consequence of removing accountability for the quality of care and costs for these patients from the primary care APMs. Patients who will imminently transition to ESRD have upfront costs associated with appropriate preparation,

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including transplant evaluation and dialysis access placement. If advanced preparation is improved for a greater number of CKD patients costs to the APM will actually increase initially, as the savings results downstream. As a result it will be the ESCO that benefits from a properly started dialysis patient and not the ACO or MSSP or other principle APM, which misaligns incentives to improve care. While ESCOs are limited in number this could be a disadvantage to efforts to improve patients' care in markets where ESCOs are present. As CMS seeks to expand the ESCO program, beneficiary alignment to APMs need to be carefully considered. NKF recommends that patients remain aligned with the principle APM for 6-12 months after they begin dialysis before being aligned to an ESCO. This may require CMS to modify the required number of patients for facilities to participate in CEC to ensure smaller dialysis organizations are not excluded.

To better align payment with value in nephrology care, managing CKD 4/5 patients not on RRT needs to be valued higher with greater accountability placed on nephrologists for proper ESRD starts. Managing these patients takes a considerable amount of time and effort as they are not a captive audience that the nephrologist interacts with on a frequent basis. CMS should align the financial incentives of nephrologists to enhance accountability for appropriate transitions to ESRD and reward them for proper ESRD starts including pre-emptive transplant. One option recommended by NKF is to provide nephrologists with an upfront care management payment, as we recommended for PCPs that is then tied to performance on quality metrics and reductions in costs. This could be incorporated into existing APMs or conducted separately.

NQF has endorsed the performance measure, 2594 Optimal ESRD Starts, which measures nephrologists or health systems performance to ensure that patients do not start hemodialysis with a catheter in place. Applying this measure to nephrologists or APM entities that have 50 new ESRD patients seen within the previous year (as recommended by the measure developer) would enhance accountability of nephrologists, and the APM entities they may participate in, for improving the transition of ESRD patients and lowering healthcare expenditures by reducing hospitalizations and vascular access surgeries associated with improper dialysis planning. Performance on this measure can also be achieved if patients receive pre-emptive kidney transplants or start on home dialysis. To further increase transplants and referral to transplantation, CMS should consider rewarding nephrologists for pre-emptive transplants with a higher payment than they would receive during the year if the patient started dialysis, and exempting the costs of transplant evaluation and surgery from APM financial benchmarks.

In addition, collaboration with community organizations that can provide patients with education, support, and disease management programs that increase shared decision making can help APMs achieve their cost and quality targets by better engaging patients. These

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community organizations are helpful because they have the ability to help patients where they live and work. They understand the unique challenges patients of different sociodemographic status face and can tailor education, programs and support to help address those needs. CMS should encourage all APMs to work with community organizations to support their patients beyond the walls of the clinic. For example, the National Kidney Foundation of Michigan delivers in many diverse communities the diabetes prevention program and administers Kidney PATH (Personal Action towards Health), which is based on the Stanford chronic disease self-management program. Both programs have had success in engaging patients in self-management of their conditions.

As CMS considers how to integrate primary care models and APMs to better address CKD the focus should not be solely on collaboration with dialysis facilities or the CEC model because the unintended consequence of doing such is to presume all CKD patients eventually will need dialysis. The focus should be on the relationship and collaboration between PCPs, nephrologists, and patients. Use of care managers properly trained in providing disease management, education, and counseling to patients may also improve patient care and enhance opportunities for patients to make informed decisions about their care.

NKF has launched a national workgroup of interdisciplinary healthcare professionals and kidney patients, in collaboration with the Renal Physicians Association and Northwell Health, to develop a patient-focused CKD payment model. The model – a work in progress - addresses the alignment of payment for primary care practitioners to detect and manage CKD stage 3b patients and refer patients at stage 4 to nephrologists. Nephrologists then receive per-member-per-month care management payments to focus on preserving kidney function, managing comorbidities, coordinating care with PCPs and appropriately transitioning patients that do progress to ESRD. We anticipate completing our work and having a recommended payment model to CMMI and PTAC this Fall.

Improvements to the CEC model

To improve the CEC model and outcomes for ESRD patients' greater collaboration and accountability for information sharing by hospitals is needed. NKF urges CMS to require hospitals to directly provide dialysis patients' discharge information to their dialysis facility. Often times the dialysis facility and the nephrologist are unaware that a hospitalization has occurred, let alone, what medications and treatments the patient was given during the stay. This makes it difficult for facilities to obtain information necessary to prevent hospital readmissions. In addition, CMS should promote collaboration in the CEC model beyond the nephrologist and dialysis facilities. ESCOs that include other care providers such as PCPs and hospitals may help provide a more holistic approach to ESRD patient care and reduce hospitalizations. In addition,

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collaboration with transplant centers may improve referrals for transplant, help patients find living donors and increase transplant rates.

ESCOs should be measured on their ability to educate patients on transplantation and the percentage of prevalent patients who are on the waitlist. Patients continue to report that they were not fully informed about transplant or were provided misinformation that led them not to not pursue transplant. Holding dialysis facilities accountable for ensuring their patient population is knowledgeable about transplant and supporting patients to maintain their status on the waitlist will help address this current gap in care. Earlier this year, CMS put out for public comment transplant waitlist measures recommended by its technical expert panel. Of those proposed measures, NKF supported the Percentage of Prevalent Patients Waitlisted (PPPW) because we believe it was the most meaningful for patients out of the two measures recommended. This measure could be used for the CEC Initiative to encourage better collaboration with transplant facilities. However, we raise some considerations for CMS as it relates to that measure.

Some patients under age 75 may not be eligible for transplantation due to other clinical reasons. In addition, in some cases even the most informed and educated patient may choose not to pursue a transplant. Limited, but additional exclusions to account for these circumstances should be evaluated. Ultimately, the decision on whether a patient is listed for a transplant is made by the transplant center that evaluated the patient (and the patient's desire for a transplant). These are complex decisions that take into account many factors and vary by transplant center and geographic region, which would make nationwide comparisons of waitlist percentages difficult to interpret. The effect of this variance in transplantation policy on dialysis facility performance on this measure should be considered prior to implementation.

In sum, to achieve better outcomes and lower costs of care for kidney patients we need to move beyond a dialysis centric focus. While dialysis facilities serve an instrumental role in improving outcomes for the 468,386 patients they treat, efforts to lower costs and improve outcomes must engage and hold other health care entities accountable for their roles in caring for patients. The greatest, missed opportunity to improve outcomes for kidney patients is to start in primary care and align payment with the value of earlier detection and treatment of CKD and align payments to nephrologist to encourage improved care management and care transitions for patients that will progress to ESRD.

This approach is likely to result in CKD patients experiencing less adverse events, less comorbidity, lower mortality, and fewer patients progressing to ESRD. For those patients that do ultimately transition to dialysis they will start better prepared, out of the hospital, and require

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fewer interventions. Collaboration and shared accountability among hospitals, dialysis facilities and transplant centers can further improve the care and outcomes for dialysis patients and provide them with greater opportunities to be engaged in their care. NKF greatly appreciates CMS soliciting comments on these important questions. We look forward to discussing these recommendations further.

For questions please contact Tonya Saffer, Senior Health Policy Director, at tonya.saffer@kidney.org or at 202.244.7900 ext. 717.

Sincerely,

Kevin LonginoKevin Longino
CEO
Kidney Patient

Jeffrey S. BernsJeffrey S. Berns, MD
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