National Kidney Foundation™

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June 22, 2015

The Honorable Johnny Isakson
United States Senate
Washington, DC 20510

The Honorable Mark Warner
United States Senate
Washington, DC 20510

Dear Senator Isakson and Senator Warner,

The National Kidney Foundation (NKF) appreciates the opportunity to share suggestions on ways to reduce Medicare spending on chronic conditions in and improve care for beneficiaries. 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).

Medicare spends $87 billion annually to care for patients with kidney disease, with $58 billion spent on individuals with CKD stages 1-4. An Avalere Health analysis of 2013 Medicare 5% claims data found that Medicare spending on CKD patients is 2-7x higher than spending on the average Medicare beneficiary (see table below).

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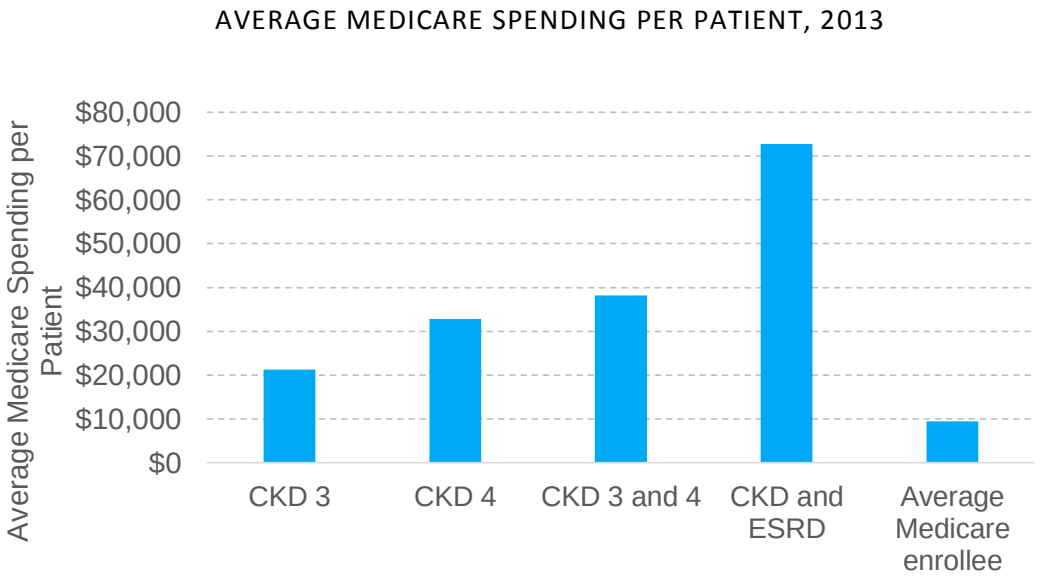

Given the uniqueness of the Medicare End-stage Renal Disease (ESRD) benefit that extends Medicare coverage to nearly all Americans, regardless of their age, we believe that specifically addressing CKD care and costs upstream is imperative. NKF encourages the Senate Finance Committee to support measures that would provide savings to Medicare by incentivizing primary care practitioners (PCPs) to test for CKD in the Medicare population and to bundle reimbursement for management of CKD; to call on the Centers for Medicare & Medicaid Services (CMS) to identify and/or develop quality measures for proper testing and management of CKD; to tie PCP reimbursement to those quality measures, and incentivize co-management between PCPs and nephrologists for patients with advanced kidney disease (CKD stage 4).

<u>Medicare payment to PCPs for Chronic Care Management</u>

Many chronic conditions are similar in that they can be managed, but not cured, and often can be prevented or managed with dietary modifications and lifestyle changes. However, each chronic disease affects different organs and systems in the body differently and therefore requires unique, tailored management strategies. Some chronic conditions can be managed early in the disease process with basic primary care strategies. However, given the multitude of conditions PCPs are looking for and the fact that reimbursement policies incentivize the treatment of acute care episodes, those conditions without early symptoms often go undetected.

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This is the case with CKD. Medicare payment does not align incentives with early detection and management, further fostering instances of missed diagnosis and spurring the ongoing challenge of our medical system to continuously treat patients as complications or acute episodes dictate. For example, while Medicare will pay for a kidney transplant and/or dialysis for nearly every American, regardless of their age, little is done in the Medicare program to encourage early management of CKD. Only one quality measure is currently used in Medicare to encourage testing for kidney disease, but that measure is not in alignment with current clinical practice guidelines and does little to actually encourage diagnosing kidney disease early. In addition, CMS recently removed risk adjustment payments from Medicare Advantage plans for CKD stages 1-3(a move that many Members of Congress on both sides of the aisle opposed), despite evidence of increased costs in caring for these patients and the fact that even simple diagnosis of a CKD has been associated with patient awareness of their CKD[i] – allowing them to make informed decisions about their health and care.

While addressing CKD in early stages could slow progression to end-stage renal disease (ESRD), even more important are the issues of patient safety and reduction in heart attack and stroke. Diagnosis of CKD serves as a catalyst to informing the PCP, the patient, and the patient's other healthcare providers of the need to adjust medicines that are typically processed through the kidney, avoid certain medications such as non-steroidal anti-inflammatory drugs (NSAIDs), avoid contrast induced media when possible, and offer the patient the opportunity to make diet and lifestyle changes – an opportunity not offered to 90% of CKD patients because they do not know they have kidney disease.

<u>$4.3 billion reduction in Medicare spending and improved outcomes with early CKD detection</u>

NKF commissioned a study to determine the amount of healthcare savings that could be identified if CKD was detected and managed before comorbidities arose. 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.[ii] NKF and the American Diabetes Association found in a study of PCPs and their practices in detecting CKD that in diabetics, who are at the highest risk, CKD goes largely undiagnosed and unmanaged.[iii] 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. Unlike CKD, quality measures for management of diabetes are used across Medicare alternative payment models and in Medicare fee-for-service, commandeering the attention of the PCP. The same could be true for CKD if the payment were aligned to incentivize the PCP to do so.

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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 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.

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 may be a stronger risk predictor of heart attack and stroke than tobacco use, blood pressure or high cholesterol.[iv] When CKD progresses to stage 4 and 5, co-management between a PCP and nephrologist is strongly recommended and associated with lower healthcare costs. Patients who are not referred to a nephrologist in advance of ESRD have a higher risk of morbidity and mortality and increased healthcare costs. In 2012, over 40,500 CKD patients, 41% of the population starting dialysis, were not referred to a nephrologist prior to initiation of kidney replacement therapy (KRT), resulting in as many as 12 days of excess hospitalization per patient at initiation of KRT.[v] Other studies have also shown that referral to a nephrologist prior to dialysis initiation leads to lower mortality and hospitalization.[vi] In addition, Medicare data suggests lower spending results for patients with CKD stage 4 when they visit a nephrologist 1-2 times per year (see table below). [vii]

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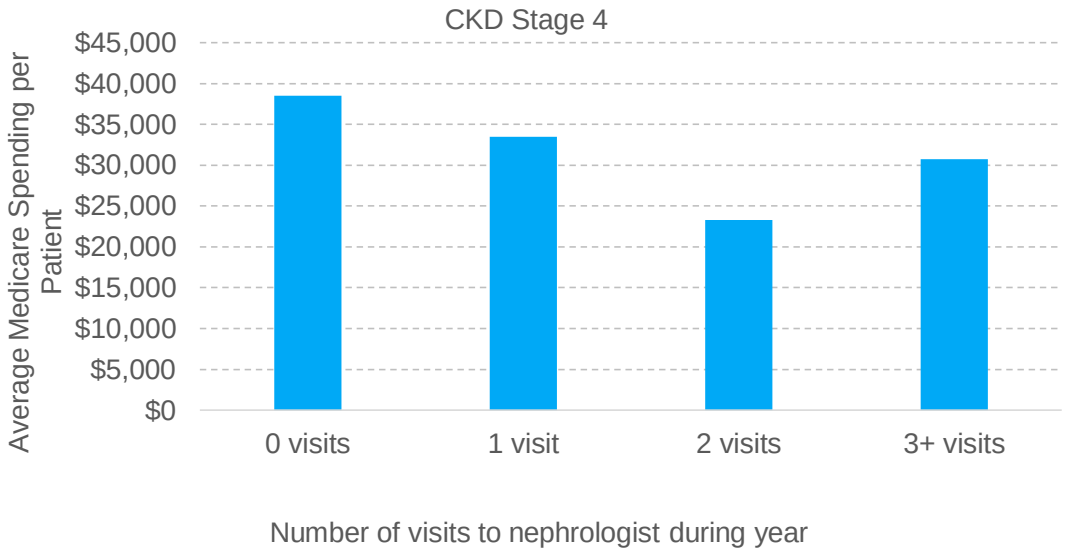

Bundling payment for management of CKD and accountability for quality care

PCP payment and CKD

Simply detecting CKD in at-risk populations has been found to be cost-effective and may result in slowing growth of Medicare expenditures and improving outcomes. However, directly engaging patients in their care through educating on dietary modifications is also grounded in evidence. A bundled or capitated payment for CKD management may include costs specific to management of CKD-like lab tests, care coordination activities (such as those in the current Medicare care coordination management code), nutritional education (currently available in the Medicare program for people with an estimated GFR (eGFR) of 13-50 ml/min/1.73m^2 under the medical nutrition therapy benefit), as well as traditional primary care such as recommended vaccinations and immunizations. Integrated primary care practices that work with ancillary health care professionals such as dietitians, and case managers and practices participating in Accountable Care Organizations, Medicare Shared Savings Programs and Advance Primary Care Initiatives through the Centers for Medicare and Medicaid Innovation (CMMI) are particularly well positioned to be reimbursed through a bundled or capitated CKD management payment for these services. Flexibility, in how these services are delivered to the patient could also help alleviate practitioner and patient burden. For example, dietary education could be provided through telehealth. Bundled payments should also be tied to performance on quality measures, as is the case with reimbursement for dialysis for

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individuals with ESRD. Two very important measures are avoidance of NSAIDS and co-management with a nephrologist once a patient is diagnosed with advanced kidney disease (stage 4).

> *Recommendation 1:* As the Committee seeks to develop chronic care legislation, NKF requests that the legislation direct the Secretary of Health and Human Services (HHS) to work with organizations and practitioners in the renal and primary care community who are experts in evidence based guidelines for the detection, diagnosis, and management of CKD to develop a bundled payment model and quality metrics to incentivize earlier detection and better management of those patients by primary care practitioners. In addition, we request that the Committee also direct the Secretary of Health and Human Services to incorporate testing for CKD, in those at risk, using a urine albumin to creatinine ratio and a serum creatinine to estimate kidney function (two simple tests) into the recently announced Million Hearts: Cardiovascular Disease Risk Reduction Model as CKD testing has been shown to be a superior risk predictor for heart attack, heart failure and stroke than traditional risk factors.

Nephrologist Payment and CKD

Referral to a nephrologist once a patient reaches advanced CKD (stage 4) is shown to improve patient outcomes and could lower healthcare costs through a reduction in hospitalizations and outpatient procedures. For patients requiring the care of a nephrologist, a population management reimbursement approach to the nephrologist could help reduce care costs and avoid duplication of necessary tests. Nephrologists are used to a capitated care model as this is how they are reimbursed for the care of ESRD patients. An advanced CKD capitated payment should account for care coordination activities, overseeing kidney disease education services (currently a Medicare benefit) and preparing the patient for dialysis or transplantation at the appropriate time. Quality measures for the care advanced CKD are currently available in the Physician Quality Reporting System (PQRS). However, improved measures should include referral to transplantation as referral for kidney transplant can be done when the eGFR is at 20ml/min/1.73m^2 or lower, but many patients have reported not being informed of this option until after initiating dialysis.

> *Recommendation 2:* NKF requests that legislation resulting from the Committee workgroup process also direct the Secretary of HHS to work with experts in evidence base clinical practice guidelines to develop a capitated payment model for the nephrologist to manage CKD stage 4 patients and to identify and/or develop quality metrics that can be tied to the nephrologist's reimbursement.

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Improving co-management of CKD patients

> *Recommendation 3:* Given that the most significant cost savings are achieved with the PCP and nephrologist co-managing patients with advanced CKD (stage 4), NKF also recommends the Senate Finance Committee direct the Secretary of HHS to develop and test a payment model through CMMI for co-management of patients with advanced CKD, who do not have ESRD. Such a payment model could facilitate best practices and shared savings to the PCP, nephrologist, and the Federa government.

Removing access barriers for beneficiaries

Any successful disease management strategy must also encourage patients to be active care participants. Copayments and coinsurance can often present barriers to care when the patient needs it.

> *Recommendation 4:* To remove these barriers, copayment for the bundle of services paid to the PCP and nephrologist should be waived or reduced. Services such as medical nutrition therapy and kidney disease education services should also be more broadly available through telehealth as an option.

Early adopters of CKD management

While currently there are no alternative payment models to address CKD, some private payers have adopted disease management programs in recognition of the opportunity to improve outcomes and lower healthcare costs. However, many of these programs focus on slowing progression to ESRD as a primary outcome rather than the more short-term achievements in patient safety, mortality and cardiovascular events. Kaiser Permanente Hawaii and Geisinger Health Systems CKD programs showed that referral to nephrologist slowed progression of CKD. Geisinger saw a 30% reduction in progression to ESRD in stage 4 patients who were seen by a nephrologist.[viii, ix]

If Medicare payments for CKD management were bundled and tied to quality metrics, it is likely more private payers will follow suit. Such a change in the private insurance market and in Medicaid could also slow growth in Medicare spending as many people with and at risk of CKD are not yet in the Medicare program. An increase in the number of individuals whose CKD is detected and managed before aging into Medicare would result in improved outcomes, fewer comorbidities, and cost savings.

In sum, the National Kidney Foundation recommends that the Finance Committee direct the Secretary of HHS to develop bundled payments for CKD management, identify and/or develop

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quality metrics where gaps in CKD detection and treatment exist and tie payments to those quality measures, incorporate the bundled payments and quality metrics into relevant CMMI models and eliminate beneficiary cost sharing for services and visits necessary for managing their CKD. In addition, we recommend that the committee require CMMI to conduct a demonstration between primary care practices and nephrologists that focuses on appropriate co-management of patients with CKD stage 4. The National Kidney Foundation with its plethora of healthcare professional and patient experts welcomes opportunity to further discuss how this alternate payment model for CKD could be further developed and we thank you for your leadership in this initiative

Sincerely,

Kevin Longino	*Kerry Willis*	*Joseph Vassalotti*
Kevin Longino	Kerry Willis, PhD	Joseph Vassalotti, MD
Chief Executive Officer	Chief Scientific Officer	Chief Medical Officer

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[i] 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.
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[viii] Lee, B. et al. Effects of proactive population-based nephrologist oversight on progression of chronic kidney disease: a retrospective control analysis. BMC Health Services Research. 2012: 12: 252.
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