National Kidney Foundation™

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January 26, 2016

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) is pleased to provide feedback on the United States Senate Committee on Finance Bipartisan Chronic Care Working Group (CCWG) Policy Options Document. 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). We work with volunteer experts to offer the scientific, clinical and kidney patient perspective on what needs to be done to prevent kidney disease, delay progression, and better treat kidney disease and kidney failure. NKF has local division and affiliate offices serving our constituents in all 50 states.

NKF appreciates your work in taking hundreds of comments and developing policy options for greater consideration. Particularly, NKF is pleased with the consideration of opportunities to improve the care of individuals with end-stage renal disease (ESRD) who are on dialysis. However, per our comments in June 2015, we also urge you to specifically address Medicare payment and delivery reform upstream in Chronic Kidney Disease (CKD). Identifying and managing CKD early will save lives, improve outcomes for Medicare beneficiaries and reduce health care spending.

Today 41% of individuals start dialysis without seeing a nephrologist prior to kidney failure. 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. Awareness of CKD is also a goal of the U.S. Department of Health and Human Services (HHS) Healthy People 2020 initiative, but unfortunately little progress towards this goal has been made.

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The Medicare program spends $99 billion on the care of individuals diagnosed with CKD.[1] CKD is a progressive disease that is the 9th leading cause of death and places patients at an increased risk for heart attack, stroke, acute kidney injury and other costly comorbid conditions. Management of CKD early on can reduce patients' risk of these events and prevent or slow progression to ESRD – reducing spending along the way. The Medicare ESRD program has been instrumental in ensuring those in need of dialysis or a kidney transplant have the access to care they need. Yet, little has been done to encourage and support clinicians to address CKD before it progresses and before costly, yet avoidable complications occur. NKF believes there are opportunities to begin to address CKD, with refinements to some of the options proposed in the CCWG' policy options document and we provide the following comments on those opportunities in addition to the proposals related to ESRD.

NKF recommendations fall within the CCWG's bipartisan goals of:

1. The proposed policy increases care coordination among individual providers across care settings who are treating individuals living with chronic diseases;

2. The proposed policy streamlines Medicare's current payment systems to incentivize the appropriate level of care for beneficiaries living with chronic diseases; and

3. The proposed policy facilitates the delivery of high quality care, improves care transitions, produces stronger patient outcomes, increases program efficiency, and contributes to an overall effort that will reduce the growth in Medicare spending.

Goal 1 - Increasing Care Coordination across Care Settings

Improving Care Management Services for Individuals with Multiple Chronic Conditions

NKF supports better payment for chronic care management and agrees that patients with multiple chronic conditions become more complicated, requiring more time to coordinate their care outside of the office visit, and that clinicians should be compensated for that increased time.

Many chronic conditions like diabetes, hypertension and chronic kidney disease are linked to one another and are also disease multipliers that, if caught and managed early, outcomes could be improved and spending reduced. While we must value the time spent caring for complex individuals

[1] *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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with multiple chronic conditions appropriately, we must also appropriately value screening for and managing these conditions earlier and hold providers accountable for delivering care that can prevent complications. As stated in the CCWG policy options document, paying more once patients become more complicated is likely to increase costs, but a balanced strategy to also appropriately pay for chronic care management before patients become more complicated can reduce spending per patient over the span of their care. Evidence to support this is clear for CKD management and we outlined the economic case for this in our June 2015 comments (pages 3-5) to the CCWG, which we have included as an appendix to this letter. In fact, integrated healthcare providers and private health plans are beginning to adopt CKD management programs as they recognize the opportunity to improve care and also lower costs – even in the short term. Both Kaiser and Geisinger have implemented strategies to facilitate improved collaborative care between primary care practitioners and nephrologists. Recently one dialysis provider, has begun to address CKD upstream and has seen that even among those that do progress to ESRD they are less likely to start dialysis in the hospital, more likely to choose home dialysis over in-center dialysis and more elderly patients choose palliative care options than is currently the case.[2] These interventions have slowed progression of CKD, delayed the need for kidney replacement therapy (KRT), and afforded those patients that did progress to ESRD the time to choose the best care options for them. Medicare payment polices should encourage providers to embrace these proven intervention methods. While Kaiser and Geisinger are integrated health networks, their results can be extrapolated to non-integrated health care providers as the published Geisinger results suggest:

> *Implementation in nonintegrated nephrology practices, either alone or in conjunction with referring PCP sites, may lead to improvements in their patients' clinical parameters and assist those practices in the documentation of quality outcomes that is frequently requested by accountable care organization, and so forth.*[3]

Given that Medicare spends $99 billion on the care for individuals with CKD and that the Medicare ESRD program cares for most Americans with ESRD, NKF believes that the Federal government has an obligation and an incentive to improve the care of individuals with CKD, which will lower costs to the system. By specifically targeting CKD improvements we can also lower the risk of cardiovascular events, acute kidney injury, and other comorbid complications that are independently associated with kidney disease. NKF has a four step approach to accomplishing this goal.

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[2] Johnson, Douglas, et al. Going Upstream: Coordination to Improve CKD Care, Seminars in Dialysis, published online: January 14, 2016.

[3] Norfolk, Evan and Hartle, James, *Nephrology Care in a Fully Integrated Care Model: Lessons from the Geisinger Health System,* CJASN, April 05, 2013 vol. 8 no. 4 687-693.

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1. Direct the HHS Secretary to develop a bundled payment tied to quality metrics that would facilitate primary care practitioners (PCPs) to properly detect at-risk patients for CKD and manage their CKD population.

2. Direct the HHS Secretary to capitate payment to nephrologists for CKD stage 4 care planning tied to quality metrics.

3. Allow nephrologists, PCPs, and other clinicians that adopt these bundled/capitated payments to form organizations and collaborate with each other and other practitioners to improve outcomes for patients with CKD.

4. Direct the HHS Secretary to develop and implement quality measures, designed to improve CKD care, to support these CKD specific payment models and that can also be incorporated into other alternative payment models and quality improvement programs.

Goal 2 - Streamlining Medicare's current payment systems

Allowing End Stage Renal Disease Beneficiaries to Choose a Medicare Advantage Plan

NKF supports the proposal to afford beneficiaries with ESRD the same options to enroll in Medicare Advantage plans and to switch plans during open enrollment as other Medicare beneficiaries are permitted. MA plans typically have combined deductibles for hospital and medical services and often include prescription drug coverage. MA plans are required to cap out-of-pocket expenses at $6,700, but many plans have much lower out-of-pocket maximums. Also, many of these plans cover additional services that Medicare FFS does not. For example, some plans cover dental benefits (important for kidney transplant eligibility) and care coordination managers to help kidney patients, who are a high risk for hospitalizations and death, receive more accountable and seamless care. This makes MA plans an ideal option for many individuals with CKD.

Providing Continued Access to Medicare Advantage Special Needs Plans for Vulnerable Populations

NKF supports a long-term authorization of chronic special needs plans (C-SNPs). Unlike fee-for-service Medicare, these plans can offer great care coordination and supplemental benefits to help individuals with complex chronic conditions like diabetes, heart disease, and ESRD overcome some of the obstacles they would face in getting care in a fee-for-service environment. Services like access to an exercise facility, transportation to medical appointments, and more can help beneficiaries better receive the care they need and self-manage their conditions.

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While NKF supports allowing MA plans to tailor and provide supplemental benefits to better support individuals with chronic conditions, we also believe C-SNPs are an important option for beneficiaries with serious chronic conditions. Unlike traditional MA, these plans are specifically intended to focus on serving beneficiaries with chronic conditions needs. C-SNPs have several years of experience in providing tailored benefits and services to beneficiaries with chronic conditions and should remain an option for those beneficiaries.

Medicare Advantage and Accountable Care Organizations: Adapting benefits and allowing supplemental benefits

NKF supports allowing MA plans to tailor benefits for individuals with chronic conditions and for MA plans and ACOs to provide supplemental benefits. This would allow for a greater number of Medicare beneficiaries to receive better personalized, coordinated, and comprehensive care. This type of care is available to some Medicare beneficiaries with chronic conditions through the C-SNP program. However, offering similar flexibility to MA plans and ACOs will allow more beneficiaries to benefit from comprehensive chronic care management as the number of C-SNPS available is quite limited.

Maintaining patient protections is also important and individuals with chronic conditions should not be adversely impacted by the design of new benefit structures. For example, patients with chronic conditions should not experience higher cost-sharing for any services and should not have more restricted provider networks than other Medicare beneficiaries. We also fully support reducing and even waving beneficiary cost sharing for enhanced chronic disease management services. This would help remove barriers that some patients have to being engaged in decision making about their care.

Ensuring Accurate Payment for Chronically Ill Individuals

NKF was deeply disappointed when CMS removed risk-adjustment payments from Medicare Advantage plans for CKD stages 1-3. There is evidence that CKD is widely undiagnosed in the Medicare fee-for-service population and that among patients diagnosed, the costs of care for those individuals are higher than the average Medicare beneficiary because their diagnosis is delayed. For example, Medicare fee-for-service patients with diagnosed CKD stages 1-2 had per-patient spending of $19,859 and patients with CKD stage 3 $21,253 in 2013. In contrast,

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spending on the average Medicare beneficiary was $10,854.[4] Risk adjustment payments for CKD stages 1-3 also encourages plans to identify and manage CKD early because of the opportunity to lower costs of care relative to a patient who is not detected or managed until they become more complicated. NKF supports revision of the risk adjustment model to more accurately reflect the costs of caring for individuals with chronic conditions and believes that a new model should risk adjust for CKD stages 1-3 to account for the increased costs of managing and treating those patients and to foster earlier detection and management of CKD under MA.

Goal 3 - Facilitating the Delivery of High Quality Care

Expanding Access to Home Dialysis Therapy

NKF supports expanding telehealth originating sites to all free-standing and hospital outpatient based dialysis facilities regardless of geographic area. This proposal will allow home dialysis patients (using either home hemodialysis or peritoneal dialysis) greater flexibility to meet with their clinicians monthly. NKF also supports taking this a step further and allowing patients' homes to be originating sites. This would make the most difference for home patients as even getting to the nearest dialysis facility can be burdensome for some patients.

NKF appreciates the patient safety considerations outlined in this section. We do agree that a telehealth visit can be substituted for the monthly face to face visit if the patient chooses. Retaining patient's choice to have a monthly in-person meeting with their clinicians is also critical. NKF believes that because telehealth adoption is an emerging new practice, clinicians should be required to meet with their patients in person no less frequently than quarterly (once every three calendar months).

Dialysis patients' homes could serve as an originating telehealth site with rather modest equipment. Patients would need a video enabled computer, smartphone, or tablet to allow the clinician to see the patient and securely transmit clinical data and information between the patient and clinician. The technology used would also need to comply with state and federal laws protecting patients' privacy and health information.

We encourage the committee to move forward with its proposal to expand telehealth access to home dialysis patients by allowing dialysis facilities and patients' homes to serve as originating telehealth sites.

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[4] *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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Developing Quality Measures for Chronic Conditions

NKF supports the development of new quality measures that are more patient-centric and focused on improved chronic care management. Per our comments and recommendations above on aligning payment with better care for people with CKD, we strongly encourage the committee to include prioritization of patient-centered CKD quality measures that do not exist today. Kidney patients should never again have to ask why they were not told they had CKD before their kidneys failed. Specifically, NKF recommends measures be developed that evaluate:

- patients at risk of CKD who receive an annual serum creatinine and albumin testing.
- patients with eGFR less than 60 who have a repeated serum creatinine and albumin test at least 90 days from initial test to confirm CKD.
- patients with confirmed CKD (as defined by two repeated lab tests at least 90 days apart) who attest that they are aware they kidney disease and feel they have been educated or referred to education and resources to help self-manage their care.
- timely and appropriate referral to nephrologist.
- practitioner avoidance of prescribing non-steroidal anti-inflammatory drugs (NSAIDs) in patients with confirmed CKD and patient understanding to avoid these pain medications (avoidance of NSAIDS s known to protect patients from adverse events such as acute kidney injury).
- appropriate prescription of blood pressure medications, ACE or ARB, for patients with confirmed CKD – the strongest evidence shown to slow progression of ESRD.

Encouraging Beneficiary Use of Chronic Care Management (CCM) Services

While $8 may seem like a trivial amount given that most Medicare beneficiaries have supplemental coverage, NKF strongly supports removing this cost-sharing for CCM services. Many beneficiaries, particularly those with ESRD or who are disabled, do not have access to supplemental coverage and any obstacle for them receiving better care management should be removed.

Expanding Access to Prediabetes Education

One important component of early detection and management of CKD is identifying those with the highest risk of developing CKD, and addressing their risk factors properly. The leading cause of CKD

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is diabetes, which in many cases can be prevented. Over 29 million Americans currently live with Type 2 diabetes, and millions more are at risk. While preventing diabetes won't stop all CKD, it will reduce the risk for millions of Americans.

Run by the Centers for Disease Control and Prevention (CDC), the National Diabetes Prevention Program (DPP) has reduced the risk of Type 2 diabetes by 58%, in participants who are currently affected by prediabetes.[5] Expansion of this program means more seniors can cut their risk of diabetes in half and avoid the complications of diabetes, including kidney failure and death. In addition, research shows that the legislation can reduce federal spending by $1.3 billion over 10 years, and savings generated by prevention of diabetes and its complications will continue to grow beyond the initial 10 years. We also support allowing entities such as non-profit organizations and departments of health to provide the benefit to Medicare beneficiaries and be reimbursed for doing so. Organizations administering the DPP should meet criteria established by the Secretary of HHS that are in line with the standards set by CDC.

NKF also supports the ability for other evidence based disease management and prevention programs to be developed in the future and considered as a Medicare benefit should they be shown to improve patient outcomes.

Establishing a One-Time Visit Code Post Initial Diagnosis of Alzheimer's/Dementia or Other Serious or Life-Threatening Illness

NKF believes that establishing this payment policy for individuals with CKD is another opportunity to improve earlier diagnosis and patient awareness of their disease. As mentioned previously, CKD is the 9th leading cause of death with most individuals dying prior to reaching ESRD, and it is largely undiagnosed until it has advanced to later stages. PCPs have reported reimbursement and time as a barrier to diagnosing and discussing CKD with patients.[6] This one time visit code could remove that barrier and provide clinicians with the opportunity to be reimbursed for their time discussing kidney disease, and helping patients understand opportunities for self-management.

However, PCPs have also reported challenges in getting patients to return to the office to discuss test results because they do not have the time or do not want to pay the cost sharing.

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[5] National Institute of Diabetes and Digestive and Kidney Disease, Diabetes Prevention Program, http://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-prevention-program-dpp/Pages/default.aspx.

[6] 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.

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NKF suggests that beneficiaries not be charged coinsurance for this service and that they have the choice to receive this visit either face to face or through telecommunication. Beneficiaries who are diagnosed with a new condition should also be referred to organizations that provide evidence-based, disease specific educational and support resources so they can learn more about self-managing their condition.

In conclusion, given the prevalence, under-diagnosis, and the investment in caring for individuals with CKD, including ESRD, we strongly encourage the committee to consider our proposal for addressing improvements in earlier CKD care. With your leadership we can ensure that patients are aware of their disease, receive the care they need, and have the opportunity to make informed decisions about that care.

Sincerely,

Kevin Longino

Kevin Longino
CEO
Kidney patient