

**STATEMENT OF THE NATIONAL KIDNEY FOUNDATION
30 EAST 33RD STREET NEW YORK, NY 10016**

**SUBMITTED TO THE SENATE COMMITTEE ON APPROPRIATIONS;
SUBCOMMITTEE ON LABOR, HHS, EDUCATION, AND RELATED AGENCIES**

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The National Kidney Foundation (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. NKF works with volunteers 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. In addition, NKF has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI). NKF has local division and affiliate offices serving our constituents in all 50 states.

NKF is pleased to submit testimony regarding the impact of Chronic Kidney Disease (CKD), and steps that can be taken by Congress to build upon the success of the existing programs at the National Institutes of Health, Centers for Disease Control, and Health Resources and Services Administration to improve early detection and treatment of the disease.

About CKD

Chronic Kidney Disease (CKD) is a condition characterized by a gradual loss of kidney function over time. CKD impacts 26 million American adults, while 1 in 3 (73 million) American adults are at risk for kidney disease. Diabetes and high blood pressure are responsible for up to two-thirds of all cases of irreversible kidney failure (end stage renal disease). Kidney disease can be detected through a simple urine test, yet the disease can go undetected until very advanced because kidney disease often has no symptoms. When kidney disease progresses, it may lead to kidney failure, which requires dialysis or a kidney transplant to maintain life. Rates of kidney failure are higher among minorities, with African Americans developing ESRD at a rate of 3 to 1 compared to Whites and Hispanic Americans developing it at a rate of 2 to 1.

The Importance of Early Detection of CKD

Only 10% of individuals with CKD are aware they have it.¹ CKD is often asymptomatic -- especially in the early stages -- and therefore goes undetected without laboratory testing. Some people are not diagnosed until they have reached end-stage renal disease (ESRD) and must begin dialysis immediately.

At the end of 2014, 661,648 Americans had End Stage Renal Disease (ESRD), including 468,386 dialysis patients and 193,262 kidney transplant recipients. Complicating the cost and human toll is the fact that it is a disease multiplier, with patients very likely to be diagnosed with

¹ 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.

cardiovascular disease. ESRD was present in less than 2% of Medicare beneficiaries but responsible for nearly 6% of Medicare expenditures.

Cost-effective early identification and treatment options exist which can slow the progression of kidney disease, delay complications, and prevent or delay kidney failure. Intervention at the earliest stage is vital to improving outcomes, lowering health care costs, and improving patient experience, yet in a recent clinical study only 12% of primary care clinicians were properly detecting CKD in their patients with diabetes who are at the highest risk of kidney disease.² There often is a misconception that once someone is diagnosed with CKD, there must be a referral to a nephrologist. However, it is not necessary in most instances for referral to a nephrologist in early stages.

The CKD Intercept Initiative

NKF is moving forward on an initiative we announced two years ago to help improve early detection and diagnosis of CKD by primary care practitioners (PCP). Our CKD Intercept initiative aims to transform PCP detection and care of the growing numbers of Americans with CKD by deploying evidence based clinical guidelines into primary care settings through education programs, symposia and practical implementation tools.

In support of this effort, NKF is advocating for Congress to enact legislation to remove the reimbursement barriers to earlier, better CKD care management by directing the Secretary of Health and Human Services to create a Medicare bundled payment demonstration for CKD management to primary care practitioners and nephrologists. Given the high costs and comorbidities associated with late diagnosis of CKD, this demonstration is expected to improve patient outcomes, lower hospitalizations and result in savings to Medicare. NKF commissioned a study to develop a cost estimate model on improving earlier detection and management of CKD. Through early intervention, Medicare could reduce spending by \$4.8 billion in year 10 and \$8.2 billion in year 20, for a total reduction in spending of \$93 billion over 20 years.

While progression of CKD can lead to ESRD, CKD patients are at a greater risk of death, cardiovascular events and adverse drug events. 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.³ . Testing for kidney disease in at-risk populations provides the opportunity for interventions to foster awareness, foster adherence to medications and control risk factors. Therefore, NKF's initiatives address three priorities in the *National Strategy for Quality Improvement in Health Care*, including 1) making care safer by reducing harm caused in the delivery of care, 2) promoting the most effective prevention and treatment of the leading causes of mortality, starting with cardiovascular disease, and 3) working with communities to promote widespread use of best practices to enable healthy living.

² 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.

³ 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](http://dx.doi.org/10.1016/S2213-8587(15)00040-6).

With the continued support of Congress, NKF is confident a feasible detection, surveillance and treatment program can be advanced to as a *first step* to slow the progression of kidney disease. These initiatives will help build on the CDC's investment in the Chronic Kidney Disease Program.

CDC Chronic Kidney Disease Program

NKF urges the Committee to provide \$2.31 million for the CKD program for FY 2017, an increase of \$200,000. Prior to the creation of the Chronic Kidney Disease Program at CDC in FY 2006, no national public health program focusing on early detection and treatment of CKD existed. The CDC CKD program has consisted of three projects to promote kidney health by identifying and controlling risk factors, raising awareness, and promoting early diagnosis and improved outcomes and quality of life for those living with CKD. These projects include (1) demonstrating approaches for identifying individuals at high risk for CKD through state-based screening; (2) conducting an economic analysis on the economic burden of CKD and the cost-effectiveness of interventions; and (3) establishing a surveillance system for CKD by analyzing and interpreting information to assist in prevention and health promotion efforts for kidney disease. The surveillance project includes a CDC website program containing information on risk factors, early diagnosis, and strategies to improve outcomes.

As a result of consistent congressional support, the National Center for Chronic Disease Prevention and Health Promotion at CDC has instituted a series of projects that could assist in attaining the Healthy People 2020 objectives. However, increasing the proportion of persons with CKD who know they are affected requires acquiring additional data sources beyond Medicare claims and NHANES survey analyses to identify the undiagnosed population and assess the burden of CKD across the country to better understand the CKD impact at a state and local level. This momentum will be stifled and CDC's investment in CKD to date jeopardized if line-item funding is not increased.

A study published by researchers leading the program shows that the burden of kidney disease is increasing and that over half of U.S. adults age 30-64 are likely to develop CKD.⁴ Congressional support for an increase in funding to the CDC program will benefit kidney patients and those at risk for kidney disease, advance the objectives of Healthy People 2020 and the National Strategy for Quality Improvement in Health Care, and fulfill the mandate created by Sec. 152 of the Medicare Improvement for Patients and Providers Act. Agency priorities going forward include assessing disparities among racial and socioeconomic populations and adding new and local data on CKD including additional risk factors.

NIDDK

NKF supports the Friends of NIDDK request of \$2.16 billion for the Institute in FY 2017. Medicare spent \$99 billion in 2014 caring for patients with kidney disease, \$68 billion of which was for individuals who do not have kidney failure, yet NIH funding for kidney disease research is only about \$600 million annually. Many research proposals with the potential to lead to

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.

improved treatments, including reconstructing the kidney to restore function, remain unfunded. Patients deserve better and we cannot allow these opportunities to slip away.

In March, NKF hosted the Third Annual Kidney Patient Summit that included participation from nearly 100 advocates from NKF and four other kidney patient organizations. Increased federal support for kidney disease research was a top priority in meetings with the advocates' congressional delegations. This is particularly important for individuals whose kidney disease is the result of genetic factors. America's scientists are at the cusp of many potential breakthroughs in improving our understanding of CKD and providing new therapies to delay and treat various kidney diseases. With the unique status of ESRD in the Medicare program, CKD research has the potential to provide cost savings to the federal government like that of no other chronic disease. We urge Congress to again provide strong bipartisan support for NIH to continue building on the success of the FY 16 efforts, and fund NIDDK at this requested level.

HRSA Organ Transplantation

NKF urges the Committee to provide \$28.5 million for organ donation and transplantation programs in the HRSA DoT. This request is broadly supported by patient and professional members of the transplant community to restore the program's purchasing power to the FY 2010 level. Activities supported by DoT include initiatives to increase the number of donor organs, and the National Donor Assistance Program which helps individuals obtain a transplant by assisting living organ donors with expenses such as travel and subsistence that are not reimbursed by insurance, a health benefit program, or any other state or federal program.

As of April 8, 2016, the kidney transplant wait list consisted of 100,269 individuals plus an additional 1,927 waiting for a combined kidney / pancreas donation. Transplantation remains the treatment of choice for most patients with kidney failure yet few will be given this opportunity. Kidney recipients often have an improved quality of life (and are more likely to stay in or return to the work force) and transplantation is tremendously cost effective -- Medicare spends \$29,920 per year on a kidney recipient after the year of transplant, compared to more than \$84,450 annually on a dialysis patient.

In 2014, NKF established an organ donation task force to review the state of organ donation and identify opportunities to expand the number of transplants. While the task force continues to develop its recommendations, some activities are being implemented, one example of which is NKF's "The Big Ask/The Big Give" campaign. This initiative, currently in the pilot phase, promotes and supports awareness of living kidney donation. It is designed for both those waiting for a kidney transplant who have trouble asking somebody to consider donation (The Big Ask) and potential kidney donors (The Big Give). The Big Ask/The Big Give provides the necessary education and platform to take the misconceptions and confusion out of what can be a very complex process. We intend to offer the program nationwide in transplant centers, dialysis centers and nephrology practices.

Thank you for your consideration of our funding requests for Fiscal Year 2017.