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January 17, 2019

Don Wright, MD, MPH
Director, Office of Disease Prevention and Health Promotion
U.S. Department of Health and Human Services
Office of Disease Prevention and Health Promotion
Rockville, MD 20852

Dear Dr. Wright,

The National Kidney Foundation appreciates the opportunity to comment on the proposed objectives for Healthy People 2030. As you know Healthy People objectives set the agenda for improving public health nationwide and are critically important in ensuring action and resources are dedicated to achieving these objectives. The National Kidney Foundation is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI).

Chronic kidney disease (CKD) is an under-recognized public health crisis affecting 30 million adults in the U.S. Astonishingly, over 90% do not know they have it. A full third of the U.S. population is at risk for this disease. Kidney disease is the 9th leading cause of death in the U.S. and is growing in prevalence and is the fastest growing of non-communicable diseases terms of in burden largely due to death caused by diabetic CKD.^{1,2} CKD costs the Medicare program alone nearly \$100 billion annually. While CKD is recognized for the costs associated with progression to kidney failure and dialysis, recent data illustrate that unrecognized CKD has significant impact on outcomes and healthcare utilization, beginning with the earliest stages.³

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¹ Hoeger, Thomas, et al. The Future Burden of CKD in the United States: A Simulation Model for the CDC CKD Initiative *American Journal of Kidney Disease* (2015); 65(3):403-411.

² Bowe, B., et al. Changes in the US Burden of Chronic Kidney Disease From 2002 to 2016: An Analysis of the Global Burden of Disease Study, JAMA Netw Open. 2018 Nov 2;1(7):e184412. doi: 10.1001/jamanetworkopen.2018.4412.

³ Golestaneh L, Alvarez PJ, Reaven NL, et al. All-Cause Costs Increase Exponentially with Increased Chronic Kidney Disease Stage. American Journal of Managed Care 2017;23:S0.

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Current guidelines for CKD testing recommend that adults with diabetes and/or hypertension be evaluated at least annually for albuminuria. Less than 10% of those with hypertension and less than 40% of those with diabetes are appropriately assessed.^{4,5} People with both low eGFR and high ACR have increased risk of cardiovascular events and death.^{6,7} Early recognition and management of CKD allows clinicians and patients more opportunities to protect kidney health.

For people with CKD who do progress to kidney failure also known as end-stage renal disease (ESRD) a kidney transplant or dialysis is necessary for survival. New projections indicate an expected 11-18% increase in ESRD incidence from 2015 to 2030.8 Currently there are over 700,000 Americans with ESRD. Nearly 500,000 ESRD patients receive dialysis at least 3 times per week to replace kidney function and over 200,000 Americans live with a kidney transplant. Nearly 100,000 individuals are waiting for a kidney transplant and last year nearly 20,000 received a kidney. Unfortunately, most ESRD patients will die without having the opportunity to receive a kidney – 12 people on the waitlist die each day.

The Healthy People 2030 CKD objectives will set the national focus on improvements in outcomes for kidney patients. The National Kidney Foundation supports all of the CKD HP2030 and offers the following recommendations and clarifications:

CKD-2030-01 Reduce the proportion of the U.S. adult population with chronic kidney disease

Reduction in the proportion of the U.S. adult population with CKD is critically important and only possible with a focus on prevention. Recognition and awareness of kidney health as a public health priority is necessary to create a focus on prevention and therefore, we believe having it as stated goal is necessary. We also believe that a focus on diabetes and pre-diabetes management as well on hypertension management is critical to the success of the goal. Therefore, we also support HDS-2030-06 Increase the proportion of adults with hypertension whose blood pressure is under control and

⁴ USRDS 2013 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. Bethesda, MD; 2013.

⁵ Navaneethan SD, et al. Facility-Level Variations in Kidney Disease Care among Veterans with Diabetes and CKD, Clin J Am Soc Nephrol. 2018 Dec 7;13(12):1842-1850. doi: 10.2215/CJN.03830318. Epub 2018 Nov 29.

⁶ Go AS, Chertow GM, Fan D, McCulloch CE, Hsu C-y. Chronic Kidney Disease and the Risks of Death, Cardiovascular Events, and Hospitalization. New England Journal of Medicine 2004;351:1296-305.

⁷ Matsushita K, Coresh J, Sang Y, et al. Estimated glomerular filtration rate and albuminuria for prediction of cardiovascular outcomes: a collaborative meta-analysis of individual participant data. The Lancet Diabetes & Endocrinology;3:514-25.

⁸ McCullough KP, et al. Projecting ESRD Incidence and Prevalence in the United States through 2030, J Am Soc Nephrol. 2019 Jan;30(1):127-135. doi: 10.1681/ASN.2018050531. Epub 2018 Dec 17.

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all of the Diabetes objectives, particularly *D-2030-06 Increase the proportion of adults with known diabetes who receive an annual urinary albumin test.*

CKD-2030-02 Increase the proportion of adults with chronic kidney disease who know they have reduced kidney function

Given the substantial underdiagnosis of CKD and lack of awareness in people with the disease, we believe this objective is the top priority for CKD. The National Kidney Foundation believes this metric should also be included as a leading health indicator because of growing CKD prevalence, disproportionate impact on minorities, and its associated healthcare costs and the large public investment in caring for CKD patients, including those who progress to ESRD as they are eligible to Medicare regardless of age.

CKD-2030-03 Increase the proportion of Medicare beneficiaries aged 65 years or older who have a follow-up evaluation of their kidney function 3 months after a hospitalization with acute kidney injury

CKD-2030-04 Increase the proportion of Medicare beneficiaries aged 65 years or older with chronic kidney disease who receive medical evaluation with serum creatinine, lipids, and urine albumin tests

The National Kidney Foundation questions why these objectives have been limited to Medicare beneficiaries age 65 years and older. Given that HP2030 drives a public health focus on improving outcomes, we believe limiting these objectives could be misleading to the public on their importance. Primary care clinicians, community health centers, commercial health insurers and others have a significant role to play in improving identification and early treatment of CKD and there is a growing burden of CKD in the under 65 population. If it is a matter of data challenges, we recognize that USRDS has been able to obtain commercial data in the past to help with CKD prevalence and diagnosis estimates and suggest that there may be additional opportunities to identify progress on this national goal using those non-Medicare data sets. Alternatively, HP 2030 could use the same language from the HP2020 objectives to articulate the goals in the absence of age, noting data limitations in the full descriptions to ensure there is not an unintended consequence of misinterpretation of the importance these goals have for all adults who experience AKI or have CKD.

CKD-2030-05 Increase the proportion of adults with diabetes and chronic kidney disease who receive recommended medical treatment with angiotensin converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs)

The KDIGO and KDOQI clinical practice guidelines for the evaluation and management of CKD recommend treatment with an ACE or ARB as the first line treatment for individuals with elevated urine albumin to prevent or slow progression of CKD.

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CKD-2030-06 Reduce the proportion of adults with chronic kidney disease who have elevated blood pressure

Blood pressure management for individuals with CKD is recommended by KDIGO and KDOQI clinical practice guidelines for evaluation and management of CKD and by the recent American College of Cardiology (ACC) and American Heart Association (AHA) Guidelines. However, we inquire as to how elevated blood pressure will be defined as part of this objective. While the KDIGO/KDOQI guidelines recommend a target equal to or below 140/90 ACC/AHA recommends a target equal to or below 130/80. Given that a couple of large trials on blood pressure management that included CKD patients were conducted after the publication of the KDIGO/KDOQI guidelines 130/80 is likely a reasonable goal for CKD patients, but there is less certainty in non-diabetics with CKD.

CKD-2030-07 Reduce the rate of new cases of end-stage kidney disease

The National Kidney Foundation strongly supports this goal. Preventing and delaying progression of CKD to ESRD can be accomplished with a focus on earlier identification and management, including treatment as appropriate with ACE/ARB, avoiding prescription and over the counter non-steroidal inflammatory drugs, control of comorbidities, appropriate referral to a nephrologist, and self-management through exercise, diet changes, and other behavioral changes. However, the focus on CKD needs to start early with proper assessment and diagnosis in primary care and continued treatment and monitoring. Over 40 percent of ESRD patients start dialysis emergently with little to no nephrology care.

CKD-2030-08 Reduce the proportion of adult hemodialysis patients who use catheters as the only mode of vascular access

The National Kidney Foundation agrees that use of a hemodialysis catheter should be limited given the significant risk of blood stream infections. This goal also aligns with the CDCs work to prevent blood stream infections in hemodialysis patients. However, we note that even the presence of a catheter increases patient's risk for infection and therefore question the wording "who use catheters..." A better change to this metric would be to state "reduce the proportion of adult hemodialysis patients who have a catheter in place."

CKD-2030-09 Increase the proportion of persons younger than 70 years receiving a kidney transplant within 3 years of initiating treatment for end-stage kidney disease

The National Kidney Foundation supports this goal. There is a need to increase both the availability of organs and removing barriers to dialysis patients receiving a transplant which include, lack of education and information on transplant and living donation and financial barriers including the cost of immunosuppressive drugs and loss of Medicare post-transplant, among others.

CKD-2030-10 Reduce the death rate for persons on dialysis

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The death rate among persons on dialysis has been declining over the past several years due to focused efforts to improve outcomes for patients. The National Kidney Foundation supports the continuation of this objective and believes strategies to increase home dialysis and investment in innovative new treatments will contribute to ongoing declines allowing dialysis patients to live longer, higher quality lives.

While the National Kidney Foundation recognizes the desire to reduce the number of Healthy People objectives for 2030, we have significant concerns about the following objectives that are missing that would drive a focus on critical gaps in care.

HP2020 CKD-7 Reduce the number of deaths among persons with chronic kidney disease

While we appreciate the focus in the core objectives of reducing the number of new ESRD starts and lowering the death rate for dialysis we believe a focus on reducing CKD mortality overall is critical. CKD is the 9th leading cause of death and people with CKD are much more likely to die than progress to ESRD. The number of CKD patients who progress to ESRD is less than 3 percent while the mortality rate for Medicare beneficiaries with CKD not on dialysis is more than double for a Medicare beneficiary without CKD.

HP2020 CKD-13.2 Increase the proportion of patients who receive a preemptive transplant at the start of ESRD

Unfortunately, the status of our healthcare system for kidney care favors ESRD starts on dialysis, particularly in-center hemodialysis because of the financial incentives and ease of burden on the nephrologist who has better access to a multi-disciplinary care team once the patient starts dialysis. The National Kidney Foundation is leading the charge to try and change this with a focus on better CKD care first and renal replacement therapy starts with a pre-emptive transplant. Preemptive transplant can be increased with a focus on increasing the supply of organs, including increasing living donation, and increasing opportunities for patients to get on the transplant waitlist before needing to start dialysis. Over the past decade early initiation of dialysis despite evidence of its lack of benefit was increasing until very recently. Preemptive transplants are associated with increased survival in patients with ESRD.

<u>The National Kidney Foundation Recommends a New Objective also be added to the Hypertension Objectives</u>

Increase the proportion of persons with hypertension who obtain a urine albumin creatinine ratio

Given the high prevalence of CKD in people with hypertension, the substantial increased risk of cardiovascular disease and the significantly low use of urine albumin assessment in those individuals the National Kidney Foundation recommends a new core **hypertension** objective to obtain a urine albumin creatinine ratio in individuals with hypertension that is similar *D-2030-06*. The ACC/AHA and KDOQI quidelines both support urine albumin assessment in this population. We believe this should be added to

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the hypertension objectives. Alternatively, since the frequency of such assessments has not been clarified in guidelines, we suggest adding annual assessment urine albumin creatinine ratio as a hypertension research objective.

The National Kidney Foundation Commitment to Driving Progress on HP 2030 Objectives

Recently, the National Kidney Foundation released the Chronic Kidney Disease Change Package, which contains suggested process improvements that health care providers and health systems can utilize to improve chronic kidney disease (CKD) screening, recognition and management. The CKD Change Package also includes discussion of these change concepts and change ideas taken directly from interviews with teams that have integrated CKD care into their practice settings.

This document was developed in collaboration with the HHS Million Hearts ® team follows the format of the Million Hearts Hypertension Change Package in compiling change concepts, change ideas, evidence-or practice-based tools and resources. For many organizations, the first step to implementing a CKD program is to increase the visibility of CKD as an important entity to follow. There is a high awareness threshold regarding CKD that must be overcome within the institution outside of nephrology. The full burden of CKD must be clearly understood across the institution for a CKD program to be successful. The National Kidney Foundation will use this tool to identify partners and work to drive practice change that will allow organizations to meet many of the newly proposed HP 2030 recommendations.

The National Kidney Foundation thanks the Advisory Committee for its continued work to set the Nations public health priorities. We stand ready to continue our work to drive forward improvements in the objectives related to kidney health and chronic kidney disease. Please contact Tonya Saffer, Vice President, Health Policy at tonya.saffer@kidney.org or 202.244.7900 extension 717, with any questions.

Sincerely,

Kevin Longino

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Kevin Longino CEO and Kidney Transplant Patient Holly Mattix-Kramer, MD President