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September 6, 2022

The Honorable Chiquita Brooks-LaSure  
Administrator, Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue SW  
Washington, DC 20201

Re: Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts

Dear Administrator Brooks-LaSure,

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the CY 2023 Payment Policies Under the Physician Fee Schedule. NKF is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention, and treatment of kidney disease in the U.S. 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).

More than 37 million Americans have chronic kidney disease (CKD), including nearly 800,000 with irreversible kidney failure. Another 80 million Americans are at risk for developing kidney disease from hypertension, diabetes, and other risk factors. Unfortunately, 90 percent of those with CKD have not been diagnosed. The Medicare program spends approximately \$153 billion – more than 24 percent of total spending – on patients with kidney disease. Further, end stage kidney disease, which affects only 1 percent of Medicare beneficiaries, accounts for 7 percent of Medicare spending.

Several policies and opportunities outlined in the proposed CY 2023 Physician Fee Schedule have the potential to improve kidney disease awareness, diagnosis, and management and to improve the lives of individuals with kidney disease and their families. NKF commends CMS for addressing many of these issues in the proposed rule and offers comments and additional recommendations on the following areas:

1. Kidney Evaluation for People with Diabetes
2. Kidney for Value Pathway
3. Medical Nutrition Therapy
4. Medicare Coverage of Dental Services



## **Kidney Evaluation for Diabetes**

NKF applauds CMS for including the Kidney Evaluation for Diabetes Measure in the Quality Payment Program. CKD stemming from diabetes specifically occurs in almost 30% of patients with diabetes<sup>i</sup> and 60% of incident ESRD patients in 2019 had diabetes (2021 USRDS Annual Data Report). Total Medicare fee-for-service (FFS) spending for beneficiaries with CKD who did not have ESRD was \$87.2 billion in 2019, representing 23% of total Medicare FFS expenditures.<sup>ii</sup> The hospitalization rate for Medicare CKD patients is 2.4 times higher than those without a CKD diagnosis and CKD patients are readmitted to the hospital more frequently than those with other diagnoses<sup>iii</sup> and CKD is the 10th leading cause of death in the U.S. If left untreated, CKD can progress to kidney failure and early cardiovascular disease (CDC, 2020). The most common risk factor for CKD is diabetes.

Unfortunately, CKD screening among at-risk patients is suboptimal. A report by the US Renal Data System found that less than half of patients with diabetes had ever undergone any urine albumin testing – an important test to assess severity of kidney disease. Furthermore, different methods of assessing albuminuria were used, such as measurement of urinary protein dipstick, which has lower sensitivity for predicting kidney events compared with the urine albumin creatinine ratio (uACR).<sup>iv</sup>

The Kidney Health Evaluation for Patients with Diabetes measure represents an important opportunity to improve the number of adult patients with diabetes who receive an annual kidney health evaluation, including both an estimated glomerular filtration rate (eGFR) and uACR, as recommended by both the National Kidney Foundation and the American Diabetes Association. Quality indicators that improve rates of routine testing for CKD in patients with diabetes are important because Americans with diabetes may not feel ill or notice any symptoms until the CKD is advanced at which time opportunities to prevent or delay progression may have been missed. Kidney Health Evaluation for Patients with Diabetes will drive important interventions to delay CKD and maintain kidney health in adult patients with diabetes.

Adoption of the Kidney Health Evaluation measure will incentivize appropriate screening of individuals at risk for CKD and should address the challenge of underdiagnosis that often contributes to missed opportunities to delay progression of kidney disease, dialysis “crash-starts” and preventable cardiovascular events. Current kidney and cardiovascular protective therapies described in the next paragraph are indicated in part based on the eGFR and uACR test results. NKF strongly supports this measure.

We also encourage CMS to develop a measure to incentivize delayed progression of kidney disease. Early detection of kidney disease needs to be accompanied by early intervention to maximize the potential for slowing or preventing progression to kidney failure. The benefits of blood pressure control and blockade of the renin-angiotensin system (RAS) with angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs), have been the mainstay of the therapeutic



armamentarium for more than two decades; however significant gaps in care have been documented. Additionally, several newer classes of medications –sodium-glucose co-transporter-2 (SGLT2) inhibitors and non-steroidal mineralocorticoid receptor antagonists (nsMRAs)– have been shown to reduce risk for kidney failure and cardiovascular disease (CVD). Despite the efficacy and value of these novel therapies, and recommendations for their use in clinical practice guidelines, a recent study found that only six percent of individuals with diabetes are accessing SGLT2s or nsMRAs. A delayed progression measure could incentivize several effective interventions, such as prescribing of these therapies, utilization of medical nutrition therapy, and meeting blood-pressure control targets, all of which would improve patient outcomes. The Medicare program would benefit from measures that promote access to therapies and services that help patients preserve their kidney function.

### **Proposed Optimal Care for Kidney Health MVP**

NKF applauds CMS for including the proposed “Optimal Care for Kidney Health MIPS Value Pathway” measure set in its updates to the Quality Payment Program. In October 2020, KDIGO (Kidney Disease: Improving Global Outcomes) published its first clinical practice guideline directed specifically to the care of patients with diabetes and chronic kidney disease. Relevant to the proposed measure set, KDIGO recommends an individualized HbA1C target ranging from <6.5 to <8.0 in patients with diabetes and CKD not treated with dialysis. KDIGO also endorses blood pressure control generally, and specifically treatment with an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) in patients with diabetes, hypertension, and albuminuria. NKF also is a proud partner with the Centers for Disease Control and Prevention, which recommends influenza and pneumococcal vaccination for individuals with kidney failure. NKF also strongly supports efforts to include patients in their care plans (e.g., Advance Care Planning discussions)

The proposed measures are patient-centered, will help slow the progression of chronic kidney disease, and will strengthen our health care delivery system to better care for individuals with kidney disease. Similar to our comments above, we believe this measure set would be strengthened by the development and inclusion of a measure aimed at broader optimization of pharmacologic management targeting delayed-progression of kidney disease.

### **Medicare Coverage of Dental Services**

Oral health is critically important for individuals with chronic kidney disease. Routine dental care is necessary for transplant recipients both before and after surgery. Because immunosuppressive medications are used to prevent organ rejection, common periodontal infections could become much more serious for transplant recipients. For this reason, the National Institute of Dental and Craniofacial Research recommends that, “Whenever possible, all active dental disease should be aggressively treated before transplantation, since post-operative immunosuppression decreases a patient’s ability to resist systemic infection.”



Further, kidney failure patients have higher rates of decayed, missing, and filled teeth, dental plaque, loss of attachment, xerostomia, gingivitis, periodontitis, as well as mouth and jaw-bone lesions, than the general population. The consequences of poor oral health are worse for kidney failure patients due to advanced age, diabetes, polypharmacy and impaired immune function.

Given the risks of poor oral health for patients across the continuum of kidney disease, NKF appreciates CMS's proposal to codify Medicare coverage of certain dental procedures when they are "inextricably linked to, and substantially related and integral to the clinical success of, an otherwise covered medical service," and other modifications. Providing greater clarity over covered dental services will undoubtedly be of value for kidney patients.

NKF also supports efforts to expand Medicare coverage for all dental services. It is well established that chronic diseases disproportionately impact Medicare beneficiaries and impose a substantial cost on the federal government. Untreated oral microbial infections are closely linked to a wide range of costly chronic conditions, including diabetes, heart disease, and stroke – all risk factors and comorbidities for CKD. Despite these risks, Medicare explicitly excludes treatments for microbial infections relating to the teeth and periodontium. There is simply no medical justification for this exclusion, especially in light of the broad agreement among health care providers that such care is integral to the medical management of numerous diseases and medical conditions. Moreover, the lack of medically necessary oral/dental care heightens the risk of costly medical complications, increasing the financial burden on Medicare, beneficiaries, and taxpayers.

The Medicare program and all its beneficiaries should not be without the vital clinical and fiscal benefits of coverage for medically necessary oral/dental health therapies. Given the significant potential to improve health outcomes and reduce program costs, NKF has joined with dozens of other patient and provider organizations and calls on the Administration to explore options for extending such evidence-based coverage for all Medicare beneficiaries.

### **Medical Nutrition Therapy**

NKF applauds CMS for its efforts to increase beneficiary utilization of the Part B MNT benefit but believes that more can be done within CMS's authority to further improve access to MNT.

**Update the definition of diabetes in § 410.130 Definitions to include HbA1c  $\geq$  6.5% as recommended in national standards of medical care for diabetes.** As is the case with classification and diagnostic guidelines for kidney disease, the definition of diabetes for the purposes of the MNT benefit has not been updated since the original NCD. HbA1c testing has been accepted among the clinical community as a diagnostic test for abnormal glycemic status for a decade. Both the United States Preventive Services Task Force<sup>v</sup> and the American Diabetes Association Standards of Care<sup>vi</sup> recommend use of any of three testing methods to screen for abnormal blood glucose: fasting plasma glucose, HbA1c, and two-hour plasma glucose.



**Further expand the definition of kidney disease in § 410.130 Definitions to include G Stage 1 Kidney Damage with normal or high kidney function (GFR 90 ml/min/1.73m<sup>2</sup> or higher), G Stage 2 Kidney Damage with mildly decreased kidney function CKD (GFR 60-89 ml/min/1.73m<sup>2</sup>) and G Stage 5... to include the full breadth of non-dialysis dependent chronic kidney disease.<sup>vii</sup>**

Section 1861(s)(2)(V)(ii) of the Social Security Act allows for MNT for a “beneficiary with ... renal disease who...is not receiving maintenance dialysis.” Medicare expenditures increase dramatically from stages 1-2 to stages 4-5.<sup>viii</sup> Covering MNT for these earlier stages of CKD is a low-cost intervention proven to slow or prevent CKD progression.<sup>ix</sup> Also, some G Stage 5 patients with a GFR below 15 ml/min/1.73m<sup>2</sup> may not yet be on dialysis and so not receiving nutrition services under the ESRD benefit. Such patients would benefit from MNT services under the Part B benefit. Of note, the ICD-10 code file associated with the MNT NCD (180.1) and issued by CMS to the Medicare Administrative Contractors for claims processing purposes includes the ICD-10 codes for all stages of CKD. To address potential concerns about risk of fraudulent billing, NKF echoes recommendations that **CMS create a modifier code (perhaps utilizing ICD-10-CM code N18.5 which is applied to patients not on dialysis) to be appended to claims for Part B MNT services to indicate when a Medicare beneficiary with Stage G5 CKD is not receiving dialysis.**

### **Medicare Potentially Underutilized Services**

NKF commends CMS for exploring strategies to increase utilization for under-utilized Medicare benefits that not only promote beneficiary health and wellbeing but are also cost-effective. Medical Nutrition Therapy (MNT) is a prime example of a significantly under-utilized benefit that could more broadly and deeply benefit patients and their families if simple policy changes are made to enhance patient access.

Similarly, Kidney Disease Education (KDE) is highly effective in promoting informed dialysis selection, optimal dialysis starts, and home-dialysis use. Unfortunately, less than one percent of patients with kidney failure receive Medicare KDE prior to dialysis initiation, and African American race, Hispanic ethnicity, and the presence of congestive heart failure and hypoalbuminemia are associated with significantly lower odds of receiving KDE services.<sup>xi</sup>

Current benefit design for both MNT and KDE restricts qualified health care professionals from delivering services and limits coverage to specific, finite settings. The public health emergency has demonstrated that safe and effective care can be achieved by health care teams who are located outside of the same physician office setting, while also expanding beneficiary access to much needed services, in particular those beneficiaries who were limited to access because of challenges related to transportation, long commutes to physician offices, inflexible work schedules, and/or provider shortages. We encourage CMS to use all potential authority to expand the universe of patients who can access these important services and to provide greater flexibility around qualifying health care professional and settings where services can be provided.

In closing, we again appreciate the opportunity to comment on the proposed CY 2023 proposed rule, and for CMS’ efforts to ensure high-quality care for individuals with kidney disease. Please contact



Sharon Pearce at [Sharon.Pearce@kidney.org](mailto:Sharon.Pearce@kidney.org) to further discuss any of NKF's positions or recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "K Longino".

Kevin Longino  
CEO and Transplant Patient

A handwritten signature in black ink, appearing to read "Paul M. Palevsky".

Paul M. Palevsky, MD  
President

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<sup>i</sup> Afkarian M, Zelnick LR, Hall YN, Heagerty PJ, Tuttle K, Weiss NS, de Boer IH. Clinical Manifestations of Kidney Disease Among US Adults With Diabetes, 1988-2014. *JAMA*. 2016 Aug 9;316(6):602-10. doi: 10.1001/jama.2016.10924. PMID: 27532915; PMCID: PMC5444809.

<sup>ii</sup> <https://adr.usrds.org/2021/chronic-kidney-disease/6-healthcare-expenditures-for-persons-with-ckd>

<sup>iii</sup> Saran R, Robinson B, Abbott KC, Bragg-Gresham J, Chen X, Gipson D, Gu H, Hirth RA, Hutton D, Jin Y, Kapke A, Kurtz V, Li Y, McCullough K, Modi Z, Morgenstern H, Mukhopadhyay P, Pearson J, Pisoni R, Repeck K, Schaubel DE, Shamraj R, Steffick D, Turf M, Woodside KJ, Xiang J, Yin M, Zhang X, Shahinian V. US Renal Data System 2019 Annual Data Report: Epidemiology of Kidney Disease in the United States. *Am J Kidney Dis*. 2020 Jan;75(1 Suppl 1):A6-A7. doi: 10.1053/j.ajkd.2019.09.003. Epub 2019 Nov 5. PMID: 31704083.

<sup>iv</sup> Lambers Heerspink HJ, Gansevoort RT, et al. Comparison of different measures of urinary protein excretion for prediction of renal events. *J Am Soc Nephrol*. 2010;21(8):1355-1360. [PMC free article] [PubMed] [Google Scholar]

<sup>v</sup> Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening. U.S Preventive Services Task Force. October 26, 2015.

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-abnormal-blood-glucose-and-type-2-diabetes>. Accessed August 17, 2021.

<sup>vi</sup> Classification and Diagnosis of Diabetes: *Standards of Medical Care in Diabetes—2021*. American Diabetes Association. *Diabetes Care* Jan 2021, 44 (Supplement 1) S15-S33; DOI: 10.2337/dc21-S002.

<sup>vii</sup> National Kidney Foundation. Estimated Glomerular Filtration Rate (eGFR). <https://www.kidney.org/atoz/content/gfr>. Accessed August 17, 2021.

<sup>viii</sup> United States Renal Data System. Chapter 6: Healthcare Expenditures for Persons with CKD.

<https://adr.usrds.org/2020/chronic-kidney-disease/6-healthcare-expenditures-for-persons-with-ckd>. Accessed August 17, 2021.

<sup>ix</sup> de Waal D, Heaslip E, Callas P. Medical Nutrition Therapy for Chronic Kidney Disease Improves Biomarkers and Slows Time to Dialysis. *J Ren Nutr*. 2016; 26(1): 1-9.

<sup>x</sup> Kramer H, Yakes Jimenez E, Brommage D, et al. Medical Nutrition Therapy for Patients with Non-Dialysis-Dependent Chronic Kidney Disease: Barriers and Solutions. *J Acad Nutr Diet*. 2018; 118(10): 1958-1965.

<sup>xi</sup> Shukla AM, Bozorgmehri S, Ruchi R, Mohandas R, Hale-Gallardo JL, Ozrazgat-Baslanti T, Orozco T, Segal MS, Jia H. Utilization of CMS pre-ESRD Kidney Disease Education services and its associations with the home dialysis therapies. *Perit Dial Int*. 2021 Sep;41(5):453-462. doi: 10.1177/0896860820975586. Epub 2020 Dec 1. PMID: 33258420.