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September 12, 2025

The Honorable Dr. Mehmet Oz Administrator, Centers for Medicare and Medicaid Services Hubert H. Humphrey Building 200 Independence Avenue SW Washington, DC 20201

Re: Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

#### Dear Administrator Oz

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the proposed CY2026 Physician Fee Schedule rule. We are writing to elevate the underrecognized public health crisis of underdiagnosed chronic kidney disease (CKD). CKD is a public health crisis hidden in plain sight. Over 35 million people are affected, and the majority are unaware. The linchpin of transforming CKD care begins with a <u>uniquely simple solution</u>: people at-risk and people who have documented evidence of kidney damage in their health record must be given this information and the health system must transform to enable them to protect their kidney health. Numerous positive outcomes desired by every stakeholder flow from this simple solution. If we can prevent and treat kidney disease early, we will dramatically improve the health of the nation.

For the purposes of the proposed CY2026 Physician Fee Schedule, the foundation of our comments is securing kidney disease screening by advocating for widespread adoption of the Kidney Health Evaluation for Adults with Diabetes (KED) quality measure. The KED measure is a foundational screening measure in kidney disease that is driving improvements in guideline-concordant detection and classification of kidney disease. Other policy recommendations outlined in this letter build on kidney disease screening to secure transformation of the beneficiary journey to focus on prevention and early detection of kidney disease:

- Provisions on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services: The National Kidney Foundation implores CMS to act on the nomination submitted to CMS for coverage under the inextricably linked standard for dental services associated with treatment of diabetic nephropathy.
- The Proposed Ambulatory Specialty Model (ASM): NKF strongly supports the ASM Model.
- **Medicare Diabetes Prevention Program (MDPP):** Diabetes is the leading cause of kidney disease. The National Kidney Foundation (NKF) supports changes to the MDPP to expand



virtual care options and simplify data collection. We strongly support refinements to the MDPP policy that would extend access to more beneficiaries.

- Updates to the Quality Payment Program and Medicare Promoting Interoperability Program: The National Kidney Foundation (NKF) supports expanded use of the Kidney Health Evaluation for Adults with Diabetes (KED) measure across MIPS for Value Pathways (MVPs).
- **Medicare Shared Savings Program**: We strongly support the inclusion of Kidney Health Evaluation for Adults with Diabetes (KED) in the APP Plus quality measure set as an approach to increasing focus on chronic disease management by APM Entities.
- Request for Information (RFI) on Prevention and Management of Chronic Disease: NKF supports regulatory changes to the Medical Nutrition Therapy (MNT) benefit, the Medicare Diabetes Prevention Program (MDPP), and Diabetes Self-Management Training (DSMT) to expand access to evidence-based prevention.

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# Provisions on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services

The National Kidney Foundation (NKF) urges CMS to act on the nomination for Medicare coverage of dental services for patients with diabetic nephropathy, also known as diabetic kidney disease, as medically necessary and integral to the treatment of their disease. Unfortunately, the proposed Physician Fee Schedule for CY2026 did not address the nomination for coverage of certain dental services that are inextricably linked to medical treatment of diabetic kidney disease. Acting on the nomination expeditiously would be consistent with the Make America Health Again (MAHA) strategy released on September 9, 2025, that directs the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) to conduct research related to the connection between oral health and chronic diseases like cardiovascular disease, diabetes, and autoimmune conditions. While the MAHA strategy focuses on pediatric oral disease, a broader lens on "Oral Health & Systemic Disease Connection" is aligned with the President's goal in establishing the MAHA Commission of "aggressively combat[ing] the critical health challenges facing our citizens" and further with his directive that "executive departments and agencies (agencies) that address health or healthcare must focus on reversing chronic disease."

Under the MAHA banner, CMS has a vital role in establishing, expressing, and acting on a vision for a healthcare system that better emphasizes evidence-based prevention. Many efforts to expand access to evidence-based prevention are stymied by the longstanding policy problem that many preventive services, including prevention-oriented dental services, struggle to demonstrate an immediate return on investment to the Supplementary Medical Insurance (SMI) Trust Fund. We understand that CMS is dubious that expanding access to dental services inextricably linked to, and essential for, the clinical

<sup>&</sup>lt;sup>1</sup> https://www.whitehouse.gov/wp-content/uploads/2025/09/The-MAHA-Strategy-WH.pdf

<sup>&</sup>lt;sup>2</sup> https://www.whitehouse.gov/presidential-actions/2025/02/establishing-the-presidents-make-america-healthy-again-commission/?utm\_source=chatqpt.com



success of services related to diabetic kidney disease, will ultimately be cost saving. We note that there is a body of evidence that suggests cost savings can accrue to payers. For diabetes patients specifically, periodontal treatment has been shown to reduce diabetes-related healthcare costs by 31 percent in a study of 41,598 patients.<sup>3</sup> Another analysis of 15,002 newly diagnosed diabetes patients found that periodontal interventions resulted in \$1,799 lower total healthcare costs and \$408 lower diabetes-specific costs.<sup>4</sup> A comprehensive study of 23,771 patients showed a four percent reduction in total healthcare costs, 13 percent reduction in hospital costs, and seven percent reduction in diabetes drug costs following periodontal treatment.<sup>5</sup>

We also note that the inextricably linked standard does not require demonstrated savings to the SMI Trust Fund over any specific period. The standard only requires that dental exams and treatment be medically necessary for, and inextricably linked to, certain major covered medical services. We know from clinical studies that treatment of oral infections, such as periodontitis and related inflammation, meaningfully improves outcomes associated with Medicare-covered treatments for diabetic kidney disease. Kidney disease is highly enriched in the Medicare population. In 2022, 15.4% of the approximately 23.2 million Medicare FFS beneficiaries aged ≥66 years had a diagnosis of CKD.<sup>6</sup> CKD is dramatically underdiagnosed, so the true prevalence of CKD in the Medicare population is likely much higher. The Centers for Disease Control and Prevention (CDC) estimate that approximately 34% of adults 65 and older have CKD.<sup>7</sup> When CKD progresses, the Medicare Trust Funds and Medicare beneficiaries, in the form of higher premiums, pay the price. Figures 1 and 2 illustrate increasing costs per patient per year (PPPY) for beneficiaries with CKD and utilization among aged beneficiaries with CKD. Note that inpatient costs are the largest proportion of costs and these are driven by cardiovascular disease and infection, among other causes. For Figure 1, PPPY (Parts A, B, and D) for beneficiaries with CKD was \$20,665 in 2022.<sup>8</sup>

<sup>&</sup>lt;sup>3</sup> Smits KPJ, Listl S, Plachokova AS, Van der Galien O, Kalmus O. Effect of periodontal treatment on diabetes-related healthcare costs: a retrospective study. BMJ Open Diabetes Res Care. 2020;8(1):e001666. Available at: https://pubmed.ncbi.nlm.nih.gov/33099508/

<sup>&</sup>lt;sup>4</sup> Nasseh K, Vujicic M, Glick M. The relationship between periodontal interventions and healthcare costs and utilization. Evidence from an integrated dental, medical, and pharmacy commercial claims database. Health Econ. 2017;26(4):519-527. Available at: https://pubmed.ncbi.nlm.nih.gov/26799518/

<sup>&</sup>lt;sup>5</sup> Blaschke K, Hellmich M, Samel C, Listl S. Impact of periodontal treatment on healthcare costs in newly diagnosed diabetes patients. Diabetes Res Clin Pract. 2021;171:108611. Available at: <a href="https://pubmed.ncbi.nlm.nih.gov/33359573/">https://pubmed.ncbi.nlm.nih.gov/33359573/</a>

<sup>&</sup>lt;sup>6</sup> https://usrds-adr.niddk.nih.gov/2024/chronic-kidney-disease/6-healthcare-expenditures-for-persons-with-ckd

<sup>&</sup>lt;sup>7</sup> https://www.cdc.gov/kidney-disease/php/data-research/index.html

<sup>&</sup>lt;sup>8</sup> https://usrds-adr.niddk.nih.gov/2024/chronic-kidney-disease/6-healthcare-expenditures-for-persons-with-ckd



Figure 1.

Per person per year spending among older adults with CKD, 2002

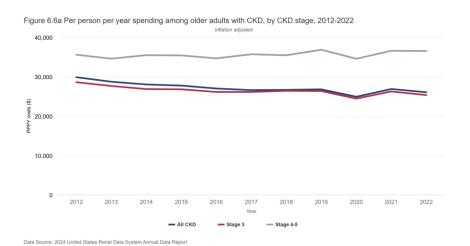
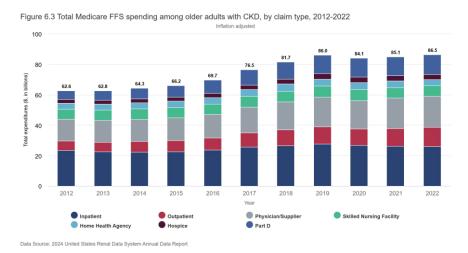


Figure 2.

Total Medicare FFS spending among older adults with CKD, 2022



Specifically, the provision of dental services (treatment of periodontitis, dental infections, abscesses, cellulitis or space infections) leads to reduction in HbA1c, improved healing, reduced rates of complications of kidney disease, improved outcomes, and the reduced likelihood of readmission and/or surgical revisions because an infection has interfered with treatment for kidney disease. Studies also show that periodontitis exacerbates kidney disease progression through multiple pathways: chronic bacterial infection leading to sustained systemic inflammation, direct bacteremia affecting renal function, and oxidative stress that damages nephrons. Research indicates that a 10 percent increase in periodontal inflammation results in a three percent decrease in renal function, with

<sup>&</sup>lt;sup>9</sup> Periodontitis Exacerbates and Promotes the Progression of Chronic Kidney Disease Through Oral Flora, Cytokines, and Oxidative Stress. Front Microbiol. 2021 Jun 11;12:656372. Available at: <a href="https://www.frontiersin.org/journals/microbiology/articles/10.3389/fmicb.2021.656372/full">https://www.frontiersin.org/journals/microbiology/articles/10.3389/fmicb.2021.656372/full</a>



oxidative stress serving as the common pathogenic mechanism.<sup>10</sup> Additional studies demonstrate that scaling and root planing in patients with type 2 diabetes can significantly decrease tooth loss by 34.1% overall and reduce microvascular complications by 20.5% in patients with CKD.<sup>11</sup>

We respectfully request that CMS take bold action to assert the importance of preventive services by committing to expanding opportunities to improve oral health for beneficiaries with diabetic kidney disease. We also note the opportunity for the traditional Medicare program to continue to set the gold standard for quality as beneficiaries transition to Medicare Advantage, where they encounter a patchwork of dental coverage policies. By asserting the value of preventive oral health services in the traditional Medicare program, CMS can scale the impact of the MAHA directive to act on the intersection of chronic disease and oral health.

## Ambulatory Specialty Model (ASM)

The National Kidney Foundation (NKF) strongly supports the proposed Ambulatory Specialty Model (ASM). Heart failure (HF) commonly occurs with kidney disease, as part of a positive feedback mechanism known as cardiorenal syndrome in which kidney disease and cardiovascular disease amplify and worsen one another. Cardio-kidney-metabolic syndrome (CKM) is also used to describe the interaction of kidney disease, cardiovascular disease (CV) and metabolic conditions like overweight and obesity. In this context, CKD is what is known as a disease multiplier, amplifying the severity of and utilization associated with this constellation of conditions.

CKDintercept, one of NKF's flagship initiatives, is a multifactorial strategy to improve CKD detection and diagnosis in the primary care setting. The initiative is achieving outstanding results with recently released data from a partnership with Sanford Health showing that a systems change approach driven by a data strategy to identify CKD based on data already documented in the electronic health record (EHR) resulted in:

- 1. The percentage of patients with diabetes receiving guideline-recommended CKD testing rising from 38% to 70%.
- 2. Diagnosis of CKD in patients with lab-confirmed evidence increasing from 20% to 73%.
- 3. Use of sodium-glucose cotransporter-2 inhibitors (SGLT2i)—a medication that slows CKD progression—jumping from under 2% to 9.6%.

The proposed ASM Model would complement strategies like CKDintercept, and other incentives deployed in the primary care setting by creating a concomitant incentive structure from the specialty

<sup>&</sup>lt;sup>10</sup> Chronic Kidney Disease and Periodontitis Interplay—A Narrative Review. PMC. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9859404/

<sup>&</sup>lt;sup>11</sup> Diabetes and Oral Health: Summary of Current Scientific Evidence for Why Transdisciplinary Collaboration Is Needed. Front Dent Med. 2021 Jul 29;2:709831. Available at: <a href="https://www.frontiersin.org/journals/dental-medicine/articles/10.3389/fdmed.2021.709831/full">https://www.frontiersin.org/journals/dental-medicine/articles/10.3389/fdmed.2021.709831/full</a>



care angle, ensuring that there is pressure on care delivery transformation and coordination across settings and ultimately, across payers. For example, NKF is the measure steward of the Kidney Health Evaluation for Adults with Diabetes (KED) measure, which drives guideline-concordant detection and classification of CKD based on two low-cost laboratory tests, the estimated glomerular filtration rate (eGFR) and the urine albumin-to-creatinine ratio (uACR). The KED measure has been adopted for use in Part B programs (the Merit-Based Payment Incentive System (MIPS), the Optimal Care for Kidney Health MVP), in the Medicare Advantage Star Ratings, and in the HEDIS measure set. The measure is promoting guideline-concordant performance of eGFR and uACR testing across federal and non-federal health programs, but its implementation must be tied to a framework for care delivery focused on prevention and early treatment of chronic disease that also emphasizes care coordination between primary and specialty care. The proposed ASM Model is an example of such a care delivery framework.

CMS proposes that the ASM Model would share some quality and cost measures with those in the Advancing Care for Heart Disease MIPS for Value Pathway (MVP) and the Rehabilitative Support for Musculoskeletal Care MVP. We hope to lend our expertise to defining specialty measure sets for cardiorenal conditions. NKF's Kidney Disease Improving Global Outcomes (KDOQI) is building on the foundational KED measure to define a core measure set for CKD. Measure concepts we are advancing include:

- Use of Novel Therapies among People with CKD and Diabetes
- Chronic Kidney Disease Diagnosis Measure Among High-Risk Populations
- Use of GFR and/or albuminuria to identify individuals with "rapidly progressing" CKD,
- Visits to nephrology among people diagnosed with late-stage CKD,
- Medical Nutrition Therapy (MNT)

As CMMI iterates on the ASM Model, some of these measure concepts may become tactical tools CMMI can deploy to encourage guideline-directed interventions to slow chronic disease progression and avoid downstream, high-cost cardiovascular utilization.

Finally, for the purposes of the Innovation Center's authorities, CMS raises questions in the proposed rule about the uptake and accessibility of annual wellness visits (AWV) providing Personalized Prevention Plan Services defined at 42 CFR 410.15. We echo comments from the Coalition for Kidney Health, which recommends the Center use its authority to increase access to kidney disease screening and care plan development as part of the AWV across the Center's Medicare model portfolio. The Innovation Center could advance this policy by requiring participants in ACO REACH, ACO PC Flex, and other models as appropriate, to offer annual wellness visits consistent with personalized prevention plan services that include the Kidney Profile, defined as an annual eGFR and uACR, among "other routine measurements as deemed appropriate, based on the beneficiary's medical and family history."

**Medicare Diabetes Prevention Program (MDPP)** 



The National Kidney Foundation (NKF) is a longtime supporter of the Medicare Diabetes Prevention Program (MDPP) and the National Diabetes Prevention Program (NDPP). We thank CMS for its steadfast stewardship of this important program. NKF participates in the Diabetes Advocacy Alliance (DAA) through which we are providing comments on the proposals in the rule. We are summarizing those comments here to amplify their importance. In summary:

- We support the asynchronous pilot program to provide the MDPP to Medicare beneficiaries with prediabetes.
- We appreciate clarification offered by CMS that weight reported by digital technology via wireless or cellular transmission is permissible and CMS' efforts to offer additional options for validated weight reporting, such as a visit to a provider office or another "reasonable location." However, we request CMS extend the timeframe for obtaining verification of the weight to a minimum of five days to account for the beneficiary burden and the reduced access to medical care in Health Professional Shortage Area (HPSA)-designated regions. We also request maximum flexibility in the process for validated weight reporting in any "reasonable location."

# Updates to the Quality Payment Program and Medicare Promoting Interoperability Program

The National Kidney Foundation (NKF) is grateful for the work CMS has done to adopt and expand use of the Kidney Health Evaluation for Adults with Diabetes (KED) measure. The KED measure is a core screening measure upon which other quality measure concepts in CKD care will ultimately build. The purpose of the KED measure is to close gaps in performance of the two low-cost lab tests needed to detect and classify CKD, particularly the urine albumin-to-creatinine ratio (uACR). Albuminuria is an established biomarker of the progression of chronic kidney disease and the risk of cardiovascular disease. There are now several therapeutic agents, in addition to focused lifestyle interventions, that can lead to albuminuria lowering and a reduction in cardiovascular risk—if patients have albuminuria detected. However, screening for albuminuria is still low, despite the very low cost of these urine-based tests.

We aim to work with CMS to define CKD quality and build on the Optimal Care for Kidney Health MVP, finalized for PY2024, although there are few measures that have been fully developed and tested that could be incorporated into a specialty measure set at present. NKF's Kidney Disease Outcomes and Quality Initiative (KDOQI) is working to advance development of the following measure concepts, some of which we believe may be of interest to CMS:

- Use of Novel Therapies among People with CKD and Diabetes
- Chronic Kidney Disease Diagnosis Measure Among High-Risk Populations
- Use of GFR and/or albuminuria to identify individuals with "rapidly progressing" CKD,
- Visits to nephrology among people diagnosed with late-stage CKD,
- Medical Nutrition Therapy (MNT)



In the interim, we encourage CMS to consider expanding the use of the KED measure in other MVPs as appropriate. We further encourage CMS to consider an MVP specifically focused on cardio-kidney-metabolic syndrome (CKM), which defines the cluster of co-occuring conditions impacting a disproportionate number of Medicare beneficiaries and incurring disproportionate costs, a key example of the costly, chronic conditions that CMS aims to make a focus.<sup>12</sup>

#### **Medicare Shared Savings Program**

The National Kidney Foundation (NKF) respectfully requests that CMS consider including the electronic clinical quality measure, Kidney Health Evaluation for Adults with Diabetes (KED) in the APP Plus quality measure set. The KED measure has been used in the Merit-Based Performance Incentive System (MIPS) since 2023. Emphasizing its relevance to the nation's health and wellbeing and the magnitude of opportunity to improve kidney disease screening, the KED measure is also a Healthcare Effectiveness Data and Information Set (HEDIS) measure and was recently included in the Medicare Advantage (MA) Star Ratings measure set.

The purpose of the KED measure is to close gaps in performance of the two low-cost lab tests needed to detect and classify CKD, particularly the urine albumin-to-creatinine ratio (uACR). Albuminuria is an established biomarker of the progression of chronic kidney disease and the risk of cardiovascular disease. There are now several therapeutic agents that can lead to albuminuria lowering and a reduction in cardiovascular risk. However, screening for albuminuria is still low. Underscoring the importance of assessing patients' cardiorenal health, new guidelines from the American College of Cardiology (ACC) and the American Heart Association (AHA) recommend that uACR tests be performed in adults who are diagnosed with hypertension to optimize management.<sup>13</sup> The American Heart Association (AHA) suggests that patients should be screened for risk factors at all stages of life to prevent and manage CKD.<sup>14</sup>

As CMS understands, many chronic conditions are closely related, and kidney disease is no exception. Kidney disease frequently occurs with diabetes, cardiovascular disease, and metabolic syndrome. This nexus of conditions is also known as cardio-kidney-metabolic syndrome (CKM). As we note elsewhere in this letter, kidney disease remains drastically underdiagnosed. Most people with kidney disease are unaware and even 1 in 3 adults with severe kidney disease do not know they have it. Individuals with CKD are more likely to die of cardiovascular disease than to progress to kidney failure. These deaths are coded as cardiovascular mortality, leading to a narrative in which the contribution of kidney disease goes underrecognized and management of the cluster of conditions with which kidney disease co-occurs is not optimized.

<sup>12</sup> https://usrds-adr.niddk.nih.gov/2024/chronic-kidney-disease/6-healthcare-expenditures-for-persons-with-ckd

<sup>&</sup>lt;sup>13</sup> Jones DW, et al. *JACC* https://www.jacc.org/doi/10.1016/j.jacc.2025.05.007

<sup>&</sup>lt;sup>14</sup> Ndumele CE, et al.

<sup>&</sup>lt;sup>15</sup> Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2023. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2023.



The APP quality measure set for CY2026 includes blood sugar and blood pressure control measures. Diabetes and hypertension are the leading causes of kidney disease, but it is imperative to note that while blood sugar and blood pressure control are cornerstones of kidney disease management, kidney disease will still go undetected without inclusion of accountability for kidney disease screening and missed opportunities to slow disease progression, particularly those where albuminuria is needed to guide treatment decisions, will persist. Making patients aware of their albuminuria levels through these low-cost tests gives them the opportunity to take charge of their own health, but that is only possible if patients receive this low-cost screening.

For the purposes of value-based care, we further note that the inclusion of the KED measure will equip APM Entities with the ability to risk stratify the attributed population based on the level of albuminuria. Risk stratification is a pillar of value-based approaches to chronic disease management, as it allows the APM Entity to target intensity of services and utilization to achieve greater value. It is also worth noting that this applies across CMMI's portfolio, and in CMS' efforts to promote value-based care for FFS patients as well. Beneficiaries with CKD are managed across the health system in a variety of settings and by a variety of providers. Some of that management may be in the primary care and family medicine settings. Beneficiaries with a higher co-morbidity burden and rapidly progressing kidney disease may need specialty referral, or even referral to a nephrology subspecialist if the cause of their kidney disease is a glomerular disease rather than diabetes or hypertension. The value-based care project depends on targeting beneficiaries to the appropriate type and intensive of care. The ability to achieve that depends on kidney disease screening.

### Request for Information (RFI) on Prevention and Management of Chronic Disease

In response to the Prevention and Management of Chronic Disease RFI in the proposed rule, we recommend the following improvements to various existing Part B benefits in Medicare:

#### **Medical Nutrition Therapy**

Nutrition counseling and structured nutrition interventions like Medical Nutrition Therapy (MNT) are essential clinical interventions for kidney patients. The Medicare program recognizes the value of care from a Registered Dietician (RD) through several mechanisms. CMS should use its existing authorities to expand access to evidence-backed nutrition interventions for beneficiaries with kidney disease. Most importantly, in alignment with the Secretary's commitment to the grassroots Make America Healthy Again (MAHA) movement, the Secretary should act to expand access to MNT for beneficiaries with CKD. Other tactical recommendations are outlined in this section.

Depending on the stage of kidney disease, people with CKD need tailored nutrition support aimed at managing blood sugar and blood pressure, reducing cardiovascular risk, controlling levels of sodium, potassium, phosphorus, calcium, and achieving a protein balance that prevents malnutrition while also reducing protein load on the kidneys. Once a patient begins dialysis, protein needs increase, and potassium and phosphorus are more restricted due to the risks of hyperkalemia and



hyperphosphatemia, respectively. Key vitamins and minerals must be replaced due to losses over the course of dialysis treatments. Patients also must deal with fluid restrictions to prevent volume overload, reduce interdialytic weight gain, and avoid low sodium concentration in the blood.

For patients with CKD, Medicare covers three hours of MNT in the first year and two hours of MNT in subsequent years. MNT regulations are codified at 42 CFR 410.130 through 42 CFR 410.134. Beneficiaries with certain stages of CKD can access MNT when referred by physician. Despite the availability of MNT, utilization is low. Several solutions have been proposed to increase MNT utilization, many of which are not actionable by CMS without new legislation. However, there are steps the Secretary should take to expand access to this essential but underused benefit. CMS should:

- Consider using the Secretary's authority to expand access to MNT for beneficiaries with all stages of CKD, thereby expanding opportunities for beneficiaries to take charge of their own health and prevent worsening outcomes from advanced CKD. The authorizing statute for MNT, enacted by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, provides wide latitude for eligibility for MNT, deferring to the Secretary to establish the criteria for eligibility "after consideration of protocols established by the dietician or nutrition professional organizations" (42 U.S.C. §1395x(s)(2)(V)). The most recent clinical practice guideline from the Kidney Disease Outcomes and Quality Initiative (KDOQI) and the Academy of Nutrition and Dietetics (AND), recommend that for adults with CKD stages 1 through 5, an RDN provide MNT with the goals of optimizing nutritional status, minimizing risks of comorbid conditions, alternations in metabolism, and adverse clinical outcomes. 16
- Resolve the longstanding issue of having codified eligibility for MNT using the outdated term "chronic renal insufficiency" rather than CKD stage. MNT regulations at 42 CFR 410.130 referring to "[c]hronic renal insufficiency" tie eligibility to glomerular filtration rate [GFR] of 15-59 ml/min/1.73m², rather than stage of CKD. Neither the National Kidney Foundation nor Kidney Disease Improving Global Outcomes (KDIGO), which produces clinical practice guidelines in nephrology, uses the phrase "chronic renal insufficiency" to mean either CKD as defined by the KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of CKD, or CKD following a kidney transplant. Updating the regulatory text to refer instead to stages of CKD would clarify eligibility in line with current guidelines, as directed by the underlying statute, and align with CMS' efforts to clarify and modernize potentially outdated regulations.
- Consider use of the CMS Innovation Center's waiver authority to waive the requirement that
  eligibility for Medical Nutrition Therapy (MNT) be based on the presence of chronic renal
  insufficiency as defined at 42 CFR § 410.130 should CMS decides not to update MNT eligibility
  regulations to cover all stages of CKD.

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<sup>&</sup>lt;sup>16</sup> https://www.ajkd.org/article/S0272-6386(20)30726-5/fulltext



• Allow Diabetes Self-Management Training (DSMT) and medical nutrition therapy (MNT) to be delivered on the same day by changing the waiting period from 1 day to 0 days.

### Medicare Diabetes Prevention Program

- We request that CMS remove the once-in-a-lifetime limit for Medicare beneficiaries to
  participate in the MDPP. CMS should allow repeat participation in the MDPP, just as it is
  allowed for intensive behavioral therapy for obesity and smoking cessation programs,
  because it is recognized that multiple attempts are often required for lasting behavioral
  changes.
- We continue to support making the MDPP a permanent benefit in Medicare to build supplier capacity to deliver the program. As CMS is aware, becoming a Medicare-enrolled supplier takes tremendous time, effort, and investment. The permanency of the program could entice more National DPP suppliers to apply to become MDPP suppliers and may entice potential suppliers to create new diabetes prevention programs and to seek CDC DPRP recognition.
- CMS requires that beneficiaries take a glucose test to enroll in the MDPP, but CDC does not require that of NDPP participants.

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The National Kidney Foundation (NKF) expresses our gratitude to CMS for its ongoing efforts to sustain and evolve the Medicare program and promote transformation in care delivery. We hope to partner to continue the transformation to improve upstream detection and management of chronic diseases like CKD, thereby making America healthy again. Please contact Miriam Godwin, Vice President of Health Policy, at Miriam.godwin@kidney.org to discuss the content of this letter.

Sincerely,

Dr. Jesse Roach, MD

Senior Vice President, Government Relations

The National Kidney Foundation