COALITION FOR KIDNEY HEALTH

September 11, 2023

The Honorable Xavier Becerra
Secretary, U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program [CMS–1784–P]

Dear Administrator Brooks-LaSure,

The Coalition for Kidney Health (C4KH) appreciates the opportunity to comment on the CY 2024 Payment Policies Under the Physician Fee Schedule. The C4KH is a multi-stakeholder group of partners with an interest in earlier detection and management of chronic kidney disease (CKD). Our mission is to transform the landscape for CKD care by advancing policies that improve awareness of CKD and screening of at-risk patients and drive forward high-quality, coordinated care focused on delaying CKD progression, preventing and managing complications and comorbidities, and empowering patients to make informed, shared decisions about their CKD in partnership with their caregivers and clinicians.

More than 37 million Americans have 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, while approximately 60-80 Americans per 100,000 have rare kidney disease that also result in kidney failure. Unfortunately, 90 percent of those with CKD have not been diagnosed. The Medicare program spends approximately $136.2 billion annually on health services for patients with kidney disease, accounting for nearly 25 percent of Medicare expenditures. The consequences of late-stage CKD and the "crash" start of dialysis cannot be overstated; End-Stage

Renal Disease (ESRD), which affects only 1 percent of Medicare beneficiaries, accounts for 7 percent of Medicare spending. [1]

Several policies and opportunities outlined in the proposed CY 2024 Physician Fee Schedule have the potential to improve kidney disease awareness, diagnosis, and management, and improve the lives of individuals with kidney disease and their families. C4KH commends CMS for addressing many of these issues in the proposed rule and offers comments and additional recommendations on the following areas:

1. Payment for Telehealth Services
2. Community Health Integration (CHI) & Social Determinants of Health (SDOH)
3. Diabetes Services and Their Implications for Kidney Health
4. Quality Measurement

Payment for Telehealth Services

C4KH commends CMS for its commitment to bolstering and refining telehealth services, especially considering their indispensable role during the public health emergency (PHE). For CKD patients, telehealth hasn't just been a convenience—it has been a lifeline. It dramatically alleviates the physical, emotional, and financial burdens associated with frequent trips to medical appointments. For ESRD patients, the relief is even more profound. Beyond the fatigue from dialysis treatments at least three times per week and the added stress of transportation and recovery, there's an often-overlooked vulnerability: their compromised immune systems. Every trip outside, be it for a check-up, consultation, or treatment, exposes kidney patients to potential health threats. Telehealth minimizes this exposure, providing a safer, more efficient care model.[2] By extending telehealth benefits, we're not just changing the mode of care delivery; we're pioneering a future where equitable access to healthcare is a reality for every patient, irrespective of where they reside. Such modalities can enable CKD management and prevention strategies to be more readily accessible, regardless of a patient's geographical location.

Health and Well-Being

While C4KH supports efforts to broaden telehealth services, we encourage CMS to be more deliberate about its extension of health and well-being coaching services through CY 24 "Specifically, the training requirements for health coaches and the adherence to best practices are of concern. C4KH advises CMS to scrutinize and align the health and well-being coaching services with those

[1] Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States (2021), https://www.cdc.gov/kidneydisease/publications-resources/CKD-national-facts.html

[2] Daugirdas, J. T., Depner, T. A., et al. (2015). KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015 update. *American Journal of Kidney Diseases, 66*(5), 884-930. https://doi.org/10.1053/j.ajkd.2015.07.015

protected under the Medical Nutrition Therapy (MNT) benefit, thereby establishing clear standards. This recommendation stems from the pressing necessity to uphold a high degree of credibility and to furnish concrete advantages to Medicare beneficiaries, particularly those living with CKD. Supporting this viewpoint is a 2021 assessment featured in Advances in Nutrition, which highlighted that "the current evidence base is not of sufficient quality to support the use of self-reported coaching as a healthcare intervention for weight loss". [3]

Implementation of Provisions of the CAA, 2023

C4KH supports the telehealth flexibilities outlined in the Consolidated Appropriations Act 2023 (CAA). By eliminating geographic and originating site constraints, an even broader spectrum of kidney patients, especially those in remote locations, can access essential care. Furthermore, the extension of payment for audio-only telephone visits through 2024 meets our objective of providing comprehensive, modality-agnostic care for CKD patients. The proposal to initiate the non-facility PFS rate for telehealth services provided in patients' homes from CY 2024 is a commendable step. Recognizing and supporting the dual, in-person and telehealth, models that many providers are adopting is crucial in fostering a patient-centered approach to care.

With the proposed delay in in-person visits for telehealth mental health services, we urge CMS to consider implementing regular quality assessments to ensure continued excellence in patient care. Given the ever-increasing reliance on telehealth, it is essential to strike a balance between flexibility and maintaining the highest standards of patient care and safety, especially for our CKD and ESRD community.

Community Health Integration (CHI) & Social Determinants of Health (SDOH)

C4KH strongly supports CMS' proposal in initiating Community Health Integration (CHI) services, especially the establishment of a distinct G code for Social Determinants of Health (SDOH) associated with an evaluation and management (E/M) visit. The risk of developing CKD is intricately linked with both medical and socio-environmental factors. Through a dedicated SDOH risk assessment, grounded in evidence-based methodology, we can better comprehend the myriad socio-environmental challenges encountered by those with CKD.

Community health workers, care navigators, and peer support specialists act as a bridge, addressing the comprehensive needs of patients who face multiple challenges and connecting them with the services and supports they need. For example, individuals in marginally food-secure households experience elevated risks of CKD compared to those in more secure situations. The challenges of

[3]Sieczkowska, S. M., de Lima, A. P., Swinton, P. A., Dolan, E., Roschel, H., & Gualano, B. (2021). Health Coaching Strategies for Weight Loss: A Systematic Review and Meta-Analysis. *Advances in Nutrition, 12*(4), 1449-1460. https://doi.org/10.1093/advances/nmaa159

managing CKD are further complicated by food insecurity, especially in low-income populations.[4] Community health workers can markedly help CKD patients grappling with food insecurity by coordinating meal services, an effort that should collaborate closely with the patient's CKD Registered Dietitian to ensure continuity of care given the intricacies of the CKD diet. By facilitating meal services for a CKD patient with food insecurity, a community health worker can help that patient remain compliant with their kidney-diet, which is tied to improved health outcomes. Measuring and reporting those social determinant risks and interventions will allow the health system to identify and expand access to the comprehensive health and human services necessary to appropriately manage CKD in the community.

C4KH further urges CMS to include the Annual Wellness Visit (AWV) in CHI services. This will provide a richer understanding of both medical and socio-environmental challenges. Given the clear disparities, especially in communities of color shaped by historical socio-political decisions, a blended approach utilizing both in-person and virtual interventions appears most beneficial.

Diabetes Services and Their Implications for Kidney Health

Expand Diabetes Screening and Modify Diabetes Definition

Diabetes is the underlying risk factor for up to 40 percent of kidney diseases[5]. Improving and streamlining diabetes definitions and management is an important strategy for reducing the incidence and progression of CKD. C4KH fully supports CMS' proposal to include the Hemoglobin A1c (HbA1c) test for diabetes screening and the proposal to remove codified clinical test requirements from the definition of diabetes and prediabetes for MNT and Diabetes Self-Management Training (DSMT) services. C4KH also supports CMS' proposal to extend telehealth provisions for DSMT and the inclusion of Registered Dietitians (RDs) in providing MNT.

It is well established that patients with diabetes are at high risk for kidney disease and that signs of chronic kidney damage can show up years before their kidney function deteriorates to a level that would qualify them as having CKD. CKD is often asymptomatic until the disease has progressed to later stages. Both the Kidney Disease Outcomes Quality Initiative (KDOQI)[6] and the Kidney Disease: Improving Global Outcomes (KDIGO)[7] emphasize the importance of screening and early intervention for CKD in at-risk populations, including those individuals with diabetes, cardiovascular disease and hypertension.

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[4] Christian A. Gregory, Alisha Coleman-Jensen. Food Insecurity, Chronic Disease, and Health Among Working-Age Adults, ERR-235, U.S. Department of Agriculture, Economic Research Service, July 2017.

[5] https://www.niddk.nih.gov/health-information/kidney-disease/high-blood-pressure

[6] DOI: https://doi.org/10.1053/j.ajkd.2021.09.010

[7] KDIGO 2012 Clinical Practice Guidelines for the Evaluation and Management of Chronic Kidney Disease. https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf Accessed Aug 23, 2023

The HbA1c test not only ensures accurate detection but also facilitates swift referrals to diabetes prevention programs, thus reducing the risk of CKD stemming from unchecked diabetes. C4KH recommends waiving cost-sharing for the HbA1c tests, as early diabetes detection is crucial to preemptively address CKD.[8] Removing financial obstacles will ensure more individuals undergo essential screenings. We also advocate for aligning the coverage of the HbA1c test for both screening and diagnosis with prevailing commercial standards.

In summary, as it relates to this section, the C4KH urges CMS to:

- Finalize proposal to simplify the regulatory definition of diabetes.
- Expand coverage of CKD to include Stage 5 (GFR < 15 mL/min/1.73 m2) when the Medicare beneficiary is not receiving dialysis.
- Explore CMS' ability to simplify the regulatory definition for chronic kidney insufficiency by removing codified diagnostic tests.

Medicare Diabetes Prevention Program (MDPP)

Diabetes is not only a primary contributor to kidney diseases but also a principal cause of kidney failure. Recognizing this intricate link, C4KH supports the proposal to extend the Medicare Diabetes Prevention Program (MDPP) until 2027.

To ensure this program has its greatest impact, C4KH endorses proposals to integrate MDPP with the CDC's National Diabetes Prevention Program (National DPP). This alignment would simplify program delivery and potentially expand the roster of MDPP suppliers. This is particularly important for kidney health, as early and consistent intervention can prevent complications that strain the kidneys. Given the growing reliance on digital health solutions, welcoming distance learning-only suppliers by adopting CDC's Diabetes Prevention Recognition Program Standards and Operating Procedures (DPRP) standards would significantly boost program reach.

C4KH's also endorses the following recommendations, which would make the program more patient centric:

1. **Multiple Participations:** Permitting beneficiaries to engage with MDPP more than once. Life events or health status changes might necessitate repeated interventions.
2. **Special Populations:** Devise strategies tailored for unique populations, ensuring every individual, regardless of their challenges, can access prevention programs.
3. **Permanent Inclusion:** The MDPP should be a mainstay in Medicare benefits, ensuring long-term commitment to diabetes and, by extension, kidney disease prevention.

[8] chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://kdigo.org/wp-content/uploads/2017/02/KDIGO-2023-CKD-Guideline-Public-Review-Draft_5-July-2023.pdf

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Medicare Shared Savings Program

The Medicare Shared Savings Program (MSSP) advances "CMS' overall value-based care strategy of growth, alignment, and equity" in support of the care provided to Medicare fee-for-service (FFS) beneficiaries by Accountable Care Organizations (ACOs). C4KH would like to comment on the following proposed changes to the MSSP for Calendar Year (CY) 2024 on behalf of people living with kidney disease at the individual and population level, particularly in rural and underserved areas:

- Medicare Clinical Quality Measures (CQMs)
- Alignment of Certified Electronic Health Record Technology (CEHRT) requirements

ACO reporting of Medicare Clinical Quality Measures (CQMs) and updates to the Alternative Payment Model (APM) Performance Pathway (APP) measure set

C4KH commends CMS' efforts to address concerns raised by stakeholders in the CY 2023 PFS proposed rule regarding "the requirement of ACOs to report all payer/all patient eCQMs/MIPS CQMS beginning with performance year 2025, such as issues related to meeting all payer data requirements, data completeness requirements, data aggregation and duplication issues, and interoperability issues among different EHRs." Considering the aforesaid concerns, the proposed rule for CY 2024 outlines steps to accompany a delayed mandatory eCQM adoption by MSSP participants in 2024 and establishes a new collection type for MSSP ACOs reporting quality data on beneficiaries eligible for Medicare CQMs. The Medicare CQMs, as stated in the rule, would serve as a transition collection type that captures a population of beneficiaries within the all payer/all patient MIPS CQM and connects them to claims encounters.

C4KH supports this provisional method, especially for ACOs with a higher proportion of specialty practices, such as nephrology clinics, or groups with multiple EHRs. Further, we whole-heartedly back the addition of three measures below as Medicare CQMs to the APP measure set for MSSP ACOs beginning with performance year 2024 and subsequent performance years:

- Quality ID#: 001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control
- Quality ID#: 134 Preventive Care and Screening: Screening for Depression and Follow-up Plan
- Quality ID#: 236 Controlling High Blood Pressure

Together, measure #001 and #236 have the potential to delay the development or progression of CKD for patients with high risk factors (diabetes and hypertension), as they address the Chronic Conditions Meaningful Measures 2.0 Area. In relation to measure #134, we have previously commented in ESRD PPS QIP proposed rules on the importance of improving the mental health of dialysis patients, as depression is the most common psychiatric condition among patients with End Stage Renal Disease (ESRD) and may exacerbate the complications of ESRD, treatment adherence, hospitalizations, and mortality findings. Additionally, the inclusion of diabetes and hypertension measures in the chronic conditions domain for the Preliminary Adult Universal Foundation Measures

speaks to the opportunity for future development and inclusion of a paired screening measure for kidney health for increased provider attention to CKD education and management. We encourage CMS to consider the development of future measures that can help increase the rate of CKD cases that are diagnosed, including for the wide array of rare kidney diseases that can lead to ESRD if not diagnosed.

Aligned Certified Electronic Health Record Technology (CEHRT) requirements for MSSP ACOs with the Merit-Based Incentive Payment System (MIPS)

C4KH applauds and supports CMS' efforts to align CEHRT requirements for ACOs between MSSP and MIPS. Comprehensive reporting requirements that address key functions to facilitate better care coordination and quality measurement is of the utmost importance to the kidney care community, as increased measure performance for kidney health can lead to higher rates of multidisciplinary care and the reduction of racial or ethnic and socioeconomic disparities in clinical outcomes.

Quality Payment Program

The Quality Payment Program (QPP) promotes the continuous improvement of quality health care services furnished by clinicians through the administration of MIPS and Advanced APMs. MIPS advances interoperability through the submission and reporting of evidence-based specialist-specific quality measures through CEHRT. Payment adjustments are reflective of performance across four categories: Cost, Quality, Improvement Activities, and Promoting Interoperability. Advanced APMs enable clinicians to ensure beneficiaries receive optimal and quality care, minus fragmentation and duplication of services. C4KH would like to comment on the following proposed changes to the QPP for Calendar Year (CY) 2024 on behalf of people living with kidney disease at the individual and population level, particularly in rural and underserved areas:

- MIPS Quality Measure Inventory
- MIPS Performance Threshold Increase
- Modifications to previously finalized MIPS Value Pathways (MVP)

MIPS Quality Measure Inventory

<u>New Quality Measures Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years:</u>

- The Gains in Patient Activation Measure (PAM®) Scores at 12 Months (PAM performance measure, PAM-PM)

  C4KH is pleased to see the proposed adoption of The Gains in Patient Activation Measure (PAM®) Scores at 12 Months (PAM performance measure, PAM-PM) in several MIPS specialty sets, including Nephrology, as well as several MIPS MVPS, including Optimal Care for Kidney Health. As CMS continues to consider new quality

measures for relevant programs, we encourage future consideration for the inclusion of PAM-PM in the ESRD PPS QIP and the Universal Foundation of Measures as the only CBE-endorsed measure of change in patient activation.

- First Year Standardized Waitlist Ratio (FYSWR), Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) measures

  C4KH strongly believes in the development of effective quality measures that address the CMS high priority clinical topic of patients with ESRD. We advocate for all patients to have access to the treatment modality of their choice and experience minimal time on the transplant waitlist or receive a living donor kidney transplant if circumstances permit. We are pleased to see the proposed adoption of the FYSWR, the PPPW, and the aPPPW measures into the MIPS Nephrology specialty set. In addition to our sentiments previously shared in review of the measures during the 2022 MAP MUC Cycle, we agree with matters raised by the former NQF Renal Standing Committee and look forward to reviewing future iterations of these measures.

<u>Modifications to previously finalized specialty measure sets Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years:</u>

- Kidney Health Evaluation measure

  C4KH is pleased to see the proposed adoption and/or continued use of the Kidney Health Evaluation measure in several MIPS specialty sets, including Family Medicine, Internal Medicine, Preventative Medicine, and Urology. As CMS continues to reassess the appropriateness of individual measures for inclusion in specialty sets, we encourage future consideration for the addition of the Kidney Health Evaluation measure to the Urgent Care specialty set. The inclusion of this measure into the Urgent Care specialty set will assist in capturing at-risk patients who may lack a primary care physician. CMS may also wish to consider, at some point, the expansion of a kidney health assessment to include patients with other risk factors besides diabetes, such as those that may increase the likelihood of glomerular disease or other rare kidney diseases.

MIPS Performance Threshold Increase

The proposed rule states for consideration of the CY 2024 performance period/2026 MIPS payment year, the performance threshold will cover a range from 75 points to 82 points. The Regulatory Impact Analysis (RIA) estimates this change would result in approximately 46 percent of MIPS eligible clinicians receiving a negative payment adjustment. While C4KH understands the need for more robust data and gradual increases in performance thresholds that best reflects MIPS eligible

clinicians' recent performance, we encourage further deliberation on the use of performance threshold ranges from alternative years.

Modifications to previously finalized MIPS Value Pathways (MVP)

Value in Primary Care MVP

CMS is proposing to modify the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled Value in Primary Care MVP. This substantial change promotes alignment with the adult core set from the Universal Foundation and the Patient Care First CMMI Model primary care measures. C4KH is supportive of this proposed change, particularly for the inclusion of Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) and Q236: Controlling High Blood Pressure that speaks to potential delays in the development or progression of CKD, as discussed above.

Optimal Care for Kidney Health MVP

C4KH supports CMS' proposal to add the following quality measures to the Optimal Care for Kidney Health MVP: Q487: Screening for Social Drivers of Health, Q488: Kidney Health Evaluation, TBD: First Year Standardized Waitlist Ratio (FYSWR), and TBD: Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW).

C4KH seeks additional clarification regarding the First Year Standardized Waitlist Ratio and Percentage of Prevalent Patients Waitlisted measures. The intent of the Optimal Care for Kidney Health MVP is towards optimal CKD care. However, there are many existing programs and quality measures already focused on end stage renal disease (ESRD) care, and there is potential for redundancy as well as misalignment. The goal of the MVP is to optimize care for patients with CKD to slow the progression of kidney disease. Towards this goal, C4KH encourages CMS to develop and implement measures that support medications such as sodium-glucose cotransporter-2 (SGLT2) inhibitor therapy and other measures to delay CKD progression.

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In closing, we again appreciate the opportunity to comment on the proposed CY 2024 proposed rule, and for CMS' efforts to ensure high-quality care for individuals with kidney disease. Please contact Ignacio Alvarez at Ignacio.alvarez@kidney.org to further discuss any of C4KH's positions or recommendations.

Sincerely,

Coalition for Kidney Health (C4KH)