COALITION FOR KIDNEY HEALTH

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Cc: Jacob Schiff, *Chief AI & Technology Officer, Center for Medicare and Medicaid Innovation*

March 9, 2026

Dear Abe,

We are writing regarding the recently announced Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model. We are writing regarding the initial tracks, including early CKM (eCKM), CKM, chronic musculoskeletal pain (MSK), and behavioral health (BH) (Appendix I). **We request that the Innovation Center include guideline concordant screening for kidney disease to the eCKM track at the next opportunity to refine the ACCESS Model policy.** We believe there may be opportunities for the Innovation Center to make this change as it has stated its intent to enroll subsequent ACCESS Model cohorts beginning January 1, 2021, and quarterly thereafter through July 1, 2033.

Our coalition is enormously gratified to see the Innovation Center taking an interest in early kidney disease. As the Center knows, kidney disease exemplifies the chronic disease crisis in the United States: a highly prevalent condition that is under-detected and under-diagnosed with extraordinary downstream consequences for Medicare beneficiaries, the Medicare program, and American taxpayers. For too long, the kidney care paradigm has been driven by the inevitably of dialysis, rather than by the opportunities to detect, diagnose, and prevent kidney disease from becoming more severe. We thank the Innovation Center for its vision in advancing an earlier stage paradigm for kidney disease treatment.

> **Patient Story**: "For ages, we have waited for sickness to tell the story of kidney disease. A patient centered approach fueled by early prevention rewrites the story. It will ensure that every person with kidney disease not just lives longer but has a much better quality of life."
>
> – ***Mary Baliker***, *Kidney Patient, Co-Chair of the National Kidney Foundation Public Policy Committee, and member of the Coalition for Kidney Health*

<u>Cardiovascular-Kidney-Metabolic Syndrome (CKM)</u>

We are especially interested in the framing of kidney disease within the larger constellation of interrelated conditions known as Cardiovascular-Kidney-Metabolic Syndrome (CKM) (Figure 1). Cardiovascular disease, kidney disease, and metabolic conditions like diabetes and overweight frequently occur together and are categorized as (CKM). The CKM model helps to explain the relationship between the cardiovascular system, metabolic risk factors, and chronic kidney disease. Taken together, 1 in 3 US adults have three or more risk factors leading to CKM syndrome, emphasizing the value of addressing CKM as a means of Making America Healthy Again.

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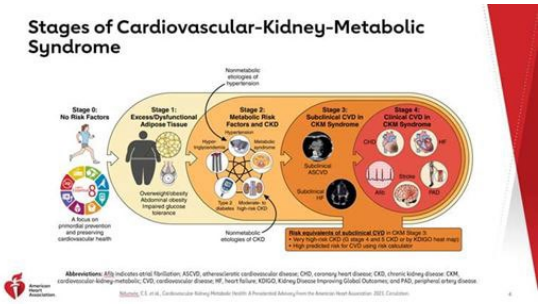
Primary care is the front door to chronic disease management, and particularly to the detection and diagnosis of kidney disease within the CKM framework. We are interested in solutions that will support primary care in co-managing kidney disease and CKM. Stage 3 CKD is the most prevalent form of kidney disease, much of which can be managed in the primary care setting depending on cause and the rate of progression (for example, kidney disease caused by underlying genetic conditions may need referral to specialty care sooner for proper diagnosis, though the same simple screening tests of estimated glomerular filtration rate (eGFR) and uACR (urine albumin-to-creatinine ration) can provide clinical information that supports risk stratification and triage to specialists more quickly, to the benefit of both rare kidney disease patients and payers like CMS).

Figure 1. *Stages of Cardiovascular-Kidney-Metabolic Syndrome (CKM)*



We understand and broadly agree with CMS' underlying rationale for the eCKM track, namely that the management of related comorbidities like hypertension (HTN), prediabetes, and obesity or overweight, could result in **prevention** of kidney disease. However, for practical purposes, it will be impractical to define a beneficiary population for the ACCESS – eCKM track with the qualifying conditions of hypertension or dyslipidemia, obesity or overweight with a marker of central obesity and prediabetes who do not already have reduced kidney function.

Failing to include baseline submission of estimated glomerular filtration rate (eGFR) and urine albumin-creatinine ratio (UACR) data simply ensures that any underlying kidney disease will go undetected and undiagnosed, consistent with the existing kidney disease journey in which kidney disease is not prioritized relative to the management of other chronic diseases. Once kidney disease is present, it is the amplification mechanism for cardiovascular risk, driving a positive feedback loop of systemic vascular damage. The assumption that kidney disease will be both absent and ultimately preventable in the eCKM track is inconsistent with clinical reality. In addition, the absence of requirements for guideline-concordant kidney disease screening in the ACCESS Model will reduce the ability of model participants to successfully achieve the Outcome Aligned Payment (OAP) measures in the eCKM track, as CKM demands a holistic approach that targets all the underlying drivers of the syndrome. Since OAP Measures data will be reported via a FHIR®-based API, we do not believe it would be burdensome to either ACCESS Participants or CMS to include submission of annual eGFR and uACR data. We note that in the CKM track, CMS does not require kidney disease specific outcome requirements, but rather a simple submission of relevant process data. The same approach would be appropriate in the eCKM track.

The Coalition for Kidney Health is eager to see the ACCESS Model advance. In our white paper, *A Vision for Value-Based Approaches to Early Kidney Disease Prevention and Management*, we recommended the Innovation Center support the development and deployment of technology to identify kidney patients at the greatest risk of progression and streamline co-management of kidney disease between primary and specialty care. Care transformation that enables more touchpoints with chronic disease patients is highly relevant to the system-wide changes we hope to see in kidney disease. In

addition, other policy approaches that CMS aims to test through the ACCESS Model have potentially important implications for subsets of the kidney disease population that can and desire to be activated through technology-enabled value-based care:

- Use of the Beneficiary Claims Data API to address the longstanding challenge of lack of real-time information on quality and utilization outcomes for model participants.
- Offering integrated chronic disease management services like medication management, interpretation of labs and diagnostics.
- Advancement of Software as a Medical Device (SaMD).

We hope to be a resource to the Innovation Center as it sees the ACCESS Model through the process of continuous improvement to the Model's policy framework. Again, we appreciate all the work the Innovation Center is doing to change the patient journey from one of kidney sickness to one of kidney health.

Sincerely,

The Coalition for Kidney Health

Appendix I.

Table 1. Initial Tracks Overview

Track	Qualifying Conditions[4]	OAP Measure[5]
eCKM	Hypertension (HTN), or two or more of the following conditions: dyslipidemia, obesity or overweight with a marker of central obesity,[6] prediabetes	- Control or minimum improvement in blood pressure (BP), lipids, weight, and hemoglobin A1c (HbA1c)
CKM	One or more of the following conditions: diabetes mellitus, chronic kidney disease (CKD),[7] atherosclerotic cardiovascular disease (ASCVD)	- Control or minimum improvement in BP, lipids, weight, and HbA1c - Submission of estimated glomerular filtration rate (eGFR) and urine albumin-creatinine ratio (UACR) data
MSK	Chronic musculoskeletal (MSK) pain[8]	- Minimum improvement in pain intensity, interference, and overall function (assessed via validated PROMs)
BH	One or more of the following conditions: depression, anxiety	- Control or minimum improvement in symptoms (assessed via PHQ-9 for depression and GAD-7 for anxiety)- Optional: Submission of WHODAS 2.0 12-item, a validated PROM of overall function