

March 3, 2023

Jonathan Blum Principal Deputy Administrator and Chief Medical Director, Center for Medicare Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, MD 21244

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies

Dear Mr. Blum

The Coalition for Kidney Health (C4KH) thanks the Center for Medicare for the opportunity to comment on the Medicare Advantage (MA) Advance Notice. C4KH aims to provide comments on behalf of the 37 million Americans with chronic kidney disease (CKD). C4KH is a multi-stakeholder group of partners with an interest in earlier detection and management of chronic kidney disease (CKD).

We believe that MA policies, when well designed, can improve awareness of CKD 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. Our comments on the 2024 MA Advance notice advocate for changes that promote awareness of CKD as a disease multiplier, increase screening of at-risk patients, and drive forward high-quality, coordinated care focused on delaying CKD progression. With that in mind, C4KH is focusing its comments for the CY 2024 Advance Notice on the following concerns and priorities:

- 1) Ensuring appropriate risk-adjustment for Chronic Kidney Disease (CKD) and associated risk factors
- 2) Expansion of the MA Star Rating program to promote kidney health.
- 3) Expansion of the ESRD C-SNP to include patients with CKD G3a, G3b, 4 and non-dialysis dependent 5.

About CKD

Only 10 percent of the 37 million adults with CKD in America are aware and have access to the care, education, and monitoring needed to manage the condition. The absence of policies to standardize early CKD screening, detection, and intervention is harmful, especially to historically marginalized communities facing health disparities because of racial, social, economic, and environmental inequities. At its onset, CKD is asymptomatic, and only routine screening can identify it in its earliest stages. Even among at-risk populations, such as those with diabetes and hypertension, CKD often goes undetected until its later stages. Approximately half of CKD stage 3 patients are undiagnosed and, as a result, are less likely to access guideline-concordant care for delaying and managing CKD. More troubling, as many as thirty-eight percent of patients with end-stage kidney disease learn of their diagnosis only after their kidneys have failed, requiring them to initiate dialysis in the emergency room in what is known as a



"crash" start. As much as sixty-three percent of patients begin unplanned, emergent dialysis. Crashing into dialysis is traumatic for patients, increases mortality, and creates an economic burden.

The fee-for-service (FFS) environment has had a profound impact on patterns of kidney care. Medicare payments to nephrologists and dialysis facilities reinforce in-center dialysis delivered in a facility three times a week for four hours at a time as the default modality to treat kidney disease, despite that kidney disease is preventable, its progression can be slowed or stopped, and that other modalities to treat kidney failure offer better outcomes at lower costs.

The influx of kidney patients and patients at risk of kidney disease into MA provides a unique opportunity to improve quality of care and outcomes in this highly vulnerable population. The perbeneficiary per-month capitated payment in MA naturally aligns with the framework for kidney care created by the Innovation Center, thus offering an opportunity to increase patient access to value-based plan designs. C4KH is committed to maximizing the benefits of MA to kidney patients while minimizing features of policies and plans that may not be in patients' best interest.

Ensuring Appropriate Risk Adjustment Factor (RAF) for Chronic Kidney Disease (CKD)

The Coalition for Kidney Health is also concerned about CMS's proposal to remove 2,269 unique codes from the Hierarchical Conditions Category (HCC) model, impacting conditions such as major depressive disorder, diabetes with chronic conditions, cardiovascular disease and other comorbidities that are common among people with chronic kidney disease.

Diabetes is the leading cause of kidney failure in America, accounting for approximately 40 percent of all cases. One in three people with diabetes will develop CKD. Moreover, CKD is a disease multiplier among people with diabetes, contributing to significantly greater risk of cardiovascular disease. The risk of heart failure, atrial fibrillation, stroke, and coronary heart disease is approximately double in patients with CKD.¹ The adjusted mortality is also twice as high among Medicare beneficiaries with CKD compared with those without CKD. Not surprisingly, per beneficiary spending for patients with CKD and diabetes is significantly higher than for patients with diabetes alone. According to the US Renal Data System, patients with both diabetes and CKD had 50 percent higher Part A and B costs than patients with diabetes alone.

Unfortunately, CKD screening among people with diabetes is suboptimal. Even among people with diabetes and hypertension – the two leading causes of kidney disease -- CKD screening is inadequate. Albuminuria is an essential component of chronic kidney disease diagnosis, staging, and prognosis but it is significantly underutilized, with annual testing rates of approximately 40 percent for diabetes and less than 10 percent for hypertension according to national data. Elevated urine albumin can detect CKD in people with diabetes and monitor its progression, but obstacles preventing early detection persist, including lack of awareness of CKD in the general population, poor adherence to clinical guidelines, and county-level variations in screening and treatment incentives.

¹ https://www.ajmc.com/view/medical-costs-for-managing-chronic-kidney-disease-and-related-complications-in-patients-with-chronic-kidney-disease-and-type-2-diabetes



Given the significant underdiagnosis of CKD within the Medicare population and the increased cost of CKD and its comorbid conditions, the C4KH is gravely concerned that the proposed modifications to the Risk Adjustment factor will disincentivize CKD screening, diagnosis, and management. Accurate diagnosis and coding of diabetes with complications, notably diabetes with chronic kidney disease, and appropriate risk adjustment can ensure that plans have the resources to effectively manage CKD and that providers have the information they need to provide high quality, coordinated care to uniquely vulnerable populations.

The Coalition for Kidney Health joins with other patient advocacy organizations and calls on CMS to delay implementation of the revisions to the HCC system and work with stakeholders to ensure that risk adjustment is data driven, evidence based, and drives guideline concordant, patient centered care. Further, any proposed changes to the risk adjustment model should be appropriately phased-in to ensure successful implementation of clinically-based updates and ensure stability and predictability in the risk adjustment model.

Expansion of MA Star Ratings to promote kidney health

The C4KH applauds CMS for its plans to expand the MA Star Ratings to include measures targeted at kidney health. Kidney disease is a prominent area of missed opportunities to provide high quality care, from the under detection of CKD, poor data collection to capture CKD care, and the absence of quality measures to close gaps across the kidney care continuum.

Quality measurement in nephrology has historically focused on dialysis. An evaluation of 60 national kidney metrics by the American Society of Nephrology (ASN) Quality Committee found that half were related to dialysis management and none pertaining to CKD. Of the evaluated measures, over half were of medium to low validity.² Many of the 14 measures in the Quality Incentive Program (QIP) are not patient-centered (e.g., Standardized Fistula Rate), are topped out, or fail to target meaningful outcomes for patients (e.g., Standardized Transfusion Ratio). Concerns have been raised that the QIP is not driving improvement at all; rather, it is penalizing facilities that serve structurally disadvantaged populations.³

Similarly, quality initiatives for MA plans, namely, the Star Ratings, similarly fail to account for kidney disease, dialysis, transplantation, or palliative care. C4KH strongly urges CMS to work with the kidney care community to develop a suite of kidney health and kidney disease measures.

A simple first step would be to expand the Kidney Evaluation for Diabetes (KED) measure to kidney health evaluation for adults with hypertension, the second most common cause of kidney disease. Although hypertension is a common risk factor for CKD, it is uncontrolled in half of U.S. CKD patients. In addition, despite demonstrated efficacy of ACEi/ARB treatment in reducing progression to ESRD, reninangiotensin-aldosterone blockade is underused and has declined over time. Statins in patients with CKD over 50 are also dramatically underutilized.⁴ Notably, health services research of a type-2 diabetes (T2DM) population with over 80% prevalence of hypertension demonstrated low use with inequities in access to disease modifying, kidney and cardiovascular protective sodium glucose co-transporter-2

² https://jasn.asnjournals.org/content/31/3/602

³ https://www.acpjournals.org/doi/pdf/10.7326/M20-6662

⁴ <u>https://cjasn.asnjournals.org/content/14/8/1142</u>



(SGLT-2) inhibitors.⁵ We strongly support the development, testing, and implementation of other kidney disease process measures given that gaps in CKD are prominent.

Expansion of ESRD C-SNPs

Another priority for C4KH continues to be the expansion of the ESRD C-SNP to include patients with chronic kidney disease stages G3a, 3b, 4, and non-dialysis dependent 5. ESRD C-SNP expansion is consistent with a recent CMS ETC final rule on Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model. We applaud CMS's ongoing effort to improve kidney health, kidney failure modality education, increase preemptive transplantation (i.e., transplantation prior to dialysis), support safe transitions between CKD and end-stage kidney disease (ESKD) or kidney failure, and provide more equitable transitions of care.

Access to pre-ESRD nephrology care is essential to realizing opportunities to slow progression and achieve optimal transitions to kidney failure, meaning that patients can prepare for kidney failure rather than crashing into dialysis in the Emergency Room (ER) having had little to no knowledge of declining kidney function and no preparation for kidney failure. A combined CKD-ESRD C-SNP creates the infrastructure to provide safer, more equitable transitions of care. Expanding the ESRD C-SNP is a concrete policy that can support the goals described in the recent kidney care RFI.

Finally, an expanded ESRD C-SNP is aligned with the Innovation Center KCC model, a voluntary ACO-like arrangement where groups of clinicians and providers take responsibility for fee-for-service (FFS) beneficiaries with CKD and ESKD with the potential for shared savings tied to quality measures around delayed CKD progression, patient activation, depression management and optimal transitions to kidney failure.

CMS defines a "special needs individual" eligible for a C-SNP as one who has one or more co-morbid and medically complex chronic conditions that are substantially disabling or life-threatening, has a high risk of hospitalization or other significant adverse health outcomes, and requires specialized delivery systems across domains of care. MA eligible CKD stages G3a, 3b, 4 and 5 patients meet each of these criteria.

Conclusion

The C4KH appreciates CMS' attention to the experience of Medicare beneficiaries with CKD and ESRD in MA plans and the quality of care these enrollees receive. We would welcome the opportunity to discuss these comments further, particularly the value of a combined ESRD-CKD C-SNP and CKD measure concepts to prioritize for development in concert with NCQA. Please contact Ignacio Alvarez, Health Policy Director, at Ignacio.alvarez@kidney.org to set up time to discuss.

Sincerely,

⁵ Eberly LA, Yang L, Eneanya ND, et al. Association of Race/Ethnicity, Gender, and Socioeconomic Status With Sodium-Glucose Cotransporter 2 Inhibitor Use Among Patients With Diabetes in the US. JAMA Netw Open. 2021; 4(4):e216139.