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Meena Seshamani Deputy Administrator and 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) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies

### Dear Dr. Seshamani,

The National Kidney Foundation (NKF) thanks the Center for Medicare for the opportunity to comment on the Medicare Advantage (MA) Advance Notice. Medicare Advantage (MA) has increasing relevance for kidney patients. Chronic kidney disease (CKD) is more prevalent in the Medicare eligible population, with a prevalence among those 66 and older nearing 40 percent.<sup>1</sup> Under provisions of the 21<sup>st</sup> Century Cures Act, people with end-stage kidney disease (ESKD) became eligible to enroll in MA. Enrollment of ESKD beneficiaries has soared. Davita, one of the two largest providers of dialysis in the United States, reported 42.3% of its Medicare eligible patients on MA in its latest <u>quarterly earnings report</u>. Like any insurance coverage option, including traditional Medicare, MA provides benefits to patients, such as the maximum out-of-pocket (MOOP) limit, that come with tradeoffs, such as limited provider networks. NKF 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.

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 CMS Innovation Center created the framework for value-based kidney care first through the Comprehensive ESRD Care Model and now through its second-generation kidney models, the mandatory ESRD Treatment Choices (ETC) model and the voluntary Kidney Care Choices (KCC) model. We expect that MA will have an equal impact on kidney care, though it is too soon to understand what these impacts will be. We encourage CMS to adopt incentives to preserve kidney health, increase affordability, and enhance patient choice to treatment modalities for kidney failure, particularly kidney transplantation and home dialysis.

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 valuebased plan designs. NKF is eager to partner with the Administration and health plans to achieve better health for kidney patients.

A priority for NKF is 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 Request for Information (RFI) on kidney disease and kidney transplantation that solicited stakeholder input on how CMS can 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.

White, Asian, and Native Americans are significantly more likely to receive pre-ESRD care than Black, Native Hawaiian/Pacific Islander, and Hispanic individuals.<sup>1</sup> 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 ACOlike 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 (see Appendix I for further information).

# Section E. ESRD Rates

As CMS is aware, MA plans are underpaid for ESRD beneficiaries due to the discordance between the FFS payment subtracted from the 20% coinsurance and the MOOP limit of \$7550. ESRD beneficiaries, who accrue six times the expenditures of aged beneficiaries, rapidly meet the MOOP limit, creating a

<sup>&</sup>lt;sup>1</sup> https://adr.usrds.org/2021



gap between the FFS expenditures and the MA payment. Underpayment is compounded by <u>inconsistent payment</u> across metropolitan and rural areas.

We thank CMS for its attention to these issues and for undertaking analyses of MA ESRD rates based on core-based statistical areas (CBSAs). While payment rates set at the CBSA level are not tenable for the reasons outlined in the Advance Notice, we ask CMS to continue to explore methodologies to provide for adequate and consistent payment to MA plans for ESRD beneficiaries.

## Attachment IV. Updates for Part C and D Star Ratings

In the <u>2022 Advance Notice</u>, CMS wrote of its intention to report the measure, Kidney Health Evaluation for Adults with Diabetes (KED), on the display page for the 2022 Star Ratings and consider adding it to Star Ratings through future rulemaking. The KED measure targets diabetes, the leading cause of kidney disease, and so is the core kidney health process measure. NCQA measure testing of the plan-level measure revealed the need for a process measure. Testing data revealed that more than half of MA and commercial members with diabetes did not receive guideline-concordant kidney health evaluation including measure of kidney function, i.e., estimated glomerular filtration rate (eGFR), and kidney damage, urine albumin-creatinine ratio (uACR).<sup>2</sup> NKF asks CMS to ensure that KED is expeditiously adopted into the Star Ratings.

NKF supports the stratification of Star Rating for social risk factors (SRFs), particularly of the KED measure. CKD is under-detected across all populations, but particularly in populations with SRFs. Diabetes is frequently associated with low socioeconomic status (SES), which is accordingly a major mediator of CKD. In addition to disability, Low-Income Subsidy (LIS), and dual eligible (DE) status, **we ask CMS to stratify the KED measure by race and ethnicity.** We ask CMS to include KED in the display measures on CMS.gov so the stratification data are publicly available to beneficiaries and on the Plan Finder tool.

NKF endorses the proposal to support NCQA in developing a suite of kidney health and kidney disease measures. A simple first step would be to expand the KED measure to kidney health evaluation for adults with hypertension, the second most common cause of kidney disease. We support the development, testing, and implementation of other kidney disease process measures given that gaps in CKD are prominent. 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, renin-angiotensin-aldosterone blockade is underused and has declined over time. Statins in patients with CKD over 50 are also dramatically underutilized.<sup>3</sup> Notably, health services research of a type-2 diabetes (T2DM) population with over 80% prevalence of

<sup>&</sup>lt;sup>2</sup> https://www.ncqa.org/wp-content/uploads/2020/02/20200212\_08\_KED.pdf

<sup>&</sup>lt;sup>3</sup> https://cjasn.asnjournals.org/content/14/8/1142



hypertension demonstrated low use with inequities in access to disease modifying, kidney and cardiovascular protective sodium glucose co-transporter-2 (SGLT-2) inhibitors.<sup>4</sup>

We agree that referral to Medical Nutrition Therapy (MNT) and preparedness for kidney are important measure concepts. CMS and NCQA can also consider a plan-level version of NQF #2594: Optimal End Stage Renal Disease (ESRD) Starts, which targets multiple elements of high-quality kidney care including receiving a preemptive kidney transplant, initiating home dialysis, and initiating outpatient in-center hemodialysis via arteriovenous fistula or arteriovenous graft. NCQA can also consider standalone measures of home dialysis and transplantation, perhaps following the blueprint of the home dialysis and transplant waitlist measures used in the Innovation Center ETC model.

NKF appreciates CMS' attention to the experience of Medicare beneficiaries with CKD and ESRD in MA plans and the quality of care these beneficiaries 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 Miriam Godwin, Health Policy Director, at <u>miriam.godwin@kidney.org</u> to set up time to discuss.

Sincerely,

Kevin Longino CEO and Transplant Patient

Paul Palevsky, MD President

# Appendix I.

# CKD G3a, 3b, 4 and 5 Patients Are C-SNP Eligible

CMS defines a "special needs individual" 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. The Coalition for Kidney Health believes that MA eligible CKD G3a, 3b, 4 and 5 patients meet each of these criteria as follows:

1. CKD is a Medically Complex Chronic Condition

<sup>&</sup>lt;sup>4</sup> 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.



CKD is a uniquely complex condition, interacting with hypertension, DM, cardiovascular disease, obesity, and the numerous complications of progressive loss of kidney function. The complexity of CKD increases in the later stages of the disease. CKD stage G4 patients have severe kidney damage with less than 30 percent function. CKD stage 5 denotes kidney failure. CKD patients in Medicare are older, have more comorbid conditions and are thus more complex patients. The mean age of Medicare patients was 74.7 years. Over half of the CKD patients in the 2016 Medicare 5% sample had at least one comorbidity.

Cardiorenal syndrome is the term used to describe the compounding relationship between CKD and cardiovascular disease. This interplay adds to the challenges in the management of CKD. Medicare eligible (age 66 and older) CKD patients have a much greater burden of cardiovascular disease than in those without (65.1% versus 32.6%) that includes a range of cardiovascular conditions including stable coronary artery disease (CAD), acute myocardial infarction (AMI), heart failure (HF), valvular heart disease (VHD), stroke (cerebrovascular accident/transient ischemic attack, or CVA/TIA), peripheral arterial disease (PAD), atrial fibrillation (AF), sudden cardiac arrest and ventricular arrhythmias (SCA/VA), and venous thromboembolism and pulmonary embolism (VTE/PE). CKD worsens the long-term prognosis for several cardiovascular diseases and for patients who undergo cardiovascular procedures. Unsurprisingly, CKD stage G4 and 5 patients have the lowest probability of survival among Medicare CKD patients with prevalent cardiovascular disease and for Medicare CKD patients with prevalent cardiovascular disease and for Medicare CKD patients with prevalent cardiovascular disease and for Medicare CKD patients with prevalent cardiovascular disease and for Medicare CKD patients undergoing cardiovascular procedures.

Complications of decreasing kidney function further increase the complexity of CKD. As kidney function declines, patients may experience anemia, mineral and bone disease, secondary hyperparathyroidism, volume overload, and electrolyte and acid-base dysfunction. These complications of CKD often require unique approaches to management. Salt and water retention can cause or exacerbate hypertension and can cause edema which contributes to reduced quality of life. Metabolic acidosis may contribute to CKD progression. Further, uremic symptoms including pruritus and restless leg syndrome are associated with sleep disturbance, depression, poor quality of life, higher cardiovascular morbidity, and higher mortality.<sup>5</sup> Certain complications of CKD can exacerbate other complications of CKD as well as CVD.

2. Advanced CKD is Substantially Disabling and Life-Threatening

Kidney diseases, largely CKD, are the ninth leading cause of death in the United States, causing more deaths than widely known cancers such as breast and prostate cancer. CKD stages 4 and 5 have nearly double the mortality rate of Medicare patients with CKD stage G3, and a four-fold increased rate of mortality compared with Medicare patients without CKD. Mortality rates increase with advancing CKD stage and are magnified by the occurrence of

<sup>&</sup>lt;sup>5</sup> <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6341007/</u>



CVD and diabetes.<sup>6</sup> CVD is the most common cause of death for CKD patients. The proportion of CKD patients who die from cardiovascular disease increases as eGFR decreases, as do deaths from infections and other causes.<sup>7</sup>

CKD is associated with higher prevalence of disability. Limitations in activities of daily living (ADL) have been reported in nearly 25% of patients 65 years old and older with CKD G3 and 4. Muscle wasting, and diminished physical performance occur in concert with CKD, resulting in diminished physical performance overall. Impaired physical performance of the lower extremities in CKD is also associated with all-cause mortality.<sup>8</sup> Further, lower socioeconomic status increases disability among adults with CKD.<sup>9</sup> In addition to disability, advanced stages of CKD are associated with lower quality of life.

3. Advanced CKD has a High Risk of Hospitalization or Other Significant Adverse Health Outcomes

All stages of CKD are associated with increased inpatient costs, which represent an increasing proportion of spending at each CKD stage. Approximately 80 percent of the cost increases observed in Medicare and commercially insured patients with CKD stages G3b, 4, 5 and ESKD are associated with inpatient utilization.<sup>10</sup>

In 2016, the hospitalization rate for Medicare beneficiaries with CKD was 147 percent greater than for those without CKD. In a younger population of patients 22 and older from the Optum Clinformatics data set, the hospitalization rate for patients with CKD was 831 percent greater than for those without CKD. Hospitalizations increase with disease severity and in the presence of comorbidities such as DM and CVD. The additional disease burden of both DM and CVD with CKD is extremely significant for patients with CKD stage G4 and stage 5. Patients with both comorbidities have 3 times as high a hospitalization rate as late-stage CKD patients without either comorbidity.

Inpatient readmissions contribute substantially to inpatient costs for CKD patients in both Medicare and commercial cohorts. 30-day readmissions increase at every CKD stage, accounting for 33 percent of inpatient costs among patients with CKD stages G3a, 3b, 4, and 5. Average length of hospital stay (AHOS) also increases at every CKD stage. <sup>11</sup>

<sup>&</sup>lt;sup>6</sup> <u>https://www.usrds.org/media/1720/v1\_c03\_morbmort\_18\_usrds.pdf</u>

<sup>&</sup>lt;sup>7</sup> https://jasn.asnjournals.org/content/26/10/2504

<sup>&</sup>lt;sup>8</sup> https://pubmed.ncbi.nlm.nih.gov/23599380/

<sup>&</sup>lt;sup>9</sup> https://pubmed.ncbi.nlm.nih.gov/22172179/

<sup>&</sup>lt;sup>10</sup> https://www.ajmc.com/view/all-cause-costs-increase-exponentially-with-increased-chronic-kidney-disease-stage-article



4. Advanced CKD Requires Specialized Delivery Systems Across Domains of Care

The complexity of CKD, especially at its advanced stages, lends itself to specialized care delivery. The transition between CKD and ESKD is a vulnerable time for patients, where care coordination across multiple providers, including nephrologists, nurses, vascular surgeons, transplant nephrologists, transplant surgeons, and dialysis facilities and staff, has a clear value proposition. A multidisciplinary model of care specifically implemented with CKD patients approaching dialysis demonstrated improvements in optimal starts to dialysis, leading to reduced risk of being admitted to the hospital for dialysis initiation, less lengthy hospital stays and fewer admissions for the 90-days after the transition to dialysis-dependent kidney failure.<sup>12</sup> While some studies have found that integrated care for patients with CKD can be effective at improving outcomes and reducing expenditures, a 2018 meta-analysis of 14 eligible studies found only weak evidence of the effect of person-centered integrated care strategies for CKD stages G3 through 5, though suggested the potential for improvements in all-cause hospitalizations and blood pressure control.<sup>13</sup> Interestingly, integrated care has been demonstrably beneficial in other closely related conditions such as heart failure and diabetes.

<sup>12</sup> https://pubmed.ncbi.nlm.nih.gov/21520695/

<sup>&</sup>lt;sup>13</sup> <u>https://cjasn.asnjournals.org/content/13/3/375.long</u>