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August 31, 2022

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services (CMS)
Hubert H. Humphrey Building
Room 314G-01
200 Independence Avenue SW
Washington, DC 20201

Re: CMS-4203-NC – Request for Information on Medicare Advantage

Dear Administrator Brooks-LaSure,

The National Kidney Foundation (NKF) applauds the Centers for Medicare and Medicaid Services (CMS) for prioritizing health equity, expanding health coverage, and improving the patient experience. We are thankful for the opportunity to respond to the request for information (RFI) on Medicare Advantage (MA). MA plans have the potential to significantly improve the lives of individuals with chronic kidney disease (CKD), kidney failure, and those with risk factors for kidney disease. As you contemplate changes to the MA program, NKF encourages you to focus on policies that achieve the following objectives:

1. Driving early awareness, detection and management of chronic kidney disease (CKD).
2. Empowering individuals with kidney failure to choose a full spectrum of high-quality treatments that align with their goals, preferences, and values for care, including expanded access to dialysis centers and alternatives to in-center dialysis, such as staff-assisted home dialysis.
3. Enhancing access to transplantation.

As CMS is aware, kidney disease is a prominent example of the impact of racism and injustice on health. Type 2 diabetes (T2DM), one of the leading causes of kidney disease and kidney failure, is mediated by poverty.[1] American Indian/Alaska Native, Black, and Hispanic populations have 168%, 136%, and 91% higher poverty rates than White populations.[2] When taken with other factors, the result is higher percentages of adults with diabetes in American Indian/Alaska Native, Hispanic, Black, and Asian

[1] Gaskin DJ, Thorpe RJ, McGinty EE, et al. Disparities in Diabetes: The Nexus of Race, Poverty, and Place. *Am J Public Health*. 2014;104(11):2147-2155. doi:10.2105/AJPH.2013.301420

[2] Kaiser Family Foundation. *Poverty Rate by Race/Ethnicity*. Kaiser Family Foundation; 2019. Accessed January 3, 2022. https://www.kff.org/other/state-indicator/poverty-rate-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

populations.[3] The burden of chronic kidney disease (CKD) disproportionately falls on the poor. People from systematically disadvantaged racial and ethnic minority populations progress to end-stage renal disease (ESRD) more quickly and are more likely to die before the need for dialysis. A kidney transplant is an optimal treatment for ESRD, but Black/African American people are disadvantaged at every step of the transplant process.

We have consolidated our comments into three sections. Section I of this letter addresses chronic kidney disease, section II focuses on ESRD, and lastly, in section III, we share recommendations that would improve access and equity for kidney transplantation.

Section I: Addressing Chronic Kidney Disease

Quality Measure: Kidney Health Evaluation for Patients with Diabetes

Early intervention with high-risk populations, such as diabetes and hypertension, can improve kidney disease management. The Kidney Health Evaluation for Patients with Diabetes (KED) measure is one means to ensure diabetic patients are receiving the kidney profile. Still, primary care and family medicine clinicians must also have the incentives and resources to implement simple CKD interventions, including blood pressure (BP) checks, BP control, A1c control, and/or ACEi or ARB and statin prescribing. As patients progress to CKD 3, NKF recommends a paradigm of co-management between primary care and nephrology to make the best use of each specialty in delaying and managing further progression. Including the KED measure in the HEDIS set is a valuable first start and will promote earlier detection among MA plan enrollees; CMS should explore other strategies to enhance CKD management in the value-based purchasing arrangements. For example, NKF's CKDintercept initiative is a resource that MA plans should leverage in the primary care setting.

Medication Affordability: Sodium-Glucose Co-Transporter-2 (SGLT-2) Inhibitors

The US Food and Drug Administration (FDA) approved several new medications for kidney indications to reduce the risk of kidney failure and cardiovascular disease (CVD). Specifically, sodium-glucose co-transporter-2 (SGLT-2) inhibitors show extraordinary efficacy at attenuating the risk of progression to kidney failure by approximately 30 to 45% and reducing CVD risk, particularly heart failure, in patients with type-2 diabetes and CKD, as well as in patients with CKD without diabetes. In addition, the first-in-class non-steroidal mineralocorticoid receptor antagonist (nsMRA), finerenone, reduced the risk of kidney failure by approximately 20% and demonstrated effectiveness in lowering heart failure hospitalization risk.

The American Diabetes Association standards of care in diabetes recommend SGLT-2 inhibitors independent of glycemic control in patients with type-2 diabetes mellitus and CKD to reduce CKD progression, attenuate CVD risk, and recommend using the non-steroidal MRA for patients with type-

[3] Centers for Disease Control and Prevention. Addressing Health Disparities in Diabetes. Published online August 10, 2021. Accessed January 3, 2022. https://www.cdc.gov/diabetes/disparities.html

2 diabetes and CKD to reduce CKD progression and attenuate CVD risk. The recommendations for using both SGLT-2 inhibitors and non-steroidal MRA are supported by A-level evidence.

Despite the efficacy and value of these novel therapies, we are troubled by reports that patients cannot access these medications due to restrictive coverage requirements and utilization controls by health plans; this limitation is especially problematic for Medicare Advantage beneficiaries. Given the significant proportion of aged individuals at risk of kidney failure and the costs of kidney disease to the Medicare Trust Fund, we note a recent study that only six percent of individuals with diabetes are accessing SGLT2s or nsMRAs[4]. Even when their physician prescribes these medications, many patients face coverage barriers, including step therapy, higher co-pays or deductibles, tiered formularies, or denial of coverage. Policies that require patients to "fail first" on lower-cost alternatives come at a high cost, as failure includes the potential risk of cardiovascular disease, hospitalization, and loss of kidney function – and a person cannot regain kidney function once it is lost. Medicare Advantage enrollees must have prompt and affordable access to these lifesaving therapies.

Medicare Advantage Risk Adjustment

NKF continues to encourage CMS to risk-adjust MA payments for the differential costs associated with CKD 3a and 3b. In mid-2020, CDC adopted CKD 3a and 3b ICD-10 CM codes for FY 2021 (for use in discharges and patient encounters occurring from October 1, 2020, through September 30, 2021).
There are essential distinctions between CKD Stages 3a and 3b. At Stage 3a, a CKD patient's kidney function ranges from 45% to 59% of normal. At Stage 3b, a CKD patient's kidney function ranges from 30% to 44%. If left unmanaged, Stage 3b patients have a greater risk of progressing to dialysis in the long-term and CKD Stage 4 in the short term. These clinical differences are associated with greater costs related to CKD3b patients. Therefore, Medicare Advantage plans must compensate for the differential costs to provide the highest quality care for CKD 3b patients.

Section II: Addressing End-Stage Renal Disease

ESRD Chronic Care Special Needs Plans

Chronic Care Special Needs Plans (C-SNPs) are models of care designed to meet the needs of Medicare beneficiaries with severe and disabling chronic conditions. We believe the ESRD C-SNP has shown some promise in better managing care, coordinating, and preempting hospitalizations and readmissions associated with ESRD. Expanding the ESRD C-SNP to earlier CKD stages would allow the MA plan to implement strategies to delay the transition to ESRD when possible and better manage the transition to ESRD. This strategy would thus preempt the status quo whereby CKD patients "crash" into kidney failure, start dialysis in a center and miss opportunities for preemptive transplantation, vascular access preparation, education on home dialysis, and management of comorbidities.
In December 2021, CMS sought input from the stakeholder community on policies that could improve care transitions between CKD and ESRD and health equity. White, Asian, and Native Americans are

[4] https://www.iqvia.com/locations/united-states/blogs/2022/03/impact-of-payer-access-controls-chronic-kidney-disease-patients-type-ii-diabetes

significantly more likely to receive pre-ESRD care than Black, Native Hawaiian/Pacific Islander, and Hispanic individuals.[5] Access to pre-ESRD nephrology care is essential to taking advantage of opportunities to slow progression and achieve optimal transitions to kidney failure. Doing this would mean patients can prepare for the treatment modality, i.e., kidney transplantation, home dialysis, in-center dialysis, or conservative management, that aligns with their goals and preferences. A combined CKD-ESRD C-SNP creates the infrastructure to provide safer, more equitable care transitions.

Studies have found that C-SNPs achieve better outcomes by providing targeted care to address beneficiaries' chronic conditions, including diabetes mellitus, the most common cause of CKD and kidney failure.[6] Patients benefit from CKD through ESRD care when treating kidney disease as a spectrum. A combined CKD-ESRD C-SNP aligns with the Center for Medicare and Medicaid Innovation (CMMI) Kidney Care Choices (KCC) model that affiliates late-stage CKD and ESRD patients under a single nephrology practice or contracting entity. The care coordination offered by C-SNPs plans may help patients with CKD better manage their disease and delay or even avoid the progression of their condition by improving adherence to blood glucose targets, blood pressure management, angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy, as well as access to underutilized benefits such as Medical Nutrition Therapy (MNT). In addition, expanding C-SNPs to CKD patients will allow for coordinated pre-ESRD care that can lead to later and better starts on dialysis and greater utilization of home dialysis, a goal of the federal government. Optimal starts to dialysis, defined as starting dialysis with an arteriovenous fistula or graft (AVF/G), preemptive transplant, or home dialysis, may result in lower morbidity and mortality, inpatient utilization, and fewer outpatient specialty visits.[7] We again emphasize that planning for dialysis must begin during CKD care. Numerous opportunities to improve both the experience of care for the patient and deliver improved outcomes and cost savings are lost when ESRD is treated in a silo.

Finally, CKD patients meet the C-SNP eligible criteria. CMS defines a "special needs individual" as one with 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 3a, 3b, 4, and 5 patients meet each criterion.

Quality Measures

MA plans have virtually no accountability for transitions to ESRD or ESRD management. The lack of responsibility is likely due to the historical restrictions on ESRD enrollment in MA. NKF believes that new quality measures that follow ESRD MA enrollment trends are warranted to ensure that MA enrollees receive optimal care. ESRD patients should benefit from pre-emptive transplant, deceased and living donor transplantation. We also recommend CMS prioritize incentives for home dialysis and management of the complications and comorbidities associated with ESRD. NKF encourages CMS to

[5] https://adr.usrds.org/2021

[6] Avalere Health. "Effects of Chronic Condition Special Needs Plan Enrollment on Outcomes for Medicare Beneficiaries with Diabetes." October 2017. https://www.antheminc.com/cs/groups/wellpoint/documents/wlp_assets/d19n/mziw/~edisp/pw_g320739.pdf.

[7] https://www.ajmc.com/journals/issue/2018/2018-vol24-n10/clinical-outcomes-and-healthcare-use-associated-with-optimal-esrd-starts

convene a Technical Expert Panel (TEP) on the future quality measurement of ESRD care in MA. Possible future quality measures for adoption could include:

- Optimal End Stage Renal Disease (ESRD) Starts; NQF #2594
- Depression Remission at Twelve Months – Progress Towards Remission; NQF #1885
- Measure of preemptive transplantation (plan-level)
- Measure of home dialysis utilization (plan-level)
- Measure of home dialysis retention (plan-level)
- Measure of ESRD patients transplanted (plan-level)

Home Dialysis Access

Despite being preferred by many dialysis patients, home dialysis is underutilized compared to dialysis delivered in a facility, particularly among patients of communities of color. Black/African American and Hispanic patients are less likely to initiate home dialysis. They are more likely to fail on the modality within the first 90 days, after which point disparities in home dialysis utilization widen. Common barriers to home dialysis, such as unstable living situations, poor health literacy, and lower socioeconomic status, may be overrepresented among Black/African American and Hispanic dialysis patients. Patients can overcome hurdles to home dialysis with appropriate empowerment and support from trained staff who can assist with dialysis needs, address other physical or medical challenges, and provide emotional and moral support to patients as they transition to home dialysis. Shen et al. demonstrate those disparities in the selection of modality narrow when adjusted for demographic, medical, and socioeconomic factors.[8] Daniel E. Weiner and Klemens B. Meyer have suggested that paid caregivers for home dialysis patients can overcome common socioeconomic barriers in social and health literacy domains.[9] The National Kidney Foundation requests authorization by the Medicare program, including Medicare Advantage, for reimbursement to dialysis providers for in-home caregivers for home dialysis patients. Doing so will provide the necessary support for diverse patients to transition and be successful on home dialysis, thus allowing these patients to benefit similarly to White dialysis patients from the advantages that home dialysis can provide.

Section III: Addressing Kidney Transplantation

Network Adequacy for Transplant Centers

NKF would ask CMS to prioritize including all transplant centers as in-network to ensure that all ESRD patients have access to the closest transplant program. Transplant centers often require multiple patient visits for evaluation testing to determine if a person is healthy enough to be added to the national transplant waitlist. Patients must travel to the transplant center for surgery and frequently visit for post-transplant follow-up appointments to receive proper care and maintain optimal organ function. Without access to a local transplant center, patients remain on dialysis, the disparity gap widens for

[8] https://www.kidneymedicinejournal.org/article/S2590-0595(20)30023-6/fulltext#intraref0005
[9] https://www.kidneymedicinejournal.org/action/showPdf?pii=S2590-0595%2820%2930042-X

underserved communities in their access to transplantation, and patients are relegated to dialysis despite transplantation being the optimal treatment for ESRD.

Preemptive Kidney Transplantation

NKF recommends that CMS create a mechanism to provide transplant centers with the assurance of coverage for people approaching kidney failure who wish to receive a preemptive transplant and who will be Medicare eligible in the month the hospital admits them for their kidney transplant. A kidney transplant is most people's gold standard of treatment for kidney failure. Yet, the prevalence of kidney transplants is not commensurate with their value to individuals and the health system. Approximately 30 percent of the US ESRD population live with a functioning kidney transplant. The remaining 70 percent is dependent on dialysis to survive.[10] A preemptive transplant, one a patient receives from a living donor before initiating dialysis, provides the best outcomes and the lowest costs to CMS and other payers. Yet, of the 131,636 incident ESRD patients in 2018, fewer than 4,000 individuals, less than three percent, received a preemptive transplant.

Medicare coverage is associated with a lower likelihood of preemptive transplant.[11] This finding is attributable not to age but rather to Medicare policy. Preemptive transplant is nearly impossible without pre-ESRD nephrology care. Thirty percent of incident ESRD patients with Medicare as the primary payer had between zero and six months of nephrology care before kidney failure. Another 20 percent had between six months and a year of pre-kidney failure nephrology care.[12] In addition, Medicare coverage for an ESRD beneficiary seeking a transplant begins the month the patient is admitted to the hospital for the transplant. This process creates considerable uncertainty for the transplant center regarding reimbursement for the evaluation and workup, should the individual not meet the eligibility criteria for Medicare. For this reason, we urge CMS to expand access to Medicare and Medicare Advantage to allow beneficiaries approaching ESRD the chance to receive a preemptive living donation transplant before beginning dialysis.

Access to Medical and Psychological Care for Living Donors

As CMS continues to examine ways to improve health equity, NKF would implore the agency to design Medicare Advantage policies to mimic traditional Medicare benefits for living donors. Medicare offers lifetime coverage for medical and psychological complications post-living organ donation, yet Medicare Advantage does not extend coverage for donation-related complications after living donation. Some Medicare Advantage plans have restrictions on initial living donor evaluations that are barriers to living donation. Examples include only approving biologically-related donors for evaluation testing, not permitting the evaluation of a living donor until after the recipient has been financially cleared to be listed, and limiting donor evaluations to only one donor at a time. These

[10] https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities
[11] https://cjasn.asnjournals.org/content/13/8/1280
[12] https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities

practices are inconsistent with current CMS rules that specify that if a private company sells a Medicare Advantage product, the plan is required to cover, at a minimum, any Medicare-covered services.

Of the approximate 106,000 people on the national transplant waitlist, nearly 100,000 await a kidney transplant, and most of those who are listed represent communities of color.[13] The United States is facing a public health crisis, as an insufficient number of deceased organs are available for transplant; thus, we need policies that encourage living donation, not act as a deterrent. CMS can improve health equity by expanding Medicare Advantage coverage for living donors to mirror the benefits offered by traditional Medicare.

Conclusion

Medicare Advantage patients need access to affordable healthcare that provides CKD prevention and awareness, medical screening that offers early detection of CKD, and interventions that slow or stop its progression. Making treatment therapies, including home dialysis and kidney transplantation, accessible and affordable is imperative for all Medicare Advantage beneficiaries—regardless of ethnicity or socioeconomic status—to attain an improved quality of life. Lastly, those who choose to generously donate a kidney as a living donor should also receive psychosocial and medical care in the same way as Medicare beneficiaries. NKF would welcome the opportunity to work with CMS to determine how best to meet the needs of kidney patients in MA plans. Please contact Sharon Pearce, Senior Vice President of Government Relations, at Sharon.Pearce@kidney.org with questions or comments.

Kind Regards,

Kevin Longino
CEO and Transplant Patient

Paul Palevsky, MD
President

[13] UNOS Data and Transplant Statistics | Organ Donation Data