March 4, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs/ 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 Secretary Becerra and Administrator Brooks-LaSure,

On behalf of the more than 37,000,000 Americans living with kidney disease and the 21,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to respond to the proposed rule for Policy and Technical Changes to Medicare Advantage (MA) and the Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for MA Capitation Rates and Part C and Part D Payment Policies.

ASN supported efforts to expand MA, allowing individuals already diagnosed with kidney failure or end-stage renal disease (ESRD) to join these plans. Prior to CY2021, beneficiaries with kidney failure, in general, were not allowed to enroll in MA plans but could be enrolled in MA plans in limited circumstances. For example, Medicare beneficiaries with ESRD could remain in MA plans if they were designated as ESRD while already enrolled in an MA plan. In 2019, there were 534,000 Medicare beneficiaries with ESRD, of whom approximately 25 percent (131,000) were enrolled in MA plans. The CY2021 policy change, which Congress required in the 21st Century Cures Act (Cures Act; P.L. 114-255), is expected to significantly increase the number of MA enrollees with ESRD.

ASN has four major issues of interest with the rapidly expanding cohort of individuals with advanced chronic kidney disease (CKD) in MA plans:

- Aligning Care Models for CKD and ESRD Care in MA Plans with Traditional Medicare
- Harmonizing measurement of care quality
- Expanding C-SNP plans to CKD care

- Addressing the widening data gap. Only limited data on MA beneficiaries exist in the United States Renal Data System (USRDS) – the legislatively-mandated national ESRD registry that collects, analyzes, and distributes information about CKD and ESRD in the United States and primary source for capturing trends and outcomes for kidney patients. Additionally, quality metrics in the ESRD Quality Incentive Program for dialysis facilities require claims data for case mix adjustment; this process becomes far less robust when a substantial proportion of beneficiaries receiving dialysis are covered by MA plans.

Aligning Care Models for CKD and ESRD Care in MA Plans with Traditional Medicare

Historically, policymakers have focused their efforts on improving care provided to individuals receiving in-center hemodialysis. While these past efforts are laudable, traditional Medicare is currently broadening its efforts to improve care across the entire spectrum of kidney disease and all modalities of kidney replacement therapies. Key initiatives include improving the care of people with chronic kidney disease (CKD) to slow its progression and prevent the need for dialysis as well as offering individuals with kidney failure alternatives to in-center hemodialysis such as home dialysis and kidney transplantation.

CKD is the gradual loss of kidney function over time, and the prevalence of CKD in the 65+ Medicare eligible population nears 40 percent. Diabetes and high blood pressure account for two-thirds of cases. Patients with mild or moderate forms of CKD have no or few symptoms attributable to kidney disease. Accordingly, CKD may go undiagnosed until its latest stages as the complications from loss of kidney function become apparent. Over half of patients with CKD stage 4 remain undiagnosed in the primary care population. Consequently, between 30 and 40 percent of patients “crash” into dialysis, meaning they emergently initiate dialysis in the hospital when their kidney disease becomes acutely life-threatening. These suboptimal dialysis starts could be avoided if more people with CKD were effectively managed with improved education, planning, and care-coordination prior to kidney failure. Expenditures for people with CKD progressively increase as kidney function declines, driven largely by inpatient visits for cardiovascular disease and infections. Medicare spending for all beneficiaries who had CKD (12.5 percent of total) exceeded $79 billion in 2016.

ESRD occurs when CKD has progressed to the point that an individual requires dialysis or a kidney transplant to survive. Medicare (Parts A, B, and D) spends approximately $35 billion or 7% of its budget on kidney failure annually, although ESRD patients represent only 1 percent of the Medicare population. This amounts to approximately $90,000 per beneficiary per year. Despite these significant expenditures, clinical outcomes and quality of life remain poor with approximately half of dialysis patients living for fewer than 5 years.

Recognizing the impact of kidney disease, the Centers for Medicare & Medicaid Services' (CMS) Innovation Center (CMMI) is currently conducting two kidney care models:

- ESRD Treatment Choices (ETC) Model
- Kidney Care Choices (KCC) Model

All stakeholders, including CMS, have acknowledged the value of accountability by a single provider entity for later stages of CKD and ESRD. Therefore, CMMI launched the ETC and KCC Models. The ETC Model aims to increase access to home dialysis and rates of kidney transplantation. The KCC model aims to improve CKD care by slowing progression, preparing for a more patient-centered transition to kidney replacement therapy when and if kidney failure occurs by increasing home dialysis and kidney transplantation.

In the KCC Model, groups of clinicians and providers can enter into a voluntary ACO-like arrangement to take responsibility for fee-for-service (FFS) beneficiaries with CKD and ESRD, spanning the silos that currently exist between advanced CKD and dialysis. The Kidney Contracting Entity (KCE) options within the KCC tie shared savings and losses to quality measures around delayed CKD progression, patient activation, depression management, and optimal transitions dialysis or kidney transplantation, while the Kidney Care First option ties nephrologist payment bonuses and penalties to these same metrics as well as a total cost of care metric. All options within the KCC have substantial incentives for successful kidney transplant.

Capitated payments in MA plans replicate only a portion of the incentives created in these novel payment models. ASN would like to see all of these goals replicated in MA policies. This includes the alignment of key quality measures such as the optimal starts metric and home dialysis rates that capture high-quality, coordinated advanced CKD to ESKD care, and incentives for kidney transplant.

Since Medicare enrollees in MA are excluded from the CMMI models, ASN would like to collaborate with CMS and MA payers to develop similar pathways for patients enrolled in MA plans. Specifically, patients enrolled in MA deserve to have the same quality care with respect to improved CKD care, increased home dialysis access, and kidney transplantation. ASN encourages CMS to work with MA payers on developing quality benchmarks and systems to assess patient experiences that are consistent across MA plans. Promoting home dialysis should be a key priority; providers and plans should be held accountable for home dialysis and transplantation rates, and plans need to report those rates. CMS should also ensure that MA plans can support patients by 1) providing therapies that slow the progression of CKD; 2) ensuring patients receive education about kidney replacement options prior to ESRD transition; and 3) supporting home modifications and expenses related to issues associated with home dialysis such as electrical and water requirements.

Harmonizing Measurement of Care Quality

In addition to the alignment of care models, ASN urges CMS to incorporate new five-star ratings aimed at improving CKD care. One measure that could already be incorporated is the Kidney Health Evaluation for Adults with Diabetes (KED), a measure of guideline concordant CKD screening in adults with diabetes, the leading cause of kidney disease. ASN recommends that KED be adopted into the Star Ratings. KED exists in the HEDIS measure set and commercial plans already report this measure. The clinician-level measure occurs in pre-rulemaking and will most likely be adopted for use in the Merit-Based Payment Incentive System (MIPS) beginning in 2023. KED would replace the existing active Part C measure, Diabetes Care Kidney Disease Monitoring. Thus, the inclusion of KED in the Star Ratings would place no additional reporting burden on health plans.

ASN seeks to work with the National Committee for Quality Assurance (NCQA) and CMS on developing several other CKD measures including:

- Angiotensin converting enzyme inhibitors (ACE inhibitors) and Angiotensin-receptor blockers (ARBs) use;
- Sodium-glucose cotransporter-2 inhibitors (SGLT-2 inhibitors) use;
- Optimal dialysis starts (i.e., initiating home dialysis or in-center hemodialysis via an arteriovenous fistula or graft without a concurrent hospitalization); and
- Slowing CKD progression to kidney failure.

Expanding C-SNP Plans to CKD Care

ASN is a founding member of the Coalition for Kidney Health (C4KH), which has 13 members spanning patient groups, healthcare providers, physician groups, and pharmaceutical companies. In recent meetings, the Coalition has asked the Medicare Contracts Administration Group to include patients with CKD Stages 3-5 (i.e., patients with kidney disease and not currently on dialysis) be eligible for a chronic condition special needs plans) (C-SNP) – currently only Medicare beneficiaries with dialysis dependent CKD stage 5 are covered. The complexity of CKD care and the high risk of downstream complications makes this population ideal for the targeted and specialized care provided by C-SNPs.

As of January 2022, C-SNPs enrolled 404,385 Medicare beneficiaries across 283 plans. More than half of the existing C-SNPs are in cardiovascular disease, heart failure, and diabetes. Although there is some overlap between CKD and these comorbid conditions, the existing C-SNP offerings do not address the specific concerns of CKD care. Although diabetes is the leading cause of kidney disease, CKD care is not the focus of the C-SNP; only between 20 and 25 percent of individuals with diabetes carry a diagnosis of CKD. Similarly, the heart failure and cardiovascular disease C-SNPs cannot address the primary needs of patients with CKD, especially those close to developing ESRD.

A CKD C-SNP in MA would introduce a set of incentives to slow CKD progression and provide patients with a smoother transition to kidney failure that is similar to the current KCC model, additionally improving the quality of care received by patients with advanced CKD stages 3-5 while generating savings to MA.

Addressing the Widening Data Gap in the United States Renal Data System (USRDS) and ESRD Quality Incentive Program (QIP)

The USRDS receives funds directly from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). USRDS staff collaborate with members of Centers for Medicare & Medicaid Services (CMS), the United Network for Organ Sharing (UNOS), and the ESRD networks, sharing datasets and working to improve the accuracy of information on individuals with kidney disease. As more patients shift from FFS Medicare to MA, data from the USRDS become less representative of the entire ESRD population. Patients on MA tend to healthier, but also are more likely to have lower income, less education, and be Black or Hispanic. Data provided by the USRDS remain critical to the ongoing understanding and research into the trends and distribution of kidney diseases across the United States. ASN strongly urges the Department of Health and Human Services to expand the purview of the USRDS contract to include data collected on patients enrolled in MA (currently, the dataset is limited to fee-for-service Medicare claims).

Additionally, quality metrics for dialysis facilities, such as many of the measures used in the ESRD Quality Incentive Program, require claims data for case mix adjustment; this process becomes far less robust when a substantial proportion of beneficiaries receiving dialysis are covered by MA plans. Current workarounds require using shadow data limited to hospitalizations of MA beneficiaries, but these are insufficiently assessed, inadequately transparent and limited to only hospital data, meaning that patients who are not hospitalized, potentially representing major successes in care, will have no available comorbidity data for these quality programs.

ASN appreciates the opportunity to provide comments on the MA proposed rule and advance notice and stands ready to work with CMS to align the quality and treatment goals in Traditional Medicare with MA. To discuss the contents of this letter, please contact ASN Regulatory and Quality Officer David L. White at dwhite@asn-online.org or call (202) 640-4635.

Sincerely,

Susan E. Quaggin, MD, FASN
President