Nonprofit Kidney Care Alliance

March 4, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-2022-0021, 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 Administrator Brooks-LaSure,

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer our comments and recommendations on the Centers for Medicare & Medicaid Services (CMS) Advance Notice of Methodological Changes for CY 2023 for MA Capitation Rates and Part C and Part D Payment Policies. NKCA represents eight nonprofit dialysis providers: Centers for Dialysis Care; Central Florida Kidney Centers, Inc.; Dialysis Center of Lincoln, Inc.; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; Northwest Kidney Centers; Puget Sound Kidney Centers; and The Rogosin Institute. Collectively, we serve more than 22,500 patients at more than 326 facilities in 32 states. In an effort to keep patients off dialysis, we also serve more than 10,000 patients with chronic kidney disease (CKD), with the goal of avoiding, or at least delaying, the onset of end-stage renal disease (ESRD). Approximately 85 percent of our patients are covered by Medicare, including Medicare Advantage (MA) plans.

Enrollment of ESRD patients in Medicare Advantage has grown to almost a third of all ESRD patients. With ESRD patients now free to enroll in MA plans, ESRD policy in Medicare Advantage takes on a much more serious set of concerns, first and foremost for patients, but also for plans and ESRD providers who serve them. For patients already on dialysis, the option to enroll in a MA plan can bring improved coordination of care, particularly if they are a dual eligible, as well as additional benefits beyond standard Medicare Part A and B benefits. At the same time, it may create additional burdens and costs, with higher copays for certain services, more burdensome prior authorization and step therapy protocols, and fewer, and less convenient access to providers made worse by CMS' decision to eliminate specific time and distance standards for dialysis in the MA network adequacy standards. As we have noted previously, while we understand CMS' concern with inappropriate leveraging of those standards by some, current policy now falls short of protecting beneficiaries. And while the number of ESRD beneficiaries in Medicare fee-for-service (FFS) and in MA are relatively small, their per capita costs are among, if not *the* highest in the program.

We thank CMS for its efforts to continually improve the payment for ESRD coverage under the Medicare Advantage program, particularly in the risk adjustment system, as well as its request for comment around the current state-based rate. We recognize that due to the small population/sub-population numbers involved with ESRD policy, even routine adjustments can be more challenging, requiring work arounds that would normally be unnecessary. Indeed, these challenges make it even more difficult to evaluate the effects of CMS' proposed policies. In the short period of time (30 days) in which comments are due on the Advance Notice, we can only point to *concerns* around these policies. Accordingly, we urge CMS to look more closely at its analyses as well as provide more opportunity going forward for stakeholders to understand possible changes in future rulemaking and guidance.

Turning first to CMS' request for comment on a possible change in the future, but not in this Advance Notice, of the current use of the single statewide rate for ESRD payment. Unlike MA writ large which is based on county fee-for-service rates, the ESRD rate has always been based on a statewide rate, largely due to small numbers on a county-by-county basis. With the growth in MA ESRD enrollees, CMS is now considering a change in the use of a statewide rate. CMS reports that one option which stakeholders have raised is to use core-base statistical areas (CBSAs) as the geographic unit, not unlike FFS rates for hospitals and other providers.

Using CBSAs could provide a sub-state geographic unit—or multi-state unit—that more closely corresponds to labor costs and commuting patterns in predominately urban counties, though still picking up some less urbanized counties that might not be "rural" per se and are affected by a CBSA's labor and commuting patterns. We do want to raise a concern here. One which CMS, on the FFS side of the agency is well aware. The ESRD wage adjuster is based on the inpatient prospective payment system (IPPS) hospital wage rate; however, it is a pre-adjustment rate that does not reflect reclassifications and the floor, resulting in lower payment as well as an unlevel playing field with respect to labor.

A second, and related concern would be the effect on patients and their providers in non-CBSA (i.e., rural areas.) CMS notes that such areas would see a significant decline. To address this, CMS should consider an adjustment for those rural locations, analogous to the ESRD FFS low volume/rural adjuster which recognizes that dialysis clinics have significant equipment and other capital costs. They also require specialized staffing, such as dialysis nurses, who can command higher compensation, a growing problem in both urban and rural markets, but particularly so in rural areas in which the supply of skilled labor can be more acute. Indeed, this would become even more necessary because of CMS' change in network adequacy requirements. We look forward to hearing more from CMS about such a policy change and encourage it to post its analysis followed by opportunities for stakeholders to provide their input before CMS embarks on formal notice and comment rulemaking.

Regarding proposed changes to the ESRD risk adjustment model, we are concerned that CMS proposed grouping of partial dual eligibles, and non-duals may understate the costs associated with care for partial duals. The 21st Century Cures Act amended Section 1853(a) of the Social Security Act requiring an adjustment for dual eligibles, both full duals and partial duals. CMS proposes to build on its prior policy by breaking out aged and non-aged in both sets of dual

eligibles. In doing so, CMS proposes to use *non-dual* data to compensate for small numbers in the partial dual population, both in the ESRD and functioning graft components. We are concerned that this approach understates the cost of care for partial duals and ask CMS to review more closely before adopting such a policy.

Dual eligible status has been demonstrated to be a useful proxy for health disparities, and multiple health conditions which have often gone unaddressed. At the same time, dual eligibility, particularly full dual, has always been subject to state-by-state variation as some states impose stricter Medicaid eligibility requirements. Many of those states are ones which have disproportionate numbers of beneficiaries subject to kidney failure and who have historically been subject to health disparities. Consequently, some partial duals might be full duals, but for their state of residence. Since Congress required both full dual and partial dual breakouts, CMS properly implements the policy. However, in the case of partial duals, we are concerned that the problem of state variation would be made worse by diluting the partial dual factors with non-dual data, in effect squeezing partial duals from both ends of the spectrum. With further review, CMS might consider using multiple years of partial-dual data, rather than borrowing from the non-dual population.

A second area of concern in the proposed risk adjustment policies is around the application of only demographic factors for new enrollees. We understand the problem that as a new enrollee, there is a lack of Part A and Part B claims data on which to base clinical factors that correspond with hierarchical condition categories (HCCs). However, we are puzzled by CMS' assertion in both its 2018 and 2021 reports to Congress ("Report to Congress: Risk Adjustment in Medicare Advantage") in which it states that there is an over-prediction problem leading to further proposed adjustments in the 2023 Advance Notice. CMS proposes to use three years of continuing dialysis patient data to adjust for its concern about over-prediction. From what is provided in the Notice, it is unclear why CMS believes there continues to be over-prediction. Moreover, it is generally well accepted that the first year on dialysis is accompanied by significant health care complications and costs as the patient adjusts to the dynamic challenges of dialysis treatment. The first year of dialysis is also accompanied by high mortality rates and hospitalizations. If there is an over-prediction problem, then it should be addressed; but, diluting the costs of year one with three years of data from surviving patients is, on its face, concerning.

A third area of concern or question revolves around the transplant factors and the functioning graft component. CMS proposes to further refine the time period and subpopulation factors for months 1 through 3 as the costliest, with months 4 through 9, and 10+ progressively lower. We raise this concern, in particular, with the increased use of high kidney donor profile index (KDPI) kidneys.

In some cases, a post-transplant patient continues to need to be dialyzed to enable their new kidney to become fully functional. This *may* be being captured in the hospitalization costs in month 1, though that is unclear. In some cases, however, it may extend beyond the one-month period and hospitalization. We urge CMS to pay close attention to months 2 and 3 as well as the 4-to-9-month window particularly with the increasing use of higher KDPI kidneys which may result in higher costs than it currently assumes.

Higher KDPI kidneys may be accompanied by additional costs, including post-transplant "bridge" dialysis treatments to allow a transplanted kidney to reach full function. Other costs might include treatment of Hepatitis C, HIV and Cytomegalovirus (CMV) in the transplant recipient that were transmitted from the donor and extend to months 4 through 9 and beyond. Recent trends to use higher KDPI kidneys in older recipients may increase these costs. For the foreseeable future these numbers may be small, but we hope that CMS is sensitive to this development, for example, in the way it applies filtering protocols to its modeling.

Thank you for the opportunity to comment on the CY 2023 Advance Notice and for all that CMS is doing to make the experience of beneficiaries with kidney disease a positive one. If you have any questions, please feel free to contact me at 202-580-7707 or info@nonprofitkidneycare.org.

Sincerely,

Martin Corry
Executive Director