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Nonprofit Kidney Care Alliance

April 6, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4190-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4190-P)

Dear Administrator Verma:

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer our comments and recommendations regarding the Centers for Medicare & Medicaid Services (CMS)'s Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Proposed Rule. NKCA represents six nonprofit dialysis providers: Centers for Dialysis Care; Dialysis Center of Lincoln; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; Northwest Kidney Centers; and The Rogosin Institute. Collectively, we serve more than 21,000 patients at more than 300 facilities in 30 states. In an effort to keep patients off dialysis, we also serve more than 5,700 patients with chronic kidney disease (CKD), with the goal of avoiding, or at least delaying, the onset of end-stage renal disease (ESRD). Four of our members are also participating in the Center for Medicare and Medicaid Innovation (CMMI) alternative payment model, the Comprehensive ESRD Care (CEC) model.

For Medicare beneficiaries with end-stage renal disease and CKD, Medicare Advantage provides an important and, as we discuss below, a growing role. Even before the ESRD provisions of the 21st Century Cures Act take effect, a quarter of ESRD beneficiaries participate in MA. Because MA plans have an obligation to coordinate care, unlike traditional fee-for-service Medicare, and have additional tools at their disposal, such as supplemental benefits, MA plans can provide better care for beneficiaries with ESRD, who also bear the burden of other comorbidities.

Special Supplemental Benefits for the Chronically Ill (SSBCI)

The Balanced Budget Act of 2018, building on MA's existing supplemental benefits provisions, authorized additional supplemental benefits for those with chronic conditions that go beyond those that meet CMS' requirement to be *primarily health-related* to encompass supplemental benefits that can contribute to the improvement or maintenance of health or overall function, but are ***not*** primarily health related, such as transportation. CMS implemented these benefits through sub-regulatory guidance in 2019 and proposes to codify SSBCI in the proposed rule. NKCA supports this proposal as it will provide beneficiaries and plans with greater confidence that these new benefit flexibilities will be a more integral part of the MA program, by putting them on firmer ground. We also support CMS' intent to not only rely on its existing list of chronic conditions, but also provides that a plan may come forward with proposed SSBCI chronic conditions that may not be on the CMS list. In addition, we support CMS' intent to allow plans to include consideration of social determinants of health as a supporting, *though not exclusive*, factor in assessing eligibility for SSBCI. This seems a prudent limitation on what could otherwise be an open-ended provision. Finally, we support the CMS proposal to make SSBCI subject to the usual appeals and grievance protections applicable to plan organization determinations. As we have seen already, plans are referring to these benefits in the enrollment marketing to attract and/or keep members. Without appeals and grievance safeguards, these supplemental benefits could fall victim to bait and switch tactics.

Improvements to Care Management Requirements for Special Needs Plans (SNPs)

As part of the Balanced Budget Act (BBA) of 2018, Congress adopted a series of provisions designed to strengthen the requirements for Chronic Special Needs Plans (C-SNPs). Since fist enacted in 2003, the history and performance of the C-SNP program has been mixed, thus these new requirements represent overdue improvement. CMS, however, proposes to go further, and extend these same requirements to all Special Needs Plans (SNPs). We agree that having one set of model of care (MOC) requirements for C-SNPs and another for other SNPs make little sense (beyond some differences in the populations served). While much of these requirements have been subject to sub-regulatory guidance, e.g. through the annual Call Letters, the setting of annual benchmarks and evaluation of year-over-year attainment of model of care goals as required under the BBA would go somewhat further. While the overall direction that CMS proposes to take in implementing the new requirements is appropriate, we recommend that CMS retain some flexibility *in the regulatory text* if a plan fails to meet the proposed 50 percent threshold on one or more measures but, overall, demonstrates continued improvement. Terminating a plan which is achieving most of its goals overall has consequences for disruption in beneficiaries' lives – most of which are challenged enough.

Implementation of Certain Provisions of the 21st Century Cures Act:

A. MA Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries

The proposed rule provides for implementation for plan years beginning January 1, 2021 for ESRD beneficiaries to enroll in an MA plan. The rule includes several technical provisions, and asks for comment on one, related to current coverage (under 42 CFR 422.66(d)(1), of beneficiary seamless enrollment from a health plan to an MA plan offered by the same parent organization. We agree with CMS that there is no need to amend this provision in the regulation.

B. Medicare Fee-for-Service Coverage of Costs for Kidney Acquisitions for MA Beneficiaries

Under the 21st Century Cures Act, kidney acquisition costs (KAC) for transplant will be covered under original Medicare, rather than borne by MA plans, effective January 1, 2021. At the same time, CMS proposes a corresponding change to exclude such costs from MA benchmarks and capitation rates. CMS details this process in its 2021 Advance Notice, on which it took comment earlier this year. However, even with the description of the methodology to be employed in the Advance Notice, it is not clear whether the payment via fee-for-service (FFS) for KAC balances out the FFS costs being pulled out of the benchmarks. We ask that CMS provide greater transparency so that all stakeholders can have confidence that this is a one-for-one exchange. While this is important to plans, it is just as, if not more important, to CKD and ESRD beneficiaries for whom transplant represents the best renal replacement therapy. We also ask how CMS, in assessing kidney acquisition, addresses the difference between cadaveric organ acquisition vs living donor organ donation. And, while CMS proposes to pull FFS acquisition data by county, the use of statewide ESRD benchmarks could average out costs for organ acquisition, which is more likely to be associated with transplant centers that are more likely to be located in urban, high cost, locales.

Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services

Among other proposed changes to the MA Maximum Out-of-Pocket (MOOP) limits, CMS proposes a transition of three years (or more) of ESRD costs (ESRD differential) into the MOOP limit calculations. The rule refers to a Table 11 for more detail on how this would work, but there does not seem to be such a table. In general, CMS proposes to introduce ESRD costs into the MOOP calculation at the rate of 60 percent in year one (2022), 80 percent in year 2 (2023), and 100 percent in year 3 (2024), though this could be extended. CMS proposes a similar transition of ESRD related costs in adjusting cost sharing for inpatient and psychiatric services. Alternatively, CMS asks for comment on a more gradual transition, starting with 50 percent in year 1, 70 percent in year 2 or later; and 100 percent in whatever is the final year. As with other aspects of the transition of ESRD beneficiaries, the challenge of relatively small numbers of beneficiaries coupled with high costs makes the inclusion of the ESRD differential more difficult. We recommend that CMS follow its first alternative path: 60 percent in year 1; 80 percent in year 2, and then assess whether to proceed to 100 percent in year 3 or 4.

MA and Cost Plan Network Adequacy

CMS proposes to codify an extensive set of network adequacy requirements that have been part of the MA program for many years, which have assured beneficiaries access to Medicare providers and suppliers. In addition, CMS proposes several changes, most with general application, and one specific to ESRD. CMS also asks for comment—but does not make specific proposals—on several issues related to ESRD. In particular, it notes the "provider consolidation and its impact on higher costs for patients" in the dialysis sector. We comment on each of these matters below in more detail, but first we address the issue of consolidation and the four questions on which CMS asks for comment.

As nonprofit providers, most of whom are small, local or regional providers, we are acutely aware of the market consolidation issues referenced in the proposed rule. In our view, the network adequacy

proposals in the proposed rule should help address the concern that network adequacy requirements have been leveraged. Notwithstanding these concerns, we strongly urge CMS to make beneficiary access to care its number one priority. ESRD patients (except those fortunate enough and able to benefit from home dialysis) must dialyze three times a week, for four hours at a time, plus recovery and travel. Robust MA network adequacy standards are arguably more critical to the lives of ESRD beneficiaries than any other category of MA beneficiaries. Moreover, while some beneficiaries are fortunate enough to benefit from pre-emptive transplant, most are on dialysis while they await a suitable organ match and must remain healthy enough to remain a good transplant candidate.

CMS asks for comment on four questions that it may address in the future as to minimum access standards for dialysis services:

1) Removing outpatient dialysis from the list of facility types for which a plan must meet time and distance standards;
2) Allowing plans to attest to meeting medically necessary services, as is the case with home health, durable medical equipment (DME) and transplant;
3) Allowing exceptions to time and distance standards, in lieu of the provision of home dialysis; and
4) Customizing time and distance standards.

With respect to #1, we must ask, what would be the alternative standards to assure beneficiaries access to care? Is the suggestion that there would none? How would CMS hold MA plans accountable to access to care absent any standards? For the reasons noted above, this would put current MA ESRD beneficiaries and future enrollees at serious risk.

As to #2, the analogy to home health and DME is inappropriate, and potentially harmful. Home health agencies deliver care in the beneficiary's place of residence, regardless of where the home health agency is quartered. Similarly, DME is typically delivered to the beneficiary's home by a local vendor or available through a nearby pharmacy, regardless of where the DME provider is located. Transplant is delivered in hospital transplant centers specifically approved to provide transplant.

Regarding #3, CMS does not provide any detail as to how this would work. Home dialysis is an option which we strongly support and in which our member companies have established robust programs. We have been very supportive of CMS and the Department of Health and Human Services (HHS)' initiative to promote home dialysis, however, many beneficiaries are not good candidates for home dialysis. Still, this is an area in which much more can be done, and which MA plans could promote. We recommend that CMS engage a cross section of stakeholders to develop a set of policies that will help promote home dialysis for consideration in future rulemaking.

Question #4 is very difficult to assess. Is this an extension of CMS' existing network adequacy exceptions process? It is not clear what this represents or how it would function. If CMS is looking for a means to address those situations referred to in the perambulatory discussion wherein a dialysis provider "leverages" MA network adequacy standards, it would be well to describe how, and by what criteria it would function. Heretofore, CMS has declined to "get in the middle" between plans and providers when they could not reach a contractual agreement. CMS might consider a policy in which

either a dialysis provider or a plan could present comparable prevailing market terms to demonstrate its case to uphold or waive network adequacy requirements.

We turn now to the specific network adequacy proposals in the rule and offer the following comments.

CMS proposes to codify time and distance standards in new 422.116(b) that have been listed in the health service delivery (HSD) tables and to propose that it may add new types of providers and/or facilities through rulemaking but appears to propose that it be able to remove a provider or facility type by simply dropping them from the HSD tables without notice and opportunity to comment. If so, we believe this could jeopardize beneficiary access and health and recommend that ***both*** additions and deletions be subject to notice and comment.

CMS proposes to clarify that outpatient dialysis includes hospital-based outpatient dialysis services for purposes of network adequacy. We recommend that CMS assure that such hospital-based outpatient dialysis entities meet the same, or at least substantially similar, requirements, as current Medicare outpatient dialysis facilities to assure patients are provided the same level of care and quality requirements.

CMS proposes three additional network adequacy changes that are generally applicable, and which should, taken together, help address concerns expressed elsewhere regarding market consolidation in dialysis. First, CMS proposes to reduce the current 90 percent standard for beneficiary access to 85 percent for micro, rural, and counties with extreme access considerations (CEAC), while preserving and codifying the current 90 percent standard for other counties. We support CMS' proposal as a reasonable adjustment in light of the limited availability of some providers in rural areas. This will also likely reduce the opportunity for some providers to leverage MA network adequacy standards.

Second, CMS proposes to give MA plans a 10 percent point bonus or credit for a limited number of specialty types that can provide services via telehealth. Under this proposal, the percentage of beneficiaries' standard of 90 percent could be satisfied at 80 percent where a plan contracts for in-network telehealth providers in certain specialties. CMS also requests comment regarding other possible specialty types. We agree with CMS' proposal to provide for a 10 percent credit as proposed. Further, we recommend that CMS consider for future rulemaking the addition of nephrology, which could be part of an effort by CMS and MA plans to increase home dialysis and better serve those beneficiaries already doing home dialysis.

Third, CMS proposes an additional 10 percent credit to apply in states with Certificate of Need (CON) laws or other state-imposed restrictions which are anticompetitive in nature. CMS proposes that this 10 percent credit could be applied in conjunction with the 10 percent credit for telehealth. CMS does not propose to apply this 10 percent CON credit in conjunction with the reduction in the rural standard to 85 percent, which we view as a prudent decision, since it could reduce the beneficiary access standard to 75 percent, which could harm access to care. While we agree with the CMS proposal to allow for a 10 percent CON credit, we would note that, notwithstanding the academic research on this subject, CON laws have, in some cases, helped preserve a mix of providers within the larger national marketplace which would otherwise be lost to larger entities with greater access to capital. However,

while we can support CMS' proposal with respect to state CON laws, we do not support, and would be very concerned with the extension to "other state-imposed restrictions" as far too vague, unless this is only meant to encompass state laws that are the same as CON laws, but under a different name.

Finally, CMS proposes to codify its existing practice of considering exception requests from plans unable to satisfy specific network adequacy requirements. While not specifically addressed as part of CMS' proposal in this rule, we recommend that CMS consider addressing the issue that it raises with respect to ESRD access and provider consolidation here. A plan, which can demonstrate to CMS that it has made good faith offers to a dialysis provider that reflect prevailing rates of payment in comparable markets, could be considered to have satisfied network adequacy for a plan year, provided it can provide assurance that beneficiary access will be protected.

Conclusion

Thank you for the opportunity to comment on the MA and Part D Proposed Rule. The NKCA appreciates the opportunity to provide input to ensure that the MA system supports quality of care to the patients we serve. We would be pleased to discuss these comments and suggestions in greater detail at any time. If you have any questions, please feel free to contact Martin Corry at 202-580-7707 or info@nonprofitkidneycare.org.

Sincerely,

Martin Corry
Executive Director