KIDNEY CARE PARTNERS

March 4, 2020

Demetrios Kouzoukas
Principal Deputy Administrator
Centers for Medicare & Medicaid Services
Director, Center for Medicare
200 Independence Avenue, S.W.
Washington, DC 20201

Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
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Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
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Dear Principal Deputy Administrator Kouzoukas and Director Wuggazer:

The members of Kidney Care Partners (KCP) appreciate having the opportunity to provide comments on the "Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part II" (Advance Notice). KCP is also submitting comments on the "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 Proposed Rule" (Proposed Rule) in a separate letter.

KCP is an alliance of members of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies that support the provision of high quality care for individuals with chronic kidney disease (CKD), including End-Stage Renal Disease (ESRD).

As a threshold matter, KCP thanks the Administration for the work it is undertaking to implement the statutory provisions that allow beneficiaries who qualify for Medicare on the basis of their diagnosis of End Stage Renal Disease (ESRD) to finally have access to MA plans. Patients have long advocated for the ability to enroll in MA plans. While every plan is different, many MA plans offer care coordination services, transportation to appointments, mental health care, and dental coverage (which is essential for patients seeking to be accepted on a transplant waitlist), as well as other services, that can make MA plans preferable to the traditional Medicare fee-for-service plan for many patients. As the Sprint to Coordinated Care has recognized, care coordination services for patients living with chronic conditions can lead to better patient outcomes and improved quality of life. Once again, KCP applauds the Administration for its efforts to improve the lives of Americans living with kidney failure. We welcome the opportunity to work with you to make sure that dialysis patients have the information they need to make the informed decision as to whether traditional Medicare or an MA plan in their area is the best option for them.

In addition, KCP applauds the Administration for recognizing the importance of implementing the statutory anti-discrimination provisions that are outlined in the preamble to the Proposed Rule. While we recognize the need for plans to have some flexibility, we urge CMS to protect beneficiaries by enforcing these provisions, especially in terms of ensuring that the maximum out-of-pocket (MOOP) limits and the network adequacy time and distance requirements (which we recognize are part of the Proposed Rule and not in the Advance Notice) do not result in a *de facto* elimination of the expansion of MA plan options for dialysis patients. Given that 2021 marks the first year that CMS is implementing the statutory requirement to expand access to MA plan options for people who need dialysis or have a kidney transplant and qualify for Medicare because of their disease status, it seems inappropriate to change the long-standing rules that have applied to MA plans for purposes of determining cost-sharing amounts and network adequacy standards. To effectuate the will of the Congress, it would seem more appropriate to maintain the current requirements and make changes only if the current standards were shown not to provide sufficient protection to patients.

I. KCP recommends that CMS review the MA ESRD rates and use its existing authority to adjust them upward and to address the chronic underfunding in the ESRD PPS, ensuring that the rates cover the cost of services provided to these patients.

The ESRD Prospective Payment System (PPS) sets the foundation of the MA ESRD rates. KCP has raised concerns about the chronic underfunding of the PPS during the past several rulemaking cycles. MedPAC's annual margin analysis has shown that the program is underfunded as well. In its annual *Report to the Congress*, MedPAC has reported falling margins for the last several years, with recent analyses showing negative margins.

As CMS expands MA plan access to dialysis patients, it is important that the MA rates are set in a manner that covers the cost of providing care to dialysis patients. The first step in meeting this goal is to address the problems in the underlying PPS system. Inadequate rates would create a significant disincentive for (or in some instances make it impossible to enroll patients) MA plans to provide coverage to dialysis patients and thwart the will of the Congress. Therefore, KCP strongly urges CMS to use its existing authority to address the underlying problems within the ESRD PPS and to use its discretionary authority to make sure that the rates for 2021 do not disincentivize plans from enrolling dialysis patients. Addressing this shortfall rather than making changes to network adequacy time and distance and MOOP makes more sense as an effective first step to supporting the will of Congress and the statutory anti-discrimination provisions

II. KCP remains concerned about the negative impact of the normalization factor on the ESRD rate.

As we have indicated in previous years, KCP remains unclear as to how the changing demographics, implementation of alternative care models, and migration to ICD-10 coding impact the determination of the normalization factor. It is important that the community have a greater opportunity to review the data and methodology used to determine the normalization factor, which will allow us to offer more meaningful comments, because of the impact the factor has on the MA ESRD rates. We are concerned that the negative impact applying the factor has on the MA ESRD rates will make it difficult for MA plans to sustain coverage for these patients. Providing greater transparency, particularly in relationship to the impact of the ICD-10 code transition, could show that over time there will be greater stability and address concerns that plans might have about enrolling these patients.

III. KCP reiterates our request that CMS reassess the use of dialysis new enrollee data.

As we raised in our comment letter last year, KCP remains concerned that CMS is relying on modeling that includes only continuing enrollees who have been treated with dialysis for three years or less. We again reiterate our recommendation that CMS use the Five Percent Standard Analytic File (SAF), which includes a larger amount of member months of new dialysis enrollees with less than one year of Part B enrollment to address the Agency's small number concerns. Using these data on dialysis new enrollees would provide a more accurate assessment of their expected costs than the approach adopted previously, which is based on an incorrect assumption that the new enrollee data and continuing enrollee data are comparable. As noted previously and recognized by CMS in the use of an onset of dialysis adjuster in the PPS, new enrollees have higher costs that should be taken into account when CMS sets the MA ESRD rate.

Given the problems with the sample and the fact that the proposed reduction is inconsistent with USRDS data and other CMS policies that recognize the higher cost of new dialysis patients, we ask that CMS not implement the reduction in the CY 2021 ESRD dialysis model risk scores for the dialysis new enrollee segment. Not applying the reduction would allow CMS time to reassess its analysis using an appropriate dialysis new enrollee sample. Postponing the adjustment should not impact the normalization factor calculation.

IV. Recognizing the policies related to Maximum Out-of-Pocket (MOOP) limits and network adequacy standards are addressed in the Proposed Rule, KCP believes it is important that CMS consider the potential unintended consequences these proposals may have on the enrollment of dialysis patients in MA plans, especially if the ESRD rate is not adjusted.

KCP understands that the policies related to MOOP and network adequacy are outlined in the Proposed Rule and not necessarily germane to the Advance Notice; however, we believe that some of the interest in loosening these requirements may be related to concerns about the MA ESRD rates expressed by some stakeholders. Thus, we wanted to share our concerns related to MOOP limits and the network adequacy standards with CMS in this letter about the Advance Notice as well.

In sum, KCP is deeply concerned that if the proposed changes to the MOOP are finalized, dialysis patients may be asked to pay higher copayment amounts that will discourage their enrollment in MA plans. Similarly, we strongly urge CMS not to weaken the network time and distance standards that apply for outpatient dialysis. As CMS recognizes in several places in the preamble to the Proposed Rule, the statute prohibits discriminatory practices. It will be important to ensure that the ESRD rates, the MOOP limits, and the network adequacy standards do not create disincentives to enrolling dialysis beneficiaries, which would be contrary to the intent of the Congress when it expanded access to MA plan options to this population.

A. MOOP limits should not be designed to allow discrimination against dialysis patients.

KCP has worked closely with its patient members in particular to promote policies that allow for more patient-center decision-making and increased coverage and treatment options for dialysis patients. As such, KCP strongly supported the Congressional decision to expand MA access to dialysis patients and is pleased that these patients now have the choice to select MA plans, if they make the decision that such a plan is the best option for them.

In talking with patients, we have heard several concerns about plans potentially using out-of-pocket cost-sharing to discourage enrollment in MA plans. These patients also have multiple physician visits that make cost-sharing a significant issue. Their concerns grow out of problems dialysis patients have had historically with some commercial plans seeking to avoid providing coverage that the plans are otherwise legally required to provide. Given these experiences, KCP is pleased that CMS has indicated that it plans to monitor beneficiary access to MA plans.[1] Such monitoring is critically important to

[1] *Proposed Rule Display Copy* at 258.

ensuring that CMS can effectively enforce the anti-discriminatory provision of the statute, which "prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals."[2]

To help ensure that discriminatory practices do not occur as a result of the proposed MOOP limit changes, KCP recommends that CMS clarify with specific language in the final rule: (1) commit to an active enforcement of the anti-discrimination provisions; and (2) state that the intent of the proposed changes to MOOP is not to allow plans to create a tier of out-of-pocket costs that are linked to a specific chronic condition, such as kidney failure or the need for dialysis. Thus, while KCP supports the proposals related to increased MOOP transparency, we want to make sure that these changes cannot be used in such a way that will thwart the intent of the Congress to allow dialysis beneficiaries to access MA plans.

B. CMS should maintain and enforce time and distance standards for outpatient dialysis services and ensure access to specialists.

Since the initial creation of the time and distance standards, KCP has supported the intent behind having such requirements. They are especially important for dialysis patients. For those patients who select the in-center treatment modality, they need to have access to facilities to receive their 3-4 hour treatments 3 times a week. Patients who select home dialysis (either home hemodialysis or peritoneal dialysis) visit a facility at least once a month to receive necessary tests and check-in with their health care professionals, as well as have access to their treatment teams to ensure they have an appropriate plan of care in place. Given the intensity of these treatments, patients often do not have the energy or ability to travel long distances, nor do they have access to caregivers who can make such journeys with them on a regular basis.

Research supports what common sense implies: patients have better compliance with their treatment and better outcomes when their facilities are closer to where they live or work. For example, one recent study evaluating the effects of one-way travel times showed that patients who must travel longer distances have a decreased health-related quality of life and greater risk of mortality. This same study also showed that travel time can affect adherence to treatment protocols, hospitalization, and transplantation. Some patients have unfortunately chosen to withdraw from dialysis therapy rather than have to endure a long commute. Perhaps most interestingly, the study found an impact even when the drive time is as little as 15 minutes one-way.[3] Other studies have shown that missed treatments (for reasons other than the patient being hospitalized) more likely to result in

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[2] *Id.* at 253.

[3] LM Moist, JL Bragg-Gresham, RL Pisoni, *et al,* "Travel time to dialysis as a predictor of health-related quality of life, adherence, and mortality: The Dialysis Outcomes and Practice Patterns Study (DOPPS)," 51 Am J Kidney Dis 641-650 (2008).

inadequate fluid removal. Patients who miss treatments often show more symptoms of depression. Missed treatments have also been positively associated with all-cause mortality, cardiovascular mortality, sudden death/cardiac arrest, hospitalization, higher serum phosphorus levels, higher parathyroid hormone levels, lower hemoglobin levels, higher kidney disease burden, and worse general and mental health.[4] Longer travel times can be especially problematic for dialysis patients living in rural areas.[5]

Thus, KCP continues to support the network adequacy time and distance requirements for outpatient dialysis. In response to the request for comments on potential modifications to these requirements, our members would oppose any efforts to lessen these requirements by allowing plans to "customize" them. We also do not support suggesting that dialysis is like durable medical equipment and can be the left to contracting and attestations, rather than be the subject of direct regulatory requirements. Moreover, we are confused by the suggestion that time and distance standards would not be necessary if a plan covered patients only if they selected home dialysis. Even these patients must visit a facility at least once a month. More importantly, patients should have the ability to select the modality that best meets their needs and not be forced into one by a health plan. We are concerned if such proposal were adopted, they would act as a *de facto* prohibition on dialysis patients selecting MA plans. We also are concerned that MA plans include an adequate number of facilities to ensure real access to care. For example, including only hospital-based dialysis centers may not provide enough treatment time options to meet the needs of enrollees. To provide meaningful access to MA plans as the Congress intended, KCP believes that CMS needs to maintain outpatient dialysis in the list of time and distance standards and also to provide direct oversight of plan compliance with these requirements.

In addition, it is important to make sure that the network adequacy standards also include the specialists that dialysis patients need. Not only should there be nephrologists, vascular access surgeons, and other similar professionals, but the number of such specialists included in the network needs to be sufficient to ensure that patients have practical access to them. A network would not be adequate if there is a vascular surgeon, for example, but a patient is unable to schedule an appointment with him/her because all of the appointment slots are filled for months. Not having access to vascular surgery in a timely manner thwarts the quality indicator of a permanent rather than a temporary access and negatively impacts the patient health as well as increase long term costs. An attestation process or other policy that would remove direct CMS oversight would only make this problem worse. It would eliminate access to these plans for all practical purposes or drive up costs of care by not having the most efficacious intervention available.

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[4]Salmi, A.; Larkina, M; Wang, *et al* "Missed Hemodialysis Treatments: International Variation, Predictors, and Outcomes in the Dialysis Outcomes and Practice Patterns Study (DOPPS)." 72 *Am J Kidney Dis.* 634-43 (Nov. 2018).

[5] Stephens, JM; Brotherton, S; Dunning, SC; *et al.*, "Geographic Disparities in Patient Travel for Dialysis in the United States" 29 *J. Rural Health* 339-48 (2013).

V. KCP encourages CMS to align, to the extent practicable, the quality outcomes measures used for MA plans with those that apply to dialysis facilities and nephrologists.

KCP has been a leader in efforts to develop and implement value-based purchasing programs in the ESRD area and a strong advocate for providing accurate and meaningful quality information to patients and caregivers. Such transparency is critical to ensure accountability and allow for patient-centered decision-making.

KCP supports the proposals in the Advance Notice to develop a new kidney health evaluation measure that may in the future replace the Diabetes Care – Kidney Disease Monitoring measure. We ask that CMS work to align, to the extent practicable, the MA measures with the ESRD measures used in the Quality Incentive Program (QIP), Dialysis Facility Compare/Five Star, and the nephrologist measures. Even small differences in specifications or benchmarks can lead to differing incentivizes that make it difficult for providers and plans to work together to provide high quality care. Such differences also create confusion among patients who find it difficult to understand the inconsistencies and often end up ignoring the quality reporting entirely. We would welcome the chance to work with CMS and the plans to ensure consistency across these different quality programs.

We also encourage CMS to look at C-SNPs metrics. C-SNPs are required to submit for approval Models of Care that address care coordination, including care transition protocols and requirements that ensure that the networks have expertise in caring for the ESRD population (in the case of an ESRD C-SNP). These requirements could help inform metrics used in the MA star ratings to adequately address ESRD enrollees under the member experience and care coordination categories.

In addition, a gap has developed in the reporting of quality measures in terms of beneficiaries enrolled in MA plans. Often these patients are excluded from the ESRD quality program reporting because of disconnects in how data are provided between the traditional fee-for-service program and MA program. We encourage CMS to work with the Center for Clinical Standards and Quality to address existing data gaps to ensure that MA patients are included in the quality data being reported. KCP would welcome the opportunity to work with CMS on this issue as well.

VI. Conclusion

KCP agrees with the Congress that there can be great value to patients with kidney disease in being able to select an MA plan. MA plans have shown how effective they can be in improving health status improvement for patients with chronic diseases. Many MA plans have been treating ESRD patients for years and have shown how these important

their care coordination and management activities can be for ESRD patients. We welcome the chance to continue to work with CMS to help patients understand their options and ensure that they are able to exercise the right to enroll in MA plans that the Congress provided to them.

Thank you again for providing us with the opportunity to comment. Please do not hesitate to reach out to our counsel in Washington, Kathy Lester at 202-534-1773 or klester@lesterhealthlaw.com, if you have questions or would like to discuss our comments.

Sincerely,

John Butler
Chairman

Appendix: Kidney Care Partner Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
Ardelyx
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
AstraZeneca
Atlantic Dialysis
Baxter
Board of Nephrology Examiners and Technology
BBraun
Cara Therapeutics
Centers for Dialysis Care
Corvidia Therapeutics
DaVita
DialyzeDirect
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
Medtronic
National Kidney Foundation
Nephrology Nursing Certification Commission
National Renal Administrators Association
Otsuka
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care