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April 6, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-4190-P: 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

Dear Administrator Verma:

The American Kidney Fund (AKF) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding policy and technical changes to the Medicare Advantage (MA) and Medicare Prescription Drug Benefit (Part D) programs.

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

We focus our comments on provisions related to implementation of the statutory change that will allow individuals with end-stage renal disease (ESRD) to enroll in MA plans, starting with the 2021 contract year. AKF strongly supports increased coverage options for ESRD patients, and we appreciate CMS' efforts in implementing this change that will enable beneficiaries with ESRD to select an MA plan if they decide that is the best option for their needs. MA plans can offer additional benefits unavailable in traditional Medicare that can be important factors in a beneficiary's decision to enroll in MA, such as care

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coordination, vision and dental coverage, transportation, and an annual out-of-pocket maximum. The cap on out-of-pocket expenses is particularly important for beneficiaries who live in one of the twenty states that do not guarantee access to Medigap supplemental insurance for ESRD beneficiaries under the age of 65. These beneficiaries face financial hardship because they lack access to the supplemental coverage needed to help pay the cost-sharing in traditional Medicare, which does not have an annual out of-pocket spending limit.

However, because of their ESRD and the comorbidities that occur more commonly for people with kidney disease, CMS must ensure regulatory policies result in meaningful access to MA plans and do not effectively lead to discouraging ESRD patients from enrolling in MA plans.

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

AKF understands the need for CMS to adjust the methodology for setting MOOP limits to take into account how the MA eligibility for Medicare beneficiaries is changing to remove the current limits on MA enrollment for Medicare eligible beneficiaries with ESRD. We support CMS' proposal to increase its transparency by codifying the methodology for how MOOP limits will be set, and appreciate its goal to provide more stability and predictability to the MA program.

A concern we have is that MA plans may attempt to use different MOOP limits to create a tier of out-of-pocket costs that are related to a specific chronic condition such as ESRD. We recommend that in the final rule, CMS includes specific language that clarifies that CMS changes to MOOP limits are not intended to allow for tiers of out-of-pocket costs tied to specific conditions. We believe this would further demonstrate CMS' commitment to the anti-discrimination provisions of the MA 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."

Medicare Advantage Network Adequacy

CMS is considering several network adequacy options as it relates to measuring and setting minimum standards for access to dialysis services. CMS is soliciting comment on: (1) Whether CMS should remove outpatient dialysis from the list of facility types for which MA plans need to meet time and distance standards; (2) allowing plans to attest to providing medically necessary dialysis services in its contract application (as is current practice for DME, home health, and transplant services) instead of requiring each MA plan to meet time and distance standards for providers of these services; (3) allowing exceptions to time and distance standards if a plan is instead covering home dialysis for all enrollees who need these services; and (4) customizing time and distance standards for all dialysis facilities.

As CMS notes in the proposed rule, these options are being considered in response to providers and physician groups who have commented on limitations of current network adequacy policies

on dialysis treatment when performed in a hospital, at home, or in an outpatient facility. The options are being considered also to reflect research that demonstrates the benefits of home dialysis and to recognize that there is more than one way to access medically necessary dialysis care and wanting to encourage plans to exercise all of their options to best meet a beneficiary's health care needs.

AKF supports maintaining the current time and distance standards for outpatient dialysis and opposes the options that CMS is considering because they would decrease those standards, potentially in a way that would make MA plans impractical for patients with ESRD.

AKF strongly believes in patients choosing the modality and treatment choice that is clinically appropriate for their health needs and their individual circumstances, whether it is in-center hemodialysis, home dialysis, or transplantation. However, eliminating outpatient dialysis facilities from time and distance standards, allowing plan attestations in contract applications, permitting plan customization, or allowing exceptions for plans that provide home dialysis for all enrollees who need dialysis would impede on the patient's ability to choose the modality that is right for them within the MA program. These possible changes to network adequacy standards would place the choice of modality in the hands of plans, not patients, and would effectively prohibit ESRD beneficiaries from selecting MA plans.

As CMS notes, home dialysis can provide valuable advantages over in-center hemodialysis, including greater flexibility for people to continue working and to travel, and studies have shown that home dialysis for certain patients can lead to better health outcomes, such as lower risk of death in the initial years of dialysis treatment and lower rates of hospitalizations.[1] And as we have stated in previous letters on other proposed rulemaking, we believe more can be done to increase the use of home dialysis for patients for whom it is appropriate. However, there are factors that can be barriers to home dialysis, including housing insecurity; a lack of caregiver support; functional limitations such as poor vision or dexterity; lacking a home environment that is able to store supplies and equipment; and clinical reasons such as infections or comorbidities. Changing minimum standards for access to dialysis services, as proposed in the four options under consideration, would make MA plans an unrealistic option for ESRD beneficiaries who have decided in-center dialysis is the right modality for their care.

These network adequacy proposals would also adversely affect beneficiaries who choose home dialysis, because there are situations where home dialysis patients need access to an in-center facility. For example, home dialysis beneficiaries need to have an in-center clinical assessment at least monthly, and for beneficiaries who choose to receive their monthly clinical assessment via telehealth, they still have to have an in-person visit for the first three months of starting home dialysis and once every three months thereafter. Because many ESRD patients "crash" into dialysis, they need access to an in-center facility while they are being trained on receiving home

[1] Rivara, M. B., & Mehrotra, R. (2014). The changing landscape of home dialysis in the United States. Current opinion in nephrology and hypertension, 23(6), 586–591. doi:10.1097/MNH.0000000000000066

dialysis. There are also situations where a home dialysis patient has to switch to in-center hemodialysis due to clinical reasons or changed life circumstances.

Eliminating requirements for adequate access to in-center facilities would essentially exclude MA plans as a viable option for ESRD beneficiaries. To ensure meaningful access to MA plans, CMS should maintain time and distance standards for dialysis services.

Thank you for your consideration of AKF's comments and recommendations.

Sincerely,

LaVarne A. Burton
President and CEO