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September 16, 2019

The Honorable Alex M. Azar, II  
Secretary  
Department of Health and  
Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

The Honorable Seema Verma  
Administrator  
Centers for Medicare &  
Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: CMS-5527-P: Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures**

Dear Secretary Azar and Administrator Verma:

The American Kidney Fund (AKF) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule, "Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures."

The American Kidney Fund is the nation's leading independent nonprofit organization working on behalf of the more than 37 million Americans with kidney disease. For the past half-century, AKF has existed to help people fight kidney disease and live healthier lives. We provide a complete spectrum of programs and services: top-rated education materials; free kidney disease screenings in numerous cities across the nation; clinical research funding; and need-based financial assistance enabling one in five U.S. dialysis patients to access lifesaving medical care, including dialysis and transplantation.

AKF commends the Administration for launching the *Advancing American Kidney Health* initiative, and we fully support its three main objectives: increase efforts to prevent, detect, and slow the progression of kidney disease; provide patients with kidney disease with more options for treatment; and deliver more organs for transplant.

As part of the initiative, CMS has proposed the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC model). This mandatory payment model aims to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians "to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care."<sup>1</sup>

<sup>1</sup> 84 Fed. Reg. 34481 (July 18, 2019)

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. Given the current rate of home dialysis (about 12 percent of prevalent ESRD patients in 2016) and the percentage of ESRD patients with a functioning kidney transplant (29.6 percent of prevalent patients in 2016), there is clearly an opportunity to increase the utilization of both modalities.<sup>2</sup> Over the years through its rulemaking for the Medicare ESRD program, CMS has “established a goal of fostering patient independence through greater use of home dialysis among patients for whom it is appropriate,”<sup>3</sup> and AKF is supportive of that goal and those efforts. In line with that support, AKF fully supports the stated objectives of the ETC model.

However, we have concerns with various aspects of the model and the potential unintended consequences to the patient experience. We ask that CMS consider these concerns and work with stakeholders to address them as the agency examines possible revisions to the model to ensure that it is designed to achieve its intended goals.

AKF is also a member of Kidney Care Partners (KCP), an alliance of members of the kidney care community. In addition to our comments below, we support the comments that KCP has submitted.

### **Beneficiary Protections and Ensuring Patient Choice**

AKF appreciates and supports CMS’ commitment, as outlined in the proposed rule, to protect beneficiaries’ freedom to choose an ESRD facility, managing clinician, or any other provider or supplier, and to protect beneficiary access to medically necessary services as it applies to the ETC model. We also support the proposed requirement that ETC participants notify beneficiaries of the ETC participant’s participation in the ETC Model by prominently displaying informational materials in ESRD facilities and managing clinician offices or facilities where beneficiaries receive care.

However, to ensure true patient choice in their treatment options, we recommend that CMS allow for the exclusion from the denominator in the Home Dialysis Payment Adjustment (HDPA) and Performance Payment Adjustment (PPA) measures patients who, after appropriate patient education, decide not to proceed with home dialysis, as well as patients who may not be suitable candidates for home dialysis or transplantation due to clinical reasons. Incorporating this exclusion in the HDPA and PPA measures would help address concerns that we and other stakeholders share, which is how to appropriately account for clinical and other factors that are key considerations in modality choice.

As noted in our introduction, we believe that more should be done to increase the utilization of home dialysis and transplantation for patients for whom it is appropriate. Home dialysis can provide 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

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<sup>2</sup> United States Renal Data System, Annual Data Report, 2018. Volume 2, Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities.

<sup>3</sup> United States Government Accountability Office (GAO), *End-Stage Renal Disease: Medicare Payment Could Promote Increased Use of Home Dialysis*, 2 (October 2015).

dialysis treatment and lower rates of hospitalizations.<sup>4</sup> Many of the home dialysis patients we have talked to in our work at AKF have continually noted to us how much they value the flexibility and independence that home dialysis has given them and how they can make it work for their lifestyle and schedule. They also value being able to take more responsibility for their treatment, and some patients have said that taking that responsibility made them better prepared for their eventual transplant. With respect to transplantation, receiving a kidney transplant is considered the best treatment option for people facing kidney failure because it can increase your chances of living a longer, healthier life, and at AKF we never tire of hearing how receiving a transplant changed the life of a patient.

But there are factors that can be barriers to home dialysis and transplantation. For example, a patient may not qualify for a transplant due to infection or comorbid conditions such as heart disease. In the case of home dialysis, barriers include, but are not limited to: 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. AKF is concerned that because of the negative payment adjustments to ETC participants under the PPA and problematic issues related to the proposed scoring methodology,<sup>5</sup> the model could incentivize behavior that forces some patients into home dialysis who may not have all the tools needed to succeed.

Also, as CMS acknowledges in the proposed rule, it considered excluding beneficiaries with housing insecurity from attribution for calculating the home dialysis rate but could not find an objective way to measure housing instability. AKF helps patients who have experienced or are experiencing housing insecurity while on dialysis, and it is a major obstacle to not only being able to choose home dialysis but is a significant stressor on their overall health and well-being. Given that an objective measure for housing instability is not available, and the other barriers to home dialysis and transplantation mentioned above, we believe incorporating an exclusion from the denominator for patient choice (after appropriate education on treatment options) and clinical reasons would better account for socioeconomic and clinical factors that play a critical role in modality choice.

We acknowledge that CMS has proposed to account for underlying variation in the population of beneficiaries attributed to ETC participants by risk adjusting the home dialysis and transplant rate. To do this, CMS has proposed using the CMS-HCC (Hierarchical Condition Category) ESRD risk adjustment model that is used in the Medicare Advantage program. We believe, however, that approach will not address the concerns outlined above. As the Medicare Payment Advisory Commission (MedPAC) noted in their comment letter, “CMS-HCC risk scores are not highly correlated with the propensity to use home dialysis among beneficiaries and should not be used to risk adjust the home dialysis measure.”<sup>6</sup> Therefore, it is even more important that CMS consider our recommendation on patient choice and exclusions in the measures.

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<sup>4</sup> 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

<sup>5</sup> See the Kidney Care Partners comment letter for further details on concerns related to the scoring methodology and payment adjustments in the ETC model.

<sup>6</sup> Medicare Payment Advisory Commission (MedPAC), Letter to Administrator Seema Verma, Re: File Code CMS-5527-P (September 3, 2019).

## Transplant Rate Measurement

CMS proposes to measure transplant rates for ESRD facilities and managing clinicians based on the number of attributed beneficiaries who received a kidney or kidney-pancreas transplant during the measurement year (MY) out of all attributed dialysis treatment beneficiary years (and attributed beneficiary years for preemptive transplant beneficiaries for managing clinicians) during the MY. AKF recommends that instead, CMS should expedite its current development and testing of transplant referral measures and obtain National Quality Forum (NQF) endorsement so that it can be used in the ETC model. We support the use of meaningful transplant measures in the Medicare ESRD program that are actionable by facilities and clinicians, and we believe the use of an NQF-endorsed referral measure would be a more appropriate metric, since increasing the number of transplants that occur also depends on the actions of other stakeholders—actions that are not addressed in the ETC model.

AKF strongly supports efforts to increase the number of transplants for people with kidney disease, as it presents the best outcomes for most patients. We are pleased to see that as part of the *Advancing American Kidney Health* initiative, the Administration aims to increase access to kidney transplants by increasing “the utilization of available organs from deceased donors by increasing organ recovery and reducing the organ discard rate.”<sup>7</sup> Some of the concrete steps that the Administration will be taking, in addition to developing transplant referral measures, include:

- Convening a learning collaborative to reduce the disparity in performance among Organ Procurement Organizations (OPOs) and transplant centers with the goal of increasing recovery of kidneys by OPOs and utilization of kidneys by transplant centers.
- Developing a new model to test accelerated placement of certain kidneys that are at high risk for discard.
- Analyzing and improving transplantation metrics with a focus on increasing organ utilization while maintaining good outcomes.
- Reviewing the OPO conditions for coverage and proposing changes to the standards used to evaluate OPOs to ensure proper data collection on the availability of transplantable organs and transplants.

These actions by the Administration demonstrate that it understands that increasing the number of transplants requires reforms and improvements involving all stakeholders in kidney care, including clinicians, ESRD facilities, OPOs and transplant centers. Another area that we encourage CMS to work with stakeholders on is the standardization of transplant center waitlist criteria and development of a waitlist measure that can obtain NQF endorsement. Given that these holistic changes to the transplant process are still being developed, and in the meantime there is still a large discrepancy between the number of people on the transplant waitlist and available organs, we believe it is more appropriate for ETC participants to be evaluated on an actionable transplant referral measure.

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<sup>7</sup> U.S. Department of Health and Human Services, *Advancing American Kidney Health*, 17 (July 2019).

## Kidney Disease Education Benefit

AKF has long-advocated for legislative changes to and regulatory examination of the Kidney Disease Education (KDE) benefit in order to increase the utilization of this important tool that can help patients with chronic kidney disease (CKD) learn about their treatment options. As noted in the proposed rule, the percentage of eligible beneficiaries who have been provided the benefit is less than two percent.<sup>8</sup> Therefore, we appreciate and support CMS' proposal, for the purpose of testing the ETC model, to waive certain Medicare requirements regarding the provision of the KDE benefit. Specifically, we support CMS' proposals to:

- Allow the KDE benefit to be provided by clinical staff other than doctors, physician assistants, nurse practitioners, and clinical nurse specialists, under the direction of a Medicare-enrolled managing clinician.
- Waive the requirement that the KDE benefit is available only to Stage IV CKD patients, and allow Medicare beneficiaries with CKD Stage V and beneficiaries who are in the first six months of an ESRD diagnosis to receive the benefit.
- Provide flexibility on the content requirement of the KDE sessions as it pertains to information on the management of comorbidities, including delaying the need for dialysis, when it is provided to CKD Stage V or ESRD beneficiaries, unless the content is relevant for the beneficiary.
- Waive the requirement that an outcomes assessment that measures beneficiary knowledge about CKD and its treatment be performed by a qualified clinician as part of one of the six KDE sessions, provided that it is performed within one month of the final KDE session by qualified staff.

AKF recommends that CMS expand the KDE benefit further in the ETC model by:

- Waiving the beneficiary coinsurance requirement for KDE services. This would help make the KDE benefit more accessible to beneficiaries for whom the 20 percent coinsurance is cost-prohibitive. In addition, waiving beneficiary cost-sharing could be cost-efficient for Medicare as patients will be better prepared to begin dialysis and are better informed about managing their treatment, especially if they are choosing home dialysis.
- Waiving certain telehealth requirements to allow the KDE benefit to be delivered via telehealth for beneficiaries outside of rural areas and other applicable limitations on telehealth originating sites. Expanding the use of telehealth to more beneficiaries will allow patients to receive the benefit in a manner that may be more convenient for them.
- Permit dialysis facilities to bill for the KDE benefit for patients who are in the first six months of an ESRD diagnosis. ESRD facilities employ individuals who would be allowed to provide KDE, and permitting them to bill for the services would expand the availability of the KDE benefit to patients.

As pointed out by the Government Accountability Office (GAO), "literature and stakeholders have underscored the value of predialysis education to help patients make informed treatment decisions,

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<sup>8</sup> 84 *Fed. Reg.* 34562 (July 18, 2019)

and also indicated that patients who receive it may be more likely to choose home dialysis.”<sup>9</sup> In talking to ESRD patients, AKF has heard numerous accounts where patients were not adequately educated on their treatment options, and were not aware that home dialysis might be a good option for them until they researched it themselves or went to a different clinician. We have also heard from patients who felt their providers did an excellent job of explaining their treatment options to them, and it made a meaningful difference in their ability to make an informed decision. Given the importance of patient education in empowering patients to make the right choice for them, we recommend that CMS expand the KDE benefit further by incorporating our recommendations above.

### **Monitoring and Quality Measures**

AKF supports and appreciates CMS’ plan to monitor for inappropriate encouragement or recommendations for home dialysis by monitoring indicators such as increased hospitalizations, infection, incidents of peritonitis, and other unusual patterns in claims data. We also support CMS’ intention to examine for any unintended consequences, including an increase in clinically adverse events such as graft failures and returns to dialysis, lemon-dropping clinically complex patients, and cherry-picking less clinically complex patients.

While CMS mentions the use of patient surveys and interviews in order to look for instances of coercion on beneficiary choice of modality against beneficiary wishes, we echo the concern raised by MedPAC that the ETC model does not formally measure beneficiary experience.<sup>10</sup> As we have noted to CMS in previous comments on the Medicare ESRD Quality Incentive Program (QIP), the agency should work with stakeholders to develop a Consumer Assessment of Healthcare Providers and Systems Survey and Experience of Care (CAHPS) survey for home dialysis patients, which should be used for the QIP and the ETC model. The current CAHPS survey used in the QIP only applies to in-center hemodialysis patients. Because the ETC model is intended to have a direct impact on beneficiaries’ care, it is important that the patient experience is formally captured.

A home dialysis CAHPS survey should be designed to acquire an accurate record of the patient experience, while also minimizing patient burden and encouraging patient participation. Given that minority groups are disproportionately affected by ESRD, it is important that the lingual translations of the surveys are accurate so that foreign language speakers can provide meaningful responses. Also, allowing patients to respond to the survey through different delivery modes, such as a mobile device, would encourage participation, especially for those patients who may use a smartphone as their main connection to the internet.

### **Workforce Shortages and Training**

CMS notes that it is “seeking comment on how the proposed payment adjustments under the ETC Model may influence delivery-oriented interventions among participating ESRD facilities and Managing Clinicians (for example, increased Managing Clinician knowledge of dialysis modalities, greater patient education, increased investment in equipment and supplies), as well as how the

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<sup>9</sup> GAO, 27 (October 2015).

<sup>10</sup> MedPAC (September 3, 2019)

Model's financial incentives may affect the resourcing of these endeavors, and what are the barriers to change."<sup>11</sup>

In our interactions with patients, we have heard various experiences regarding how providers presented treatment options. Patients have described instances where they saw one provider who was clearly more comfortable explaining in-center hemodialysis and did not go as in-depth explaining peritoneal dialysis, then saw a different provider who seemed more comfortable talking about peritoneal dialysis. These patient experiences reflect what GAO found, which is that the literature and stakeholder interviews "indicated that physicians have limited exposure to home dialysis during nephrology training programs and thus may not feel comfortable prescribing it" and that "physicians who felt more prepared to care for peritoneal dialysis patients were more likely to prescribe it."<sup>12</sup> Relatedly, we have heard from patients who chose home hemodialysis that their training from facility staff was less than adequate, which, while certainly concerning, might be reflective of the low rate of home hemodialysis among prevalent ESRD patients (less than 2 percent in 2016)<sup>13</sup> and the workforce shortage in nephrology.<sup>14</sup> We also want to note that we have heard from home hemodialysis and peritoneal dialysis patients that had excellent experiences in their home training.

Given the concerns with the scoring methodology and payment adjustments in the ETC model, specifically the PPA, we are not confident that payment adjustment will have a direct impact on improved provider and nephrology staff knowledge of dialysis modalities, particularly home dialysis. Improvements in that area requires changes and enhancements in training curriculums and certification examinations for providers and staff, as well as addressing the nephrology workforce shortage. However, we reiterate our belief that the proposed waivers for the KDE benefit can lead to improvements in patient education regarding their treatment options.

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

Sincerely,



LaVarne A. Burton  
President and CEO

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<sup>11</sup> 84 *Fed. Reg.* 34565 (July 18, 2019)

<sup>12</sup> GAO, 27 (October 2015).

<sup>13</sup> USRDS, Annual Data Report, 2018. Volume 2, Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities.

<sup>14</sup> Muhammad U. Sharif, Mohamed E. Elsayed, Austin G. Stack, The global nephrology workforce: emerging threats and potential solutions!, *Clinical Kidney Journal*, Volume 9, Issue 1, February 2016, Pages 11–22, <https://doi.org/10.1093/ckj/sfv111>