April 6, 2020

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

RE: 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:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the "Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program." During this unprecedented COVID-19 public health emergency (PHE), ASN's more than 21,000 members would like to thank you for the dedication and tireless efforts of everyone at the Centers for Medicare and Medicaid Services (CMS) and the broader Department of Health and Human Services (HHS) who have worked tirelessly to address concerns, challenges, and opportunities within the healthcare system for addressing this deadly disease.

While ASN's members regularly lead the fight to prevent, treat, and cure kidney diseases while advocating for the highest quality care for the 37,000,000 Americans and more than 850,000,000 people worldwide affected by kidney disease, the current crisis demands that each and every one of us draw upon all of our skills and knowledge as clinicians and harness our individual and collective determination to prevail in this PHE for the sake of our patients. The steps you have taken to place patients first and provide greater flexibility in our practice and delivery of care has unleashed the potential of all healthcare workers across the United States.

ASN has long supported allowing Medicare beneficiaries with a diagnosis of End-Stage Renal Disease (ESRD) to have access to Medicare Advantage (MA) plans. 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. Care coordination services

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for patients living with chronic conditions – such as kidney failure – often lead to better patient outcomes and improved quality of life.

ASN will address issues of maximum out-of-pocket (MOOP) limits and the network adequacy time and distance requirements in this letter on the Proposed Rule, and refers CMS to ASN's comment letter of March 6, 2020, on the Advance Notice for any other issues regarding MA.

Network Adequacy

Regarding network adequacy time and distance requirements within MA, CMS has posed four specific questions that raise a host of implications for patients with kidney failure in MA. CMS asked the following:

Therefore, we are considering several options about how to improve our proposal as it relates to measuring and setting minimum standards for access to dialysis services. We solicit 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.

The timing of these questions is particularly unique. During the past month, ASN and others in the kidney community have made numerous requests for increased flexibility in care delivery for patients with kidney diseases—especially those with kidney failure—in light of the COVID-19 pandemic and the need to reduce exposure to the virus. CMS has moved with alacrity to support those requests ranging from broadly expanding the use of telehealth and the coding to support that use to providing flexibility in care venues to granting relief from reporting requirements during the PHE. ASN believes there will be a great deal to learn clinically and regarding care delivery during this period and beyond.

As such, ASN offers its comments grounded in long-term goals for care innovation with a healthy dose of realism that care innovation is rapidly occurring right now. ASN encourages CMS to maintain protections for patients and avoid a wholesale removal of time and distance protections (T&DPs). However, ASN realizes significant changes in care delivery are forthcoming with the expected finalization of the ESRD Treatment Choices (ETC) model, the introduction of innovative devices for dialysis care delivery, greatly expanded telehealth, and the entrance of new providers into the kidney space. In such a dynamic environment, it seems logical to ASN that network adequacy in the future might be achieved differently than it was in the past.

While ASN does not advocate for CMS to eliminate these standards for the entire kidney patient population, ASN would welcome the opportunity to dialogue with the agency over what might constitute network adequacy in the future, particularly regarding home dialysis patients. ASN underscores that there may be a middle ground in which T&DPs are modified, but not wholly eliminated, and encourages CMS and the community to consider scenarios in which patient access is maintained and choice either maintained or even expanded. In general, ASN supports the concept that access to care in the future that might be adequate in terms of T&DPs but might permit MA plans to offer a different mix of care options to achieve that adequacy.
As this dialogue progresses, ASN encourages CMS to additionally consider:

- Using a nuanced approach that considers how network adequacy might be achieved in the future before modifying T&DPs.
- Recognizing unique challenges that patients with kidney failure face due to the need for frequent travel to a dialysis facility, when considering network adequacy.
- Remaining open to the idea of future care delivery looking different than the current predominance of in-center dialysis care with the entrance of new providers.
- Ensuring patients have options among which to choose.
- Dealing with transplant patients separately.
- Ensuring latitude for managing chronic illness by covering such services as meals and transportation.
- Reconsidering maximum out-of-pocket expenses (MOOPs) for this patient population.
- Risk adjusting MA plan quality metrics to align with the ESRD Quality Incentive Program (QIP).
- Protecting the integrity of the US Renal Data System (USRDS) by ensuring the inclusion of MA data.
- Monitoring effects of the proposed rule's approach to dealing with organ acquisition costs.

Maximum Out-of-Pocket (MOOP) Limits

ASN shares the concerns of others in the kidney community that the ESRD benchmark is inadequate to cover the costs associated with ESRD coverage for patients with kidney failure due to the $6,300 difference between the fee-for-service (FFS) out-of-pocket expenditures and the MA MOOP limit.[1] ASN believes the current ESRD reimbursement is not sufficient to prevent premium increases across MA plans and will limit patients' ability to benefit from MA's supplemental benefits and care coordination services that are especially valuable for patients with kidney failure and other chronic conditions.

[1] Blum, J., Hammelman, E., & Ipakchi, N. (2020, February 12). End-Stage Renal Disease and Medicare Advantage. Retrieved March 6, 2020, from https://www.healthmanagement.com/wp-content/uploads/Health-Management-Associates-ESRD-and-Medicare-Advantage-White-Paper.pdf

While ASN realizes CMS has proposed enabling MA plans to increase the MOOP for all beneficiaries in that plan in order to accommodate the higher costs of ESRD care, the MOOP limit is an essential patient protection and one of the advantages to patients of enrolling in an MA plan. Accordingly, passing the costs of ESRD care on to all MA beneficiaries, including ESRD beneficiaries, is not an appropriate solution. ASN encourages CMS to look to alternative approaches to fully accounting for the $6,300 differential between the FFS OOP responsibility and the MA MOOP.

ASN also understands that there can be a significant variation in the expenditures for kidney failure patients within states.[2] ASN encourages CMS to evaluate whether setting the ESRD benchmark at the level of a smaller geographic area could enable MA plans to better target their offerings to the local patient population.

These are indeed extraordinary times for health care and the people the health care system serves in both the United States and around the world. There will be much to learn from the changes we have already undergone and the changes we will undergo. In that context, the opening of MA plans to patients with kidney failure is an opportune time to discuss the questions CMS has posed and how society will view healthcare adequacy in general and for kidney care—especially for people with kidney failure who depend on the Medicare ESRD Program—in the future. ASN stands ready to continue this dialogue with CMS as we collectively learn from our current dynamic and develop a vision for our future one. ASN appreciates the opportunity to make these comments. If you have questions or would like to discuss these comments further, please contact David White, ASN Regulatory and Quality Officer at dwhite@asn-online.org.

Sincerely,

Anupam Agarwal, MD, FASN
President

[2] *Ibid.*