National Kidney Foundation®

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September 10, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Room 314G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS 1693-P: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma,

The National Kidney Foundation appreciates the opportunity to comment on 2019 proposed changes to the Physician fee Schedule and Quality Payment Program. The National Kidney Foundation is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI). Our comments focus on proposed policies related to access and quality improvement for patients who have or are at risk for CKD.

Home dialysis

We appreciate the agency's implementation of provisions from the Bipartisan Budget Act of 2018, which will increase home dialysis patient's access to telehealth consultations. This will allow patients to benefit even more from the flexibility that home dialysis offers since they will have the option to receive monthly consultations with their

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healthcare team from home using telehealth. This new option also helps patients receive care that is tailored to their personal life goals, values and preferences by providing flexibility for patients to better design their treatment schedule around their lives rather than designing their lives around their treatment. We appreciate CMS support of this flexibility for home dialysis patients.

We also encourage CMS to further look at ways to increase access to home dialysis by removing payment barriers. CMS notes for a third year in a row that the CPT codes for home dialysis are mis-valued, but does not propose a plan to review or the update the codes. NKF urges CMS to align these codes with the MCP used for in-center patients. The current MCP structure allows for physicians to receive a higher payment for rounding on in-center patients multiple times in one month, whereas the home dialysis MCP is capped at a lower amount. Equalizing the payments would help remove a current barrier to home dialysis uptake since nephrologists who have more patients conducting dialysis at home could be unfairly disadvantaged.

<u>Expanding facility-based measurement for eligible clinicians to ESRD</u>
The National Kidney Foundation opposes expanding facility-based measurement to dialysis facilities. In addition to treating patients on dialysis, nephrologists and advanced practitioners treat patients with advanced CKD and those who have received a kidney transplant. Many nephrology practitioners see patients at multiple dialysis facilities making it difficult to attribute them to one facility. The National Kidney Foundation is also concerned that dialysis facility-based measurement for MIPS eligible clinicians could unintentionally discourage a focus on earlier CKD and post-transplant care and discourage participation in future payment models that are more holistic of kidney care and not solely dialysis focused.

In November 2017, the National Kidney Foundation shared it's CKDintercept alternative payment model for the comprehensive care of CKD patients. The CKDintercept model focuses on identifying CKD earlier to improve outcomes and delay progression to ESRD. Total Medicare expenditures for all stages of kidney disease were nearly $100 billion in 2015, not including prescription medications. Approximately $68 billion of the total expenditures were spent caring for those with CKD who did not have renal replacement

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therapy.[1] The impact of CKD is further amplified as the disease burden is growing. A study published by researchers leading the Centers for Disease Control and Prevention's (CDC) CKD surveillance program shows that over half of U.S. adults age 30-64 are likely to develop CKD.[2] Furthermore, CKD is a disease multiplier that leads to cardiovascular disease, bone disease, and other chronic conditions; contributing to poor health outcomes and increased health spending for this population. These are outcomes and costs that CMS could better control with a comprehensive CKD payment model that encourages earlier detection and treatment of CKD in the primary care setting and primary care and nephrology collaboration. We continue to talk with CMMI on opportunities to implement a patient-centered alternative payment model that would be physician-focused and achieve improved outcomes for patients while also lowering costs to Medicare and private payers. We encourage CMS to implement pilot testing of this model.

Gaps in measurement for Earlier CKD Care

The National Kidney Foundation continues to urge CMS to support and accelerate development of new measures that focus on earlier CKD care. We appreciate this Administration's focus on improving kidney care, promoting transplant and home dialysis, and spurring innovation in new treatments. However, there is much that can be done now to delay progression and ease transitions of care for those who do progress to ESRD. Patients with ESRD often ask why they were not diagnosed sooner or informed of opportunities like medical nutrition therapy (MNT) to allow them to have an active role in managing their condition.

There is only one measure in the QPP that addresses identification of CKD that is the Diabetes: Medical Attention for Nephropathy. Unfortunately, it is a poor indicator of appropriate assessment of CKD in people with diabetes and excludes other populations at greatest risk of kidney disease most notably hypertension – the 2nd leading cause of ESRD. National surveys and studies of individuals with CKD consistently demonstrate low awareness, specifically approximately 10% awareness among those with laboratory

[1] United States Renal Data System. 2017 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2017.

[2] Hoeger, Thomas, et al. The Future Burden of CKD in the United States: A Simulation Model for the CDC CKD Initiative *American Journal of Kidney Disease* (2015); 65(3):403-411.

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evidence for the condition.[3, 4] However, there is a better measure used by the Indian Health Services, Diabetes: Nephropathy Assessment that is supported by the KDOQI guidelines and the American Diabetes Association's Standards of Care. This measure evaluates whether patients with diabetes, those at highest risk for kidney disease, have both a measure of estimated glomerular filtration rate (eGFR) and urine albumin to creatinine ratio (UACR) during the performance year. At minimum annual testing of people with diabetes is recommended by KDOQI and the American Diabetes Association.[5] KDOQI also recommends testing for those with hypertension and annual testing for individuals with diagnosed CKD to monitor progression and appropriately tailor intervention to the stage of CKD. [6] We strongly recommend that CMS replace measure #119 and instead work with the National Kidney Foundation to tailor the IHS measure for individuals with diabetes and hypertension and include it in the MIPS program as it would address a substantial gap in the care of patients who often ask why they weren't told they had kidney disease before their kidneys failed.

To improve the care of CKD patients, the National Kidney Foundation has also developed and tested measures that would improve patient safety and timely referrals to nephrologists. These measures will improve current gaps in the treatment of CKD. The measures address: avoidance of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) in those with CKD, as NSAID use increases risk of acute kidney injury and faster progression to ESRD, and timely consultation with a nephrologist for patients with CKD stage 4 or who are at high-risk of mortality and progression to ESRD. We are interested in working with CMS to further refine and test these measures to maximize their impact. In addition, we are interested in developing a quality measure for patient receipt of medical nutritional therapy. A recent publication shows, despite Medicare coverage of

[3] Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Data. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 1999-2012.
[4] Szczech LA, et al. Primary Care Detection of Chronic Kidney Disease in Adults with Type-2 Diabetes: The ADD-CKD Study (Awareness, Detection and Drug Therapy in Type 2 Diabetes and Chronic Kidney Disease), PLOS One November 26, 2014.
[5] ADA Clinical Practice Recommendations for Diabetes American Diabetes Association. Standards of Medical Care in Diabetes 2017. Diabetes Care 2017;40(Suppl. 1):S1–S2
[6] Inker, Leslie A., et al. KDOQI US Commentary on the 2012 KDIGO Clinical Practice Guideline for the Evaluation and Management of CKD, AJKD, May 2014, 63: 5; Pages 713–735.

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MNT for CKD patients with an eGFR of 50 or less and effectiveness of dietary changes, 90% of non-dialysis CKD patients have never met with a dietitian.[7]

A truly patient-centered approach to kidney care needs to start with a focus on earlier identification and treatment of CKD and opportunities for patients to engage in self-management and participate in shared decision making about their treatment options. Significant gaps in the care of patients with CKD stages 3-5 remain. The refinement and development of measures that address earlier treatment of CKD will help improve outcomes and afford patients the opportunity to manage their condition to delay or prevent ESRD.

Comprehensive ESRD Care (CEC) Model Quality Measures

The National Kidney Foundation generally supports the measures proposed for the CEC Initiative. In our comments on the proposed 2019 ESRD PPS and QIP rule we offer suggestions for how many of those measures could be improved.

- Transplant Waitlist Measures
  In regards to the transplant waitlist measures that were included in CEC for 2018 and have been proposed for inclusion in the ESRD QIP in 2021 and 2023, while we are not supportive of including these in the ESRD QIP we do believe the CEC model is an appropriate setting to test performance of these measures. However, we caution that some ESCOs may be disadvantaged by national average comparisons. The ultimate decision on whether to place a patient on the waitlist is made by the transplant center. These are complex decisions that consider many factors and vary by transplant centers even within the same geographic region, which could make nationwide comparisons of waitlist percentages difficult to interpret.

  We also strongly urge that modifications be made to the standardized first kidney transplant waitlist ratio for incident patients to allow ESCOs whose participants are involved in early CKD care and education to receive credit for preemptive transplants. Otherwise, we are very concerned that this measure creates a perceived incentive to allow patients to initiate dialysis before being evaluated for a transplant. The Kidney

[7] Kramer, Holly, et al. Medical Nutrition Therapy for Patients with Non-Dialysis-Dependent Chronic Kidney Disease: Barriers and Solutions. Journal of the Academy of Nutrition and Dietetic, Article in Press, published online July, 28, 2018, https://doi.org/10.1016/j.jand.2018.05.023.

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Allocation Policy allows for patients to be placed on the waitlist with an eGFR of <20 far before needing to start dialysis. This allows for patients to have the best opportunity to receive a preemptive transplant either from a living or a deceased donor, which is associated with better outcomes than those who start dialysis and then receive a transplant.

- Include NQF 2594 Optimal ESRD Starts Measure in the CEC Model
  In addition, we reiterate our comments on the 2018 proposed rule and encourage CMMI to include the *Optimal ESRD Starts* quality measure, developed by the Permanente Federation, in the CEC measure set. Since nephrologists receive credit under MIPS for participating in CEC we believe this is an appropriate measure to include that will help create a focus on timely preparation for ESRD. Approximately 80% of patients start hemodialysis with a tunneled catheter, increasing susceptibility to infection versus a permanent vascular access, such as an AV fistula. This measure would encourage improvements in the number of patients starting renal replacement therapy optimally whether that be in-center dialysis with a working fistula and no catheter, home dialysis or receiving a pre-emptive transplant. Any of these options would be a significant improvement and likely result in cost savings to Medicare and the ESCOs participating in the CEC Model.

The National Kidney Foundation appreciates the opportunity to share our comments on how the proposed rule can be further strengthened to achieve the Administration's stated goal of improving the quality of care for patients with CKD. Please contact Tonya Saffer, Vice President for Health Policy with any questions at tonya.saffer@kidney.org or 202.244.7900 extension 717.

Sincerely,

Kevin Longino
Kevin Longino
CEO and kidney transplant recipient

Michael Choi
Michael Choi, MD
President