National Kidney Foundation®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

August 21, 2017

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

Re: CMS 5522-P: Medicare Program; CY 2018 Updates to the Quality Payment Program

Dear Administrator Verma,

The National Kidney Foundation appreciates the opportunity to comment on the proposed rule for CY 2018 Updates to the Quality Payment Program (QPP). 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).

I. Advanced APM: Physician Focused Payment Model Proposals

The National Kidney Foundation strongly supports broadening the definition of PFPMs to be considered for Medicaid implementation. This is particularly important for people with Chronic Kidney Disease (CKD) who are not yet on renal replacement therapy and do not qualify for Medicare. Implementation of a comprehensive CKD model in state Medicaid programs would significantly improve earlier detection and treatment of CKD, lowering the costs to Medicaid and future costs to Medicare through delayed progression, reduced adverse

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events, and optimal preparation for renal replacement therapy. Medicare makes substantial investments in kidney disease care as the primary payer for most Americans with end-stage renal disease (ESRD), regardless of their age. Total Medicare expenditures for all stages of kidney disease were nearly $103 billion in 2014, not including prescription medications. Approximately $70 billion of the total expenditures was spent caring for those with CKD who did not have renal replacement therapy. The impact of CKD is further amplified as the disease burden is growing. A recent 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.[1] Furthermore, CKD is a disease multiplier that leads to cardiovascular disease, bone disease, and other chronic conditions; further 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 includes non-Medicare beneficiaries with CKD.

As a stakeholder engaged in building a patient-focused payment model to support comprehensive CKD care for submission to the Physician-Focused Technical Advisory Committee (PTAC), the National Kidney Foundation appreciates the opportunity to share our comments on the Secretary's criteria and opportunities to better address stakeholders' needs. Particularly challenging in building alternative payment models is the requirement to develop a reimbursement methodology that ideally includes the payment amount. For untested and novel models being developed for consideration by PTAC, this can be a difficult task as stakeholders may have to rely on retrospective data and informed assumptions to create the methodology. Organizations without a statistician on staff are likely to have to invest in a consultant, as CMS also does to develop CMMI models. The National Kidney Foundation recommends that CMS require only a qualitative description of the reimbursement with quantitative data to support the cost savings or cost neutrality. Should the PTAC recommend the model to CMS and CMS be interested in advancing the model, we suggest CMS work with the submitter to

[1] 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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develop a more robust reimbursement methodology either by providing technical assistance or support or by developing cooperative agreements or grants to support stakeholders work in developing Physician Focused Payment Models (PFPM), as the agency plans to do to support stakeholders with MIPS measure development.

II. Selection of MIPS Quality Measures for Individual MIPS Eligible Clinicians and Groups Under the Annual List of Quality Measures Available for MIPS Assessment:

a. Background and Policies for the Call for Measures and Measure Submission Process

As a new stakeholder developing quality measures to improve kidney care, the National Kidney Foundation encourages CMS to be very clear in its requirements for measure submission. We appreciate the flexibility in allowing measures to be submitted that are not endorsed and that have started, but not completed, testing. However, CMS should state specifically its criteria under which scenarios it will consider measures for referral to the Measure Applications Partnership when reliability and feasibility testing have not yet been completed. Specifically, is there a time frame for expected measure completion that CMS will require? Will CMS permit incomplete testing only if the measure is considered a priority for CMS? If so, which areas of measurement is CMS prioritizing for where completion of testing may be waived in order to advance the measure faster? Greater clarity around these considerations will help stakeholders better plan for a successful submission.

b. Topped Out Measures

The National Kidney Foundation appreciates that CMS proposes to publish potentially topped out measures for comment. There are measures that should be retired because they no longer foster quality improvements, but in some cases should be maintained for various reasons, including limited measures for a particular specialty or a particular area of care, care gaps among certain practitioner types or in rural areas, as well as other potential reasons. Providing stakeholders the opportunity to comment on topped out

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measures will help better inform CMS of their value.

One measure not included in this proposed rule's topped out list is the Diabetes: Medical Attention for Nephropathy measure #119. It was however alluded to in the 2018 Medicare Advantage and Part D Advanced Notice and Draft Call Letter that this measure was topped out, but not removed from the Medicare Advantage Star Ratings program. While this is the only measure in the QPP that is intended to address both identification and treatment of CKD patients not on renal replacement therapy, the measure is misleading to clinicians and patients and not in alignment with the KDOQI guidelines on CKD assessment or treatment. Specifically, the measure allows practitioners to receive credit without conducting the two simple tests, a serum creatinine and a urine albumin-creatinine ratio test, needed to identify CKD and to monitor established disease for progression. 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[2] and the American Diabetes Association.[3] The National Kidney Foundation strongly recommends that CMS retire measure #119 and instead adopt the IHS measure for 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. National surveys and studies of individuals with CKD consistently demonstrate low awareness, specifically approximately 10% awareness among those with

[2] 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.
[3] ADA Clinical Practice Recommendations for Diabetes American Diabetes Association. Standards of Medical Care in Diabetes 2017. Diabetes Care 2017;40(Suppl. 1):S1–S2

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laboratory evidence for the condition.[4, 5]

To improve the care of CKD patients, the National Kidney Foundation is testing three 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 referral to a nephrologist for patients with CKD stage 4 or who are at high-risk of mortality and progression to ESRD. The use of these measures along with an appropriate assessment measure, such as that used by IHS, will help improve outcomes for CKD patients.

III. Measures proposed for the Comprehensive Primary Care Plus Initiative

The National Kidney Foundation strongly believes that a measure for assessment for CKD detection should be part of this program. However, we believe for the reasons stated above that the Diabetes: Medical Attention for Nephropathy is a poor indicator of appropriate assessment of CKD in people with diabetes. We recommend the IHS Diabetes Nephropathy Assessment, as it is a better quality measure for ensuring assessment of CKD in people with diabetes. For fostering improvements in CKD, we also highlight that the measures we are developing related to NSAID avoidance and nephrology referral would enhance attention on managing CKD by primary care clinicians. Other areas appropriate for CKD quality improvement include patients receiving nutritional counseling and taking an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) for CKD patients with hypertension and moderately or severely increased albumin in the urine.

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[4] 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.

[5] 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.

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The National Kidney Foundation notes the proposed measure Statin Therapy and Treatment of Cardiovascular Disease for use in CPC Plus. Statin therapy in CKD patients with diabetes who are not on renal replacement is supported by the KDOQI commentary on KDIGO clinical practice guidelines for the evaluation and management of CKD.[6] In addition, Healthy People 2020 objectives call for an increase in the percentage of CKD patients over age 50 receiving statin therapy to 25.6%. From 2001-2006 only 21.6% of CKD patients over age 50 were on a statin. As of 2012, there had been no significant change in statin use in this population.[7] This further underscores the need for improved detection and appropriate management of CKD patients. Including the IHS Diabetes Nephropathy Assessment Measure would improve identification of CKD, which would likely detect an additional population at high risk of cardiovascular events that would benefit from statin-based therapies to improve cardiovascular outcomes.

IV. Measures proposed for the Comprehensive End-Stage Renal Disease Care (CEC) Initiative

The National Kidney Foundation generally supports the measures proposed for the CEC Initiative. However, we offer suggestions for how some of these measures could be further improved.

a. ICH CAHPS based measures

While the National Kidney Foundation is supportive of quality measures that reflect patient satisfaction with the care they receive, we remain concerned with the length of the ICH CAHPS survey and the frequency it is given. This survey requires a considerable amount of time to complete and patients already spend a great deal of their time focused on dialysis. If only a few questions from the survey are to be used to evaluate patient satisfaction in

[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.
[7] Health People 2020 Objectives: Chronic Kidney Disease 6.2 Data Report, https://www.healthypeople.gov/2020/data-search/Search-the-Data#objid=4100; accessed August 17, 2017.

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the ESRD Seamless Care Organizations (ESCOs), we recommend the survey be shortened to focus on those items or to administer the survey in two parts. We also note this survey and these measures do not capture home dialysis patients' satisfaction and hope there will be satisfaction measures developed that apply to their care in the near future.

b. Screening for Clinical Depression and Follow-Up Plan

The National Kidney Foundation suggests that this measure be modified to specify the appropriate standardized screening tool validated in the ESRD population so that future outcomes data can be compared across ESCOs.

c. Include NQF 2594 Optimal ESRD Starts Measure in the CEC Model

The National Kidney Foundation recommends that since nephrologists receive credit under MIPS for participating in CEC that the NQF endorsed *Optimal ESRD Starts* quality measure, developed by the Permanente Federation, also be included in the CEC measure set. 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 the ESCOs participating in the CEC Model.

V. Complex Patient Bonus

The National Kidney Foundation appreciates the intent to ensure clinicians are not penalized for caring for complex patients. We support proceeding with a temporary measure to account for the additional time and resources used to care for complex patients, but note some concerns. Individuals with CKD are more complex than most and have the some of the highest costs in the Medicare program. This is reflected in the tables using HCC risk scores to determine complex patient bonuses as nephrologists would have the highest average risk

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scores. In fact, the costs of CKD patients' care doubles from one stage to the next, with the most significant increases beginning at CKD stage 3.[8] However, the HCC methodology accounts only for the complexity of caring for CKD 4 and ESRD patients, not CKD 3 patients as this stage was removed from the methodology in 2016. As a result, we believe this bonus would not account for the complexity of caring for these patients and could further exacerbate efforts to improve identification and treatment of this patient population. The National Kidney Foundation also does not believe that basing the methodology for complex bonus payments on the ratio of dual eligible patients would appropriately capture the complexity of caring for patients with CKD. We encourage CMS to adopt a solution that would capture the complexity of caring for CKD 3 patients.

The National Kidney Foundation appreciates the opportunity to comment on the second year of implemenation for the Quality Payment Program. We believe this program has great potential to improve the care and outcomes for individuals with CKD, while also substantially lowering Medicare spending on their care. The National Kidney Foundation stands ready to work with CMS to realize this goal. If you have any questions please contact Tonya Saffer, Senior Health Policy Director at tonya.saffer@kidney.org or at 202.244.7900 extension 717.

Sincerely,

Michael Choi
Michael Choi, MD
President

Joseph Vassalotti
Joseph Vassalotti, MD
Chief Medical Officer

[8] Honeycut t AA, Segel JE, Zhuo XH, Hoerger TJ, Imai K, Williams, D: Medical Costs of CKD in the Medicare Population. J Am Soc Nephrol 2013. 24.