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June 27, 2016

Andrew Slavitt  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Room 445–G  
Hubert H. Humphrey Building,  
200 Independence Avenue, SW  
Washington, DC 20201

RE: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS–5517–P)

Dear Acting Administrator Slavitt:

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the proposed rule for the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (PFPMs). NKF is America's largest and long-established health organization dedicated to the awareness, prevention, and treatment of kidney disease for hundreds of thousands of healthcare professionals, millions of patients and their families, and tens of millions of people at risk. In addition, NKF has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI).

NKF believes the programs included in Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) have the opportunity to improve the quality of care patients receive. As stated in our response to the November 2015 request for information (RFI), each element of the program should reinforce one another and ensure alignment in quality across MIPS and alternative payment models (APMs) rather than simply be discrete activities with differing goals. All quality activities should address gaps in patient care by eligible clinicians (ECs) and these gaps in performance should ultimately determine which quality measures and clinical improvement activities ECs choose to

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participate in each year. In addition, patients should be central and involved in all aspects of quality improvement to include the development of alternative payment models (APMs), Advanced APMs, and Physician-Focused Payment Models (PFPM). Ultimately, these new models of care should all be considered **patient**-focused payment models. With these goals in mind, NKF offers the following recommendations to strengthen the proposed rule.

**I. Advanced APMs and Physician Focused Payment Models.**

NKF encourages CMS to include the involvement of patients and their families in the development and review of new payment models. Excluding patient input and involvement in such a monumental change in healthcare delivery is a missed opportunity that does not align with CMS's stated goals to incentivize patient-centered care. To deliver true value in healthcare new models should ensure that patients are engaged. This means that patients' individual values, goals, and needs are considered at all points in healthcare. To ensure this happens, CMS should include patients in the development and review of these new models and also require such involvement as additional criterion for PFPMs.

NKF appreciates that CMS agreed with our comments, and those of others, that clinicians participating in other payment models should not be excluded from new PFPMs. As we stated in our November response to the MACRA RFI, those clinicians already participating in an APM (APM Entities) have experience that can elevate PFPMs and improve patient outcomes. Those ECs should not be excluded from participation, or limited to just one model type. While it is critically important that the development of new APMs encourage new participants, it is equally important that new models enhance patient care. However, we also recognize new models of care should not duplicate existing efforts and should harmonize with one another to ensure appropriate care coordination and transitions of care for patients. NKF also believes new models of specialty care that focus on the management of patients with chronic conditions should be prioritized.

NKF has convened a national workgroup of interdisciplinary healthcare professionals including primary care practitioners, nephrology practitioners, a dietitian, nurses and patients to develop a patient-focused Kidney Care Payment model. This model will partner primary care and nephrologists to identify kidney patients with CKD stages 3-5, who are not on a renal replacement therapy, encourage care coordination, and cost-effective, patient-centered care that can help slow progression to end-stage renal disease (ESRD), reduce adverse events, and help patients that do progress to ESRD properly prepare for transplant or dialysis. We believe this model would align with other existing APMs and enhance the care of individuals at risk and

with CKD.

## II. **Clinical Practice Improvement Activities (CPIA)**

NKF is pleased with the diversity of activities that allow for ECs to participate in CPIAs (Table H). We see particular opportunities for NKF to align our continuing education and medical education (CME/CE) and practice transformation activities in improving CKD care with several of the CPIA descriptions including:

- A. Participation in research that identifies interventions, tools or processes that can improve a targeted patient population;
- B. Implementation of regular reviews of targeted patient needs which includes access to reports that show unique characteristics of eligible professional's patient population, identification of vulnerable patients, and how clinical treatment needs are being tailored, if necessary, to address unique needs and what resources in the community have been identified as additional resources;
- C. Providing longitudinal care management to patients at high risk for harm;
- D. Provide condition-specific chronic disease self-management support programs or coaching or link patients to those programs in the community as well.

However, we are concerned about the lack of standards around these opportunities. Without criteria, built-in metrics, and assessments the CPIAs may not encourage meaningful improvements in patient care. NKF is also concerned, that as proposed, the CPIAs amount to a check the box activity without any tie to outcomes assessments. While we understand that there is no endorsing entity or accrediting body for CPIAs like there are for quality measures and CME activities, we do not believe it precludes CMS from developing criteria that CPIAs and ECs participating in them should meet. NKF supports the subcategories for CPIAs and agree that multiple entities should have the opportunity to provide CPIAs. However, in order to drive improvement in EC's performance, standards should be implemented for the activities.

ECs should be able to demonstrate that participation in a CPIA filled a knowledge or practice gap and has led to process improvement and overtime better outcomes for patients. In the first couple of years of MIPS, EPs should be given credit for participation in CPIAs that address gaps in their own practice. In future years, the bar should be set higher where credit is provided for achievement of the metrics and assessments built into CPIAs, and eventually EPs should be held to improving patient outcomes through CPIA participation.

CPIAs could also serve to provide an evidence base for which outcomes based quality measures could be developed and used in the quality, resource, and advancing care information components of MIPS. This creates a cycle for which participation in a CPIA also helps the EC meet their other MIPS goals – better connecting each component of MIPS and preparing MIPS ECs for participation in APMs. The proposed rule states a similar goal that:

*Ideally, clinicians in the MIPS program will have accountability for quality and resource use measures that are related to one another and will be engaged in CPIAs that directly help them improve in both specialty-specific clinical practice and more holistic area.<sup>1</sup>*

However, the CPIA proposal does not go far enough to achieve this goal either.

### III. **Quality Measures**

The proposed rule allows flexibility for physicians to choose at least six measures for the quality measures domain stating that only one of the measures must be a cross-cutting measure and one be an outcome measure. NKF appreciates that emphasis is placed on outcomes measures, but also allows for flexibility in the case where an appropriate outcomes measure for the EC may not exist. NKF agrees that when an outcome measure does not exist that the EC should report on one of the high priority quality areas which include: appropriate use, patient safety, efficiency, patient experience, and care coordination measures. Similar to our comments on CPIA participation, NKF believes ECs should report on quality measures that focus on gaps in care and ultimately outcomes. However, there are some conditions for which outcomes measures are not available, but for which improvements in care processes have observational data that show improvement in outcomes. The use of process measures often serve as the first step in educating and transforming clinical practice to align with evidence based care. In addition, with chronic conditions, like CKD, certain outcomes like progression to ESRD, may take several years to show results making intermediary outcomes or process measures necessary for annual reporting.

The proposed rule states ECs may report on either individual measures or select from specialty measures and requests information on measures that could be added to the specialty measure sets. NKF notes that currently there are no individual measures or measures for the general practice/family medicine or internist groups addressing early diagnosis and treatment of CKD. In considering new measures of care, NKF appreciates the proposed rule's emphasis on looking at measures of appropriate diagnosis and use of therapeutics and offers the following recommendation for measures related to diagnosis and treatment of individuals with CKD to be included in these two specialty measure sets:

The Indian Health Services (IHS) uses a measure for detecting CKD in people with diabetes that aligns with the KDIGO guidelines on Chronic Kidney Disease Evaluation and Management, the KDOQI

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<sup>1</sup> Federal Register / Vol. 81, No. 89 / Monday, May 9, 2016 / Proposed Rules, p. 28184.

commentary on these guidelines, and the American Diabetes Association's Standards of Care. The 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). The measure proposed for MIPS and currently used in the current Physician Quality Reporting System (PQRS), Diabetes: Medical Attention for Nephropathy (NCQA) permits practitioners to skip testing and diagnosis of CKD as long as the patient is prescribed Angiotensin-converting enzyme inhibitors (ACEi) or an Angiotensin II receptor blocker (ARB). This measure allows practitioners to forgo follow-up monitoring of CKD progression, but still meet performance on the measure. NKF proposes that CMS remove the NCQA measure 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 laboratory evidence for the condition.<sup>2, 3</sup>

- A. While evidence shows that treatment with an ACEi or ARB can slow progression of kidney disease with albuminuria and hypertension, the importance of albuminuria testing and regular monitoring of patients with CKD as well as other evidence-based interventions is overlooked by the NCQA Measure and may lead to clinicians incorrectly thinking that they have satisfactorily addressed the care of CKD patients.
- B. The Renal Physician's Association has developed a measure for the appropriate prescribing of an ACEi or ARB that recognizes the importance of albuminuria or proteinuria testing for CKD and hypertension and aligns with the KDIGO guidelines on Chronic Kidney Disease (CKD) Evaluation and Management and the KDOQI commentary on these guidelines.
- C. In addition, to protect the safety of patients with CKD and improve care coordination and appropriate care transitions, NKF is in the process of developing two new measures targeted for primary care practitioners to report on.
  - i. Avoidance of non-aspirin NSAIDs for individuals with CKD as a component of a CKD management strategy. NKF is in the process of developing and e-specifying such a measure. Adopting a patient safety measure for NSAID avoidance in patients with two eGFR values  $< 45 \text{ ml/min/1.73m}^2$  at least 90 days apart will

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<sup>2</sup> 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.

<sup>3</sup> 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.

reduce the occurrence of acute kidney injury (AKI) and prevent progression of CKD.

More than 98 million NSAIDs prescriptions were filled in 2012 and NSAIDs.<sup>4</sup> Over-the-counter and prescription NSAIDs are frequently associated with community-acquired acute kidney injury (AKI), a strong risk factor for development and progression of chronic kidney disease.<sup>5</sup> A recent analysis showed that among the U.S. stratified random sample of 12,065 individuals in the cross-sectional National Health and Nutrition Examination Survey with estimated glomerular filtration rates between 15 and 50 mL/min/1.73m<sup>2</sup>, 5% reported using OTC NSAIDs regularly and 66.1% had used these agents for 1 year or longer.<sup>6</sup> A U.K. population study showed over 4000 fewer NSAID prescriptions following eGFR reporting (adjusted odds ratio 0.78). Furthermore, follow-up data confirmed that the 1511 individuals with eGFR < 60 mL/min/1.73m<sup>2</sup> experienced significant improvement in kidney function following withdrawal of NSAIDs.<sup>7</sup>

- ii. Timely referral and closing the referral loop are relevant to CKD. NKF agrees with CMS that measures that encourage primary care practitioners to submit supporting documentation along with referrals to specialty care are important and we also agree that having specialists report back to primary care is an essential addition incorporated in *PQRS Measure #374 Closing the Referral Loop – Receipt of Specialist Report*. Such a measure could be tailored and targeted to address gaps in the care of patients with chronic care needs and to also measure appropriate/timely referrals, which would help ensure timely, quality care is delivered in a cost-effective manner.

NKF is working to develop such a measure for kidney disease. A care

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<sup>4</sup> Delmas PD. Non-steroidal anti-inflammatory drugs and renal function. *Br J Rheumatol* 1995; 34 (suppl 1): 25–28.

<sup>5</sup> Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2012 clinical practice guideline for the evaluation and management of chronic kidney disease. *Kidney Int Suppl.* 2013;3:1-150.

<sup>6</sup> Plantinga L, Grubbs V, Sarkar U, et al, CDC CKD surveillance team. Nonsteroidal Anti-Inflammatory Drug Use Among Persons With Chronic Kidney Disease in the United States. *Ann Fam Med.* 2011; 9: 423-430.

<sup>7</sup> Wei L, Macdonald TM, Jennings C, Sheng X, Flynn RW, Murphy MJ. Estimated GFR reporting is associated with decreased nonsteroidal anti-inflammatory drug prescribing and increased renal function. *Kidney Int.* 2013;84(1):174-8.

coordination measure for co-management by nephrology and primary care for patients with patients with two eGFR values < 30 ml/min/1.73m<sup>2</sup> at least 90 days apart is an opportunity to improve outcomes and lower health care costs for those with stage 4/5 CKD, who are not receiving renal replacement therapy. Collaborative care between primary care and nephrology practitioners is critical for patients with severe or difficult to manage disease. Extensive uncontrolled observational data demonstrate that outcomes improve when patients with progressive CKD are referred to a nephrologist in a timely fashion. Patients not referred to a nephrologist in advance of ESRD have a higher risk of morbidity and mortality as well as increased healthcare costs.

The evidence that there are gaps in referral care for patients with progressive CKD is reflected by the Medical Evidence Form (CMS 2728) as virtually all U.S. citizens who are diagnosed with chronic kidney failure, administratively known as end-stage renal disease (ESRD) are eligible for Medicare. Based on CMS 2728 data collection, 41% of patients did not see a nephrologist before initiating dialysis in 2012.<sup>8</sup> To address suboptimal care in the transition to ESRD, the federal legislature created the stage 4 CKD education benefit as part of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110-275), but this benefit has been significantly underused.

Approximately 100 observational trials have demonstrated improved outcomes for patients with early versus late nephrology referral prior to the onset of kidney failure, including improved survival, reduced duration of hospitalization, increased access to home dialysis, reduced use of hemodialysis catheters, and higher utilization of pre-emptive kidney transplantation. These differences persist after statistical adjustment for selection biases between the early and late referral populations. Increasing access to nephrology services will improve outcomes for patients.<sup>9,10,11,12,13,14,15</sup>

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<sup>8</sup> U.S. Renal Data System. USRDS 2014 Annual Data Report, NIDDK, NIH. 2014.

<sup>9</sup> Chan MR, Dall AT, Fletcher KE, Lu N, Trivedi H. Outcomes in patients with chronic kidney disease referred late to nephrologists: a meta-analysis. *Am J Med.* Dec 2007;120(12):1063-1070.

<sup>10</sup> Haley WE, Beckrich AL, Sayre J, et al. Improving Care Coordination Between Nephrology and Primary Care: A Quality Improvement Initiative Using the Renal Physicians Association Toolkit. *Am J Kidney Dis.* Aug 30 2014.

<sup>11</sup> Jungers P, Massy ZA, Nguyen-Khoa T, et al. Longer duration of predialysis nephrological care is associated with improved long-term survival of dialysis patients. *Nephrol Dial Transplant.* Dec 2001;16(12):2357-2364.

While NKF has begun development of measures we note the costly, lengthy process involved with measure development. On March 30, 2016, CMS convened a meeting of key stakeholders engaged or interested in developing measures to discuss opportunities and challenges with measure development. Many stakeholders agreed that engaging in measure development was expensive and time consuming and desired the opportunity to work with CMS on the more technical aspects of measure development and implementation, such as e-measure specification, measure testing and assessment as well as measure stewardship. NKF is hopeful that CMS will soon propose new opportunities for stakeholders involved in measure development to partner with CMS on these aspects of measure development for high priority areas where current measures do not address gaps in care.

#### IV. Resource Use Measures

NKF agrees that resource use measures and clinical quality measures should be aligned to ensure that reductions in spending are not resulting in adverse outcomes for patients. An approach where performance on clinical quality measures can also be tied to cost reductions by preventing adverse events and unnecessary surgeries and hospitalizations would be one way to ensure that cost and resource measures don't become the driver of clinical care trumping patient outcomes and access to care.

Given that the Medicare program is responsible for covering nearly 90 percent of Americans with kidney failure, regardless of their age, NKF believes CMS should explore the costs associated with patients who experience kidney failure and start dialysis without proper planning when they were under the care of a nephrologist at least 1 year prior to kidney failure. Many studies have shown that with proper nephrology care and preparation for renal replacement therapy patients can avoid hospitalizations and unnecessary procedures. The National Quality Forum (NQF) has endorsed measure 2594 *Optimal ESRD Starts* that measure nephrologists or health plans performance on ensuring that patients do not start hemodialysis with a catheter in place and are educated on all of their dialysis and transplant options prior to kidney failure. Applying this measure to nephrologists or practices that have 50 new ESRD

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<sup>12</sup> Kinchen KS, Sadler J, Fink N, et al. The timing of specialist evaluation in chronic kidney disease and mortality. *Ann Intern Med.* Sep 17 2002;137(6):479-486.

<sup>13</sup> Lin CL, Chuang FR, Wu CF, Yang CT. Early referral as an independent predictor of clinical outcome in end-stage renal disease on hemodialysis and continuous ambulatory peritoneal dialysis. *Ren Fail.* Sep 2004;26(5):531-537.

<sup>14</sup> Roderick P, Jones C, Drey N, et al. Late referral for end-stage renal disease: a region-wide survey in the south west of England. *Nephrol Dial Transplant.* Jul 2002;17(7):1252-1259.

<sup>15</sup> Winkelmayer WC, Owen WF, Jr., Levin R, Avorn J. A propensity analysis of late versus early nephrologist referral and mortality on dialysis. *J Am Soc Nephrol.* Feb 2003;14(2):486-492



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patients seen within the previous year (as recommended by the measure developer) would certainly lower healthcare expenditures for increased hospitalizations and vascular access surgeries associated with improper dialysis planning. This measure also incentivizes patient-centered treatment of chronic kidney failure, including pre-emptive kidney transplantation and home dialysis options. CMS could implement this measure and track changes in costs for new ESRD starts overtime, which could set a baseline for a cost/resource measure in the future. Additionally, a resource measure for ECs who have had patients under their care for at least 1 year prior to kidney failure that measures patients cost of care during the first 90 days of dialysis may also encourage greater accountability for ensuring proper transitions of care.

NKF appreciates the opportunity to comment on this proposed rule implementing the MIPS program and developing criteria for Advanced APMs and PFPMs. We look forward to the opportunity these new programs provide and to collaborating with CMS on improving outcomes for patients with kidney disease.

Sincerely,

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