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Andrew Slavitt  
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Submitted via email: [MACRA-MDP@hsag.com](mailto:MACRA-MDP@hsag.com)

RE: Public Comment on the Draft CMS Quality Measure Development Plan

Dear Acting Administrator Slavitt:

The National Kidney Foundation (NKF) appreciates the opportunity to comment on Draft CMS Quality Measure Development Plan (MDP). 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 (KDOQI).

### **Measure Development Timeline**

NKF has clarifying questions regarding the measure development timeline. While the Medicare Access & CHIP Reauthorization Act of 2015 (MACRA) does not require measures developed for the Merit-based Incentive Payment System (MIPS) to go through the Measure Applications Partnership (MAP) process, the proposed MDP does not identify the role of MAP in MIPS.

Does CMS plan to submit all MIPS measures under consideration to the MAP each year in addition to publishing a list of MIPS measures?

In addition, the MDP timeline does not identify the year in which measures will be considered for implementation. The timeline for proposed and final rulemaking on the MIPS list aligns with the proposed and final rulemaking on the Physician Fee Schedule (PFS), where proposed and final quality measures for the next reporting year have traditionally been included for PQRS.

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Is it the agency's intent that to meet the MACRA requirement for rulemaking regarding MIPS measures will follow the same timeline and also be included in the PFS? For example, the call for measures closes in June 2016, are the measures submitted by June 2016 used to determine which measures will be submitted for proposed rulemaking for MIPS in July 2016, finalized November 2016 and in use for the performance period beginning 2017 and payment year 2019?

Clarification of this cycle is important for measure developers and stakeholders. NKF requests the full details of the measure development cycle be published in the final MPD.

### **CMS Strategic Vision – Measure Development Priorities**

NKF is pleased CMS will use this strategy that aligns with the National Quality Strategy (NQS) to assess the national gaps in care and identify an overarching goal for where health care should focus to improve population outcomes. The Measure Development Plan flows from that overarching strategy to lay out the priorities and tactics to accomplishing those goals through measure development. NKF, as did many others, recommended drawing on the National Quality Strategy for prioritizing and aligning measure development and we appreciate that the process was incorporated into this proposed MDP.

To achieve the overarching goals of better care, healthier people and lower costs, gaps in care must be addressed. To that end, NKF has organized our comments to highlight the gaps in care for Chronic Kidney Disease and how those gaps pose barriers to achieving these overarching goals through measure development and clinical improvement activities. In addition, we respond to specific solicitations for comments referenced throughout the MDP.

NKF appreciates CMS' commitment to prioritize outcomes measures and recognizes that there is also a need to prioritize new process measures that flow from evidence-based clinical practice guidelines for areas where gaps in care exist, but for which outcomes measures are not available. Process measures contribute to the development of a body of evidence that can then be used to develop outcome measures.

#### Prioritizing measure development in areas with gaps in care

CKD care is an example where substantial gaps in clinical care processes strongly associated with patient outcomes exist. Approximately 26 million individuals have CKD, yet only 10% are aware they have it. This is because CKD had no distinguishable symptoms in its early stages and is often not diagnosed until complications occur or until the very late stages of the disease. Lack of awareness of the disease leaves little opportunity for patient self-management, and shared-decision making.

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To better understand the gaps in diagnosis of CKD, NKF and the American Diabetes Association partnered to conduct a study of primary care practitioners (PCP) and their practices in detecting CKD. It was noted that in adults with type-2 diabetes, who are at the highest risk for CKD, their CKD often went undiagnosed and unmanaged. The study was also the first to show that detection of CKD by the PCP was strongly associated with patient awareness.<sup>1</sup>

The KDOQI guidelines offer evidenced based strategies for PCPs to detect and manage CKD. The recommendations take into account other chronic conditions individuals have and include testing at-risk populations for CKD with estimated Glomerular Filtration Rate (eGFR) and urine albumin-creatinine ratio (UACR) including those with diabetes, hypertension and age over 60 years to promote patient safety. In individuals with CKD, certain medications need to be dose adjusted or avoided entirely to protect patients from toxic side effects and acute kidney injury, which can result in temporary kidney failure requiring dialysis and faster progression to permanent kidney failure. Both over-the-counter and prescription nonsteroidal anti-inflammatory drugs are a class of commonly used medications that cause acute kidney injury in CKD. In addition, the guidelines recommend the use of kidney-protective blood pressure medications such as an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB) for CKD with albumin in the urine and hypertension. The guidelines also identify when a referral to a nephrologist is recommended.

However, existing quality measures in PQRS do not address any of these areas. The one measure used in PQRS related to testing for kidney disease in diabetics (NCQA: Diabetic Nephropathy Assessment) permits practitioners to skip testing and diagnosis of CKD as long as the patient is prescribed an ACE inhibitor or an ARB. This measure allows practitioners to forgo follow-up monitoring of CKD and still meet performance on the measure. In contrast the Indian Health Services uses its own measure for diabetic nephropathy that requires an eGFR and UACR be documented annually (once within the reporting period). This measure meets the NKF and American Diabetes Association clinical practice guidelines for assessing kidney disease in diabetes (and would also be appropriate for use in individuals with hypertension).

#### Following patients along a care continuum

NKF supports the CMS goal to follow patients with one or more chronic condition across their care continuum. As identified above there is no current measure used in CMS programs that address

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<sup>1</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.

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CKD care management. CKD is a progressive disease that is the 9<sup>th</sup> leading cause of death, independently linked to heart attack and stroke and can eventually lead to permanent kidney failure, also known as end-stage renal disease (ESRD). KDOQI clinical practice guidelines recommend eGFR and UACR for those with and at risk for CKD at least annually (and more frequently in those with CKD at high risk of progression).

An assessment of kidney function in individuals at risk of CKD and with CKD would align with clinical practice guidelines, but also allow for following patients across the care continuum. NKF recommends that CMS prioritize development of a process measure for detecting CKD in high risk populations—starting with those with diabetes and hypertension in alignment with KDOQI guidelines. Such a measure should evaluate both eGFR and UACR as is used in the IHS measure, which is an ideal example. This measure 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.

#### Care planning in alignment with patient goals

NKF strongly supports the Institute of Medicine's (IOM) recommendation for a core quality measure on patient care planning in alignment with patient goals. Healthcare delivery that begins with patients' goals in mind affords patients the opportunity to participate in shared decision making and understanding of how different treatment options affect their personal goals. Patients that are engaged in this care planning process may be more likely to look favorably on their healthcare experience and take an active role in their care. Unfortunately, care planning related to CKD often doesn't occur until patients progress to ESRD. This is related to lack of earlier diagnosis. In addition, 41% of patients start dialysis without seeing a nephrologist in the year prior to initiation. These patients were unlikely to have been educated about their options for pre-emptive transplant, or home dialysis, prior to kidney failure and were afforded little opportunity to participate in shared decision making about their options. With improved CKD detection, patients with CKD should have the opportunity to participate in the development of care plans and make decisions about their care based off their individual goals – a laudable goal for prioritizing measure development.

#### **Solicitation of recommendations for specific measures**

In addition to an appropriate measure of CKD detection as identified above, measures of CKD management are needed. NKF and others are working on quality measures that highlight effective management strategies associated with improved outcomes for patients.

#### Patient Safety

NKF recommends CMS prioritize 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 ml/min/1.73m<sup>2</sup> at least 90 days apart will 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>2</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>3</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>4</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>5</sup>

### Care Coordination

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 for specialty care 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 coordination measure for co-management by nephrology and primary care for patients with patients with two eGFR values < 30

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<sup>2</sup> Delmas PD. Non-steroidal anti-inflammatory drugs and renal function. *Br J Rheumatol* 1995; 34 (suppl 1): 25–28.

<sup>3</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>4</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>5</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

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>6</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>7,8,9,10,11,12,13</sup>

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<sup>6</sup> U.S. Renal Data System. USRDS 2014 Annual Data Report, NIDDK, NIH. 2014.

<sup>7</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>8</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>9</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.

<sup>10</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>11</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>12</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>13</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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## **Clinical Improvement Activities**

NKF appreciates clarification that clinical improvement activities (CIA) will be established through rule making. NKF believes CIAs have the opportunity to transform clinical practice. Per our previous comments we believe participation in these activities should help eligible practitioners (EPs) improve gaps in care. Measurement of the impact of the CIA should continue well after the activity has ended so data can be collected to assess improvement in process and outcomes. Through this evaluation CIAs could also serve to provide an evidence base for which outcomes based quality measures could be developed and used in the quality measure component of MIPS. This creates a cycle for which participation in a CIA can also help the EP meet their quality measurement goals – better connecting each component of MIPS. NKF appreciates that CMS has recognized this potential opportunity and plans to review CIA submissions to evaluate whether the activity submitted can be further developed into quality measures within the defined clinical practice improvement activity subcategories.

NKF has been a leading provider of continuing medical education for kidney health for decades and has now created a curriculum and program to help implement practice transformation in primary care and nephrology to detect kidney disease early, improve patient safety, and avoid adverse events and outcomes associated with kidney disease.

## **Measure Development Challenges**

### Engaging Patients

NKF strongly encourages utilizing patient organizations to engage patients in the measure development process. These organizations are already actively engaging patients in conversations about quality measures, they understand the intricacies of the diseases their patient populations live with, the available treatments, and the challenges patients face within the healthcare system. NKF has established a Kidney Advocacy Committee comprised of patients who have a desire to engage in the policy and health care improvement process. NKF educates committee members on how to engage in the quality measure process and how to provide constructive input into the process by drawing on their own personal experiences with the health care system. In addition, the staffs at these patient organizations hear directly from patients with diverse backgrounds about their challenges with the health system on a daily basis and are already working through many channels to advocate and improve patients' experiences. As a result these organizations have the ability to communicate a comprehensive perspective of the challenges patients face and can effectively contribute to conversations on how quality improvement and measure development can be leveraged to address better care for patients. NKF believes working with patient organizations

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in the development of new measures is critical to ensuring quality measures are developed to achieve the LEAN goal of establishing value from the perspective of the end consumer, which in health care delivery is the patient.

NKF appreciates the opportunity to contribute comments to the MDP. We look forward to greater clarification in the final rule and to collaborating with agency on the development of future measures for MIPS and APMs.

Sincerely,

*Joseph Vassalotti*

Joseph Vassalotti, MD  
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