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Nonprofit Kidney Care Alliance

November 17, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW, Room 445-G
Washington, DC 20201

Re: Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models

Dear Administrator Slavitt:

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer our comments and recommendations regarding the Centers for Medicare and Medicaid Services' (CMS) Request for Information (RFI) Regarding Implementation of the Merit-Based Incentive Payment System (MIPS), Promotion of Alternative Payment Models (AMPs), and Incentive Payments for Participation in Eligible Alternative Payment Models. NKCA represents five nonprofit dialysis providers: Centers for Dialysis Care; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; Northwest Kidney Centers; and The Rogosin Institute. Collectively, we serve over 20,000 patients at more than 280 clinics in 30 states. As nonprofit providers, we receive approximately 85% of our payments from Medicare. NKCA members have been very active in the development of the Center for Medicare and Medicaid Innovation's (CMMI) Comprehensive End Stage Renal Disease (ESRD) Care Initiative and launch of the ESRD Seamless Care Organizations (ESCO's). Two of our member companies, DCI and the Rogosin Institute began operating ESCO's on October 1, 2015.

Our goal in caring for dialysis patients and others with kidney disease is to provide the best care possible by improving patients' quality of life, reducing the risk of kidney failure and increasing the number of kidney disease patients who can benefit from transplants. We believe that, on balance, the ESRD prospective payment bundle has allowed us to provide better care to our patients while achieving efficiencies in our delivery of care. It has also removed financial incentives that were not aligned with patient care.

We appreciate the opportunity to provide comments regarding implementation of the Medicare Access and CHIP Reauthorization Act (MACRA), specifically as it relates to Alternative Payment Models and Physician Focused Payment Models (PFPMs) in the RFI. We look forward to continuing to work with CMS in the future and provide additional information as these models begin to take shape. Overall, we believe it is crucial for CMS to provide flexibility to enable participation and innovation in new models.

Care transformation through APMs will likely come in many forms, one of which should be focused on major chronic conditions designed to deliver better care to a patient across multiple physicians and settings, while reducing Medicare's cost. One such chronic condition model should be focused exclusively on patients with chronic kidney disease (CKD) and related comorbidities, who are not dialysis dependent, (i.e., CKD Stages 1-5 and not on dialysis). NKCA believes that ultimately, what is needed is an integrated program that covers *all* stages of kidney disease, including its prevention (with the promotion of healthy living), screening to detect early disease, management of CKD, and the improved management of all aspects of the care of ESRD patients on dialysis with their multiple co-morbidities.

CMMI's ESCO demonstration has begun as a step in the right direction. We hope that as CMS and ESCO participants gain experience with what is successful in the program, Congress and CMS can begin to apply those lessons to the underlying fee-for-service ESRD program and future payment models. At this time the ESCO does not include CKD but with proven success, could be expanded to include those services over time. Equally important, we recommend a parallel model specific to CKD that could move forward beginning in 2019 (if not sooner) to address these specific patients.

Importance of CKD Management

Medicare has been focused on treatment of beneficiaries with kidney failure, through ESRD, but has largely neglected the potential to improve beneficiary health and lower costs by going "upstream" to address CKD. Medicare spending for patients with CKD aged 65 and older exceeded $50 billion in 2013, representing 20% of all Medicare spending in this age group. Moreover, CKD is closely associated with other comorbidities, including diabetes and congestive heard failure.

Percentage of Population Effected by Condition Related to Costs Associated With Care

	Medicare population	Total cost ($ millions)	Average per patient cost	% of population	% of cost
All Medicare patients	23,897,280	$ 250,503	$ 10,854	100.00%	100.00%
with diabetes	5,826,860	$ 87,433	$ 15,718	24.38%	34.90%
with congestive heart failure	2,208,380	$ 52,858	$ 26,750	9.24%	21.10%
with chronic kidney disease	2,506,860	$ 50,398	$ 21,909	10.49%	20.12%
CKD only	964,240	$ 14,223	$ 15,614	4.04%	5.68%

Source: USRDS 2015 Annual Data Report, Chapter 6. 2013 Medicare 5% claims data analysis.

Yet, only 7.7% of patients with Stage 3 CKD, whose kidneys are now seriously compromised, even know they have kidney disease, and only half with Stage 4 CKD, know they have kidney disease. Left untreated or poorly managed, kidney disease for these patients will continue to progress and they will become more expensive for Medicare. The cost to the Medicare program alone is stark, as shown on the chart below, growing from $23,680 per year at Stage 3, to $84,645 per year on dialysis.

There are elements in the existing Medicare program that can help identify those at risk and promote better coordination of their care: the annual wellness visit along with high risk assessment; diabetes screening; cardiovascular screening, chronic care management services; and Part D's Medication Therapy Management program. However, currently they all operate as separate and distinct payment provisions. With the enactment of MACRA and the option to adopt APMs, including PFPMs, there is an opportunity to address Medicare's current disjointed approach to CKD.

Alternative Payment Models (APMs)

Payment Incentives for APM Participation

How should CMS define "services furnished under this part through an EAPM entity"?
CMS should count all services under Part B, whether currently paid for through the Physician Fee Schedule, Outpatient Prospective Payment System, ESRD or other payment systems under Part B. Moreover, it should also count Part B services provided under Medicare Advantage. This will be particularly critical in those areas of the country where Medicare Advantage penetration exceeds 40% or even 50% of Medicare beneficiaries.

How should CMS consider payments made to EPs who participate in more than on APM?
Congress set a clear goal in MACRA to incentivize physicians to move into Alternative Payment Models. If that goal is to be achieved, CMS will need to employ a more flexible approach to physician participation and patient attribution than what has typically been employed to date in CMMI demonstrations, particularly its reliance on tax identification numbers (TINs). A physician may practice in multiple settings with multiple TINs. He/she may provide care to a single patient in more than one setting; and one patient may see more than one physician across multiple TINs for the same condition(s). At a minimum, APMs will need to incorporate physician/practitioner national provider identifiers (NPIs) tied to multiple TINs participating in each APM. Without having at least this level of "portability" it is unlikely that many physicians now operating under the current Physician Fee Schedule will be able to meet the claims (or patient count alternative) threshold in MACRA. Unlike some of the more discrete models which CMS has tested to date, such as an accountable care organization (ACO) or ESCO, establishing a new (or additional) TIN will not be a workable approach in many cases.

Patient Approach

What are examples of methodologies for attributing and counting patients in lieu of using payments to determine whether an EP is a QP or partial QP? Should this option be used in all or only some circumstances?
We believe that the statute clearly gives the Secretary broad authority on the approach to determine an eligible provider's (EP) eligibility and as such, should be applied. Patient counts should be an alterative to payment thresholds as anticipated in the statute. But if this is going to be a useful alternative, it will need to be coupled with a more flexible approach using practitioner NPIs tied to possibly multiple TINs.

CMS also needs a process of patient attribution by which CMS and physician practices can reconcile discrepancies, whether on a quarterly, rolling basis, or in an annual "look back." As long as beneficiaries have freedom of choice or otherwise disassociate themselves from a practice there will need to be a patient reconciliation process, albeit one which avoids "gaming." We have seen this issue arise with the start-up of the ESCOs, in which a significant number of attributed patients are not being treated by individual ESCOs.

EPs who want to participate in an APM ought to be given as many options as possible to meet thresholds of the program. As it is the goal of the APMs to increase participation in and services provided under APMs, EPs of different specialties and case mixes should be enabled to meet the criteria. EPs should have the option to elect to use percentage or patient count in any given year. At least initially, the criteria should not be limited to only "certain circumstances," but broadly applied.

Nominal Financial Risk

What is the appropriate type or types of "financial risk" under section 1833(z)(3)(D)(ii)(I) of the Act to be considered an EAPM entity? What is the appropriate level of financial risk "in excess of a nominal amount" under section 1833(z)(3)(D)(ii)(I) of the Act to be considered an EAPM entity?

For at least the first three years, any risk should be one sided. Many of the entities that might be expected to participate will be modest in size and financial resources. Even without incurring downside risk, as has been the case with CMMI demonstrations, entities will need to make significant up-front investment in infrastructure and human resources that will place additional burden on their financial resources.

Regarding EAPM Entity Requirements

What criteria could be considered when determining ''comparability'' to MIPS of quality measures used to identify an EAPM entity? Please provide specific examples for measures, measure types (for example, structure, process, outcome, and other types), data source for measures (for example, patients/caregivers, medical records, billing claims, etc.), measure domains, standards, and comparable methodology.

Potential metrics for CKD for primary care physicians include:

1) percent of patients with GFR < 30 being followed by a nephrologist;
2) percent of patients with CKD with GFR < 45 on an ACE Inhibitor or ARB;
3) percent of patients with CKD with GFR < 45 on a statin;
4) percent of patients with CKD with GFR < 45 on aspirin.

Potential metrics for CKD for nephrologists include:

1) percent of patients with CKD on an ACE Inhibitor or ARB;
2) percent of patients with CKD on a statin;
3) percent of patients with CKD on aspirin;
4) percent of patients with GFR < 20 who have selected modality at transition in care;
5) percent of patients with GFR < 20 who have implemented steps necessary to be ready for transition in care.

Additional metrics could include:

1) eGFR at start of dialysis;
2) percent of patients with a pre-emptive transplant;
3) percent of patients with a transplant within one year of dialysis;
4) percent of patients starting dialysis with permanent access (fistula or graft); percent of patients with a permanent access (fistula or graft) within 120 days of starting dialysis;
5) percent of patients starting dialysis at home (peritoneal dialysis or home hemodialysis);
6) percent of patients dialyzing at home (peritoneal dialysis or home hemodialysis) within 120 days of starting dialysis;
7) percent of outpatient starts for dialysis, avoiding initial hospitalization;
8) percent of patients starting dialysis who have been educated on medical management without dialysis.

Use of Certified EHR Technology

What components of certified EHR technology as defined in section 1848(o)(4) of the Act should APM participants be required to use? Should APM participants be required to use the same certified EHR technology currently required for the Medicare and Medicaid EHR Incentive Programs or should CMS other consider requirements around certified health IT capabilities?
An essential tool in an APM is proper electronic health record (EHR) technology which appropriately captures and shares needed information based on each model. For a CKD model, an EHR that enables all clinicians to access and share progress notes, and thereby coordinate care, is necessary. Importantly, such an EHR should be coupled with two-way electronic patient outreach, further coordinating care and ensuring that therapeutic interventions are implemented fully.

Clearly, the capabilities necessary to produce a truly interactive and meaningful EHR system are coming together to provide a solid underpinning for care that is integrated and of better quality care at lower cost. Importantly, this is care that should be available to everyone everywhere across the U.S.

Physician-Focused Payment Models

What criteria should be used by the Physician-focused Payment Model Technical Advisory Committee for assessing PFPM proposals submitted by stakeholders?
As noted previously, NKCA believes that models should be developed based on patient needs, specifically for chronic conditions like CKD. Having broad criteria to enable participation and innovation is essential for the Committee to consider new models. With that in mind, a CKD model should have the following objectives:

- Slowing progression of CKD, i.e. fewer patients progressing from CKD 3 to 4, 4 to 5, and 5 to dialysis;
- Decreasing the cost of care within each stage of CKD;
- Improving management of diabetes and hypertension (the primary causes of CKD);
- Reducing the number of patients starting dialysis with a GFR > 15;
- Increasing the rate of transplant (both pre-emptive transplant and transplant within one year of starting dialysis)

In addition we'd recommend the following elements be included in any CKD model:

- Early identification and raising patient awareness through physician and other clinician referral, group education;
- One-on-one in person counseling and care coordination to increase patient engagement;
- Identification of those patients at highest risk and referral to a nephrologist;
- Education on choices of care:
  - transplant—and then getting on transplant list earlier (rather than after start of dialysis
  - home dialysis
  - medical management (without dialysis)
  - in-center dialysis with permanent access, preferably fistula;
- Working with patients to delay progression, implement a choice of care, and start the next step in care later in the progression of CKD (ideally when the patient has a GFR of less than 15).

One of our members is currently testing such a model with over 3,450 patients in 22 sites, including 550 who are at Stage 5, *but not on dialysis.* We would be pleased to provide further information on progress to date.

We are considering that proposed PFPMs should primarily be focused on the inclusion of participants in their design who have not had the opportunity to participate in another PFPM with CMS because such a model has not been designed to include their specialty.
Since Congress clearly intended to incentivize physicians to move from the existing system (with MIPS) into APMs it would be inconsistent with that intent for CMS to impose a barrier based on some entity, individual or group having previously participated in another model. Recognizing many positive demonstrations that have been carried out by CMMI, the implementation of MACRA creates in effect, a new fee schedule and should not preclude anyone from participating. Physicians could have any number of reasons for participating or not participating in previous models in which they might have been eligible.

Conclusion
Thank you for the opportunity to comment on the MACRA RFI. The NKCA appreciates the opportunity to provide input to ensure the implementation of this law continues to support quality of care to the patients we serve. As nonprofit providers, these changes impact us much differently than others.

We would be pleased to discuss any of these suggestions in greater detail at any time. If you have any questions, please feel free to contact Martin Corry at 202-580-7707 or info@nonprofitkidneycare.org.

Sincerely,

Martin Corry
Executive Director