



August 23, 2016

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, D.C. 20201

RE: CMS 1651-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Furnished to Individuals with Acute Kidney Injury, End Stage Renal Disease Quality Incentive Program...and the Comprehensive End Stage Renal Disease Care Model Proposed Rule; June 30, 2016

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) 2017 End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Incentive Program and the Comprehensive End-Stage Renal Disease Care Model Proposed Rule (Proposed Rule). 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. Consistent with our belief that we can do more to keep patients *off dialysis*, we also serve more than 4,500 patients with chronic kidney disease with the goal of avoiding, or at least delaying, onset of end stage renal disease (ESRD). As nonprofit providers, approximately 85% of our patients are covered by Medicare, including Medicare Advantage plans. Two of our members also have experience participating in a current Center for Medicare and Medicaid Innovation (CMMI) alternative payment model, the Comprehensive ESRD Care (CEC) model.

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 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. At the same time, we believe that it is critical that CMS "go upstream" to address chronic kidney disease (CKD) and transplant so that fewer beneficiaries start dialysis or at least delay its start.

Comments Regarding Specific Aspects of the ESRD PPS Proposed Rule:

Outlier

When the bundle was established, certain factors were included to better ensure appropriate payment, particularly for sicker, higher-cost patients. To account for these higher “outlier” payments, providers do not receive the full base rate for each treatment. From 2011 through 2013, actual program experience fell well short of the 1% outlier target withheld (0.3% – 0.5%), resulting in an unnecessary loss to the base rate. In the 2016 Proposed Rule, CMS reported that outlier payments were much closer to the 1% target, estimated to have been 0.9% in 2014. For the 2017 Proposed Rule, CMS again reports that outlier payments fell short of the 1% target, coming in again at 0.9%. Accordingly, CMS proposes to reduce both the outlier threshold and the Medicare Allowable Payment (MAP) for 2017 for adult patients. CMS reports relatively stable erythropoiesis stimulating agent (ESA) utilization over the past two most recent years for which it has data in support of its belief that it will achieve the 1% proposed threshold in 2017. While the last two years have seen outlier payments closer to the 1% threshold, payments have yet to reach the threshold in any year since the implementation of the bundle. If this continues to be the case in the future, we urge CMS to revisit the outlier policy in next year’s rulemaking. As we have noted in prior comments, while an outlier adjustment is required under the statute, a 0.5% outlier threshold would reduce the offset to the base payment and still provide for payment in the case of extraordinary costs.

Home Dialysis Training Adjustor

In prior years’ comments we have urged CMS to review and update the home dialysis training adjustor annually, including that CMS continue its review of payments for home dialysis training and establish training rates that are more closely related to the actual cost of providing the service both for hemodialysis (HD) and Peritoneal Dialysis (PD). Therefore we are very pleased that CMS proposes to increase the training add-on payment for 2017 from the current \$50.16 to \$95.57. While this is a “budget neutral” adjustment, it is well worth the price to help promote greater utilization of home dialysis.

While this ad hoc increase is a welcome one, as we have noted previously, CMS should provide for an annual inflationary adjustment to the training add-on payment. A separate inflationary adjustment is necessary as the training add-on payment is outside the bundled base rate and is not adjusted by the annual market basket update. Given that the training add-on adjustment is directly related to nursing salaries and those salaries and staffing costs increase over time, the training add-on payment should be adjusted accordingly.

At the same time, CMS is embarking on a three part data collection and analysis initiative to better understand the cost of training *and retraining* and notes that under current claims processing the two are not distinguished. CMS also notes, that the current claims processing system limitation that led it to propose the HD “equivalency” adjustments also constrains the collection of data on training and retraining “treatments”. Accordingly it believes that its proposed equivalency changes will also improve the data on training costs. The second part of CMS data initiative in home dialysis is based on the audit of ESRD providers provided for under Protecting Access to Medicare Act (PAMA) from which CMS expects greater uniformity and data quality in future years. Third, CMS states that it is

considering the ESRD facility cost report (CMS 265-11) with new fields and revised worksheets to capture better data on home training with new requirements to assure that key data fields are completed.

We are pleased that CMS is embarking on an effort to better understand the costs associated with home dialysis, including better distinguishing between training and retraining. We urge CMS, in doing so, to be mindful of the burden that additional data collection and systems can pose, particularly for smaller providers. Currently CMS captures training with codes that distinguish by type of dialysis. A new revenue code, or modifier to the existing codes, could most efficiently address the concern about distinguishing between training and retraining. Regarding reasons for retraining, CMS Claims Manual already specifies the five reasons that apply to retraining, e.g. change in equipment or patient's medical condition. Currently, the reason for the retraining must already be in the medical record. It is not required to be on the claim. If a new code were to be developed, we recommend CMS update the reasons for retraining which could include failure to learn puncture skills and failure to safely follow steps for home dialysis.

With respect to new fields on the cost report forms, while NKCA supports modifications that can provide additional information on patient training resource allocation (among other issues), we strongly recommend that the new fields be designed to have clear and concise microspecifications (i.e. specific description of definitions/criteria/contents) to avoid ambiguity and multiple interpretations among dialysis facility personnel and IT vendors. We further recommend that these microspecifications be released for public comment in order for CMS to appreciate how the different stakeholders interpret them and to allow for feedback and questions, thereby allowing for clarification and/or modifications prior to implementation. We also urge CMS to implement such changes in a manner that recognizes that providers have different cost reporting periods, requiring longer—at least six months—lead time to implement. As CMS begins this data collection and analysis initiative, we recommend inclusion of industry stakeholders to provide input on appropriate changes.

Hemodialysis Payment When More Than 3 Treatments Are Furnished Per Week

Unless medically justified, CMS pays for hemodialysis(HD) treatments for up to three times per week. CMS points to stakeholder comments, and variability in data regarding treatments provided and treatments billed and paid for HD. It attributes at least some of the occurrence of more than three treatments (other than those medically justified) to evolving technology and providing patients with greater flexibility in managing their ESRD treatments and other activities.

To address the discrepancies between treatments provided and those billed and paid, CMS proposes a new HD equivalency system. CMS does not propose any change in overall payments, but only to require facilities to report all treatments so that it has better data on the total services being provided. Recognizing that this change will require adjustments in CMS claims systems, Medicare Administrative Contractors (MACs) systems and provider systems, CMS proposes to defer implementation to July 1, 2017 (though it would be effective January 1, 2017). With all the other requirements being placed on providers, particularly smaller providers, NKCA does not see how mere “better data” outweighs the additional burden at this time and strongly oppose CMS finalizing this proposal.

Proposed Coverage and Payment for Renal Dialysis Services to Individuals with Acute Kidney Injury (AKI)

Section 808(a) of the Trade Preferences Extension Act (TPEA) provided for coverage and payment for renal dialysis services by ESRD providers to individuals with Acute Kidney Injury (AKI). CMS proposes, consistent with the statute, to pay for dialysis services to patients with AKI at the ESRD PPS base rate, adjusted for the ESRD wage index of the facility. Since AKI services are intended to be curative, CMS proposes to pay for each day's service, regardless of how many are provided in a week. We support CMS' decision to pay for each day's treatment since this is intended to be a curative benefit and different patients will require different treatment regimens in order to promote recovery of renal function. While Congress provided the Secretary with additional authority to modify payment, CMS declines to do so, at least in the first year of implementation. We support CMS' decision in this regard until there is more experience with this treatment in the ESRD facility setting. There are a number of conditions that may lead to AKI, and some patients will have more severely compromised systems than others. With one to two year's experience CMS should then consider whether additional adjustments are appropriate.

In addition, recognizing that AKI patients may require additional services beyond those included as part of the bundled base rate, CMS proposes to pay for additional, separately billable items, such as drugs, biologics, and laboratory services *not part of the underlying base rate*. However, based partly on comments from stakeholders, CMS states that it will closely monitor utilization of AKI services to ensure that they are being utilized to promote recovery of renal function and appropriate utilization of services. We concur in CMS' intent to closely monitor separately billable services, so that there is not inappropriate utilization. However, we also point out that because these patients will need to be monitored to assess their progression toward recovery, there *will* be additional services, particularly laboratory services. We urge CMS to strike a careful balance between these two factors.

CMS proposes to not extend AKI services to home dialysis on the grounds that these patients require much closer supervision. We understand and agree with CMS' concern that AKI patients require close supervision. However, we urge CMS to reconsider a blanket rejection of home dialysis care. For some patients, peritoneal dialysis, at first in-clinic, could be appropriate in the home. For patients in rural areas or for whom transportation is challenging, it may be appropriate. Regular monitoring, such as regular visits to the clinic for laboratory services could be a condition. For patients in remote areas they might not come into the clinic to get labs drawn, but get labs drawn at a local lab more convenient for them. Ultimately, we believe that the decision as to whether to dialyze at home should be with the patient and their physician(s).

CMS proposes that payment for AKI services would be identified with a specific payment code, denoting AKI and a Current Procedural Terminology (CPT) code. CMS notes that more specific payment guidance will be forthcoming in sub-regulatory guidance. We agree with CMS' intent to create a specific payment code and identify a corresponding CPT code to distinguish AKI patients from ESRD patients. We believe it is critical not only for claims payment but also other reporting that AKI patient data not be included with other data and reporting requirements which ESRD facilities are required to submit. For example, while NKCA agrees that monitoring of quality of outpatient dialysis care for AKI is critical, these patients' care needs and clinical context are very different from patients with ESRD and should not be included in ESRD quality of care clinical performance measures such as

the Quality Incentive Program (QIP), Dialysis Facility Reports (DFRs), Dialysis Facility Compare (DFC), 5-star, etc. In order to ensure that this situation does not occur inadvertently, we recommend a review of the patient inclusion eligibility criteria for each of the current and future proposed ESRD clinical performance measures to include a requirement that only data on patients with a valid 2728 form is included.

Aside from a technical change in ESRD Conditions for Coverage, CMS does not propose any Conditions for Coverage changes for 2017. However, CMS requests comment on whether changes might be considered in the future to address medical planning, or medical records. We agree with CMS that no changes in Conditions for Coverage are needed at this time, but may be useful in the future. Indeed if issues arise around medical planning or medical records as CMS suggests, these might better be left to sub-regulatory guidance, such as program memoranda and/or Manual changes.

Comments on Comprehensive End-Stage Renal Disease Care Model and Future Payment Model Questions

As noted previously, NKCA members have been very active in the development of the CMMI CEC model and the launch of the ESRD Seamless Care Organizations (ESCOs). Two of our member companies, Dialysis Clinic, Inc. and The Rogosin Institute began operating ESCOs on October 1, 2015, and we are pleased to see the second round application process has been opened. If our applications are approved, as many as four members of the NKCA will have an ESCO in 2017 and could operate as many as nine ESCOs in 2017. We see the ESCO as the primary model of integrated care for patients with ESRD, and hope that this model will be expanded to include patients with chronic kidney disease (CKD) and patients who have received a kidney transplant. We appreciate CMS' focus on this initiative and its commitment to its growing and evolving the model.

NKCA believes the single most important change that can occur for patients with kidney disease is to change the focus of the current reimbursement system from care for patients on dialysis to care for patients with kidney disease, at whatever stage of their journey they may be. To provide optimal care, interventions should focus on the patient where that person currently sits, instead of seeing the patient as someone who may need dialysis in the future. As we note above, we believe that by focusing on CKD "upstream" we can reduce the number of patients who need dialysis, and increase those who can benefit from transplant.

Our comments to the ten questions below are based on our experience in caring for patients with both CKD and ESRD as well as the ESCO models. We have noted some of the successes and data of our member companies' programs as examples of innovative approaches.

1. How could participants in alternative payment models (APMs) and advanced alternative payment models (AAPMs) coordinate care for beneficiaries with chronic kidney disease and to improve their transition into dialysis?

Overall, we believe it is critical to expand the current ESCO model by going "up-stream" to include patients with CKD. As discussed in the following questions, there are many opportunities for coordination of care through expansion of the existing ESCOs as well as integrating care through other

primary care models to identify and refer appropriate patients for CKD care. It is also important to note that that most CKD care is not related to preparing for dialysis.

For those individuals who choose or need dialysis as a therapy, it is still valuable to work with the patient early enough that the patient can make the best decision for his or her care. We recommend providing this education when the patient has a GFR less than 20. By preparing patients early, and following them closely, we are seeing that:

- **More patients will receive a pre-emptive kidney transplant and avoid dialysis.** Nationwide the pre-emptive transplant rate is 2.6%. In the Rogosin CKD program, patients have a 19% pre-emptive transplant rate.
- **Patients will be educated on medical management without dialysis and appropriate patients will choose this option.** In the DCI CKD program in Spartanburg, SC, more than 10% of patients are choosing medical management without dialysis.
- **More patients will receive education on and choose home dialysis.** In the Northwest Kidney Centers' Choices CKD program in Seattle, WA, 26% of patients start dialysis at home.
- **More patients will start hemodialysis with a permanent access.** In the Northwest Kidney Centers' Choices CKD program, more than 56% of patient start hemodialysis with a permanent access and never have a catheter.
- **More patients will receive their first dialysis treatment as an outpatient and will avoid the initial hospitalization.** In the DCI program in Spartanburg, SC, 58%, and in the Northwest Kidney Centers' Choices CKD Program 64% of patients starting dialysis in 2015 from the CKD program avoided a hospitalization for their first treatment.

2. How could participants in APMs and AAPMs target key interventions for beneficiaries at different stages of chronic kidney disease?

We recommend that a program focused on improving care for patients with CKD start with patients with a GFR < 45. Although optimally we would like to provide care for all patients with CKD, the number of patients with GFR > 45 is so large that it would potentially overwhelm the program. We recommend going back to at least a GFR less than 45 so that there will be the opportunity to slow progression of CKD and ideally avoid dialysis.

We estimate that a program managing this population would have the following distribution of patients based on the National Health and Nutrition Examination Survey (NHANES) data¹:

- Stage 3b (GFR 30 – 45): 69.2% (14,750 patients per 1 million patients)
- Stage 4a (GFR 20-30): 15.0% (3,200 patients per 1 million patients)
- Stage 4b (GFR 15-20): 7.5% (1,600 patients per 1 million patients)
- Stage 5, not on dialysis (GFR < 15): 6.6% (1,450 patients per 1 million patients)
- Transitioning to renal replacement therapy each year: 1.7% (359 patients per 1 million patients)

¹ 2015 USRDS

The cost of care for these patients is significant and as the patient's kidney disease progresses, the cost of care increases. The following is an estimate of cost of care by stage, based on an analysis of 2013 Medicare 5% claims data:

- Stage 3: \$23,680 per year (2.2 times the cost of care for typical patient with Medicare coverage)
- Stage 4: \$33,374 per year (3.1 times the cost of care for typical patient with Medicare coverage)
- Stage 5 not on dialysis: \$36,147 per year (3.3 times the cost of care for typical patient with Medicare coverage)
- Stage 5, on dialysis: \$84,645 per year (7.8 times the cost of care for typical patient with Medicare coverage)

We note the change in cost of care for a patient with stage 5 CKD not on dialysis and a patient on dialysis. For every month that we can delay the start of dialysis, we can decrease the cost of care for Medicare by more than \$4,000 per patient and provide a better quality of life. These costs can also be compounded since many CKD patients also have diabetes and hypertension.

Currently, there is a huge missed opportunity to improve care for these patients, since most of these patients are not receiving care related to their kidney disease. According to the USRDS, only 7.7% of patients with stage 3 CKD even know that they have kidney disease and for patients with stage 4 CKD, only 53% of the patients even know that they have kidney disease. Data suggests that earlier referral to nephrologists can slow the rate of progression of kidney disease and better prepare a patient for transition to the next step in care. Equally important is that patients' primary care physicians diagnose CKD earlier. Unfortunately in the United States, the majority of patients still "crash" into dialysis without having the opportunity to be educated and explore the full set of options available to them.

Below we describe examples of needed interventions for each stage of kidney disease based on the experience of one of our member's program, Reach Kidney Care, currently serving 3,500 patients across 27 sites.

Stage 3b (GFR 30-45)

We start our formal interventions at stage 3b. The fact that a patient has lost more than 50% of kidney function is often an indicator that this patient has some condition that has not been adequately controlled, and therefore has damaged their kidney function. We strongly believe that in person, one-on-one care coordination is essential to provide optimal care, with significant time spent for a first visit. This first meeting does not focus specifically on kidney disease, but instead on the patient's life goals.

For patients with a GFR 30 – 45, our intervention is primarily focused on population health:

- Improved blood pressure control
- Improved blood sugar control
- Increased exercise
- Smoking cessation
- Weight loss
- Cardiovascular Disease (CVD) Screening & Referral/Management as needed

In addition, we also work with patients to protect their kidney health and educate them on kidney disease, with topics including:

- Avoidance of nonsteroidal anti-inflammatory drugs (NSAIDS)
- Protecting their potential access arm
- Diet
- Sodium
- Anemia
- Phosphorous

It is important that CKD programs partner with the patient's primary care physician and other physicians in order to coordinate care. Progress notes should be shared between the program and the primary care physician to provide clinical updates. It is critical to ensure that adequate kidney screening has been performed for these patients. If the patient has not been checked for urine proteinuria, we recommend that this be checked. If a patient has rapidly progressing kidney disease and/or significant proteinuria, a referral to a nephrologist is recommended.

Stage 4a (GFR 20 – 30)

If a patient's kidney disease does progress to stage 4a, care is intensified and we recommend a patient be seen by a nephrologist. In addition, we review the patient's medication list to ensure that the patient is on the correct medication, at the correct dose for their current renal function. We also continue to provide population health management for these patients and intensify the efforts started for a patient with stage 3b CKD.

Stage 4b (GFR 15 – 20)

At stage 4b, in addition to the interventions and education in previous stages, it is important to carefully manage those patients who will progress to renal replacement therapy so that they can begin as late as possible in the progression of their CKD. In addition, it is important to start preparing the patient for their next step in care, educating the patient on the following four options:

- Transplant
- Home Dialysis
- In Center Dialysis, preferably with a fistula
- Medical Management Without Dialysis

NKCA believes it is necessary to not only provide education on the various treatment options available, but also provide navigation services to help patients prepare for transition.

Stage 5, not on dialysis (GFR < 15)

We believe patients can still be effectively managed at stage 5 CKD, without dialysis. One of our members, DCI is currently following more than 600 patients with stage 5 CKD and effectively keeping them off dialysis. These patients should be seen more often to manage their symptoms and push back the start of dialysis as far as possible while maintaining patient safety, ability for self-determination and patient-expressed expectation of acceptable quality of life. Each patient is different and should be treated as such. By individualizing the care for each patient, a patient can safely start on dialysis later

in the progression of their CKD. In the Spartanburg, SC program operated by DCI, more than half of our patients are starting dialysis with a GFR of 5-10.

Transition in Care

As we've discussed, patients should be educated and afforded all their options for care as their disease progresses. Below we've provided recommendations on the appropriate care transitions that should be made available to patients and the coordinating question based on CMS' request for information.

These transitions include

- Transplant (see question 3)
- Medical management without dialysis
- Home dialysis (see question 9)
- In center dialysis

Medical Management without Dialysis

For most patients starting dialysis, they are making a commitment to start a therapy that will require them to receive three, four hour treatments per week. After including the time for travel to and from dialysis, and the recovery from dialysis care, many patients essentially "lose" three out of seven days a week because of the obligations of dialysis care. Based on recent published literature, we know that patients who are older than 80 with multiple comorbidities have similar survival outcomes if they choose medical management without dialysis instead of dialysis. For those who live longer on dialysis, most of those extra days were spent in a dialysis clinic or in a hospital.

We strongly believe that a patient with CKD should have the right to choose that dialysis is not the right choice for him or her. If the patient makes this decision, we recommend that the care coordinator meet with the patient's family and help them understand the patient's decision. In addition, it is critical for the patient to know that they will not be abandoned if s/he makes the decision to select medical management without dialysis and will continue to intensively manage the patient, if requested. The only difference would be that the patient would not start dialysis. Finally, it is critical for the patient to know that s/he can change her decision at any time. Following this process in Spartanburg, SC, DCI is seeing that less than 5% of patients who select medical management without dialysis change their mind and start dialysis.

In Center Dialysis

For patients choosing in center dialysis, we recommend they start dialysis with a permanent access and never have a hemodialysis catheter. These patients are less likely to have an infection, less likely to be in the hospital, and more likely to live and their care is less expensive. Although a fistula is the ideal access for many patients, other patients (especially elderly patients) will receive most effective care with a graft. By educating patients early about the importance of a permanent access, more patients can start dialysis with a permanent access and never have a catheter. Currently nationwide, only 24% of patients start dialysis with a permanent access.² In the DCI program in Spartanburg, SC, 65% of patients starting dialysis in 2015 from the CKD program started dialysis with a fistula and never had a catheter.

² Dialysis Facility Report (DFR) for FY 2017

NKCA also believes that this early education and intervention will decrease the likelihood that a patient will receive his or her first dialysis treatment in a hospital. We see this as an important improvement in care since patients avoiding a hospitalization will also be able to avoid the complications from a hospitalization. In addition, we have seen that patients can have a smoother transition to dialysis if their first treatment is in the outpatient setting instead of the hospital. We recognize, however, that certain patients should receive their first treatment in the hospital to ensure that they receive safe care and therefore err towards starting a patient in the hospital if there is a clinical indication to do this. In addition, we expect that Medicare will see significant savings if we can increase the number of patients avoiding the first hospitalization before a dialysis treatment. We estimate that the cost of hospitalization and follow-up care is \$25,000 for a patient on dialysis. Clinical experience indicate that the vast majority of patients receive their first dialysis in the hospital; in contrast, in the DCI CKD program 58% and in the Northwest Kidney Center CKD program 64% of patients started dialysis as an outpatient and avoided a hospitalization for their first treatment.

3. How could participants in APMs and AAPMs better promote increased rates of renal transplantation?

NKCA believes that transplant is the optimal therapy for patients with kidney failure in order to improve life expectancy, increase quality of life, and reduce the number of people who need dialysis. We believe there is a great deal of work to do in order to increase access to pre-emptive transplants, lower the current organ discard rate, and promote policies that do not inadvertently penalize transplant centers for utilization of high risk organs. Over the past several months our member companies have engaged with the Administration on increasing access to transplant and have made our own commitments to this at the White House Organ Summit in June of this year. We believe that by counseling patients early on their treatment options along with CKD education, patients are able to consider transplant options and make decisions early. By doing so, they can get on the wait list sooner making them more likely to receive a pre-emptive transplant.

As nonprofit dialysis providers serving over 20,000 patients on dialysis at more than 280 clinics in 30 states, and more than 4,500 patients with CKD in 29 locations across the country, NKCA member companies have the opportunity to educate and counsel patients on their treatment options regarding transplant and maximize their opportunity of receiving a kidney transplant. To this end, we recommend expanding the current ESCOs to transplant and specifically pilot new programs that utilize high risk organs without inappropriately penalizing transplant centers. Transplant education is an important part of CKD education, and works best with early identification of CKD, and education and navigation on treatment options. We were pleased to see changes being made in the May 13, 2016 Revised Guidelines from CMS' Survey and Certification group and the Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule. We look forward to providing comments on that proposal as well.

Patients who receive a kidney transplant are more likely to live longer, have a better quality of life and require fewer hospitalizations. Additionally, a transplant can "pay" for itself in about 2.5 years and allow for savings in a healthier patient. Currently, there are no incentives or benchmarks that promote referral of patients for consideration of their transplant options. Additionally, many transplant programs exist without any real integration into the local dialysis or CKD community. By

coordinating education and outreach with dialysis providers, CKD education programs and transplant programs, there is the potential to increase the early and overall referral rates.

4. How could CMS build on the CEC Model or develop alternative approaches for improving the quality of care and reducing costs for ESRD beneficiaries?

As noted, NKCA feels strongly that the current CEC Model is a great start to providing coordinated care for ESRD beneficiaries and the best way to achieve further success is to evolve the current program. We believe that would include expanding the CEC model to include both CKD and transplant. We believe this would not only expand the use of these services, but would ultimately provide savings by going upstream to provide care. We appreciate the opportunities CMS has provided to work with our industry to refine the model, and look forward to additional dialogue in the future.

Participation as an ESCO can be challenging for small dialysis providers due to limited resources and capacity. While most of our members are participating or have applied to participate as an ESCO, it is a significant commitment in staff time and financial resources that many are excited to pursue based on the benefits of care coordination. However, it is challenging for providers, particularly smaller providers to analyze the data they are receiving as ESCO's and therefore they are less able to benefit from that information to improve their programs. Because of this, we recommend that CMMI provide data analytics assistance for providers to assist in their participation. By providing this service based on claims reports, participation in the ESCO would be less challenging for non-LDOs and enable them to better focus on care delivery.

5. Are there specific innovations that are most appropriate for smaller dialysis organizations?

Small dialysis organizations are deeply rooted in their communities and therefore have the unique opportunity to tailor care based on knowing both the needs of their population, community organizations and other health care providers and health systems with which to partner to promote better outreach and care. Smaller organizations know their health systems, hospitals, doctor groups, and primary care and public health resources because they are part of the fabric of the health care community. Additionally, they know their Area Agency on Aging, social resources, transportation services and senior resources. This knowledge of the local community is invaluable to design services that best meet individual beneficiary needs.

Through these networks and built relationships, small dialysis organizations may develop local models of care coordination that remain consistent with national standards yet is not necessarily scalable at a national level by virtue of local resources and health system characteristics that may be unique and can't be duplicated. NKCA supports policies that allow small dialysis providers to continue to build on the work and outreach they do every day and provide care to the patients in their communities without additional barriers.

Many of our NKCA members are small dialysis providers who have been highly successful in their community initiatives that have ultimately led them to provide better services. For example, Northwest Kidney centers developed an Access to Dental program along with a local non profit agency using volunteer dentists in the region to provide dental clearance for those patients eligible for

transplant. Since its creation, the program has assisted 50 patients receive their clearance and a subsequent transplant.

The Rogosin Institute partners with community organizations, local government and local businesses from schools and religious institutions to barbershops and nail salons to educate the population on kidney health and organ donation. For example, Rogosin recently partnered with the Brownsville Recreation Center of the New York City Parks Department to host a kidney health and kidney transplant education program for several hundred local residents.

6. How could primary-care based models better integrate with APMs or AAPMs focused on kidney care to help prevent development of chronic kidney disease in patients and progression to ESRD? Primary-care based models may include patient-centered medical homes or other APMs.

We believe primary-care based models like Accountable Care Organizations (ACOs) could and should easily integrate with ESCOs in order to identify and track kidney disease progression. This would allow referral and transitioned care to a nephrologist when appropriate to begin managing the disease to slow the progression to prevent or delay dialysis or make them better candidates for transplant. Currently about 23 percent³ of patients who start dialyses have not even seen a nephrologist by their first treatment. By going up-stream to identify these patients much earlier in the process by utilizing primary care physicians, patients can get the care they need so that their kidney disease does not worsen to end stage kidney disease. For example, at Northwest Kidney Centers, through efforts to work with primary care to increase CKD education, only 14% of patients do not see a nephrologist before their first treatment. To achieve this, for a primary-care model it is necessary to require measures for CKD symptoms such as obesity, diabetes, and high blood pressure.

It would also be helpful for estimated Glomerular Filtration Rate (eGFR) to be reported by primary care physicians and addressed. Currently, very few physicians are billing the ICD-10 code for CKD stage 3, which is ideally when a patient should begin managing their CKD, so it is difficult to track and identify patients. We recommend this be a requirement in claims data to capture eGFR for patients with diabetes and hypertension, which are typically precursors to the disease. This requirement could be expanded in the future to track for additional patients at risk. Physicians receiving lab reports should have a protocol for patients with an eGFR less than 45, such that patients are informed and referred to a nephrologist to offer opportunities to manage the progression of kidney disease.

7. How could APMs and AAPMs help reduce disparities in rates of CKD/ESRD and adverse outcomes among racial/ethnic minorities?

There are three major intervention points that we believe can make a difference with respect to reducing existing disparities in rates of CKD/ESRD and of the adverse outcomes among racial/ethnic minorities. By incentivizing interventions of all three types, APMs and AAPMs could achieve the disparity reductions that are so badly needed.

³ Dialysis Facility Report (DFR) for FY 2017

The first point of intervention is reflective of the generally long course of the development of kidney disease and its progression from Stage 1 through Stage 5. It consists of health promotion and disease prevention education focused on adults ages 20-45. A provision within APMs and AAPMs for reimbursement for the conduct of such education in communities at high risk for renal disease and/or well-documented poor overall health statistics should be part of an overall approach to kidney disease. The health promotion and disease prevention education programs should be designed with culturally appropriate language, imaging and recommendations for nutrition and physical activity. Review by an advisory committee composed of members of the particular community to be addressed should be mandatory. Pre- and post-education surveys (with predetermined level of change) would assess quality, as well as the number of people educated, and provide one basis for the level of reimbursement under the APM or AAPM.

The second point of intervention is screening for the presence of risk factors for kidney disease and for early evidence of its existence. The number of individuals (ages 20-60) presenting themselves for screening, as compared to the baseline, would further assess the effectiveness of the education program defined above and the effectiveness of the screening program itself. Critical to the assessment of this screening program is the identification of the principal risk factors of hypertension, diabetes, and obesity. A provision for APM or AAPM reimbursement for such a program would depend on the number of individuals presenting for screening, as well as the proportion of the total number of community residents screened. A third reimbursable measure would be the number of documented referrals to the appropriate primary care physician or nephrologist.

The third point of intervention is the documented management of individuals with risk factors for, or evidence of, kidney disease. The first measure here would be the number of individuals identified at screening who enter into, and are retained in, a management program. The second measure of quality determining the reimbursement level would be the evidence of the management of blood pressure reduction, glucose and HgbA1C control, weight loss, improved creatinine and BUN levels with stabilization of GFR, and improvement in or absence of proteinuria. For the more advanced CKD, reimbursement would also depend on the evidence of education regarding dialysis and transplantation, and, if progression continues, numbers of patients receiving fistulas or grafts in expectation of a transition to dialysis.

For all of the above intervention measures, incentives within APMs and AAPMs would be built in to encourage physicians to take the extra effort required to reach patient populations with less than desired knowledge and health status, as well as more intensive management, with the end result of reducing both disparities and adverse outcomes. While the quality of care would improve, there would also be potential for substantial cost savings, particularly in light of the high cost of a patient on dialysis. It is important to emphasize that such a program would ensure better quality of life for those so treated and, very likely, the maintenance of a capacity for gainful employment among a larger proportion of the patients.

8. Are there innovative ways APMs and AAPMs can facilitate changes in care delivery to improve the quality of life for CKD and ESRD patients?

NKCA believes there are four areas that can be addressed by new and existing models to improve the quality of life for patients with CKD and ESRD including; employment assistance, a focus on mental

health, symptom management, and end of life care. These four areas are common roadblocks for patients with CKD and ESRD that, with proper assistance, could increase quality of life and general health.

First, there is a large decrease in employment from pre-dialysis to a patient's first dialysis visit. This is largely due to the progression of their disease, difficulty managing symptoms, and the struggle to dialyze numerous times a week while working. We believe that by slowing the progression of the disease and educating patients early on their treatment options, not only can patients delay the start of dialysis, but can mitigate its impact by preparing for home dialysis or even a transplant. Furthermore, social workers may be able to educate and provide guidance to the patient regarding what to expect in terms of future health-related expenses and how best to manage and/or maintain existing insurance coverage particularly for employed patients. Having options and managing the disease and its symptoms is important to maintain employment, an adequate standard of living and quality of life.

Additionally, for patients going through progression of the disease, mental health may become a struggle that should not go unaddressed. Nephrologists and other care providers may see the signs of mental illness, particularly depression, and in many cases diagnose and facilitate or refer the patient to an appropriate mental health professional. Providing greater focus for providers to engage with patients to catch the signs of mental health needs is an important part of care for patients with CKD or ESRD.

Providing symptom management for this patient population is a critical intervention that can improve the quality of life for patients. Providers taking the time to address needs outside of the administration of dialysis can not only improve the patient's daily comfort, but can also help with some of the other struggles faced by patients described above. In APMs and AAPMs, CMS should provide incentives for providers to increase this type of care.

Finally, end of life care is an important part of the care continuum, particularly for CKD and ESRD patients in order to educate them on their options so that they can plan early based on their wishes. NKCA applauds CMS for including an Advanced Care Planning measure in the ESCO to be reported and recommends that it to be utilized in other models as well.

9. Are there specific innovations that are most appropriate for evaluating patients for suitability for home dialysis and promoting its use in appropriate populations?

NKCA sees home dialysis as optimal dialysis care. A person dialyzing at home has more independence, is more likely to be able to continue to work, and has much higher satisfaction in their dialysis care. In addition, the cost of care for a patient dialyzing at home is lower than the cost of care for a patient dialyzing in center.

As part of early discussions on treatment options, we believe the earlier patients are educated on this option, the more likely they are to start dialysis at home. Currently about 9.3%⁴ of patients start dialysis at home. We believe there are policy changes that could be made to increase home dialysis

⁴ 2015 USRDS ADR. Vol. 2. Figure 1.1.

such as increased screening and suitability, availability of staff assisted care partners, the use of telemedicine, remote monitoring, and respite care. One of the biggest challenges we see for home dialysis is not necessarily screening and starting them at home, but keeping them as home patients. These changes, when packaged together as a service, would promote sustainable growth in home dialysis.

The use of staff assisted care partners has been a helpful tool for patients and their families to dialyze at home by having assistance connecting and disconnecting from the dialysis unit. By providing this option to patients, and providing payment for these services, patients who may not otherwise have help to achieve this care option would be able to take advantages of the positive impact of home dialysis while still having trained care and assistance. We recommend CMS consider the addition of these services to assist in the promotion of home dialysis.

Another innovative way patients can utilize home dialysis is telemedicine and remote patient monitoring. For patients and their families this can be an extension of staff assistance and in many cases can provide a feeling of safety when a family member or caregiver cannot be present. Many patients must travel long distances for their monthly physician visit. If a patient were able to have a portion of those visits by telehealth, this would substantially decrease the burden on some patients who would otherwise need to travel a long distance or traverse a congested urban area. We recommend that a dialysis clinic as well as the home should be an originating site for this purpose regardless of whether it is in an urban or rural area. For healthier patients who have to drive twice a month (once for clinic visit and once for physician visit), allowing a telehealth option from the patient's home could give a patient the convenience they need. Subject to their physician's concurrence, this could be helpful to patients whose doctor may be at a distance, whether rural or within a large urban metro area and/or during periods of winter weather. We believe there is an opportunity to test a telemedicine model in the ESCO under a technology waiver. Telemedicine has increasingly been used by CMS and in particular, has expanded under the Medicare Access and CHIP Reauthorization Act (MACRA). Results could provide needed data to expand for all home dialysis patients.

Finally, we recommend the use of respite care at home to assist patients and provide family members a break from care-giving. This would make it easier for patients to remain at home safely. Caregiving can and often does take a huge toll on friend and family caregivers, often compromising their own health. CMS should test a respite program with a set number of hours or days that can be drawn on annually to determine whether it results in better quality of life for the patient (and caregiver), better health outcomes, and lower incidence of abandonment of home care and return to in-clinic care.

10. Are there specific innovations that could most effectively be tested in a potential mandatory model?

NKCA strongly opposes a mandatory payment model for CKD or ESRD at this time. We believe there is enough interest in the community that a requirement isn't needed, that it would not provide additional value to the program, and it could potentially get in the way of the substance and policy that continues to grow in the ESCO. Indeed, such a mandatory model could, unwittingly, lead to more consolidation in an already highly concentrated sector since many small providers couldn't meet or wouldn't have the required resources to meet the requirements.

As we've discussed, NKCA members have been very active in the creation of the ESCO and our members are excited at the potential for new models through the second round of applications submitted earlier this year. From our experience, there are already a limited number of providers already, and a mandatory model would prove overly difficult. Additionally, we remain concerned that for small dialysis providers a mandatory model could be overly burdensome, and in some cases, isn't appropriate.

Conclusion

Thank you for the opportunity to comment on the ESRD PPS Proposed Rule. The NKCA appreciates the opportunity to provide input to ensure the rule's impact 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,

A handwritten signature in blue ink that reads "Martin Corry". The signature is written in a cursive, flowing style.

Martin Corry
Executive Director